

Medication use in rest and nursing homes in Belgium

KCE reports vol.47 C

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FOREWORD

Older people consume more medication than any other age group. They tend to have more long-term, chronic illnesses and since many elderly have multiple diseases, it is common for them to take multiple medications at the same time. About 8% of the Belgian population aged 65 years and over and 42% of those 85 years and over live in a rest or nursing home. The quality of medication use by residential elderly is a major policy concern because this segment of the population increases. In the next decade the number of people aged 85 years and over in our country will increase from the current 180,000 to 285,000.

The Belgian model of long-term residential care for the elderly is rather unique. Rest and nursing homes offer a home-replacing environment when possibilities for long-term care at home or short-term residential care are no longer sufficient. They have a mix of residents where slightly and highly dependent patients and demented and non-demented patients live together in one institution. The elderly can move between different levels of care - from a rest home to a nursing home - without leaving the institution. Rest and nursing homes are spread all over the country. Nearly every municipality has its own rest or nursing home.

The objective of this study was to investigate the quality of medication use and of prescribing behaviour in rest and nursing homes and to analyze the possible impact of organizational characteristics of the institutions. To answer these questions reliable data at the level of the institution and at the level of the resident are indispensable. As a supplement to the information in the available administrative datasets such as Farmanet, a field study was carried out in a selection of institutions and residents in the provinces of Antwerpen, Oost-Vlaanderen and Hainaut. Therefore we would like to thank cordially the many institutions, their coordinating physician, the general practitioners, the nurses and caregivers who enthusiastically participated in this study. This expresses in the first place the commitment and concern of all those involved to improve, where possible, the quality of care.

This report is the outcome of a collaboration of the KCE with RIZIV and a consortium under the guidance of the Heymans Institute of Pharmacology (Ghent). The report provides a point of departure to monitor and improve the quality of medication use in Belgian rest and nursing homes. This will require constant effort.

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Executive summary

BACKGROUND

On January 1, 2005 the elderly (aged 65 and older) represented about 17.2% of the 10.4 million Belgian inhabitants, 1.6% was over 85 years. Approximately 8% of the 65+ elderly live in rest or nursing homes. The quality of medication use by residential elderly is a major policy concern because of an increasing number of people in this segment of the population and the fact that they are major consumers of medicines. It is well-known that older people consume more medication than any other age group. Elderly tend to have more long-term, chronic illnesses than younger people. Since many of them have a number of diseases or disabilities, they also take multiple medications at the same time.

Contrary to other countries, little empirical evidence exists regarding the quality of medication use and the quality of prescribing in residential homes for the elderly in Belgium. This is mainly due to a lack of readily available data. The objective of this study was to investigate the quality of medication use and the quality of prescribing in residential homes for the elderly and the relation with organizational characteristics. We translated this broad research question into some more specific questions: What is the magnitude of medication use and costs for long-term residential elderly in Belgium? What are the medical needs of residential elderly? Which quality indicator(s) should be recommended to assist in monitoring and improving the quality of care provided to residents of Belgian nursing homes? What are the general characteristics of medication management in Belgian nursing homes? Which organizational characteristics are associated with the quality of medication use? Since the available administrative databases do not contain all the information needed, a field study was carried out in a selection of nursing homes and residents.

GENERAL CHARACTERISTICS OF THE BELGIAN RESIDENTIAL LONG-TERM CARE FOR THE ELDERLY

Belgium has a rather unique model of long-term residential care for the elderly. Rest homes (ROB, MRPA) offer a home-replacing environment when possibilities for at-home care or short-term residential care are not sufficient anymore. Nursing homes (RVT, MRS) are designed for patients with long-term care needs, who are heavily dependent on the help of others for the activities of daily living. Belgian residential homes for the elderly have a mix of residents where slightly and highly dependent patients and demented and non-demented patients live together in one institution. Elderly can move between different levels of care - from a rest home to a nursing home- without leaving the building. On December 31, 2004 there were 665 institutions which were pure rest homes, 970 mixed rest/nursing homes and 45 pure nursing homes. About 150,000 elderly were resident in a rest or nursing home in 2004. More than 75% of them were women, 46% was older than 85 years.

Residential homes for the elderly are spread all over the country. Nearly every municipality has its own rest or nursing home. However, there are substantial regional differences in residential home beds between the provinces and within one province. At the level of the province, Hainaut and Liège have by far the largest number of age-stratified residential home beds for the elderly (>4,099 beds per 100,000 inhabitants over 50 years of age), while the provinces of Limburg and Vlaams-Brabant (<2,700 beds) have the lowest number.

AGGREGATED MEDICATION USE IN REST AND NURSING HOMES

The majority of rest and nursing homes buy their drugs through community-based pharmacies. Drugs are reimbursed on a fee-for-service basis in Belgium. The Farmanet database contains detailed information on prescriptions dispensed from community-based pharmacies in Belgium. Since prescriptions dispensed from hospital pharmacies are not included in Farmanet, our estimates of medication use are slightly underestimated. The data on medication use are classified according to the Anatomical Therapeutic Chemical (ATC) Classification System. To estimate the distribution of medication use, we use the Defined Daily Dose (DDD).

The four main ATC classes of drug consumption in elderly people living in Belgian rest and nursing homes are related to the cardiovascular, nervous, gastrointestinal and respiratory system. For cardiovascular disease molsidomine is the most prescribed drug, followed by several antihypertensive agents, class III anti-arrhythmics and statins. The group of drugs for the nervous system is largely dominated by antidepressants, the second place is taken by atypical antipsychotics. Furthermore, betahistine is still widely used. For the gastro-intestinal system, drugs to treat peptic disease are the largest groups. Oral antidiabetics dominate the group of drugs affecting the metabolism. Mucolytics are still widely used. They are followed by several inhalation preparations used for obstructive pulmonary disease. Clear geographical variations exist for the prescription of several drug classes.

AGGREGATED EXPENDITURES IN REST AND NURSING HOMES

Total expenditures on pharmaceutical specialties dispensed by the community pharmacy for residential elderly added up to more than 130 million € of which 82% was paid by the health insurance and 18% out of pocket by the residents. Antidepressants, antipsychotics and antithrombotic agents are rivaling for the highest health insurance cost. Together, the 10 most prescribed ATC3 classes amount to almost half of the total budget. However, the price of an individual drug is also a major determinant of the budgetary impact for health insurance. Especially drugs used to prevent or treat infectious diseases represent a higher individual cost: influenza vaccination, several antibiotics and antimycotic drugs. In addition, several hormones, anti-Alzheimer drugs, antipsychotics and opioids represent a relatively high individual cost.

LITERATURE ON MEDICATION USE IN NURSING HOMES

The review of the international literature on the use of medication in nursing homes was conducted in MEDLINE, International Pharmaceutical Abstracts and in EMBASE, using a search strategy based on 6 sets of keywords. Relevant references from relevant articles were retrieved (snowballing). A limited set of 40 highly relevant articles was used as starting point for using the “related articles” algorithm in Pubmed and for a search in Web of Science, resulting in a final set of 170 relevant articles.

These articles were reviewed in a narrative review, not a systematic review. Its purpose was to provide a broad overview of the subject, in preparation to the field study, to provide the necessary elements for constructing questionnaires, and to review existing sets of prescribing quality indicators, pertinent to the setting of nursing homes. No attempts have been made at formal data extraction for pooling of data.

The major conclusion of this literature overview is that several intervention strategies in nursing homes have the potential to increase the quality of prescribing. Some evidence of effectiveness is available for pharmaceutical care and multidisciplinary interventions, involving the whole team of caregivers. The size, expertise and culture of the nursing staff are important for the quality of medication distribution and monitoring processes.

More research is needed on the implementation of drug formularies in nursing homes and on how to use information technologies in order to enhance medication management.

Existing research focuses on structural indicators (general characteristics of institutions and the characteristics of their medication management systems). The impact of these structural indicators on the process of prescribing has been studied through recently developed process indicators of prescribing quality. Several sets of prescribing quality indicators have been developed for nursing homes, each measuring different aspects of prescribing quality and none of them fully validated or universally applicable. Moreover, evidence is lacking on the link between structural indicators, process indicators and direct measurements of outcome at resident level.

FIELD STUDY

Rationale

The rationale for conducting a field study was the observation that not all questions addressed in this report can be answered solely on the basis of the available administrative datasets, such as Farmanet. To assess the quality of medication use of residential elderly, reliable data at the level of the institution and at the level of the resident are indispensable. A field study overcomes most of the limitations of the administrative datasets.

The primary aim of the field study (Prescribing in Homes for the Elderly in Belgium/PHEBE-study) was to investigate the relation between the institutional characteristics, the medication management systems and the quality of medication prescribing. Additionally the study aimed to evaluate existing sets of prescribing quality indicators with regard to their suitability for application in the Belgian context.

Design and sampling procedure

The study was set-up as a cross-sectional descriptive study of a representative sample of nursing homes (pure and mixed) and their residents. Nursing homes (>30 beds, including RVT beds) were randomly selected (N=76) in the provinces of Antwerpen, Oost-Vlaanderen and Hainaut based on a stratification according to size (up to 90 or more than 90 residents) and type (public, private). In each selected institution, 40 residents were randomly selected.

Data collection

At the level of the nursing home, data were collected by a structured interview of the nursing home manager and one or two head nurses. The structured questionnaire focused on the characteristics of the medication management system. The organizational characteristics of the medication process were translated in a scoring system with an evaluation of the quality of the different aspects of the medication management system (use of formulary, communication, storage, preparation and administration of medication).

At the level of the residents, administrative data were collected and a copy of the medication chart was taken. The medication on the chart was entered into a database and a print was sent to the treating physician asking to check the medication and to complete with information on clinical and care problems of the resident. Hence, it was possible to assess the quality of the process of prescribing medicines. We used three existing sets of prescribing quality indicators, specially adapted to the setting of the elderly: the BEERS criteria of potentially inappropriate prescribing in the elderly, the ACOVE (Assessing Care of Vulnerable Elders) criteria of under-prescribing in the elderly and BEDNURS (Bergen District Nursing Home Study). In addition, we added two other approaches to quality of prescribing: chronic benzodiazepines use and Belgian medication with low benefit/risk ratio. This study was performed in 76 randomly

selected nursing homes, including 2,510 residents with administrative data and a medication chart available.

Organizational characteristics of the nursing homes

The selected nursing homes had a mean capacity of 106 beds (range: 35 - 306) and between 1 and 7 wards, mainly with a mixed character open for all kinds of residents. The vast majority of nursing homes purchased the medication from a community pharmacy (83%), 1/4 with prices based on a public tender and 1/3 based on an informal agreement. Most of the nursing homes worked with a drug formulary, but the degree of implementation differed considerably. The medication charts used were still handwritten in 21% of the nursing homes. One or more of the mandatory items on the chart were lacking in 30% of the institutions. Quality scores of the medication management system showed wide variation in all the different domains evaluated. For most domains, the median value was close to zero, indicating that only the legal obligation was achieved.

The quality of the medication management system was influenced by the location of the nursing home, the activities of the local pharmacist and mainly by the quality of the nursing staff (number of residents treated per qualified nurse and percentage nurses-bachelor level on the total number of nursing staff).

Residents' characteristics

The selected residents had a mean age of 85 (range 36-104), 77% of them were women. Clinical problems scored by the responsible physician ranged from 0 to 12 (mean 2.7). Cardio-vascular pathology was observed the most frequently. Additionally, residents had between 0 and 15 care problems (mean 2.7), 46% had dementia and 35% were depressed.

Residents had between 0 and 22 medications noted on their medication chart (mean 8.1). Most were for chronic use (88%), 3% was acute medication and 9% "as needed". Highest consumption was observed for psycholeptics (benzodiazepines or antipsychotics) (68% of residents), laxativa (50%) and antidepressants (46%). The total mean expenditure per month and per resident for chronic medication was estimated at 140 €, including a mean co-payment for reimbursed medication of 23 € and a mean out-of-pocket payment for non-reimbursed medication of 27 €.

Quality of medication prescribing

Assessment of the quality of prescribing revealed that most problems were noted using ACOVE, BEDNURS and BEERS criteria. Undertreatment was mainly observed in patients with heart failure. BEDNURS scored particularly high for the combination of psychotropic medication. BEERS identified most frequently the potentially inappropriate use of digoxin, oxybutynin and amiodarone. The overall prescribing quality problem score ranged from 0 to 13 per resident (median 2) and showed a wide variation between nursing homes.

The amount of chronic medication used was mainly influenced by poly-pathology and the number of care problems of the resident. The number of medication used decreased in the very old, in the demented population and in the last phases of palliative care. At the level of the institution, the amount of medication used was lowest in large nursing homes run by the local community social service (OCMW/CPAS) and was mainly influenced by the activities of the local pharmacist.

Institutional characteristics had an important influence on expenditures for chronic medication. The percentage of cheap medication used was influenced by the location of the nursing home, the use of a drug formulary, the activities of the coordinating physician and the local pharmacist and the existence of a price competition system for the delivery of medication.

The total score of prescribing quality problems increased with higher poly-pathology and in larger institutions, and decreased with a higher number of residents treated by

the CRA, a larger number of activities performed by the pharmacist, a higher mean age of the residents and a higher percentage of dementia.

DISCUSSION AND GENERAL CONCLUSIONS

Belgium has a well-established network of rest and nursing homes within its cities and villages, mainly run by community social services, by private not-for-profit and for-profit corporations. Rest and nursing homes are not specialized in specific illnesses but residents with different medical problems live together in one institution. Many residents are still supervised by their former general practitioner, but in some nursing homes the coordinating physician is responsible for more than half of the residents of the home.

The large majority of nursing homes are served by community pharmacists, with little engagement in clinical pharmacy activities. About one in ten nursing homes is served by a hospital pharmacist. The medication management systems in the nursing homes are poorly developed and focus mainly on the distribution process inside the institution, and less on the appropriateness of prescribing. Few residents manage to keep some form of autonomy with regard to medication, except in institutions with limited staff and poor distribution management. Although a formulary (RVT Formulierium) for nursing homes is available as a guide to pursuing rational prescribing since 2004, the implementation of this formulary and its impact on the drug choice process of the visiting physicians seem to be limited. Nursing homes run by the local community social service (OCMW/CPAS) more often had a hospital pharmacist running the medication supply to the institution, more often had a coordinating physician treating a high number of residents within the institution, and more often had more intense medication management systems.

Residents of rest homes and nursing homes generate considerable public expenditures for pharmaceutical specialties (123 million € per year). The field study revealed that residents also pay hefty amounts of personal money out-of-pocket for co-payment of chronic reimbursed medicines as well as for payments to the pharmacy for non-reimbursed medication. Albeit only 1.4% of the population lives in rest or nursing homes, the data from this study and data from national claims databases indicate that more than 5.6% of the public expenditures on medication (pharmaceutical branded products) may be generated by nursing home residents.

With regard to quality of prescribing we observed considerable poly-pharmacy in the majority of the residents. The high number of drugs and drug combinations in itself could be a reason for concern. On the other hand, half of the residents had at least one potential problem of under-prescribing. The prevalence of chronic use of benzodiazepines, antidepressants, and antipsychotics (often combined) was strikingly high. Both the analysis of the national aggregated data as well as the field study found evidence for the continuing use of several drugs that are obsolete or where the clinical and cost-effectiveness should be questioned.

There is clearly a relation between the number of observed quality problems and the presence of poly-pathology. We observed a decrease in the number of quality problems in those institutions, where the coordinating physician treated a high number of patients and where the local pharmacist played an active role in medication management. To fully understand the variation in prescribing quality, the key role of the prescribing physician needs to be taken into account.

Interventions to enhance the quality and the affordability of medications in rest and nursing homes will be more cost-effective when these interventions not only have an impact on the drug choice process for residents of nursing homes, but also on the drug choice process for all elderly patients on the list of the general practitioners.

POLICY RECOMMENDATIONS

1. There is a legal obligation for nursing homes to have a formulary as a guide to pursuing rational prescribing since 2004. Measures should be taken to increase the implementation and impact of the formulary in nursing homes and rest homes. Based on the evidence provided in this study, the medical coordinator should play a larger role in this process. A formulary can play a pivotal role in the knowledge transfer of best practices towards prescribing physicians in rest and nursing homes and in the local implementation of prescription guidelines and quality control systems. A continuing close collaboration with several scientific and professional associations is crucial. Independent drug information and pharmacovigilance centres should enhance their efforts to provide evidence summaries on appropriateness of and to increase awareness for risks associated with drug utilization in the elderly population.

2. Local agreements between institutions, prescribing physicians and pharmacists on the concrete choice of generic drugs could increase their use. At this moment the wide availability of different molecules as well as switches in the delivery depending on the pharmacist, may limit the practical feasibility to decide in favour of generic drugs. The possibilities for applying unit-dose – packaging per individual patient-, should be investigated.

3. Orientation of the professional training of nurses and pharmacists towards their new role in medication management in health care institutions is needed. This should be done in collaboration with the medical coordinator. Better training in pharmacology of the nursing staff and enhanced communication with the dispensing pharmacist and the prescribing physicians has the potential to improve the quality of pharmaceutical care in nursing homes. Clinical pharmacists should assist and participate more in all stages of the medication use process: the prescribing of the medication, purchase, packaging, administration and distribution system and the follow-up of the effectiveness and safety of pharmacotherapy.

4. Drugs dispensed by the community pharmacist are currently reimbursed on a fee for service basis. The advantages and disadvantages of a fee-for-service system are well-known. In an attempt to combine incentives for quality enhancement and cost containment, other financing systems should be explored. Case-mix budgeting and reference pricing are two possible alternatives which should be examined in more detail.

5. Research agenda:

- Based on the volume of prescriptions of certain drugs, further epidemiological studies on the incidence and prevalence of disorders such as major depression, behavioural and psychological symptoms of dementia, Menière's disease, deep venous thrombosis, coronary syndromes and angina pectoris are needed in certain Belgian regions from a public health's point of view.
- There is a need for reliable and feasible scales to assess the case mix of institutions and the continuous functional assessment of individual residents. Given the imminent digital revolution in health care facilities, the transformation of the pharmaceutical and clinical data collection methods in this cross-sectional research to tools for continuous, automated data-collection and feedback based on computerized nursing records should be investigated. Methods are needed to define and incorporate outcomes (quality of life, mortality and hospital admissions whether or not drug-related) into the research designs pertaining to the quality of prescribing and medication management.
- An analogous epidemiological study of medication use and quality of prescribing should be carried out in vulnerable elderly receiving at-home care.

Scientific summary

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I ORGANIZATIONAL CHARACTERISTICS AND AGGREGATED MEDICATION USE IN BELGIAN REST AND NURSING HOMES

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I.1 INTRODUCTION

On January 1, 2005 the elderly (aged 65 and older) represented about 17.2% of the 10.4 million Belgian inhabitants, 1.6% was over 85 years. Current demographic projections suggest that approximately 19% of Belgium's population will be more than 65 years by the year 2015, and that people more than 85 years will make up 2.7% of the total population. Furthermore it is projected that by the year 2030 almost 25% of the population will be aged 65 and older and 3.2% will be 85 or older.¹ These projections mean that increasing numbers of Belgians will be "the oldest old". The potential consequences of this demographic shift over the next decades for the organization and financing of long-term care are a major policy concern and research topic in Belgium and other countries facing the same demographic evolution.²

Although the health care needs of many older people are not so different from those of the rest of the population, for the oldest old and those with chronic diseases or disability the prevalence rate of long-term care is high and increasing in Belgium.^{3, 2, 4, 5}

One element of caring for the elderly is by making sure they get the right medical care. The most common intervention that older people experience is the use of medication. It is well-known that older people consume more medication than any other age group. They tend to have more long-term, chronic illnesses such as arthritis, diabetes, high blood pressure and heart disease than do younger people. Since many elderly have a number of diseases or disabilities at the same time, it is common for them to take multiple medications at the same time. The hazards of prescribing many drugs, including side-effects, drug interactions, under-prescribing of potentially beneficial drugs and difficulties of compliance, have been recognized in the international literature as particular problems when prescribing for elderly people.

The quality of medication use by residential elderly is a major concern because of an increasing number of people in this segment of the population and the fact that they are major consumers of medicines. The quality of medication use depends both on the quality of prescribing and the quality of medication management. The medication management includes the whole process from the prescribing of the medication, through the purchase, packaging, security, administration and distribution system, until the follow-up of pharmacotherapy. The determinants of prescribing and of the medication process for nursing home residents are not well understood, but organizational characteristics of residential settings are a plausible candidate. Identification of factors influencing the patterns of medication use in residential elderly could lead to development of strategies to optimize medication use with consequent improvement in residents' health.

In other countries, an increasing number of studies were carried out on the quality of medication use in elderly residents during the last decade. In Belgium very little research has been conducted on this topic, mainly due to a lack of readily available data on the consumption and quality of medication. The use of medication and prescribing patterns in old age and in residential elderly are hardly documented.

Belgium has rather limited experience with medication management in residential care for the elderly. Yet, during the last years some initiatives have been taken to improve the quality of the medication policy. Since 2000 each nursing home must have a medical coordinator^a. This is a general practitioner, preferably with an additional formation in

^a Royal Decree of June 24, 1999. Coördinerend en raadgevend arts (CRA) in Dutch, médecin coordonnateur et conseiller (MCC) in French.

gerontology, who is responsible for the coordination of quality initiatives and for the training of the staff. Regarding medication policy the responsibility of the medical coordinator includes the development and use of a formulary. Since 2004 such a formulary (RVT Formularium^b) for nursing homes is available as a guide to pursuing rational prescribing.

The objective of this study was to investigate the quality of medication use, prescribing and medication management in residential homes for the elderly in Belgium. Since the available administrative databases do not contain all the information needed, a field study was carried out in a selection of nursing homes and residents.

This introductory chapter presents a general overview of the organization and financing of the Belgian residential long-term care for the elderly (section 1.2). Section 1.3 specifies the research questions. Some previous studies on medication use in residential homes for the elderly in Belgium are summarized (section 1.4) and aggregate data on medications use and expenditures are provided (section 1.5). Section 1.6 introduces the rationale for the field study.

Chapter 2 provides a report of an international literature search on the needs of nursing home residents, on the medication use in nursing homes and on organizational characteristics which may affect the quality of prescribing and the quality of medication management.

Chapter 3 is the main part of the report and contains the setting, objectives, methods and results of the field study carried out in a selection of nursing homes and their residents.

Chapter 4 discusses and concludes the findings of the report and presents the policy recommendations.

1.2 A BRIEF DESCRIPTION OF THE BELGIAN RESIDENTIAL LONG-TERM CARE FOR THE ELDERLY^c

1.2.1 Residential long-term care settings

“Long-term care” and “residential care” are not easy to define. However, defining the boundaries among primary, acute and long-term care and the role of residence for an elderly population go far beyond the limits of this study. Instead, we follow the definition of long-term residential care of the WHO^d: “Institutional or residential long-term care is defined as the provision of care to three or more unrelated people in the same place. Activities undertaken by formal caregivers “may be publicly financed and organized, but the services may be provided by governmental organizations, NGOs or by the private sector. Formal care is usually provided by professionals (doctors, nurses, social workers) and auxiliaries, such as personal care workers”.

The Belgian elderly care infrastructure comprises at-home care and community services, short-term and long-term residential care and hospital care. Long-term residential care includes rest homes or homes for the elderly^d and nursing homes^e.

A rest home (ROB) is defined as one or more buildings that functionally generate a collective residence in which elderly people live on a long-term basis. In the rest home, the usual family and household care is given completely or partly^f. The legislator defines elderly people as people aged 60 years and older. Younger people can be admitted only when approved in writing by the responsible authority. Rest homes offer a home-

^b See <http://www.formularium.be/nl/formularium/frameset.htm> for more information.

^c All results in section 1.2 were calculated using administrative databases made available by RIZIV/INAMI (National Institute for Sickness and Invalidity Insurance), unless mentioned otherwise. A description of the data and record-linkage are provided in the technical note in Appendix 1.

^d Rusthuis (ROB) in Dutch, Maison de repos pour personnes âgées (MRPA) in French.

^e Rust- en verzorgingstehuis (RVT) in Dutch, Maison de repos et de soins (MRS) in French.

^f Article 2, §6 of the Decree of the Flemish Government of December 18, 1991. Article 2 of the Decree of the French Region of June 5, 1997.

replacing environment when possibilities for long-term care at home or short-term residential care are not sufficient anymore.

Medical characteristics of the residents differentiate rest homes from nursing homes. Nursing homes (or beds) are designed for patients with long-term care needs, who are heavily dependent on the help of others for the activities of daily living. Eligibility for admission to a nursing home rests on the following criteria^{g,7,8}

1. The elderly person has undergone all active and reactivating treatment but has not regained full competency in activities of daily living (ADL). However, daily medical supervision or a specialized medical treatment is not necessary.
2. All possibilities for at-home care have been explored so that a nursing home admission is needed.
3. The general health status of the elderly person demands, apart from medical care provided by a general practitioner and nursing care, paramedical and/or physiotherapeutic care and help with activities of daily living.
4. The elderly person has a degree of care dependency equal to B or C (see section 1.2.2.1).

Rest homes and nursing homes can impose further criteria for admission. Some for example do not admit people suffering from dementia, while others exclusively admit people with a diagnosis of dementia.⁷

For placement in both residential settings, an assessment with multi-disciplinary evaluation reports and standardized evaluation scales takes place (see section 1.2.2.1). The general practitioner or the nurse (providing hospital or at-home care) fill in the evaluation scale. This assessment together with an evaluation of social conditions determines eligibility for placement in a rest or nursing home.

The first nursing homes were created in 1982 with the explicit intention to create an intermediary structure between a rest home and a hospital. Nowadays nursing home beds are in distinct parts of hospitals or rest homes. There is a merged system of rest home and nursing home, which means that the elderly can move between different levels of care without leaving the institution.

The Belgian model of long-term residential care for the elderly is rather unique. Rest and nursing homes are not specialized in specific illnesses – except for dementia- but accept residents with different medical problems. Moreover, residential homes for the elderly are spread all over the country. Nearly every municipality has its own rest or nursing home.⁹ Although many homes have waiting lists, most elderly have the opportunity to go to a home in the municipality they live or a neighbouring municipality when moving into a residential care home.

Rest and nursing homes are mainly run by community social services, by religious charities and to a more limited extent by private for-profit corporations.

^g Article N1 – appendix I of the Royal Decree of September 21, 2004.

Terminology

In chapter 1 we use 'rest home' to refer to that part of the institution or building with accredited rest beds (ROB-bedden). A 'nursing home' refers to the part with accredited nursing beds (RVT-bedden).

In chapters 2 and 3 we use 'nursing home' for an institution with exclusively nursing beds or with rest and nursing beds. In this way the term 'nursing home' is used according to the international literature.

1.2.1.1 The responsibilities of authorities for residential long-term care

The responsibility for residential long-term care is shared between the federal and regional authorities^h.

The Federal Minister of Social Affairs and Public Health determines the planning and accreditation criteria for the nursing homes and the daily lump sumⁱ allocated by RIZIV/INAMI to rest and nursing homes. The Federal Minister of Economy, Energy, Foreign Trade and Science Policy fixes the price for hotel (accommodation) services to be paid by the resident (see section 1.2.2.2).

The planning and accreditation criteria for the rest homes are determined by the communities (Flemish, French and German-speaking communities).

The distribution of responsibilities between the different authorities is complicated. However, since 1997 three protocol agreements (1997, 2003 and 2005) between the federal government and the communities have formulated common objectives of elderly care. These agreements allow each authority to flesh out the common objectives autonomously according to the local demographic needs.

1.2.1.2 Number of institutions

There were 1,678 rest homes (ROB) and 1,015 nursing homes (RVT) with at least one bed on December 31, 2004. In a majority of the cases, an institution comprised both a rest home and a nursing home. In this way, 970 rest homes and 970 nursing homes were each part of a single institution. In other words, 708 rest homes and 45 nursing were single entities. The geographical distribution by province is shown in table 1.1.

Table 1.1 : Number of residential homes by type and province on December 31, 2004

Provinces in Flanders	ROB ⁱ	RVT ⁱ	Total
Antwerpen	197	162	359
Vlaams-Brabant	116	83	199
Limburg	74	55	129
Oost-Vlaanderen	194	153	347
West-Vlaanderen	163	150	313
Provinces in Wallonia			
Hainaut	294	117	411
Liège	220	107	327
Namur	102	41	143
Brabant wallon	68	28	96
Luxembourg	50	20	70
Brussels - Capital Region			
Brussels - Capital Region	200	99	299

ⁱ ROB: rest home; RVT: nursing home; Source: RIZIV/INAMI

^h See Appendix 2 for more details on the responsibilities of the different authorities for residential long-term care in Belgium. Appendix 2 also provides a detailed overview of the data the rest and nursing homes have to report to the responsible authorities.

ⁱ See section 1.2.2.1 for more details on the financing of residential long-term care.

1.2.1.3 Number of residential home beds

On average, the distribution of number of beds for rest homes and for nursing homes is fairly similar (see table 1.2). About 25% of both rest homes and nursing homes had approximately 30 beds or less on December 31, 2004, while about 25% had more than 60 beds.

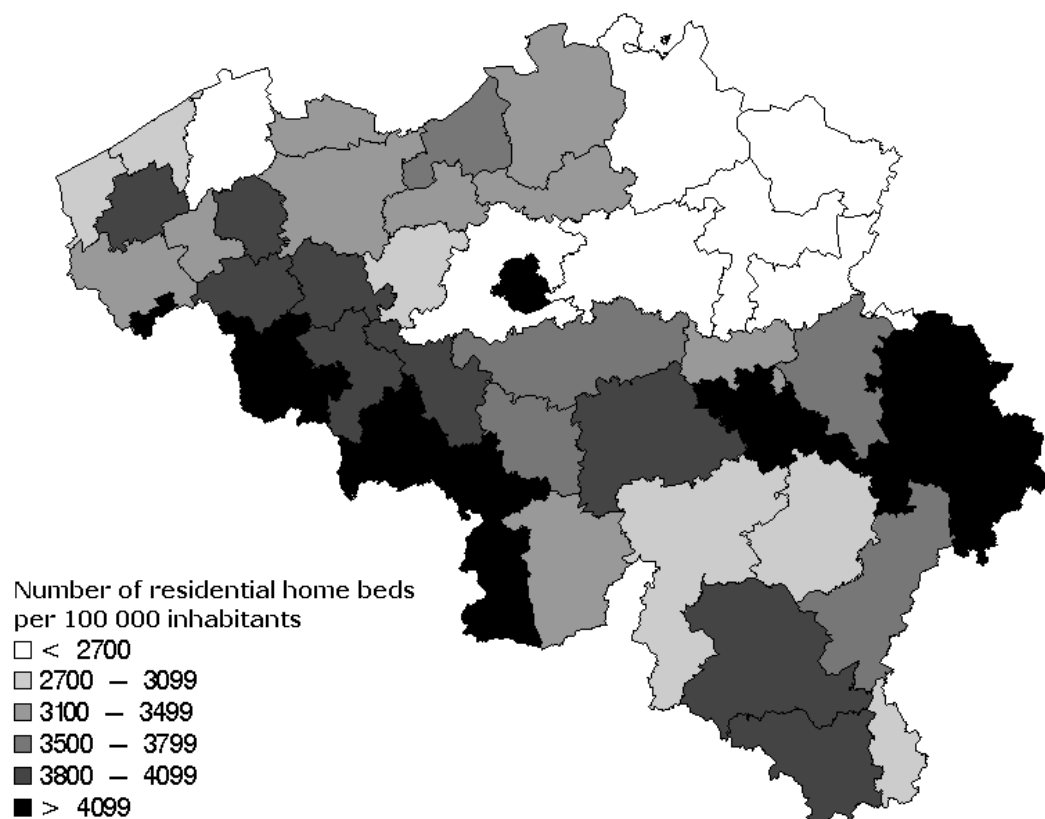
Table 1.2 : Descriptive statistics of the number of residential home beds by type of home on December 31, 2004

	N	Min	Max	Q1	Median	Q3	Mean	SD
ROB	1,678	2	234	27	41	59	47.03	28.66
RVT	1,015	1	347	25	37	58	46.73	28.91
All	2,693	1	347	27	40	59	46.92	28.75

Source: RIZIV/INAMI

An age-stratified number of residential home beds by district suggests a larger potential of beds in the Walloon region and the Brussels-Capital region compared to the Flemish region (see figure 1.1). This tendency is more pronounced in the provinces of Limburg, Hainaut, Liège and Vlaams-Brabant. Although figure 1.1 reveals substantial differences in the number of residential home beds within one province and between the provinces, the differences between the regions dominate the picture. These regional differences in residential home beds for the elderly have to be compared with at-home care and community services and short-term residential care for the elderly in the different regions to get an overall picture of care infrastructure for the elderly. A typical example is the province of Limburg. While the number of residential home beds per 100,000 inhabitants over 50 years is among the lowest in Limburg, the number of elderly making use of at-home care services is substantially larger than in the rest of Flanders.²

Figure 1.1 : Number of residential home beds per 100,000 inhabitants over 50 years of age by district (2005)



Source: RIZIV/INAMI (number of beds on December 31, 2004); FOD Economie - Algemene Directie Statistiek en Economische Informatie, Dienst Demografie (population on January 1, 2005)

1.2.1.4 Number of patients

The distribution by age and by gender indicates that elderly rest and nursing home residents are predominantly women above 80 years of age (table 1.3ⁱ). More than 75 percent of residential elderly are women. There are some striking differences in the age distribution between men and women. Beneath the age of 80, the percentage of men in rest and nursing homes is larger than that of women. Above the age of 80 the opposite is true. This means that when abstracting from the total number of residential men and women, the male population is relatively younger than the female residential population. About 51 percent of residential elderly women are above the age of 85, while this is only the case for about 33 percent of men^k.

ⁱ The results in table 1.3 were calculated using an administrative database made available by IMA (Intermutualistisch Agentschap- Agence Intermutualiste - Intermutualistic Agency). IMA is a non-profit institution with all Belgian sickness funds as its members. A description of the selection of patients is provided in the technical note in Appendix 3.

^k In Pacolet et al. 2004-p208² the number of long-term residential elderly is substantially lower than in table 1.3. In the former study the number of residents is a picture on June 30 of each year, while in table 1.3 all residents for whom a rest or nursing home received a lump sum from RIZIV/INAMI (see section 1.2.2.1) during the year 2004 are included.

Table 1.3 : Age and gender distribution of elderly residents in rest and nursing homes (2004)

Age groups	Total	%	Women	%	Men	%
Age 95+	10,227	6.8	8,948	7.9	1,279	3.5
Age 90-94	28,784	19.2	24,009	21.3	4,775	12.9
Age 85-89	30,435	20.3	24,430	21.6	6,005	16.2
Age 80-84	38,661	25.8	29,398	26.0	9,263	25.0
Age 75-79	20,849	13.9	14,732	13.0	6,117	16.5
Age 70-74	9,916	6.6	6,066	5.4	3,850	10.4
Age 65-69	4,902	3.3	2,579	2.3	2,323	6.3
Age 60-64	2,574	1.7	1,213	1.1	1,361	3.7
Age 55-59	1,726	1.2	761	0.7	965	2.6
Age 50-54	983	0.7	413	0.4	570	1.5
Age <50	854	0.6	351	0.3	503	1.4
Total ^l	149,911	100.0	112,900	100.0	37,011	100.0

Source: IMA

Table 1.4 offers some insight in the rate of institutionalization of the elderly in Belgium. We compared the number of elderly women and men in rest and nursing homes (in 2004) with the total population of the same age (on January 1, 2005). Approximately 8% of the 65+ and 42% of the 85+ elderly lived in a rest or nursing home in the course of 2004^m. Noticeable are the increase in the rate of institutionalization with higher age and the larger rate for women than for men.

Table 1.4 : Institutionalization rate by age and gender (2004)

Age groups	Total (%)	Women (%)	Men (%)
Age 95+	82.8	85.7	66.9
Age 90-94	54.6	59.1	39.6
Age 85-89	30.3	34.5	20.2
Age 80-84	13.7	16.3	9.1
Age 75-79	5.4	6.4	3.9
Age 70-74	2.4	2.3	1.8
Age 65-69	1.0	1.0	1.0
Age 60-64	0.5	0.5	0.6
Age 50-59	0.2	0.2	0.2
Total ⁿ	4.1	5.7	2.2

Source: IMA (residential elderly in 2004) and FOD Economie, Ecodata (elderly population by age and gender on January 1, 2005)

1.2.2 Financing of rest homes and nursing homes

Costs for staying in a rest or nursing home can be divided into two major categories: costs associated with hotel services versus medical and personal care costs. In general, the care costs are covered by the public health insurance scheme, hotel costs by the resident. In this section we do not take into account the costs for RIZIV/INAMI or for the resident associated with GP or specialist consultations, hospital admissions or medication. We also neglect subsidies for infrastructure.

^l Missing values are not included.

^m The figures are not listed in table 1.4. The percentage at one moment in time is of course lower.

ⁿ We neglect the institutionalized people younger than 50 years.

1.2.2.1 Cost for RIZIV/INAMI^o

The care costs are financed by the public health insurance scheme through an envelope funding mechanism. A pre-set per diem payment rate is allocated to rest homes and nursing homes by RIZIV/INAMI for each beneficiary^p depending on the care dependency of the beneficiaries.

The degree of care dependency is assessed according to the Katz scale^q. There are six categories of dependency with a higher care profile receiving a higher per diem (see table 1.5).

Table 1.5 : Dependency categories

Dependency category	Description
O	Physically independent / no dementia.
A	Physically dependent for personal hygiene or getting dressed; or physically independent but disoriented in time and space.
B	Physically dependent for personal hygiene and getting dressed, and for transfer or bathroom visits; or physically dependent for personal hygiene and getting dressed and disoriented in time and space.
C	Physically dependent for personal hygiene and getting dressed, and for transfer and bathroom visits, and to eat or because of incontinence.
Cd	C plus disoriented in time and space.
Cc	In a persistent vegetative state caused by an acute brain trauma followed by a coma.

Source: art. 151 of Royal Decree dated July 3, 1996 on “rustoorden voor bejaarden, rust- en verzorgingstehuizen en centra voor dagverzorging” (homes for the aged, nursing homes, and day care centres); RIZIV circular 1307/AVB/omz-ROB-RVT2004/4 to the homes for the aged and nursing homes dated November 18, 2004.; art. 148 of Royal Decree dated July 3, 1996 on “uitvoering van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen” (execution of the law concerning the compulsory insurance on health care and benefits).

Before January 1, 2004 a rest or nursing home received a daily lump sum differentiated along the degree of dependency of the beneficiary. The new financing scheme allocates an average daily lump sum per beneficiary depending on the overall dependency rate of the institution. The lump sum covers care provided by nurses and caregivers, speech therapy, assistance in activities of daily living, activities of reactivation and social integration including occupational therapy, care material^r and staff training in palliative care. In nursing homes the daily lump sum also covers the physical therapist and the activities of the medical coordinator.

Since January 1, 2004 the number of invoiced days for a calendar year (t+2) is based on a quota of days calculated during a reference period (from July 1, year t until June 30, year t+1). This quota is equal to the sum of the number of days of the beneficiaries charged to their sickness fund and the actual number of days of the other residents. This total is raised by 3 percent to meet an increase in the occupancy rate during the

^o We describe the financing system into force since January 1, 2004. A detailed description of the new financing scheme can be found at RIZIV (2004).¹⁰

^p A beneficiary is a resident of a rest or nursing home whose care costs are financed by the per diem payment. Since the financing of rest and nursing homes is part of the compulsory health insurance system, it applies only to persons covered by this system. Some residents are not covered by the compulsory health insurance system for the care costs in a rest home (self-employed without a voluntary insurance for their minor risks) or in a rest home and nursing home (some foreign patients).

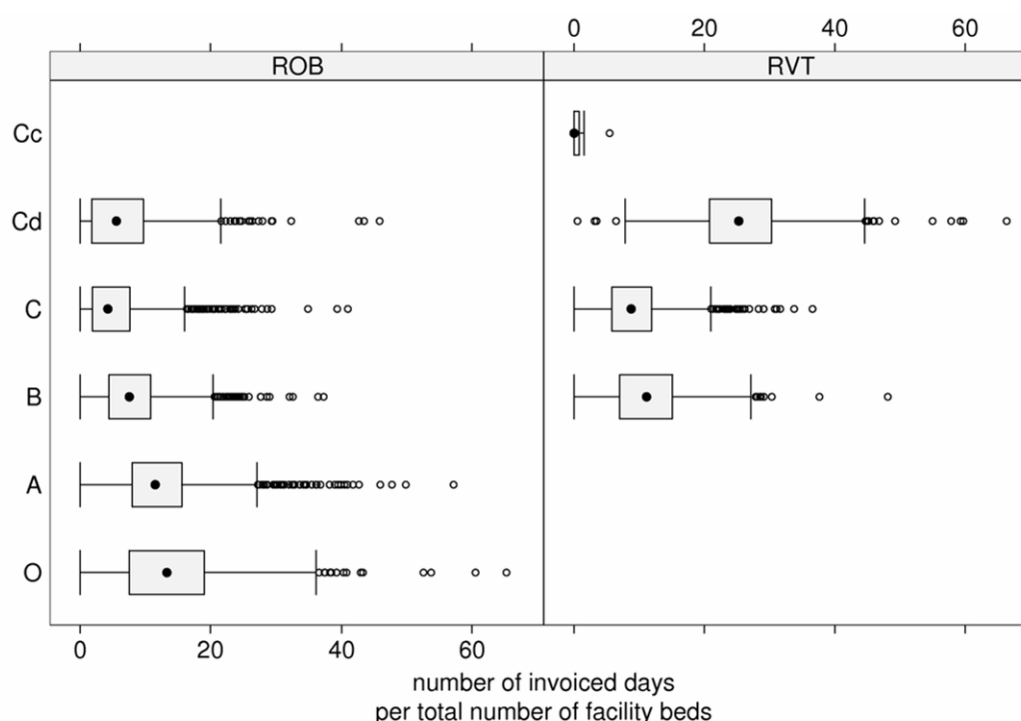
^q Since January 1, 2005 Mini Mental State Examination (MMSE) scores can be used to complete the Katz scores for persons disoriented in time and space.

^r As defined by article 147, §§ 1 and 2 of the Royal Decree of July 3, 1996.

reference period. The financing system also provides a partial contribution for days exceeding the quota.

Most invoiced days per residential home bed in the last quarter of 2004 fall into dependency categories O and A for rest homes and in dependency categories Cd for nursing homes (see figure 1.2). Figure 1.2 must not be interpreted as depicting the use of available bed capacity because the number of beds represents a snapshot on December, 31 2004 and does not reflect changes in the number of beds during the last quarter of 2004. Invoiced days were divided by the number of beds only to correct for the size of the homes. Due to the legal definition of nursing homes, there are no invoiced days in dependency categories O and A. Similarly, there are no invoiced days in dependency category Cc for rest homes.

Figure 1.2 : Number of invoiced days of residents divided by total number of beds per home in function of dependency and type of home (ROB: rest home, RVT: nursing home).



Source: RIZIV/INAMI

In general, the large majority of the residents in rest homes and nursing homes are beneficiaries. A marked difference between beneficiaries and non-beneficiaries is found for the distributions of invoiced days per residential home bed for all dependency categories except O, A, and Cc. The results suggest that most homes have little or no invoiced days per residential home bed of non-beneficiaries in dependency categories B, C, and Cd.

1.2.2.2 Private spending of residents for non-medical care

The remaining costs, mainly for hotel services, are met by the residents^s. These costs include food, administration and maintenance costs. They do not depend on the dependency category of the resident. The Federal Minister of Economy, Energy, Foreign Trade and Science Policy fixes the price for hotel services to be paid by the resident^t. Table 1.6 learns that the daily price residents of rest and nursing homes have to pay for hotel services differs substantially between and within provinces. However, since the daily price is not an all-in price we should be cautious when comparing the daily prices between residential homes for the elderly. On top of the daily price homes may ask supplements or advances on behalf of a third party^u. In the agreement between the rest or nursing home and the resident the items included in the daily price and a list of extra charges must be explicitly mentioned.

Table 1.6 : Daily price (in €) for hotel services in a single room in rest and nursing homes by province (2nd semester of 2005)

Provinces in Flanders	Mean	Min	Max
Antwerpen	42.6	24.5	86.8
Vlaams-Brabant	37.5	21.2	73.0
Limburg	37.1	25.4	66.0
Oost-Vlaanderen	37.6	18.0	125.0
West-Vlaanderen	36.8	22.3	74.9
Provinces in Wallonia			
Hainaut	31.3	18.0	75.4
Liège	31.0	16.3	76.0
Namur	30.3	18.8	75.5
Brabant wallon	37.5	18.8	86.1
Luxembourg	32.1	19.8	73.2
Brussels - Capital Region			
Brussels - Capital Region	37.2	16.7	134.7

Source: Ministerie van Economische Zaken, afdeling prijzen en mededinging

On October 1, 2001 a long-term care insurance scheme was introduced in Flanders to compensate for some of the costs of non-medical care that emerge when people become aged or disabled. Since July 1, 2006 all residents of an accredited rest or nursing home receive a monthly lump sum of €125.

1.2.3 Staff

The regulation of staffing requirements was not changed under the new financing scheme in effect from January 1, 2004. All staffing standards are expressed as 1 FTE for each 30 beneficiaries. The distribution is given in table 1.7.

^s Financial aid from the public municipal welfare centres (OCMW in Dutch, CPAS in French) or from the family of the resident is possible.

^t Ministerial Decree of August 12, 2005.

^u Voorschotten ten gunste van derden in Dutch, avances en faveur de tiers in French. When services are provided by third parties, the rest or nursing home first pays the third party and claims back the costs from the resident afterwards.

Table 1.7 : Staffing standards in rest and nursing homes, by type, occupational group and dependency category (in FTE/30 beneficiaries)

Dependency category	Occupational group	ROB	RVT
O	Nurse	0.25	Not relevant
A	Nurse	1.20	Not relevant
	Caregiver	0.80	Not relevant
B	Nurse	2.10	5.00
	Caregiver	4.00	5.00
	Reactivating personnel	0.35	Not relevant
	Physical therapist/speech therapist/occupational therapist	Not relevant	1.00
C	Nurse	4.10	5.00
	Caregiver	5.06	6.00
	Reactivating personnel	0.385	0.50
	Physical therapist/speech therapist/occupational therapist	Not relevant	1.00
Cd	Nurse	4.10	5.00
	Caregiver	6.06	6.50
	Reactivating personnel	0.385	0.50
	Physical therapist/speech therapist/occupational therapist	Not relevant	1.00

Source: RIZIV/INAMI

The difference between the actual number and the subsidized number of different categories of staff is paid by the rest or nursing home.

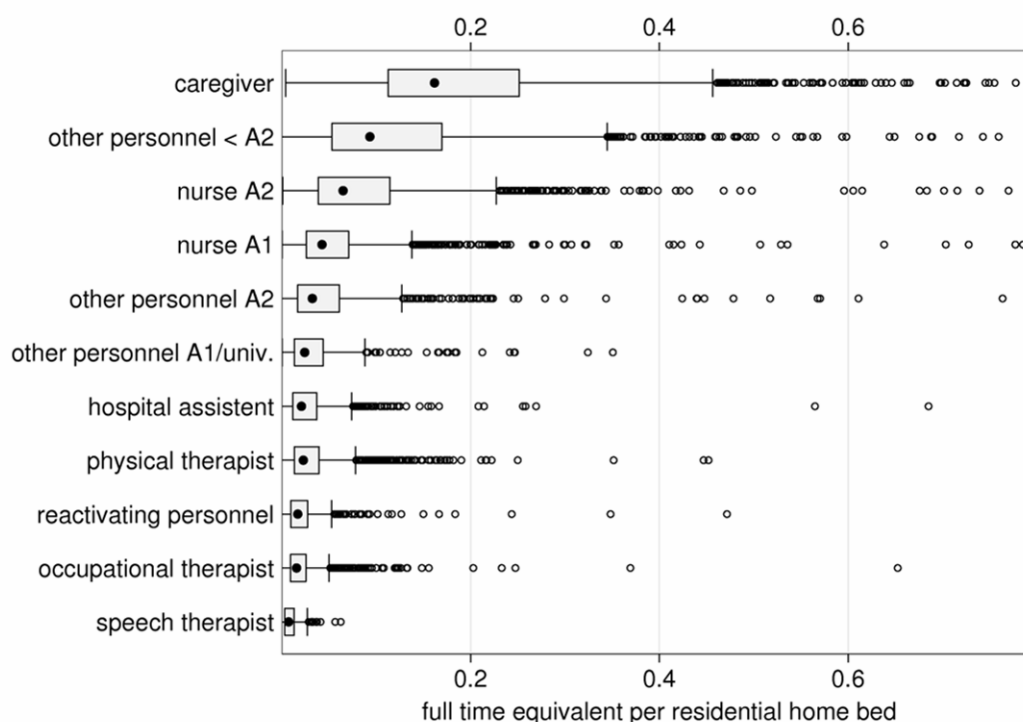
Figure 1.3 shows the distribution of staff in FTE per bed and occupational group[†].

Caregivers, other staff below level A2 and nurses comprise the largest occupational groups in rest homes and nursing homes[‡]. The variation within each occupational group is due to the way rest and nursing home staff is financed. Not only the number of beneficiaries, but also their care need is taken into account.

[†] The occupational groups in figure 1.3 can be classified according to the groups in table 1.3. Nurse = nurse A1, nurse A2 and hospital assistant; other personnel A2, other personnel A1/univ. and other personnel <A2 are not financed by the lump sum.

[‡] Due to the nature of the data file, a distinction between the FTE distributions of rest and nursing homes was not possible.

Figure 1.3 : Distribution of staff in FTE per residential home bed and occupational group in the last quarter of 2004

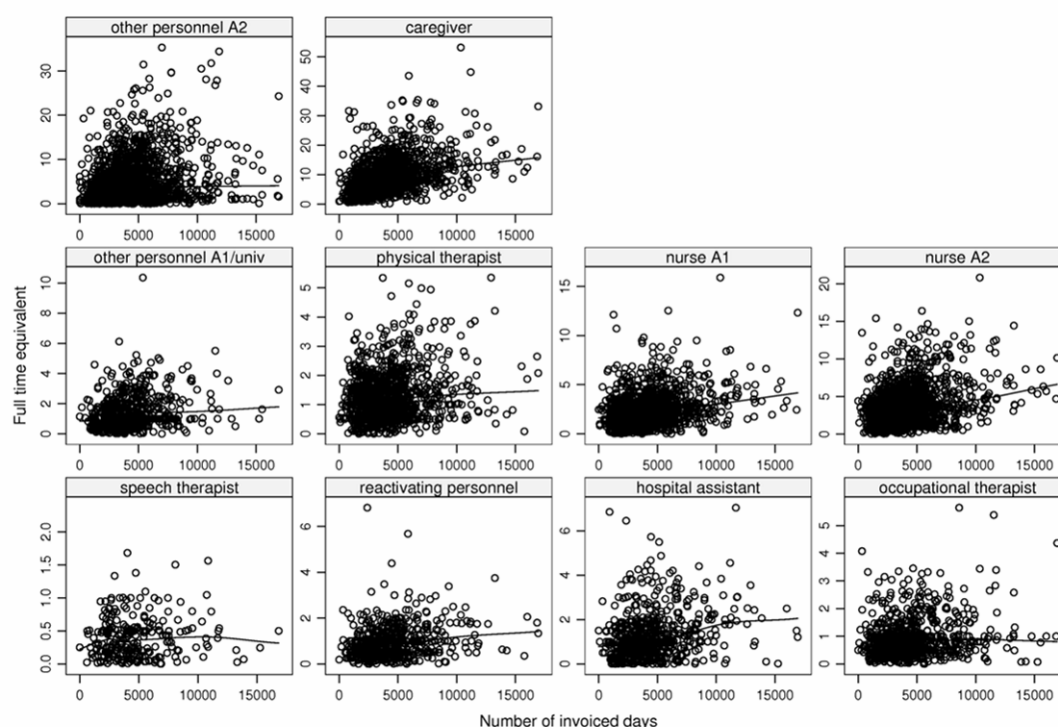


Source: RIZIV/INAMI

When comparing the number of invoiced days per residential home against the FTE per home by occupational group, we found that for most occupational groups, the more days were invoiced per home, the larger the amount of FTE per home (see figure 1.3). Given that more invoiced days generally corresponded to a larger home and hence to more available staff, this finding seemed fairly obvious but for two reasons. Firstly, speech therapists, reactivating personnel, and to a lesser extent other personnel level A2, were exceptions. That is, a larger number of invoiced days did not necessarily correspond with more FTE and vice versa. Secondly, the relation between FTE and number of invoiced days was far from perfectly linear as evidenced by figure 1.3. An explanation for both phenomena might be the governmental financing of staff in homes. Not only the number of patients but also the need for care of the residents is taken into account in the attribution of the amount of FTE per home^x. However, a more extensive exploration of this topic is beyond the scope of this report.

^x Ministerial order of 6 November 2003: “vaststelling van het bedrag en de voorwaarden voor de toekenning van de tegemoetkoming, bedoeld in artikel 37, § 12, van de wet betreffende de verplichte verzekering voor geneeskundige verzorging en uitkeringen, gecoördineerd op 14 juli 1994, in de rust- en verzorgingstehuizen en in de rustoorden voor bejaarden”; enactment of the amount and conditions of the attribution for the compensation, intended in art. 37, § 12 of the law regarding the mandatory health insurance and remunerations, coordinated on the 14th of July 1994 in the nursing homes and the rest homes

Figure 1.3. Number of invoiced days for the last quarter of 2004 in function of FTE by occupational group. Each panel has different scales.



Source: RIZIV/INAMI

1.3 RESEARCH QUESTIONS

The main objective of this study was to investigate the quality of medication prescribing in residential long-term care for the elderly in Belgium and the relation with institutional characteristics, including the quality of the medication management systems. We translated this broad research question into the following specific questions.

What is the magnitude of medication use and expenditures for long-term residential elderly in Belgium? The use and cost of medication in residential elderly are hardly documented in Belgium. We investigate the costs and use of prescribed medicines in all Belgian rest and nursing homes in 2004 using a large administrative database (Farmanet^y). In addition, we provide detailed information on the use and cost – reimbursed and private- of prescribed and over-the-counter (OTC) medication in a selection of nursing homes.

What are the medical needs of residential elderly? An assessment of clinical needs of nursing home residents is a prerequisite for any evaluation of the quality of prescribing. This assessment includes at least an evaluation of the resident's risk profile and co-morbidity.

How can the quality of prescribing to elderly nursing home residents be measured? Although many explicit, evidence-based criteria to assess the quality of prescribing to elderly nursing home residents have been developed and evaluated, debate continues regarding which indicators are most appropriate. Which (adapted) indicators to measure prescribing medication are most suited in the Belgian geriatric context? Which

^y See RIZIV (2005)¹¹ for a description of the Farmanet database.

quality indicator(s) should be recommended to assist in monitoring and improving the quality of care provided to residents of Belgian nursing homes?

What are the general characteristics of medication management in Belgian nursing homes? We examine the provision of pharmaceutical services, the organization of the medication process and the implementation of a formulary.

Which organizational characteristics are associated with the quality of medication use? We examine the extent to which the quality of medication use varies across characteristics associated with the organizational structure such as ownership, size, type, financing (reimbursements and private spending), nurse staffing levels, case-mix and geographical locations.

1.4 PREVIOUS STUDIES FOR BELGIUM

Relatively few studies on the quality of medication use in Belgian rest and nursing homes have been carried out.

In a recent study by the Christian Mutualities¹² the cost and quality of medication use by residential elderly^z were analyzed. The study included a cohort of residential elderly with no change in dependency score in 2002, without a transfer from at-home care to residential care and who did not die during 2002 and 2003 (n=5,123). For this cohort a follow-up of one year was possible in the period 2002-2003. For some of the results, a comparison was made between rest and nursing home residents and a group of elderly receiving at-home care, selected on the basis of the same criteria (n=25.532). The data on medication prescription and cost are based on the Farmanet database, which only contains medication dispersed by community-based pharmacists.

Table 1.8 shows the median cost of reimbursed medication for the health insurance (RIZIV/INAMI) and for the elderly in a rest or nursing home or elderly receiving at-home care. In view of a comparison with the results of our study, we want to emphasize the specific study population in table 1.8.

Table 1.8 : Cost of reimbursed medication for elderly in rest or nursing homes and elderly receiving at-home care

Median medication costs	ROB/RVT	At-home care	
Reimbursements by RIZIV/INAMI	480€	538€	
Co-payments ^{aa}	115€	121€	
Total	606€	672€	

Source: Du Bois et al.¹²

In table 1.9 the medication use for residents and elderly receiving at-home care is compared for medication groups or medication for specific diseases which account for a relatively large part of the cost for RIZIV/INAMI. For some medication groups the percentages of residential elderly and elderly receiving at-home care show substantial differences. However, cautious interpretation of these differences is crucial since these percentages only reflect the use of medication without correcting for differences in (co-) morbidity between the two populations.

^z Only members of the Alliance of Christian Sickness Funds were included in the study. The results were confirmed by one of the authors (M Du Bois).

^{aa} Remgeld in Dutch, ticket modérateur in French. A co-payment is a cost-sharing arrangement which requires the individual covered to pay part of the cost of care. A co-payment is a fixed fee (flat rate) per item or service.

Table 1.9 : Medication use by elderly in rest or nursing homes and elderly receiving at-home care, by medication group (% of elderly)

Medication group or disease	% of RIZIV/INAMI cost	% of ROB/RVT elderly	% of elderly with at-home care
Diabetes	3.1	12	15
Thrombosis	2.1	18	32
Diuretics	1.1	36	36
Corticosteroids	1.0	15	18
Antibiotics for systematic use	1.1	47	57
Anti-inflammatory and anti-rheumatic medication	1.1	27	48
Psycho-analeptics	2.8	36	31
Anti-asthmatics	2.0	14	18

Source: Du Bois et al.¹²

Within the group of residential elderly (percentages in the column ROB/RVT of table 1.9) medication use was not uniform across the country. Table 1.10 shows the regional variation. Contrary to table 1.1, the provinces of Vlaams-Brabant (Flanders), Brabant wallon and the Brussels–Capital Region were taken together as one province. Understanding regional variation in the use of medication is complex and is far beyond the scope of this introductory chapter. Therefore we only point out some remarkable differences or similarities in medication use between provinces. The largest regional variation in medication use of elderly residents was found for psycho-analeptics with the largest percentage in the province of Namur (52%) and the smallest in Antwerpen (38%). Antibiotics for systematic use had a similar pattern: 58% in Namur versus 38% in Antwerpen. Within Flanders the province of Limburg shows the largest percentage of elderly residents for most medication groups. In the Walloon region this is the case for Namur, followed by Liège.

In 2005 a study was carried out by the Limburgs Universitair Centrum (LUC)^{bb} in a sample of Belgian rest and nursing homes.¹³ The central research question was closely related to the key research question of the present study, viz. an analysis of the medication policy of Belgian residential homes for the elderly. A questionnaire was sent to all Belgian rest and nursing homes (n=1,722). The response rate was 33.57%. In addition, 29 interviews were conducted to complement the written questionnaire^{cc}.

The medication policy questionnaire and interviews revealed information about the prescribing, the purchase and stock of the medication, the formulary and cooperation. We only give some results, since it is very difficult to describe a study and its results solely on the basis of presentation slides. Nearly 98% of prescriptions were written by the family doctor, the other 2% by the medical coordinator. The distinction between prescription-bound and non prescription-bound medication determined to a large extent if the medication was obtained from a community pharmacy, a hospital pharmacy or from a wholesaler or manufacturer. Most rest and nursing homes purchased from only one pharmacy (69.5%), another 22.2% purchased its medication from multiple pharmacies in turn. Only 8.3% was serviced by multiple pharmacies at the same time. The most important criteria for choosing a medication supplier were good service (73.5%), proximity (11.3%) and cost of medication (8.1%). Almost 72% of the nursing homes had a formulary (with large differences between the three regions), which was used by 30% of the family physicians. The usage depended to a large extent on the origin of the formulary (from the government, own formulary, hospital formulary).

^{bb} Since June 2005 the LUC is called Universiteit Hasselt.

^{cc} There is no information whether the results are representative for all Belgian rest and nursing homes.

An older study by Vander Stichele et al.¹⁴ investigated the medication use and knowledge of medication among residents of a sample of nursing homes in Flanders^{dd}. In addition, the medication distribution and information activities inside the homes were described. The selection of nursing homes was based on the 'selection' of 23 experienced nurses working in different nursing homes but meeting regularly for postgraduate training. In each of the nursing homes a random sample of ten residents was taken.

The 23 nurses interviewed the nurse responsible for the selected resident and the resident, if possible. Eventually 198 residents (20 institutions) were included in the study, 128 of them could be interviewed directly. Although the average number of residents in the 20 institutions was somewhat larger than the Flemish average, the selected institutions were representative for Flanders. The residents had a mean of 4.5 different medicines (range 0-12) on their medication chart. 4% did not take any medication, half of them because of therapeutic abstinence in terminal care. 47% had at least 5 medicines. The number of medicines increased with age (3.7 to 4.8 medicines between the age of 60 and 79), but stabilized from the age of 80 onwards (4.3 medicines). On average 19 different GPs attended residents.

In Pitruzzella et al.¹⁵ the medication use in rest and nursing homes in the Walloon Region was analyzed for the year 2003 and compared with the results of a survey carried out in 1993. For a representative sample of elderly residents (2,343 elderly residing in 37 different institutions) the medication chart on a specific day (November 15, 2003) was analyzed. On that day a total of 16,808 medications or 7.19 drugs per resident were registered with large differences between the institutions (range of 5.9-8.7). In 1993 this was only 5.04. Almost 19% of the residents received more than 10 drugs on one day, 19.4% received less than 5 drugs. Drugs related to the nervous system (n=5,410), the cardiovascular system (n=4,133), the gastrointestinal system (n=3,713) and blood and blood forming organs (n=1,257) represented the largest groups. Age, gender and the presence of dementia were found to be explaining factors.

^{dd} As in chapters 2 and 3 we use the term 'nursing home' for an institution with exclusively nursing beds or with rest and nursing beds.

Table 1.10 : Medication use by elderly in rest or nursing homes, by medication group and by province (% of elderly residents)

Medication group or disease	Belgium	Antwerpen	Brabant	Limburg	Oost-VI	West-VI	Hainaut	Liège	Namur	Luxemb
Diabetes	12	9	11	19	11	15	11	12	9	16
Thrombosis	18	15	16	22	17	15	21	22	23	19
Diuretics	36	32	33	27	36	37	29	40	40	42
Corticosteroids	15	11	16	15	13	12	17	18	18	15
Antibiotics for systematic use	47	38	47	51	43	48	53	54	58	42
Anti-inflammatory and anti-rheumatic medication	27	21	25	33	27	26	28	34	28	26
Psycho-analeptics	36	28	38	39	28	32	41	44	52	45
Anti-asthmatics	14	11	13	17	11	12	19	18	18	15

Source: Du Bois et al.¹²

1.5 AGGREGATED DATA ON MEDICATION USE AND EXPENDITURES IN REST AND NURSING HOMES IN BELGIUM

The Farmanet database contains prescriptions dispensed from community-based pharmacies in Belgium. Prescriptions dispensed from hospital pharmacies as well as expenditures for other categories of care can be obtained from the IMA-database with claims data on all expenditures categories. Both databases contain information on reimbursements of RIZIV/INAMI and out-of-pocket payments by the residents for prescription medication.

The present study is the first to show national estimates of medication use and expenditures for elderly residents of rest and nursing homes in Belgium. Section 1.5.1 provides data on medication use by major drug classes. In the Anatomical Therapeutic Chemical (ATC) Classification System drugs are classified into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are divided into groups at 5 different levels^{ee}. Section 1.5.2 gives a general overview of the expenditures of prescribed and reimbursed medication used by elderly residents of rest and nursing homes for the year 2004. We calculated the expenditures for the health insurance reimbursed by RIZIV/INAMI as well as the out-of-pocket payments for the residents. Medicines are reimbursed on a fee-for-service basis in Belgium^{ff}. The basis for reimbursement is classification within categories fixed by Royal Decree. The classification reflects the social importance of the drug, pharmacotherapeutic criteria and price criteria.

For this population-based description of medication use in Belgian rest and nursing homes, only the data of drugs sold by community pharmacists to these homes are taken into account. A minor part of homes buy their drugs through hospital pharmacies. The hospital pharmacy data did not allow us to distinguish in a reliable way between the medication prescribed in inpatient or day case treatment from the medication delivered to the rest or nursing home of the resident. Moreover, this latter category also contains the dispensing of some expensive drugs which is legally exclusively reserved for hospital pharmacies. This bias in our estimates will lead to a small underestimation of global medication use. The utilization data are not expected to be influenced by the retailer's circuit chosen by homes. To estimate the distribution of drug utilization, the Defined Daily Dose (DDD) is used as estimate for the maintenance dose per day per drug used for its principal indications in adults. In the Farmanet data, DDDs adapted to the Belgian situation are used^{gg}. To calculate the overall expenditures of prescribed and reimbursed medication, we include the hospital pharmacy data.

1.5.1 Use of medication by different levels of ATC group

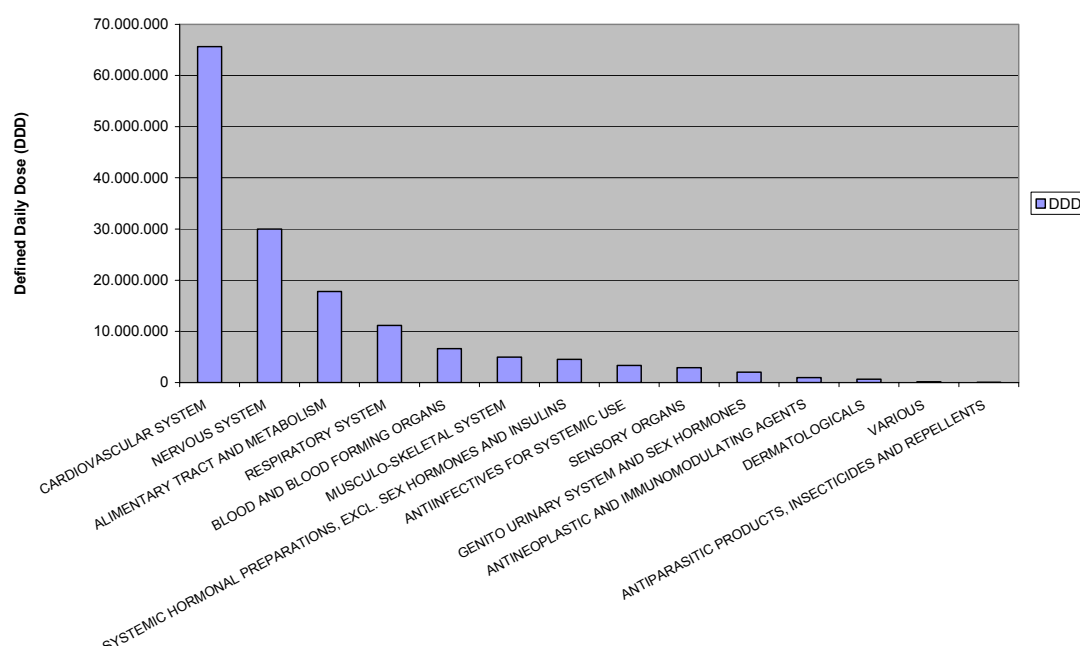
The four main ATC classes of drug consumption in elderly people living in Belgian rest and nursing homes are related to the cardiovascular, nervous, gastrointestinal and respiratory system (figure 1.5). These four classes are described in more detail in this section. A lengthy table containing the 100 most frequently used drugs (ATC5) is presented in Appendix 4 (table 4.1).

^{ee} See <http://www.whocc.no/atcddd/> for more information.

^{ff} Since July 1, 2006 a large part of hospital drugs are financed on a lump sum basis replacing the fee for service practice.

^{gg} See <http://www.bcfi.be> for more details.

Figure 1.5 : Number of medication prescriptions in Belgian rest and nursing homes, expressed in DDD for every main ATC class.



Source: Farmanet

In the drug class related to the cardiovascular system, molsidomine - a drug to treat angina - is most often prescribed (see Appendix 4 - table 4.2 for more details). ACE-inhibitors, drugs used in the treatment of heart failure and hypertension, are also widely used. Angiotensin II antagonists, a more recent antihypertensive drug class, constitute 28% of the amount of ACE-inhibitors prescribed. This ratio is an underestimate, since part of ACE-inhibitor prescription will be done to treat heart failure or in the post myocardial infarction setting. Amlodipine, an antihypertensive drug from the Ca-antagonist's class, compared to other classes such as ACE-inhibitors, ATII antagonists and antihypertensive diuretics, accounts for about 1/3 of all prescriptions. Class III anti-arrhythmics such as amiodarone and sotalol are widely prescribed in this population. Compared to the class of selective beta-blockers, used as secondary prevention treatment for post-ischemic heart disease, heart failure, angina pectoris and atrial fibrillation, all largely prevalent in this population, it represents 64%. Class I anti-arrhythmics such as propafenon and flecainide are still used for chronic treatment. Simvastatin and atorvastatin are the most popular drugs to lower cholesterol and are used to the same extent as the selective beta-blockers.

In the second ATC class, the nervous system, it should be stressed that the non-reimbursed benzodiazepines are not present in the Farmanet data. This second group is dominated by antidepressants: 71% are selective serotonin reuptake inhibitors, 5% mono-amine reuptake inhibitors and a large rest group of other molecules (see Appendix 4 - table 4.3 for more details). Of all antidepressants used in this patient population, citalopram is the most prescribed (26%), followed by sertraline (15%), escitalopram (13%), paroxetine (12%) and trazodon (10%). Next, antipsychotics are the second largest group of prescribed drugs in this class. Risperidon is the most prescribed (31%), followed by olanzapin (27%). Of the older antipsychotics, haloperidol is used most frequently (12%). Betahistine is still widely used to treat vertigo and possibly Menière's syndrome. In the class of the Alzheimer drugs, donepezil is used in over half of prescriptions of this kind. Noteworthy is the fact that ginkgo biloba is present in 0.5% of cases, probably also for this indication.

In the third ATCI class, drugs for the gastro-intestinal system, the largest group is the one with drugs to treat peptic disease (see Appendix 4 - table 4.4 for more details). Omeprazole, a proton pump inhibitor, is used in the majority of patients. Ranitidine, a drug of the older H₂-receptor blocker class, is still being used frequently. The second largest group in this class consists of several oral antidiabetics that add up to a total of more than 3.6 million DDDs, compared to over 2 million for subcutaneous insulins. Combinations are likely, so this number only represents market share and is not a proxy for the number of diabetic patients in this population. Metformin is the most prescribed oral antidiabetic drug. Otilinum is the most frequently used spasmolytic drug, followed by mebeverine. For the laxatives, it should be stressed that the majority of them are not reimbursed by health insurance. Data in Farmanet are thus incomplete.

In the ATCI class of drugs for the respiratory system, the mucolytics represent the largest group (see Appendix 4 - table 4.5 for more details). For the drugs most frequently used for obstructive pulmonary disease COPD, the sympathomimetics make up the largest group of prescriptions. They are most frequently used in combination with inhalation preparations including an anticholinergic or corticosteroid. Taken together the pure formulations and the combinations, the long acting beta-agonists constitute about 42% of this type of drug prescriptions. In the group of the H₁-antihistamics, levocetirizine has a market share of 30%.

In the class of medication related to blood and blood forming organs, the heparines are clearly heading with more than 3.8 million DDDs. Enoxaparine and nadroparine have about an equal market share of 47% and 48% respectively. Next drug class are the thrombocytes aggregation inhibitors, with nearly 1.9 million DDDs of which clopidogrel represents 79%.

In the class of drugs for the musculoskeletal system the bifosfonates, used to treat osteoporosis, lead the group with nearly 1.5 million DDDs. However, all non-steroidal anti-inflammatory drugs together represent over 2.4 million DDDs. In general they are used to treat osteoarthritis and rheumatic disorders. The Cox-2 inhibitors represented about one fourth of all prescriptions in 2004. Virtually all paracetamol is sold over-the-counter without prescription, disabling an analysis of the use of analgetics and the pharmacological strategies used in this elderly population.

The most frequently prescribed antibiotics for systemic use in rest en nursing homes is amoxicillin with a beta-lactamase enzyme inhibitor with over 750,000 DDDs. Both nitrofuranes together add up to nearly the same amount. The quinolones account for over 470,000 DDDs annually, followed by second generation cephalosporins (335,000 DDDs) and broad spectrum penicillins (278,000 DDDs). 99,000 influenza vaccines were reimbursed in 2004 in Belgian rest and nursing homes.

In the class of the antineoplastic and immunomodulating agents, tamoxifen used as adjuvant therapy for breast cancer is prescribed most (330,000 DDDs), closely followed by the gonadoreline analogues mostly used for prostate cancer in this population with 270,000 DDDs. In the group 'various', medicinal oxygen takes up 82,000 DDDs.

Regional variation in medication use based on DDD was considered for the top 10 of most frequently used drug classes (ATC level 3). Furthermore, the drugs classes that were used for the recent feedbacks of the RIZIV/INAMI for antihypertensive agents and antibiotics prescribed in general practice were assessed. This resulted in geographical variation distributions for the following classes: antidepressants and antipsychotics (psychopharmaca); ace inhibitors, angiotensin II antagonists, diuretics and potassium-sparing agents, and selective calcium channel blockers with mainly vascular effects (hypertensives); beta-lactam antibacterials and penicillins, macrolides, lincosamides, streptogramins, and quinolone antibacterials (antibiotics); drugs for peptic ulcer and gastro-oesophageal reflux disease, vasodilators used in cardiac diseases, antithrombotic agents, high ceiling diuretics, and beta blocking agents (see Appendix 5 for the Belgian maps). We found a marked but different regional variation for several medication groups. Apparently, no simple regional pattern across medication groups existed. For example, antidepressants and selective calcium channel blockers were used to a larger extent in Walloon provinces compared to Flemish provinces, while the opposite was true for beta blocking agents and diuretics and potassium-sparing agents. Several of

these drugs can be used for different indications. Since we did not dispose of other variables like clinical patient characteristics per medication group it is in general not warranted to interpret these results towards an under- or overuse of these classes and hence to appraise the drug utilization quality. We thus ascertain a clear regional variation but do not attempt to provide an explanation for these variations in this part of the report (see section 1.6 - rationale for a field study).

1.5.2 Expenditures of prescribed medicines in Belgian rest and nursing homes

In 2004 total expenditures on prescribed and reimbursed medication in Belgian rest and nursing homes amounted to almost 153 million € of which 88% was dispensed by the community pharmacy (table 1.11). As mentioned before, total expenditures on medication dispensed by the hospital pharmacy contain medication prescribed in day case treatment and the medication delivered to the rest or nursing home of the resident, including the dispensing of some expensive drugs.

Our estimate of total expenditures on pharmaceutical specialties dispensed by the community pharmacy added up to more than 130 million € of which 82% was paid by the health insurance and 18% out of pocket by the residents^{hh}. In addition, 2.8 million € was spent on magistral preparations (of which 83% by the health insurance) and another 1.46 million € on special medical nutrition and wound material (of which 84% by the health insurance). In the rest of this section we focus on pharmaceutical specialties dispensed by the community pharmacy and neglect magistral preparations or special medical nutrition and wound material as well as medication dispensed by the hospital pharmacy.

Table 1.11 : Expenditures on prescribed and reimbursed medication for health insurance and the resident, by type of medication and dispenser (2004)

Dispenser	Type of medication	Health insurance cost (€)	Out-of-pocket (€)	Total (€)
Hospital pharmacy	Specialties	16,368,403*	1,652,954	18,021,357
	Magistral preparations	149,820	25,443	175,263
	Medical nutrition and wound material	69,171	36,377	105,548
	Total	16,587,394	1,714,774	18,302,168
Community pharmacy	Specialties	106,839,205	23,516,627	130,355,832
	Magistral preparations	2,335,892	479,138	2,815,030
	Medical nutrition and wound material	1,235,698	229,294	1,464,992
	Total	110,410,795	24,225,059	134,635,854
Total		126,998,189	25,939,833	152,938,022

* About 55% of this amount was prescribed in residents of rest and nursing homes during inpatient treatment. Source: IMA

Antidepressants, antipsychotics and antithrombotic agents are rivaling for the highest health insurance cost (table 1.12). Together, the 10 most prescribed ATC3 classes amount to almost half of the total budget. However, the price of an individual drug is also a major determinant of the budgetary impact for health insurance (figure 1.6). Especially drugs used to prevent or treat infectious diseases represent a higher

^{hh} The data are not corrected for reimbursements by the system of maximum billing (MaF).

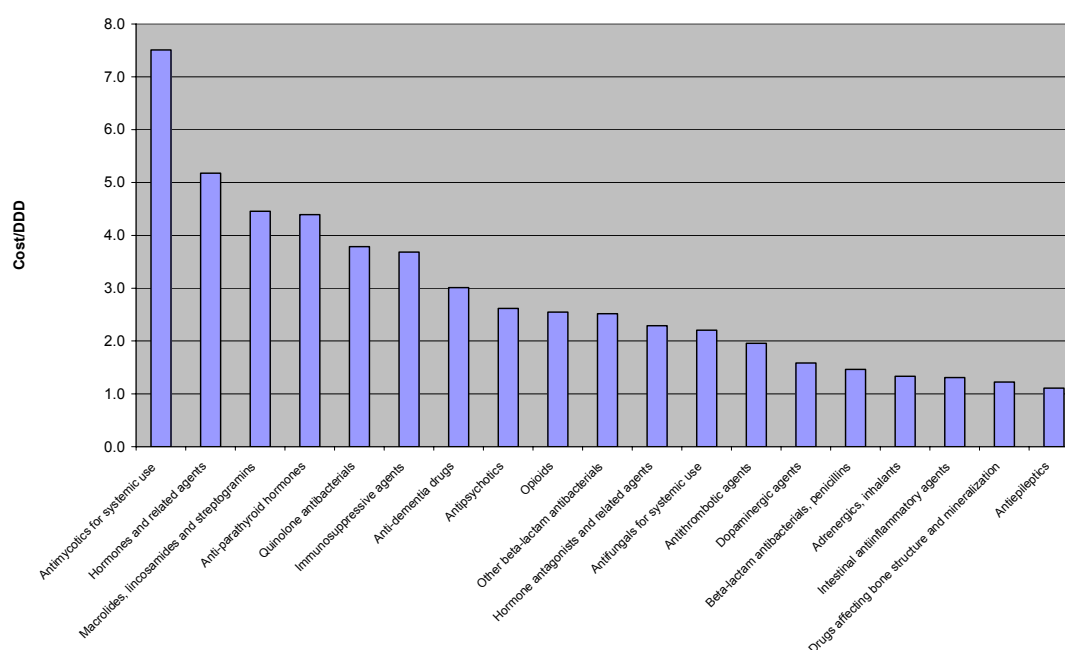
individual cost: influenza vaccination, several antibiotics and antimycotic drugs. In addition, several hormones, anti-Alzheimer drugs, anti-psychotics and opioids represent a relatively high individual cost.

Table 1.12 : DDD and expenditures by ATC-class (2004)

	ATC	Class or non-proprietary name	DDD	Health insurance cost (€)	Out-of-pocket cost (€)
1	N06A	ANTIDEPRESSANTS	15,187,938	12,429,029	3,627,857
2	N05A	ANTIPSYCHOTICS	4,651,768	10,651,173	1,516,215
3	B01A	ANTITHROMBOTIC AGENTS	6,446,832	10,617,869	1,985,108
4	A02B	DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)	10,971,741	7,890,532	1,736,477
5	C01D	VASODILATORS USED IN CARDIAC DISEASES	15,769,367	5,894,855	1,365,843
6	N02A	OPIOIDS	2,502,729	5,026,818	1,344,979
7	N06D	ANTI-DEMENTIA DRUGS	1,356,858	3,714,205	371,777
8	N04B	DOPAMINERGIC AGENTS (PARKINSON)	2,529,695	3,363,585	639,078
9	C08C	SELECTIVE CALCIUM CHANNEL BLOCKERS (HYPERTENSION)	6,722,495	3,355,252	805,498
10	R03A	SYMPATHICOMIMETICS (INHALANTS)	2,918,707	3,245,897	643,113

Source: Farmanet

Figure 1.6 : Cost per DDD for health insurance for the most costly ATC3 classes. Classes with less than 10,000 DDD were omitted. Influenza vaccination with a DDD of 1 is not represented in the graph. The class V03A is not represented. It contains mainly oxygen with a cost per DDD of 22.5€.



Source: Farmanet

To have some idea about the share of medication in total health insurance expenditures for elderly residents in rest and nursing homes, we calculated the most important cost components for this population group. Health insurance expenditures on medication dispensed by the community pharmacy accounted for about 6% of total RIZIV/INAMI reimbursements for this population in 2004 (table I.13).

Table I.13 : Health insurance cost of residential elderly (2004)

Type of cost	Health insurance cost (€)	% of total cost
Lump sum for ROB	702,021,473	39.6
Lump sum for RVT	616,518,522	34.8
GP consultations and visits	59,899,446	3.4
Hospitalization	18,837,080	1.1
Physiotherapy (ROB)	26,167,075	1.5
Medication from community pharmacy	110,526,192	6.2
Medication from hospital pharmacy	16,587,394	0.9
Total	1,773,499,831	100.0

Source: IMA

1.6 RATIONALE FOR A FIELD STUDY

Some of the research questions addressed in this report cannot be answered solely on the basis of the available administrative datasets. Although Farmanet is a very rich database containing detailed information on prescribed medication, some essential information is missing. Firstly, in Farmanet only prescribed and reimbursable medication is included. Secondly, only medication of rest and nursing homes serviced by a community pharmacy is included. Those serviced by the hospital pharmacy are not. Thirdly, Farmanet does not include diagnostic codes providing possible explanations for prescription behavior. And fourthly, possible causal relationships between the local institutional setting and prescription behavior and other confounding local more qualitative factors cannot be explored in claims data. Although a linked database consisting of Farmanet and some datasets available at RIZIV/INAMI at the level of the institution (number of beds, number of residents, number of invoiced days, number of staff) or available at IMA (medication dispensed by the hospital pharmacy) would improve substantially the potential to answer the research questions, some crucial lacuna would still remain.

To assess the quality of medication use of residential elderly, reliable data at the level of the institution and at the level of the resident are indispensable. A field study overcomes most of the limitations of the administrative datasets.

A questionnaire-based field study was carried out in a selection of nursing homes and their residents in three provinces. The selected sample of nursing homes is not a random sample but follows the Rapid Assessment cluster method of the World Health Organizationⁱⁱ. The field study was complemented by some general analyses on the expenditures and use of medication based on administrative databases and by a review of the literature on the quality of medication use in nursing homes and the impact of organizational characteristics on the quality of prescribing and the medication process.

ⁱⁱ See section 3.3 for more details.

Keypoints

- The Belgian model of long-term residential care for the elderly is rather unique. Rest and nursing homes are not specialized in specific illnesses - except sometimes for dementia - but accept residents with different medical problems. Moreover, residential homes for the elderly are spread all over the country.
- About 150,000 elderly were resident in a rest or nursing home in the course of 2004. More than 75% of them were women, 46% was older than 85 years.
- Although some studies on the use of medication in Belgian nursing homes exist, little is published on the relation between medication use and organizational characteristics and quality of prescribing.
- Total expenditures on pharmaceutical specialties dispensed by community pharmacies added up to more than 130 million € of which 82% was paid by the health insurance and 18% out of pocket by the residents (2004). Another 18 million € was dispensed by hospital pharmacies.
- The four main ATCI classes of drug consumption in elderly people living in Belgian rest en nursing facilities are cardiovascular, nervous, gastrointestinal and respiratory drugs. The group of drugs for the nervous system is largely dominated by antidepressants.
- Although clear geographical variations exist for the prescription of several drug classes, no simple regional pattern across medication groups was found.
- Antidepressants, antipsychotics and antithrombotic agents are rivaling for the highest health insurance cost. Together, the 10 most prescribed ATC3 classes amount to almost half of the total budget.

2 REVIEW OF THE INTERNATIONAL LITERATURE ON THE USE OF MEDICATION IN NURSING HOMES

Authors: Charlotte Verrue, Marc Bauwens, Robert Vander Stichele

2.1 OBJECTIVES OF THE LITERATURE REVIEW

The aim of this review was to survey the current literature on the use of medication in nursing homes, with special focus on the impact of institutional characteristics (including medication management systems) on the quality of prescribing.

2.2 METHODS OF THE REVIEW

A computerized literature search was carried out starting with a search in Medline (US National Library of Medicine), based on search profiles in Medical Subject Headings (MeSH). The search strategy is given in Appendix 6.

This review is a narrative review, not a systematic review. Its purpose was to provide a broad overview of the subject, in preparation to the field study, to provide the necessary elements for constructing questionnaires, and to review existing sets of prescribing quality indicators, pertinent to the setting of nursing homes. No attempts have been made at formal data extraction for pooling of data.

In this review, we address the following questions:

1. Why are elderly institutionalized?
2. What are the most prevalent functional and clinical problems among residents?
3. What are the most prevalent problems with regard to medication and how can the quality of prescribing be assessed?
4. Which institutional characteristics are important for the quality of prescribing?
5. What is the effectiveness of interventions (medication management systems) with regard to the quality of prescribing in nursing homes?

For the assessment of prescribing quality, a description will be given of 5 sets of prescribing quality indicators:

1. The indicators of underuse of medication within the ACOVE (Assessing Care of Vulnerable Elders) Quality Criteria
2. The BEERS Criteria for potentially inappropriate medication use in older adults
3. The BEDNURS Criteria for inappropriate medication use in nursing homes
4. The Medication Appropriateness Index (MAI).
5. UK Commission for Social Care Inspection National Minimum Standards on Medication Care Homes for Older People : Medication within the home

In addition, a brief description is given of 5 instruments for the assessment of functional status, case mix or quality of care in nursing homes:

1. Resource Utilization Groups Version III (RUG-III)
2. Dutch Care Dependency Scale
3. Functional Autonomy Measurement System

4. Resident Assessment Instrument for Nursing Homes (RAI)
5. ACOVE (Assessing Care of Vulnerable Elders) Quality Criteria

2.3 RESULTS OF THE LITERATURE REVIEW

2.3.1 Why are elderly institutionalized?

Nursing home placement is often the result of dementia, multiple illnesses, severe disease, or lack of social support. It is triggered by a sentinel event (e.g., major illness, accident, hospitalization). Wandering and disruptive behavioral problems are also significant factors leading to long-term care placement. Determining the specific circumstances that led to a nursing home admission is an important element of the initial evaluation.

The most common diagnoses at nursing home admission are¹⁶:

- Mental disorders (dementia, depression)
- Heart disease and cerebrovascular disease (heart failure, stroke)
- Nervous system disorders
- Injuries
- Endocrine disorders (e.g., diabetes mellitus)
- Respiratory tract disorders (e.g., chronic obstructive pulmonary disease)
- Musculoskeletal disorders

History taking at the moment of admission to the nursing home provides the opportunity to learn the most about residents, not only their medical condition but also their functional abilities, social background, support system, interests, hobbies, and previous daily routines. Inclusion of family members in the initial resident assessment can help allay anxiety or guilt feelings surrounding a nursing home admission and provide opportunities to discuss expectations regarding care and to establish treatment preferences.

Dementia emerged as the most potent risk factor for institutionalization in a 12-year prospective population-based epidemiological study.¹⁷ Persons with dementia had nearly five times the risk of institutionalization as those who were not demented. At 3- and 12-year follow-ups, 5.8% and 13.6%, respectively, of the cohort members had been institutionalized. Increasing age, impairment in ADL (activities of daily life) and less social support emerged as other less-critical risk factors in this study.

Interestingly, the interaction between the number of prescription medications and dementia was significant in the model predicting institutionalization. Specifically, prescription medication count had less effect on institutionalization in those with dementia than in those without dementia. A likely explanation for this phenomenon is the clinical observation that cognitively intact persons are generally institutionalized for medical rehabilitation, whereas the potency of dementia as a risk factor far outweighs the effect of medical co-morbidity in the cognitively impaired.

The burden of care to immediate care givers is a crucial element in the process of institutionalization. Often families are able to care for an elderly patient at home until he or she loses the ability to perform basic functions. The course of the events leading up to nursing home placement can provide insight into the patient's level of functioning and rate of decline. Research studies published between 1989 and 1995 were analyzed by Chenier¹⁸ to identify variables that led to caregiver burden and nursing home placement of non-demented elders. Although the variables impact each caregiving situation differently, decreased functional abilities of the care receiver, interrupted sleep of the caregiver or the presence of multiple factors within the caregiving situation were positively correlated with caregiver burden and increased risk of nursing home

placement. Increased awareness of these issues is essential to provide successfully for the aging population.

Cost savings by postponing institutionalization

Although expenditures did not increase with age for most services, the high personal cost for nursing home care among the oldest old underlines the need for increased efforts to support them in the community (USA).¹⁹ Greater spending by those in poor health highlights the importance of preventing age-related health conditions and their complications. Improved access to discretionary care among the oldest old may help to reduce the need for care in higher cost settings. The high prevalence of out-of-pocket prescription spending across the age range provides impetus for current efforts to reduce these costs.

Canadian research examined the cost effectiveness of home care for seniors as a substitute for long-term institutional services. Chappell et al.²⁰ computed the costs of formal care and informal care in both settings and ensured comparable groups of clients in both settings by comparing individuals at the same level of care. The results reveal that costs were significantly lower for community clients than for facility clients, regardless of whether costs only to the government were taken into account or whether both formal and informal costs were taken into account. When informal caregiver time is valued at either minimum wage or replacement wage, there was a substantial jump in the average annual costs for both community and facility clients relative to when informal caregiver time was valued at zero. Nevertheless, the results reveal that home care is significantly less costly than residential care even when informal caregiver time is valued at replacement wage.

Loss of independence in older persons places considerable financial burden on them, their families, and the health care system.²¹ The *Medicare Current Beneficiary Survey* estimated the additional medical and long-term care costs that occur during the year when older persons make the transition to dependency at home or move to a nursing home. Average long-term care costs were \$3,400 for persons who developed activities of daily living disability at home sometime during the year, \$6,800 for those starting and ending the year with disability who remained at home, and more than \$21,000 for those moving into a nursing home during the year.

2.3.2 What are the most prevalent functional and clinical problems among residents?

In order to assess properly the medication needs of nursing home residents, it is necessary to have an idea of the clinical problems common to this elderly population.

We will address

- Clinical Assessment
- Functional Assessment
- Nutritional assessment
- Assessment of communication needs
- Assessment of palliative care needs
- Patient Autonomy

2.3.2.1 Clinical assessment

Heckman et al.²² found that heart failure is common in Canadian long-term care (LTC) facilities, but undertreated. The prevalence of heart failure was 20%. LTC residents with heart failure were older, more often women, and more functionally impaired and burdened by co-morbidity than were participants in heart failure trials. Documentation

supporting the heart failure diagnosis was inadequate, with some symptoms possibly misattributed to chronic obstructive pulmonary disease.

Hass et al.²³ determined in a retrospective population-based study in nursing homes (Rochester USA 1989-1994) that nursing home residents with major stroke were younger and more disabled and required more services than residents without stroke. Per diem Medicaid reimbursement was 11% higher for residents with major stroke compared with residents without stroke. Nursing home residents with minor stroke appeared similar to those without stroke with respect to time to admission, characteristics at first assessment and per diem Medicaid reimbursement. They concluded that lower incidence and severity of stroke (e.g. by better controlling diabetes and hypertension) may contribute to lower care needs and per diem cost.

Rheumatic diseases are common in elderly people,²⁴ are increasing in frequency and are undertreated. Extended care facilities have special needs and restrictions, making pain management more complicated. Understanding how to assess pain in a population at risk for poor pain control is vital. Treatment individualized to the patient's special circumstances where optimal care rarely means cure or complete relief of symptoms leads to improved function and quality of life.

In a study of care homes in the UK, Sinclair et al.²⁵ found a 12% prevalence of known diabetes. In the group of care home residents not known to have diabetes and able to undergo testing, a substantial proportion (14,7%) has undetected diabetes based on a 2-h postglucose load. It is possible that residents with newly detected diabetes will benefit from early treatment of raised glucose levels by experiencing reduction of osmotic symptoms, improvement in cognition and assessment of any vascular complications. Whereas these actions are unlikely to lead to an increase in life expectancy of diabetic residents, they may add some value to their quality of life.

To determine the magnitude and distribution of nosocomial infections in LTC institutions, the Norwegian Institute of Public Health initiated a surveillance system. The system is based on two annual one-day prevalence surveys recording the four most common nosocomial infections: urinary tract infections, lower respiratory tract infections, surgical-site infections and skin infections, as well as antibiotic use. The total prevalence of the four recorded nosocomial infections varied in 2004 between 6.6 and 7.3%,²⁶ whereas the lowest prevalence was found in special units for persons with dementia. In the survey the prevalence of the four recorded nosocomial infections was higher than the prevalence of patients receiving antibiotics. After the survey, the Norwegian Institute of Public Health recommended the implementation of infection control programs in facilities that had not yet done so, stated the importance of employing more nurses in long-term care facilities, and recommended training of unskilled personnel in basic infection prevention principles.

The carriage of Methicillin Resistant *Staphylococcus Aureus* is increasing in nursing homes. The detection of MRSA carriers in nursing homes needs to be realized under particular conditions. Decolonization of carriers is absolutely essential.²⁷

Dementia, often the main cause for institutionalization, is common among nursing home residents. Measurement of cognitive ability should be performed with standardized, easy to administer instruments, such as the Mini-Mental State Examination (MMSE). Formal tests are useful because impressions based on conversations with the patient can be misleading. Patients who are aware of having a slight decline in mental processes may cope by redirecting conversations or making excuses for their memory loss in an attempt to create the impression that they have no impairment. In contrast, some patients may appear to be demented when, in fact, their function is limited by another physical or mental condition (e.g., decreased visual or hearing acuity, depression). Such patients may perform better on the MMSE than would be expected from conversations with them during history taking and physical examination. Therefore, measurement of cognitive skills with a standardized instrument is essential for establishing a baseline to assess changes or responses to therapeutic interventions. Wu N et al.²⁸ found that both nursing home staff and study nurses recorded less frequent and less severe pain for residents with more severe cognitive impairment. Their results strongly support the notion that specialized pain assessment instruments are needed to adequately detect

pain for the large proportion of cognitive impaired nursing home residents. Ten percent of the dementias show language disturbances as the first sign. Language disturbances may exist for a long time, even before the onset of the memory impairment. The language disorder causes difficulty in proper judgment of memory. Logopaedic examination is necessary to diagnose the language disorder. Neuropsychological testing should take the language disorder into account. Diagnostic accuracy is important. Distinguishing dementia from a language disorder has implications for the judgment of the patient's (dis)abilities and management.²⁹

The prevalence of depression in the nursing home population is high.³⁰ Whichever way defined, the prevalence rates found were three to four times higher than in the community-dwelling elderly. Age, pain, visual impairment, stroke, functional limitations, negative life events, loneliness, lack of social support and perceived inadequacy of care were found to be risk indicators for depression. Although depressive symptoms seriously affect the quality of life of a growing proportion of elderly people in residential care homes, many residents do not receive adequate antidepressant treatment. Lack of recognition of depressive symptoms and signs by the attending staff in the residential home is a major obstacle to the provision of adequate treatment. Eisses et al.³¹ evaluated the effects of a program of care staff training in residential homes on the recognition of depression, the treatment rate and the prognosis of those with depression. Recognition of depression increased more in homes where staff received the training than in the control homes. Treatment rates also increased compared with control homes, but the increase was not significant. Residents with depressive symptoms had a more favourable course when staff had received training. Moreover, the prevalence of depressive symptoms decreased, but the decrease was not significant.

2.3.2.2 Functional assessment

Performing functional assessment of residents may have multiple purposes:

- to reliably assess the status of the individual patient
- to assess the burden of care within an institution (case-mix assessment)
- to monitor the outcome of processes of care

Functional level can be measured with low sophistication by two general purpose scales: Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs).

In Appendix 7, a number of more sophisticated instruments are presented:

- Resource Utilisation Version III (RUG-III)
- Dutch Care Dependency Scale
- Functional Autonomy Measurement System
- Residents Assessment Instrument for Nursing Homes (RAI)

In nursing homes, some aspects of functional status are particularly important:

- Visual impairment
- Hearing handicap
- Oral health problems
- Incontinence

Vision impairment is a contributing cause of disability and activity limitation among the nation's elderly, and can have profound implications for their quality of life.³² Diminishing eyesight contributes to a reduction in their physical, functional, and emotional well being, even after controlling for gender, cognitive status, and baseline function. Furthermore, visual impairment has been related to increased risk of falls and hip fractures, depression, and cognitive decline leading to disruptive behaviors. An expert nursing home panel within The Assessing Care of Vulnerable Elders (ACOVE) study

identified 13 quality indicators relative to vision impairment that were felt valid and feasible in nursing home residents.

Garahan et al.³³ found that self-assessments of hearing handicap by residents, together with audiometric findings and expressed interest in a hearing aid, were more useful guides for aural rehabilitation needs than were nurses' assessments of residents' handicaps. Medical records failed to identify 48% of residents with moderate to severe hearing losses. They concluded that residents should have hearing evaluations with documentation of results on admission and periodically under the direction of a nurse trained as a hearing specialist.

Evaluating the realistic oral treatment need in a population in southern Sweden enrolled in long-term care, in nursing homes or home care, including dental status, oral mucosal status, oral hygiene status, oral mucosal inflammation and oral mucosal friction, Isaksson et al.³⁴ found that 61% of the sample had a need not just for an oral health evaluation but also for additional dental treatment. The results indicate that realistic oral treatment need, taking their medical condition into consideration, is modest in this population, but that regular oral screening is mandatory.

Urinary incontinence is a common but challenging problem in the long-term care environment plagued by rising costs, limited resources, and high rates of staff turnover. Successful management of incontinence in the nursing home is possible but it requires a comprehensive evaluation of the resident and a formalized plan of care that is individualized to the resident's unique needs.³⁵ Cardiovascular disease, mental disorders, and endocrine disease such as diabetes and hypothyroidism (all common afflictions in nursing homes) are all risk factors for incontinence.

2.3.2.3 *Nutritional assessment*

Patient's nutritional status should be systematically assessed, because more than one third of persons over age 75 are underweight. A weight loss of 5% in 1 month or 10% in 6 months is considered significant.¹⁶ Many factors place older patients at risk for poor nutrition. For example, the inability to feed oneself can result in inadequate caloric intake. Mechanical causes of eating difficulty (e.g., ill-fitting dentures, swallowing difficulties due to stroke) should be sought and appropriate evaluative or therapeutic measures undertaken. Also, nausea or loss of appetite resulting from use of certain medications (e.g., digoxin, antidepressants) can affect patients' nutritional status. Deficiencies of specific nutrients, such as calcium, zinc, selenium, magnesium, vitamin D, vitamin B₁₂, and folate, are important to consider in nursing home residents. Because many elderly patients have poor calcium intake and calcium supplementation is usually well tolerated, supplementation with calcium and vitamin D is advocated.

2.3.2.4 *Assessment of communication needs*

Residents' limited opportunities for communication with staff are primarily focused on care tasks. Conversations in staff-resident interaction focus on activities of daily living (ADLs), personal-social care, technical care, and health assessment. Williams et al.³⁶ described an intervention which leads to increased communication awareness among staff, with an increased ability to modify conversational topics to better meet older adults' psychosocial needs.

2.3.2.5 *Assessment of palliative care needs*

Discussion of future care plans and advance directives should be part of care planning for all elderly patients admitted to an extended-care facility. This discussion can help clarify concerns patients and families may have regarding the meaning of such decisions. By assisting patients or their designated guardians in clearly spelling out their wishes about end-of-life care, physicians can help them avoid the need to make these critical decisions in a moment of crisis.

2.3.2.6 Patient autonomy

Faced with the challenge of respecting resident autonomy and simultaneously adhering to nursing home standards, nursing home staff often experiences a frustrating ethical conflict.

Scott et al.³⁷ explored patient autonomy, privacy and informed consent in the care of elderly people in long-stay care facilities. Results indicated marked differences between staff's and residents' responses on three of the four dimensions explored: information-giving, opportunity to participate in decision-making about care and consent. There was much closer agreement between staff's and residents' responses regarding protection of patient privacy. Findings suggest there is still a significant need to educate staff concerning ethical awareness and sensitivity to the dignity and rights of patients.

Schnelle et al.³⁸ investigated the use of restraining in nursing homes. Residents in high-restraint homes were in bed more often during the day, often associated with poor feeding assistance, reflecting important differences in quality of care between homes.

Butterworth³⁹ explored the concept of consent and proposed that consent for older people in long-term care is not a discrete episode requiring a consent form, but is one aspect of the process of including service users in decisions about their care.

No formal instruments to measure patient autonomy have been developed for the setting of nursing homes.

Particularly in relation with medication, the question of patient autonomy is important. Most nursing homes have developed a rigorous distribution system for medication, to minimize medication errors. This distribution system is often forced on all residents, regardless of their cognitive status.⁴⁰ Nurses and managers may be reluctant to grant exceptions for autonomous patients, who are capable of taking responsibility for their own medication management.

2.3.3 What are the problems with medication usage and how can quality of prescribing be assessed in nursing homes?

2.3.3.1 Current problems with medication prescribing in nursing homes

To be at high-quality level, medication management in nursing homes should insure that the residents gain the maximum therapeutic benefit from their medication in order to maintain or improve the quality and duration of life, and do not suffer unnecessarily from illness caused by excessive, inappropriate or inadequate consumption of medicines.

Concern has been expressed about the quality of drug treatment in nursing homes. Anxiety about the risk of excessive prescribing of, for example, inappropriate neuroleptic drugs, is matched by concern about the consequences of underprescribing potentially beneficial drugs. Other factors impeding the quality of drug treatment in nursing homes are the prescription of contra-indicated drugs, chemical restraint of residents and drug-related hospital admissions. The latter aspect may be caused partly by medication errors, a form of system failure more related to the distribution of medicines to and inside the institutions than to the quality of prescribing.

Finally, nursing home directions should also pay more attention to the financial aspect of drug treatment.

Overprescribing

The elderly in general use more medications than any other age group. This high rate of drug use has been attributed in part to the accumulation of diseases with ageing⁴¹, but also to the inappropriate prescribing of medications outside the bounds of accepted medical standards.⁴²

A 2000 study of nursing homes revealed that individual nursing home residents receive an average of 6.7 routine prescription medications per day and 2.7 additional medications on an "as needed" basis. It is not surprising that nursing home residents

receive more medications than the community dwelling elderly.^{43, 44} For example, a study on 1,106 residents in 12 nursing homes of a large city in the US showed residents are on an average of 7.2 medications.⁴⁵ Furthermore, as people age, pharmacokinetic and pharmacodynamic changes occur that can affect the disposition of medications in the body. This combination of polypharmacy and pharmacokinetic and pharmacodynamic changes lead to an increased risk of adverse drug reactions (ADR), defined as an injury from medication. There is a linear relationship between the number of drugs taken and the increased potential for ADR.⁴⁶ The nursing home residents are the frailest segment of the geriatric population, using the highest number of medications compared to the non-institutionalized elderly, thus having the highest risk for an ADR. Further complicating this issue, ADR are often interpreted as a disease of old age resulting in another drug added to the patient's therapy by the doctor.⁴⁷

Misprescribing

Certain drugs should be avoided in older adults or should only be used under certain circumstances, since their potential risk outweighs the potential benefit.⁴⁸ The prescription of such contraindicated drugs also represents an area of concern in the medication use of nursing home residents, as it can lead to morbidity, mortality and increased costs of care.⁴⁹

The quality of drug management in nursing homes is also affected by the inappropriate use of psychoactive drugs to control problematic behaviors and induce sedation of the residents ("chemical restraint"). The effectiveness of psychotropic drugs to treat disruptive behavior remains uncertain because most episodes are self-limited. Research has shown that not only are the drugs often ineffective, but they may actually precipitate an agitated state.⁵⁰

Underprescribing

Another important and increasingly recognized problem in nursing home residents is undertreatment, defined as the omission of drug therapy that is indicated for the treatment or prevention of a disease or condition. Undertreatment has been reported for diseases as asthma, cardiovascular disease, dyslipidemia, osteoporosis, pain, hypertension and depression, and underuse of angiotensin-converting enzyme (ACE) inhibitor medications in patients with congestive heart failure, anticoagulation in elderly patients with atrial fibrillation, and preventive therapy after myocardial infarction.^{51, 42, 52} Undertreatment may have an important relationship with negative health outcomes in the elderly, including disability, death and health services use.⁴²

Drug-related hospital admissions

Many studies have shown that a high number of geriatric patients experience drug-related problems leading to hospital admission.⁵³⁻⁶² However, the definition of the problems investigated in these studies varies markedly from study to study. In all the publications mentioned in the reference list, we found that adverse drug reactions (ADRs) were considered; in some publications non-compliance, improper drug selection, untreated indications and drug use without indication were also considered. These last problems can be defined as drug therapy failures (DTFs).

The frequency of hospital admissions due to drug-related problems in the elderly is found to be 10 to 30%. The majority of these problems seem to be adverse drug reactions. Difference in incidence can be explained by a different classification system of type of problems, and of contribution to hospital admission.

Several studies have investigated the preventability of drug-related problems in the elderly, which is found to be substantial, varying from 50% to 97%.^{53, 55, 57, 59, 61, 63} From those studies criteria for inappropriate medication use in geriatric patients can be defined, with medications that should be avoided generally in the elderly, or in the presence of specific co-morbidities, or when dosages or frequencies may exceed tolerable levels.^{64, 48, 65-69} The drugs concerned are central nervous drugs, drugs with anticholinergic properties, drugs with a narrow therapeutic-toxic range, slow release

preparations... When taking these criteria into account, many drug-related problems in the elderly could be avoided. Most of the studies described above study the elderly in general and few studies specific for the nursing home setting exist.

Expenditures for medication in nursing homes

For a variety of reasons the management of prescription drugs in nursing homes is now poised to emerge as a critical policy issue.⁷⁰ Awareness of drug spending in nursing homes has grown as budget problems have forced increasingly aggressive cost containment policies. Second, as pharmaceutical innovation continues, new and expensive medications are rapidly being developed for the elderly population.

Avery et al.⁷¹ compared the costs of prescribing, the number of items on prescription and the types of drugs prescribed for older people in nursing homes with older people living at home by means of a retrospective case-control study. The mean cost of prescriptions per patient-month was almost three times higher for nursing home patients than controls (45.27£ compared to 16.46£). The mean number of items prescribed per patient-month was also higher in nursing home patients (5.60 compared to 2.55). There were differences in the types of medication prescribed between the two groups, including considerably higher costs for central nervous system drugs, ulcer healing drugs, laxatives and enteral nutrition in nursing home residents.

O'Neill et al.⁷² examined variations in prescribing costs associated with nursing home patients and patients matched by age and sex living in the community (UK). They concluded that the ability of the multivariate models they used to explain variations in prescribing costs among a group of elderly patients is poor. Adjusting weighted capitation formulae with respect to older patients to take account of such information or referring to it in negotiations on prescribing budgets would not appear to be warranted.

There are markedly different financing structures to reimburse for drugs:

- Institutions subsidized on the basis of discounted price for drugs on a per-drug basis
- Imposing financial risk on nursing homes by including drugs in the prospective payment rate
- Residents paying out-of-pocket a non-discounted price for drugs on a per-drug basis.

2.3.3.2 How can the quality of medication usage in nursing homes be assessed?

Medications are a very important aspect of the care of nursing home residents. Therefore, medication use provides an ideal opportunity for monitoring the quality of care. Explicit or implicit, evidence-based criteria for inappropriate medication use such as the Beers criteria and the Medication Appropriateness Index (MAI) are well known and implemented. However research is still ongoing in the area of the development of new quality indicators specific for the nursing home population. Prescription data are frequently used as indicators, but an important limitation is that they do not take into account information about disease and patient factors important for judging the quality of prescribing.⁷³

The most widely known explicit indicator for appropriate medication use in nursing homes is the Beers list, developed in 1991 in the US by a group of 13 national experts. This list included 19 medications that should be avoided, as well as 11 doses, frequencies or durations of medication prescriptions that should not be exceeded. The list was updated both in 1997 and 2003.⁷⁴ Drug-disease interactions and severity rankings have also been added. This type of indicators is subject to several limitations, such as a poor specificity, a not established reliability and the fact that they are not to be generalized to other countries.

The Medication Appropriateness Index (MAI) evaluates for individual patients each medication using 10 criteria that take into account efficacy, safety and cost aspects of

appropriateness.⁷⁵ These 10 ratings can be combined to produce a weighted score per medication. The MAI is a time-consuming instrument, but is currently the most comprehensive instrument to measure appropriateness of prescribing in the elderly.

In Norway, a comprehensive set of prescribing quality indicators was developed, based on data from the health care record and medication charts of institutionalized elderly.⁷⁶ More details on this list are given in the method section and the result section of this report.

The ACOVE Project (Assessing Care Of the Vulnerable Elder) used systematic literature reviews, expert opinions and the guidance of expert groups and stakeholders in the US to develop a comprehensive set of quality-of-care indicators that are relevant to vulnerable elders.⁷⁷ About a third of the indicators refer to medication. As part of the ACOVE project, Knight & Avorn⁷⁸ developed quality indicators for appropriate medication use in vulnerable elders using a systematic literature review and expert panel considerations. On the basis of the literature review and the authors' expertise, 16 potential quality indicators were proposed to the expert panel. 12 of them were judged to be valid.

Elliott et al.⁶⁸ developed a set of indicators of prescribing quality for elderly in Australian hospitals. These indicators were based on a set of indicators developed previously in the UK and were piloted at nine Australian hospitals. The indicators were divided in 3 groups: 1) summarising general prescribing activity, 2) assessing prescribing based on prescription data only, and 3) assessing prescribing based on prescription and clinical data. 24 indicators were developed and applied on the prescriptions of 1,416 patients. Following pilot audits, 5 indicators were deleted, resulting in a final set of 19 indicators. The review of prescription by 2 pharmacists (n=66) showed also a good inter-rate reliability. The developed indicators provide a tool that can be used to assess, monitor, benchmark and improve prescribing for the age.

Oborne et al.⁷⁹ aimed to modify previously developed indicators and algorithms from the hospital setting for use in nursing homes, and to apply these indicators in the nursing home setting. 13 indicators were successfully modified and applied on 934 residents in 22 nursing homes in the UK. These objective, evidence-based and simple to use prescribing appropriateness criteria provide an objective audit tool that can be of use in comparing prescribing between units and to enhance prescribing quality.

A remark on outcomes

The above described sets of quality of prescribing are all measures of the quality of process to achieve better outcome among patients. They are not direct measures of outcome such as mortality, morbidity, hospital admissions, or quality of life. Few studies on inappropriate prescribing look directly at health outcomes. Only preliminary attempts to link outcomes, measured by the Resident Assessment Instrument with drug utilization data, have been published.^{80, 81} The measurement of quality of life may be difficult to measure with generic instruments, given the high prevalence of cognitive disabilities and disabilities of the senses.

2.3.4 Which institutional characteristics are important for the quality of prescribing?

The organizational characteristics of nursing homes can substantially influence the quality of prescribing in nursing homes. This chapter will give an overview of the nursing home characteristics and their impact upon quality of prescribing (expressed by volume, expenditures and appropriateness of prescribing). Only studies explicitly exploring the relationship between institutional characteristics and quality of prescribing are listed. We examined the following characteristics:

- Size and type of the institution
- Case-mix of the institution
- Staffing within the institution

- General approach to management of care processes
- Approach to medication management

2.3.4.1 *Size and type of the institution (public, private not-for-profit, private for profit)*

There is some evidence that organizational factors can have a significant impact on both the quantity and quality of psychotropic drug use in nursing homes. However, the relationships are complex and poorly understood. A few studies found higher rates of drug use in larger facilities and for-profit facilities, but other studies found that facility size and ownership had no effect.⁸²⁻⁸⁶

2.3.4.2 *Case-mix*

In the sample of Schmidt et al.,⁸⁶ all nursing homes were non-profit and operated by public municipalities and there was no functional difference in financial status among the residents -all were covered by the Swedish universal health care insurance plan. Residents' clinical and demographic characteristics did not account for variations of drug use from one facility to another, suggesting that facility differences are not due simply to resident mix.

Mylotte et al.⁸⁷ determined significant correlations between the antibiotic use and cost indicators, overall infection rate and case-mix index at the facility level, between 11 long-term care facilities (USA). There was no correlation between the CMI of the RUGs II system as a measure of functional status and infection rate. Nevertheless, there was a trend toward a significant correlation between mean facility CMI and mean facility incidence of antibiotic use (AUR antibiotic utilization ratio), and cost per RCD (resident care day).

2.3.4.3 *Staffing*

Shorr et al.⁸⁸ found more extensive antipsychotic drug use in those Tennessee homes with poorer third-shift staffing. Svarstad et al.⁸⁹ used a more refined measure of home staffing in their study of private- and public-pay residents in Wisconsin homes. As predicted, residents in homes with less adequate nurse staffing and resources were more likely to have an order for an antipsychotic or anxiolytic medication, more likely to receive such medications, and more likely to have inappropriate use, even after controlling for residents' clinical and demographic characteristics. The hypotheses suggest that home differences in drug use are due largely to organizational factors such as: resource availability and demand (low/high nurse staffing; low/high resident functioning); caregiver communication (presence/absence of intervention team meetings); facility size (small/large number of beds; reflecting a measure of institutional environment).

Mullins et al.⁹⁰ examined nursing home personnel's perceptions of patient autonomy in their home. Findings indicated staff members' education and race had the greatest effect on their perceptions of personal autonomy. Somewhat surprisingly, staffing levels, turnover rates, and restraint usage did not affect their views of autonomy ("whether the resident would be allowed to make his or her own decisions or whether the nursing home staff would decide for the resident").

Schnelle et al.³⁸ compared nursing homes that report different staffing statistics on quality of care. Staff in the highest staffed homes (California), according to state cost reports, reported significantly lower resident care loads during onsite interviews across day and evening shifts (7.6 residents per nurse aide [NA]) compared to the remaining homes that reported between 9 to 10 residents per NA). The highest-staffed homes performed significantly better on 13 of 16 care processes implemented by NAs compared to lower-staffed homes.

Castle et al.⁹¹ examined the association between nurse aide (NA) plus licensed practical nurse (LPN) and registered nurse (RN) turnover and quality indicators in nursing homes. Indicators of care quality used are the rates of physical restraint use, catheter use, contractures, pressure ulcers, psychoactive drug use, and certification survey

quality of care deficiencies. In addition, they used a quality index combining these indicators. Turnover information came from primary data collected from 354 facilities in 4 states and other information came from the 2003 Online Survey, Certification and Reporting data (OSCAR). The turnover rates were grouped into 3 categories, low, medium, and high, defined as 0% to 20%, 21% to 50%, and greater than 50% turnover, respectively. The average 1-year turnover rates identified in this study were high at 85.8% for NAs and LPNs and 55.4% for RNs. Multivariate analysis showed that decreases in quality are associated with increases in RN turnover, especially increases from low-to-moderate levels of turnover, and with increases in NA and LPN turnover, especially increases from moderate-to-high levels of turnover. These findings are significant because the belief that staff turnover influences quality is pervasive. The cross-sectional results are only able to show associations, nonetheless, few empirical studies in the literature have shown this relationship.

2.3.4.4 *General approach to management of care processes*

Increasingly, health care providers are acknowledging that organizational culture is crucial to understanding and managing the complex demands of a health care organization. The definition of organizational culture may include the social climate, quality of communication among staff, and informal values, norms, beliefs and attitudes shared by members of the organization. It has been shown that an organizational culture based on a teamwork approach (as opposed to a traditional hierarchy of authority) can significantly improve patient outcomes.⁹²

Co-ordination of care can be considered as one of the three dimensions of quality of nursing care in nursing homes. The other two dimensions are instrumental care and the quality of the social climate and living environment. In this concept, co-ordination of care is one of the aspects of quality of care.

Holtkamp et al.⁹³ investigated the quality of co-ordination of care and the way it is related to gaps between needs and care supply, the quality of life and health status of residents living in Dutch nursing homes. The results of this investigation showed a relation between the co-ordination of care and care discrepancies; the higher the quality of co-ordination of care, the fewer the gaps between residents' needs and the care they received. The psycho-social aspects in particular showed a gap between the needs and care supply. As regards the relation between co-ordination of care and quality of life, the strongest positive relations were found between taking case histories, patient allocation and dimensions of quality of life. No direct relations were found between the co-ordination of care and care discrepancies on the one hand and the health status of the residents on the other. In conclusion, this study showed that the quality of co-ordination of care can affect the perceived quality of life of nursing home residents. The relation is even stronger when the unmet needs of the residents are also taken into account. To meet the residents' needs it is important to assess their physical and psycho-social needs accurately. An integrated instrument such as the Resident Assessment Instrument (RAI) in which the physical and psycho-social assessment procedures are both represented may help nurses to complete the assessment of residents' needs. In a review Wagner et al.⁹⁴ identified 21 empirical studies concerning quality system activities such as the implementation of guidelines; providing feedback on outcomes; assessment of the needs of residents by means of care planning, internal audits and tuition and an ombudsman for residents. The effects on care processes and the health outcomes of long term care residents were inconsistent, but there was some evidence that specific training and guidelines can influence the outcomes at the patient level. The design of most of the studies meant that it was not possible to attribute the results entirely to the newly implemented quality system.

A nursing home that creates a culture that supports open communication and relationships, based on trust, respect, and leadership, ensures that staff members have the environment and resources to make and sustain improvement.⁹⁵ However communication and relationships remain a concern, with more than 50% of staff suggesting that communication is not open, accurate, timely, or understandable. Although less has been learned about management infrastructure, there is no question that traditional management practices also send mixed messages and do not support an

environment where high-performing teams feel confident and supported. Information mastery is an evolving skill in the nursing home setting with high performing teams needing access to information, guidance in how to process information, and the ability to make an impact once they have used this information to fuel quality improvement efforts. Nurse leaders must carefully assess their personal preparation and understanding how they do partner with their administrators and other key leaders to create an environment that supports and values the voice of staff and the use of high performing teams as the main engine of improvement in their nursing home. This sustained improvement will ensure the best possible care of the frailest citizens for years to come.

Some institutions have a culture of inaccurate documentation, often created by a discrepancy between care expectations placed on nursing homes by regulatory guidelines and inadequate reimbursement to fulfil these expectations. Nursing home staff has little incentive to implement the technologies necessary to audit and assure data quality if accurate documentation reveals that care consistent with regulatory guidelines is not or cannot be provided. Schnelle et al.³⁸ reviewed methods to improve the accuracy of nursing home medical record documentation and to create data systems useful for staff training and management.

Identification of residential care as a separate quality domain is important conceptually and pragmatically. Conceptually, it acknowledges the nursing home as the resident's home and the consequent importance of the ongoing interaction between care providers and residents. It also distinguishes residential care as a key factor among the many that determine residents' quality of life. The interactions of nursing home staff with residents powerfully determine residents' quality of life. The residential care process measures developed by Saliba et al.⁹⁶ are intended to measure the manner in which, or the extent to which, need is met on a day-to-day basis. Experts identified 19 specific care processes as valid and important measures of the quality of nursing home residential care. Nine of these quality indicators may be measured best by direct observation of nursing home care, rather than by interviews or review of existing nursing home records. Almost half of the quality indicators were viewed as discriminating between better and average nursing homes.

Pressure ulcers, a prevalent healthcare problem in long-term care homes are useful indicators of nursing home quality. Pressure ulcers are associated with considerable morbidity, mortality, and cost. In addition, nursing homes with high pressure ulcer prevalence are likely to have problems with other quality measures. Identifying LTC residents who are at risk for pressure ulcers is important because the Centers for Medicare and Medicaid Services consider a pressure ulcer to be a sentinel event in someone who has been assessed as low risk. Although researchers have examined skin conditions using the MDS, the relationship between risk assessment and pressure ulcer quality indicator scores from the MDS has not been evaluated. Wipke-Tevis et al.⁹⁷ measured pressure ulcer quality indicator scores and pressure ulcer prevention and treatment practices in long-term care facilities in Missouri. Fewer than 13% of homes used the Agency for Health Care Policy and Research pressure ulcer prevention and treatment guidelines. No relationship was found between the number of prevention strategies or the number of treatment strategies and the pressure ulcer quality indicator scores. Valid and reliable pressure ulcer risk assessment tools are seriously underused. Evidence-based pressure ulcer prevention and treatment guidelines appear to be rarely implemented. This study provides a basis for developing educational and quality improvement programs.

Excessive time in bed has negative effects on both physical conditioning and functioning. There are no data or practice guidelines relevant to how nurses should manage the in-bed times of nursing home residents, although all nursing homes receive a bedfast prevalence quality indicator report generated from the Minimum Data Set. Bates-Jensen et al.⁹⁸ found significant differences between upper (i.e., higher prevalence of bedfast residents) and lower quartile nursing homes in the proportion of time residents were observed in bed (43% vs. 34%, respectively; $p = .007$), and in the proportion of residents who spent more than 22 hours in bed per day (18% vs. 8%, respectively; $p = .002$). All nursing homes underestimated the number of bedfast residents. The residents of upper

quartile homes showed more activity episodes and reported receiving more walking assistance than the residents of lower quartile homes. Minimum Data Set bedfast quality indicator identified nursing homes in which residents spent more time in bed, but did not reflect differences in activity and mobility care. In fact, upper quartile homes provided more activity and mobility care than lower quartile homes. Across all the nursing homes, most of the residents spent at least 17 hours a day in bed. Further study of activity and mobility care and bedfast outcomes in nursing homes is needed, and nurses need to note the amount of time nursing home residents spend in bed.

Wagner et al.⁹⁹ described a method for measuring and reporting the costs of quality management in a national survey in 489 organizations providing long-term care (nursing homes, home health care organizations, and homes for the elderly). Site visits and a questionnaire were used to measure the existence of quality management activities and investigate the costs per quality management activity in more detail. Health care organizations differentiate between regular activities and quality management activities. The costs of quality management activities were found to vary between 0.3% and 3.5% of the budget in three nursing homes. An extrapolation of the costs of quality management activities to the entire sector shows that the long-term care sector spent between 0.8% and 3.5% of the overall budget for quality management in 1999. The costs of developing and implementing quality management activities are higher than the costs of monitoring. Most long-term care organizations have no insight into failure costs (i.e. the costs of quality deviations). This makes it impossible for health care organizations to draw conclusions about the cost-effectiveness of quality management. Understanding how quality improvement affects costs is important. Lee et al.¹⁰⁰ built on the principles of process improvement to develop a costing strategy. Process-based costing has 4 steps: developing a flowchart, estimating resource use, valuing resources, and calculating direct costs. The researchers conclude that process-based costing is easy to implement, generates reliable, valid data and allows nursing managers to assess the costs of new or modified processes.

Finally, there are some indications in the literature that there is a positive relationship between the level of subsidizing or payment rate of the institution and the quality of processes and better outcomes in nursing homes.¹⁰¹ The results from this analysis imply that a 10 percent increase in Medicaid payment was associated with a 1.5 percent decrease in the incidence of risk-adjusted pressure ulcers. These findings provide support for the idea that increased reimbursement may be an effective means toward improving nursing home quality.

2.3.4.5 Approach to medication management systems

Different initiatives have been taken in order to manage the quality of the drug consumption in nursing homes. We will review the literature on approaches to improve the quality of drug consumption in nursing homes:

- The implementation of drug formularies
- Organization of the medication distribution
- Informatization of this medication distribution process
- Pharmaceutical care in the nursing homes
- An example of a quality management intervention: multidisciplinary case conferences in nursing homes

In the next section we will review the literature on the evaluation of the effectiveness of these approaches to enhance the quality of prescribing.

Medication management is closely related to other clinical activities such as screening activities (see the sections on clinical assessment) and preventive medicine activities such as vaccination. Vaccinations for pneumonia and influenza are well accepted by patients and help prevent respiratory tract illness that can lead to hospitalization or premature death. On nursing home admission, the patient's record of these vaccinations should be reviewed and diphtheria-tetanus immunization updated.¹⁶

2.3.5 What is the effectiveness of interventions (medication management systems) with regard to the quality of prescribing in nursing homes?

2.3.5.1 *Implementation of formularies in nursing homes*

Little is known about the implementation of formularies in nursing homes. The published papers mostly refer to formularies as known in the US insurance system (the third-tier does not reimburse all of the drug-related expenses made, but only the ones that refer to the formulary accepted by the insurance). On the other hand, geriatric formularies for nursing homes are standard lists with affordable, safe and active medicines for the most frequently occurring diseases.¹⁰² The aim for implementation of this kind of formulary can be an increased safety, disposing of a list of always available medication, disposing of a list with the cheapest medication or an evidence-based prescribing behavior.

Drug formularies have long been used and accepted in hospitals, but the concept is still quite new in nursing homes. A possible explanation is that nursing homes lack the organizational structure and communication systems that would cause the visiting physicians to meet and discuss an issue as a drug formulary. Therefore, the Pharmacy Corporation of America (PCA) decided to offer an open formulary specific to geriatric population to all medical directors, key attending physicians and directors of nursing in more than 2,000 nursing homes served by PCA. The formulary is presented in a handbook complete with monographs. The monographs display clinical dosing information, note federal and state nursing home regulations that apply, and list special considerations for geriatric patients, such as drug half-time or alternative dosage forms. PCA consultant pharmacists reported that the formulary served as an excellent starting point for developing a closed, limited formulary.¹⁰³

Drug formularies can theoretically increase the quality of prescribing and reduce the costs of prescription drug therapy. But Gross¹⁰⁴ found that formularies do not actually enhance the quality of care. Neither do they adversely affect the quality of care, but more research is required.

Peer-reviewed publications evaluating the impact of drug formulary use in nursing homes on the cost of care could not be found.

2.3.5.2 *Organization of the medication process*

Two studies conducted by Gurwitz et al.^{105, 106} showed that errors occurred most commonly at the ordering and monitoring stages of the medication process and less commonly at the dispensing and administration stages. Nevertheless, the dispensing and administration stages are problematic essentially for two reasons. Medications can be split or otherwise altered during the dispensing stage, and covertly (unknown to the resident) administered. Evidence shows that both practices are widespread in nursing homes and are potentially problematic.¹⁰⁷⁻¹¹⁰

Medication splitting or alteration is usually performed by the nurse in charge of the dispensing. Even with appropriate devices, the splitting practice does not produce equal halves.¹¹¹ The dose can deviate by more than 20% from the intended one.^{112, 113} Inaccurate dosing may result in ineffective disease management.¹⁰⁷ Moreover, when tablets are split or otherwise altered, the effects of specific tablet formulations (such as enteric coated or sustained release formulations) may be negated and the drugs may be subject to increased degradation as a result of exposure to air.^{111, 114} Therefore, guidelines outlining best practice for the alteration and administration of medication in nursing homes are required. Accurate and up-to-date information needs to be available, detailing those medications which should not be altered, the potential risk of altering medicines and possible alternatives.¹⁰⁸

Covert administration of medications is also common practice in nursing homes. But most concerning are the poor recording and the secrecy around it.^{115, 110} The practice is found to be paternalistic and rarely ethically justifiable.¹¹⁶ It could be acceptable in extreme circumstances, for example if patients suffer from permanent mental incapacity

and refuse needed treatment.^{115, 117} But disguising medication simply for the convenience of the healthcare team is totally unacceptable.¹¹⁸

2.3.5.3 Informatization in nursing homes

Prescribing for elderly people is problematic for numerous reasons. The information necessary to general practitioners is usually fragmented across many isolated sources (different specialists, hospitals, nursing home records) and most records are still paper-based. Moreover, drug treatment of elderly is a complex issue requiring dose adjustments, specific attention for interactions and for the ability of the patients to actually take the medications as prescribed.

A computerized prescription order entry (CPOE) system equipped with a clinical decision support (CDS) module is a potentially powerful tool to prevent medication errors.¹¹⁹ CPOE and CDS systems have already been implemented successfully in a hospital setting. However, few descriptions of their use in nursing homes are available.^{120, 121}

Evidence indicated that computer support reduces serious prescribing errors by 55% and overall prescribing errors by about 83%.¹²² Also a significant decrease in medication error rates was observed. This reduction can be ascribed to the prevention of errors and adverse events, the facilitation of a more rapid response after an adverse event has occurred, the tracking of adverse events and the provision of feedback about these adverse events.¹²³ However, the CPOE system also has several limitations. First of all, CPOE systems are challenging to implement in nursing homes.¹²⁴ In order to facilitate the overall implementation of electronic prescribing, a few improvements of the system are also necessary: the user interface should be adapted, structured drug databases should be constructed, the system should have the capacity to generate both criticisms and suggestions during the prescription, and software for retrospective analysis of the prescribing habits should be developed.¹¹⁹ Medications differ from country to country, making it impossible to just take over an existing system and implement it abroad. Besides, CPOE systems have been designed for use in adults in general and need to be adapted to the specific needs of the geriatric population.¹²¹ Moreover, as CPOE systems are implemented, attention must be paid to the errors that these systems can possibly cause and not only to the errors that they prevent.¹²⁵ For elderly with multiple medical conditions and polypharmacy, too many unimportant recommendations are made, by which important warnings may be ignored.^{126, 127}

In the light of the success in hospital settings, the implementation of a CPOE system in a long-term care facility has been studied. These studies agreed that the CPOE system is a very promising new technology that may be very useful in nursing homes. But a change in mentality and full facility commitment are needed to implement such a major change as the switch to electronic prescribing.^{126, 128, 129}

Whenever organizations finally decide to take the big step and adopt electronic prescribing, they can select from a wide variety of commercial systems. These systems are often complex and heterogeneous. That is why a conceptual framework for evaluating electronic prescribing systems as developed for outpatient settings by Bell et al.¹³⁰ could be of great help.

Information technologies can also provide a great support during the monitoring stages of the medication process. A computerized monthly drug regimen review can help the pharmacist in reducing the number of medications per patient, which in turn decreases the costs for the residents.¹³¹ A computerized system can also detect some adverse events in a timely and cost-effective way. This has mainly been tested in hospital settings, but could also be applied to nursing homes.¹³²

Another way of preventing medication errors is the implementation of a 'closed loop system' as described by Lenderink & Egberts.¹³³ The essence of this system is that at the moment of medication administration, the medicine that is about to be given to the patient is verified against the medication order with respect to the necessary medicine characteristics (name, form, dose) and time. In order to make this possible, automated bar coding seems to be the most feasible instrument. This means that there should be a

specific barcode as well on each medicine as on a wristband that each patient should wear. A disadvantage is that mobile registration equipment is needed. The system was successfully tested in different wards of a hospital, and in a nursing home.

2.3.5.4 *Pharmaceutical care in nursing homes*

For a long time, the role of the community pharmacist was purely limited to compounding, packaging and dispensing medications, and advising about over-the-counter drugs. Recently, this role has evolved, in some European countries and mainly in the US, to become one of pharmaceutical care provider. The American Society of Hospital Pharmacists (ASHP) defines pharmaceutical care as “the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve patient’s quality of life”.¹³⁴ Pharmaceutical care involves pharmacists taking responsibility, in conjunction with physicians and patients, for the outcomes of drug treatment and not simply for the accurate dispensing of medications. This increased responsibility would require pharmacists to take a more active role in assuring that therapy is appropriate, that patients understand regimes, and that therapeutic outcomes are met. Improving drug therapy of elderly in nursing homes (e.g. by identifying, resolving and preventing drug-related problems) could form part of this reorientation of the pharmacy profession.

Pharmaceutical care was implemented in the USA about 35 years ago. As a result of increasing public concern about the overuse of neuroleptics in nursing homes, the US-government passed in 1987 the Omnibus Budget Reconciliation Act (OBRA-87), a law creating a set of national minimum standards of care and rights for people living in certified nursing facilities. One of the changes OBRA-87 brought to nursing home care was a mandatory monthly medication regimen review performed by a consultant pharmacist. But already before 1987, the effects of a drug regimen review were investigated. Cooper¹³⁵ showed that the consultant pharmacist had an effect on drug costs in long-term care, which was reversed when the drug regimen review was removed and renewed when services were reinitiated. The provided pharmaceutical care also frequently included advice to GPs about choice and duration of drug therapy, as well as the participation in staff education about medication.

In Europe (except in the UK), pharmaceutical care services are not so widespread. The services provided to nursing homes are primary the dispensing of medication and the provision of basic advice about documentation and storage.^{136, 137}

Different studies have explored what potential roles of a pharmacist can be. Pharmacists can promote safer prescribing practices, provide additional information to the nursing home staff, and identify potential adverse drug reactions and interactions. Some community pharmacists provide pharmaceutical advice and services to residential and nursing homes such as the management of repeat prescriptions and the monitoring of treatment. But they also can assist GPs with medication reviews, provide information to prescribing committees and compile drug formularies.¹³⁸ Crotty et al.¹³⁹ assessed the effects of a pharmacist as transition coordinator for transfers from a hospital to a long-term care facility. The use of a pharmacist as transition coordinator improved the appropriateness of medication use across health sectors. Therefore, pharmacists should not restrain their activities to what happens inside the walls of the nursing home.

Most studies are very positive about the effects of pharmaceutical care provided to nursing homes. Drug use decreases, which results in a decrease of the costs for both the residents and the government, without affecting the morbidity or mortality of the residents.¹⁴⁰⁻¹⁴⁴ However, one should be careful with the interpretation of such results. Majumdar & Soumerai¹⁴⁵ argue that the often chosen goal of reduction of the number of prescribed medication is misdirected. It should actually be abandoned as a measure of quality, since underuse of medication and undertreatment are also common in nursing homes. In this case, the pharmacist’s intervention does not increase the number of prescribed drugs (which would be interpreted as a negative result), but does increase the quality of care. Harjivan & Lyles¹⁴⁶ state that although the purpose of monthly drug regimen reviews is to improve drug use and to avoid adverse drug events, the current guidelines focus on a limited selection of medications and indications rather than on

patient outcomes. Therefore, the pharmacist's role should be more one of a clinical pharmacist than of a simple consultant pharmacist.

But not all studies are positive about the effects of pharmaceutical care. A randomised controlled trial in primary care showed that the pharmacist intervention did not have a significant effect on patient outcomes.¹⁴⁷ A study by Crotty et al.¹⁴⁸ focused on stroke prevention and fall reduction rather than on a decrease in medication use. This study showed no change in prescribing patterns of the GPs, even if they were receptive to the idea of pharmaceutical care.

Briesacher et al.¹⁴⁹ argue that the effectiveness of drug use reviews in improving patient safety in nursing homes is actually unclear, even though state and federal agencies in the USA have widely adopted this strategy.

2.3.5.5 *Multidisciplinary case conferences in nursing homes (an example of a quality management intervention)*

Pharmacists can not improve the quality of medication use in nursing homes all by themselves.¹⁵⁰ Collaboration between different healthcare providers and nursing home staff is required in order to modify suboptimal drug use in older people.¹⁵¹ The quality of drug use is indeed positively associated with the quality of communication between healthcare providers.^{138, 152}

Multidisciplinary teams seem to be useful for various aspects of the care process. The teams reduce the number of inappropriate medications, decrease the number of medication orders and increase the staff knowledge about drug therapy in the elderly. The composition of those teams is not a constant and varies from nursing home to nursing home. However, GPs, a pharmacist and nursing staff are almost always involved. But the team can also involve physicians specialized in a specific area (geriatrician, neurologist, neuro-psychiatrist, clinical pharmacologist, ...) or other members of the nursing home healthcare team (dietitian, dentist, rehabilitation therapist, social worker, activities coordinator), sometimes under the supervision of the management.¹⁵³

These multidisciplinary teams meet on a regular basis in order to discuss the different aspects of care for the elderly in the nursing home, or the medication in particular. Medication errors or inappropriate medication use can thus be identified.

Most studies showed positive results on the quality of prescribing, and thus benefits for the residents.^{86, 154, 49, 155, 152, 156-158} One study was rather sceptical because interventions with a multi-speciality group showed no effect other than the decrease of the number of prescribed drugs.¹⁵³ However, no negative results were found.

2.3.5.6 *Changing organizational culture*

Svarstad et al.¹⁵⁹ hypothesized that reduction in use of antipsychotic drugs was more likely to occur in homes with a resident-centered culture emphasizing psychosocial care, avoidance of psychotropic drugs, pharmacist feedback, and involvement of mental health workers. In this study, they examined four types of factors that can influence an organization's ability or motivation to change: need, structure, capacity, and culture. The results of the study suggested that homes with higher reimbursement and stable nursing leadership are more responsive to new drug guidelines. How do these factors actually influence a home's response? One obvious hypothesis is that better funding and leadership produce better nurse staffing, which is essential for improving care. In addition, directors of nursing with longer tenure may acquire the experience or legitimacy needed to identify appropriate tools, mobilize staff, and facilitate communication between nurses and other providers.

Schmidt et al.¹⁵² explored the impact of the quality of nurse-physician communication on the quality of psychotropic drug use in Swedish nursing homes, while controlling for resident mix and other nursing home characteristics. The quality of drug use was positively associated with the quality of nurse-physician communication and with regular multidisciplinary team discussions addressing drug therapy and negatively associated with prevalence of behavioral disturbances among residents. Facility size, level of

staffing, resident's diagnostic mix, and demographic mix were unrelated to the two drug quality measures.

Manias et al.¹⁶⁰ examined the extent of adherence to various protocols in relation to medication activities and determined how the ward environment impacts on graduate nurses' use of protocols to manage patients' medications. Such protocols included guiding statements for preparing medication for administration, assessing patients before administering medication, checking the patient's identity before giving medication, the process for administering medication, evaluating desired and adverse effects, checking specific medications with other nurses before giving and the desired times of day to administer medication. The study showed that graduate nurses adhered to protocols if they were perceived not to impede with other nursing activities; were more likely to follow protocols if they felt encouraged to make their own decisions – “effective and safe medication management involves creating the appropriate balance between standardizing practice in protocols and allowing flexibility and autonomy to take responsibility”-; were reluctant to follow protocols about documenting medication errors if there was a likelihood that disciplinary action would be involved.

A special study report from the UK Commission for Social Care Inspection (CSCI 112 February 2006) revisited the management of medication to find out whether homes had improved their performance (see Appendix 8). It used statistical information that the Commission gathers from rating homes against national standards and enhanced this with qualitative data from inspectors to highlight best and poor practice. The report shows that there has been some slight improvement in performance overall (since March 2004), with the exception of nursing homes for older people. But the rate of improvement in such a crucial area of care has been disappointingly slow, with nearly half the care homes for older people still not meeting the minimum standard relating to medication. Of particular concern is the very high percentage of homes, which having achieved the minimum standard, then slip back and fail. The broad range of evidence used for this report has strengthened the finding that homes need to address core management issues – such as training of staff and the development and monitoring of practices and procedures – to safeguard residents from abuse through medication mismanagement and to maximize their wellbeing.

2.4 DISCUSSION AND CONCLUSION OF THE LITERATURE REVIEW

The major conclusion of this literature overview is that different intervention strategies in nursing homes have the potential to increase the quality of prescribing. Some evidence of effectiveness is available for pharmaceutical care and multidisciplinary interventions, involving the whole team of caregivers. The size, expertise and culture of the nursing staff are important for the quality of medication distribution and monitoring processes. Medication errors occurring during the medication distribution process may have important clinical consequences. Preventing medication errors may have a great potential for improvement in outcomes. However, interventions to prevent medication errors differ from interventions to improve the quality of prescribing. More research is needed on the implementation of drug formularies in nursing homes and on how to use information technologies in order to enhance medication management.

Existing research focuses on structural indicators (general characteristics of institutions and the characteristics of their medication management systems). The impact of these structural indicators on the process of prescribing has been studied through recently developed process indicators of prescribing quality. Several sets of prescribing quality indicators have been developed for nursing homes, each measuring different aspects of prescribing quality and none of them fully validated or universally applicable. Moreover, evidence is lacking on the link between structural indicators, process indicators and direct measurements of outcome at resident level.

3 FIELD STUDY: PRESCRIBING IN HOMES FOR THE ELDERLY IN BELGIUM (PHEBE)

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3.1 SETTING

The study was conducted in Belgium, an industrialized Western-European country with 10.4 million inhabitants, with 17.2% elderly (65+), of which 8% live in nursing homes in the course of one year. Belgium is divided in 10 provinces (5 Dutch-speaking and 5 French-speaking) and Brussels-Capital Region. Nursing homes are multifunctional institutions, where residents are often treated by their former GP, and where one of the attending general practitioners has a role of coordinating physicianⁱⁱ.

3.2 OBJECTIVES

The aim of this study was to investigate the relation between institutional characteristics (including the characteristics of the medication management system) and the quality of medication prescribing.

The secondary aim of the study was to evaluate existing sets of prescribing quality indicators with regard to their suitability for application in the Belgian context.

3.3 METHODS

3.3.1 Design

This study was a cross-sectional, descriptive study of a representative sample of nursing homes and residents with an exploratory analysis of the relation between institutional characteristics and prescribing quality.

3.3.2 Sampling procedure

We selected three provinces for participation in the study: Oost-Vlaanderen, Antwerpen (both Dutch-speaking) and Hainaut (French-speaking). In each of these provinces a two-stage (institutions and residents) sampling procedure was used, based on the Rapid Assessment approach of the World Health Organization.

In the first stage of sampling the population of institutions was defined. Only institutions with at least 30 beds and having a certification for high intensity care beds (RVT beds) were eligible for selection. Nursing homes were selected in 4 strata based on size (up to 90 or more than 90 residents) and type of nursing homes (public, private), with a random selection of 5 institutions per stratum in each province. Hence, in each of the 3 participating provinces, 20 institutions (and 5 reserves) were selected with this stratified random selection procedure. In the sample of the province of Hainaut, 4 institutions of Brussels were included.

In the second stage of sampling, in each of selected institutions, first the coordinating physician of the nursing home (CRA) was contacted to ask for participation. Then, written consent of the management of the nursing home was asked. Umbrella organizations of CRAs and nursing homes were contacted to stimulate participation. Refusals were replaced by a new random selection within the same stratum. Per province, refusals ranged from 0 to 3 nursing homes per stratum.

In the second stage of sampling, residents were selected in the selected institutions. In each of the participating institutions, 30 residents (and 10 reserves) were randomly selected. The treating physician of each selected resident was contacted by the CRA to

ⁱⁱ The Dutch acronym CRA for “coördinerende, raadgevende arts” will be used hereafter.

ask for participation. In case of refusal, a new resident, treated by another GP, was selected.

Random selection was performed by the research team based on a numbered list of all eligible residents of a nursing home, with random computer generated selection of 20+10 residents. Researchers were blinded for the responsible GP of selected residents. All contacts with GPs were handled by the CRA of the participating nursing home. All contacts with the CRAs were coordinated by one of their peers, who had a representative function at the provincial level for nursing home health care policy.

3.3.3 Data collection at the level of the nursing homes

Junior researchers of the department of Pharmacy of the University of Gent and Master students of the department of Pharmacy of the Catholic University of Louvain visited all participating nursing homes. They first interviewed the director or a member of the management team using a structured questionnaire. Data collection focused on general characteristics of the nursing home (number of beds, number and type of wards), general care management (presence of a quality coordinator and quality management handbook), the medication management systems (presence and use of a drug formulary, organization of the medication distribution process, handling of medication errors), and the pharmaceutical care activities of supplying pharmacists.

Additionally, they interviewed the head nurse of one or two wards. If two wards were available, preferentially one ward for residents with good cognitive functions and one for demented residents were selected. Data collection concentrated on the different aspects of the medication distribution process (registration, storage, distribution and intake control of medication).

3.3.4 Data collection at the level of residents

Master students of nursing sciences of the Universities of Gent and Antwerpen visited all Dutch-speaking participating institutions and master students of the Public Health Department of the University of Louvain visited the institutions in the French-speaking Province of Hainaut, to collect administrative data of selected residents (age, gender, WIGW/VIPO^{kk}, OCMW/CPAS and Katz scale). They obtained a copy of the medication chart of selected residents. These copies were put into an electronic format with automatic assignment of ATC/DDD^{ll} to estimate the volume of medicine consumed and the expenditures at ex-pharmacy retail price (the fixed total price paid by patients in the community pharmacy, including 6% VAT) and the out-of-pocket expenditures (co-payment for reimbursed medicines, payment for non-reimbursed prescription medication and payment for over-the-counter (OTC) medication).

Special procedures were used to transfer the data from the collected medication charts into computerized databases. A data entry program was written allowing trained pharmaceutical and medical personnel to recognize brand names on the medication chart, assure correct data entry of brand, strength and pack size, posology and status of the medication (chronic use, acute use, use on an "as needed" basis). Entry lines on the medication chart not referring to officially registered medication were entered in free text (including prescriptions for magistral preparations by pharmacists). Posologies of anticoagulantia, insulin therapy and topical treatment were not recorded in detail. Data entry for registered medication was based on recognition of the unique medicinal product package (defined uniquely by the active substance, strength, pack size, pharmaceutical form and marketing authorization holder). Identification of the medicinal product package was facilitated by a quick search entry facility where each additional letter limited the choice possibilities down to a small list of possibilities from which the right package could be easily picked. Positive identification was then confirmed, initiating a procedure to get from a supporting database the unique identification code of the medicinal product package, the number of the international classification for medicines, namely the Anatomical Therapeutic and Chemical Classification (ATC). In addition, the

^{kk} WIGW/VIPO pay lower co-payments.

^{ll} Anatomical Therapeutic and Chemical Classification/ Defined Daily Dose

appropriate reference measure for volume, the Defined Daily Dose (DDD) was added, as well as the prescription status, the ex-pharmacy retail price (including VAT), and the co-payment price in case of reimbursed medication.

Data from the provinces of Antwerpen and Gent were entered by a team of highly specialized data encoders from a billing service of the association of community pharmacists. Data from the province of Hainaut were entered by the master students who were also responsible for data collection. The students received a formal training with exercise before entering the data. The information on posology (number and strength of dose units per day or per week) was combined with the standard price for daily consumption to calculate the expenditures per month for chronic medication. For anticoagulantia and insulin therapy (for which no individual posology was recorded) a standard Defined Daily Dose of 1 was assumed. Expenditures per treatment course for acute medication were calculated assuming 7 days per treatment course, with more or less days for some predefined specific treatment courses (e.g. one day for one shot treatment of urinary or vaginal infection). No attempt was made to calculate expenditures for medication on an “as needed” basis.

Once the data were entered, a thorough process of data cleaning commenced with identification of those magistral preparations which mimic existing, officially registered medications.

The finalized medication database was then printed out again on preformatted double pages, mimicking a medication chart. This outprint was double checked against the original medication chart based on anonymized patient codes. A computer program generated preformulated questions added to the appropriate medicines, to ask more detailed information on indication (only when the medication had multiple common indications), to ask for missing information on posology or the status of the medicine (chronic, acute or “as needed”). This double-sided outprint was put in a sealed and coded envelope, together with a one page questionnaire. On this questionnaire, a number of common diagnoses and care problems were listed to be ticked when appropriate. The envelope was sent to the CRA of each participating nursing home, with the request to distribute the correct envelope to the treating physician of the resident. This triage was performed by the CRA based on a list of patient codes (with the coordination physician blinded to the identity of the patient and the content of the envelope) matching with the name and address of the treating physician.

The responsible GP was asked to control the prescribed medication, to confirm the chronic, acute or “as needed” nature of the medication, to specify the indication for medication with multiple possible indications, and to provide clinical characteristics by ticking a checklist of common pathologies and care problems, and to specify whether the patient was or was not in palliative or terminal care.

Completed forms were sent back in a prepaid envelope directly to the researchers with no identification but the patient code. The CRAs assured the necessary reminders by mail, telephone, and e-mail, if necessary.

On the basis of the returned medication outprints, the existing medication database was amended and augmented, when necessary, and the clinical data were added to the resident database.

3.3.5 Construction of databases

3.3.5.1 *Level of the medication chart*

The first database was constructed at the level of separate entry lines on the medication chart and contained name, dose and frequency, type of medication and ATC/DDD code, as well as the code of the resident to whom this medication was prescribed. For chronic medication, full expenditures at ex-pharmacy retail prices and out-of-pocket expenditures per month per resident were calculated. For acute medication, cost was expressed as the expenditures for one complete treatment for the main indication.

3.3.5.2 Residents' level

At the level of residents, the database consisted of administrative data and clinical characteristics of all sampled residents, as recorded from the questionnaires to the direction and the treating family physicians.

A number of data from secondary analyses were added:

- the scores of each resident on the separate prescribing quality indicators (and several sum-scores for each set of prescribing quality indicators and overall sum-score);
- the aggregated medication data from the medication chart database;
- the main characteristics of the nursing home in which the resident resided.

3.3.5.3 Institution level

This database contained the results of the institution questionnaire and the calculated institutional quality scores of medication care. The institution database was completed with

- descriptive institutional characteristics derived from external administrative databases of RIZIV/INAMI (size, case mix, personnel);
- aggregated data from the residents' database describing clinical characteristics, medication use and prescribing quality of included residents.

3.3.5.4 Ward level

This database contained

- the results of the ward questionnaire;
- the results of the institution questionnaire;
- the calculated institutional quality scores of the medication management systems;
- aggregated data from the residents' database describing clinical characteristics, medication use and prescribing quality of included residents.

3.3.6 Construction of quality scores

3.3.6.1 Quality of medication management systems

In order to link the quality of the medication management system with the quality of prescribing, the organizational characteristics of the medication process were translated into a score. The practical organization of the medication process in each nursing home was assessed via a semi-structured interview with both the nursing home director (or another member of the nursing home management) and the senior nurses of the selected wards. The topics investigated in this interview were categorized in different domains: medication management, formulary and pharmacy for the nursing home management; work procedures, communication, medication chart, medication storage, residents' medication autonomy, preparation of medication, administration of medication and information about medication for the divisional head (see table 3.1 for a more detailed description of the domains). Per investigated topic, a score was attributed to the different answering possibilities by a panel consisting of field experts: 1 nursing home director, 1 medical coordinator, 3 head nurses, 1 nursing director, 3 pharmacists, 1 epidemiologist and 1 social worker. To each answering possibility a score ranging from - 3 to + 3 was attributed by the panel. The 0 was chosen whenever the answer reflected a legal obligation or a situation without impact on the quality of care. The

gradations 1, 2 and 3 (positive or negative) respectively reflected a small, moderate or serious impact on the quality of provided care. The individual domain scores were summed to a total score for both the wards and the nursing home management. The total score, which is a sum-score of all the different domain scores, reflects the quality of the medication process in the nursing home.

Table 3.1: Domains of medication management systems

Institution Level	
Pharmacy	Aspects of delivery of medications from the pharmacy to the nursing home
Formulary	Availability of the formulary in the institution
Medication Management	The procedures pertaining to quality management and evaluation
Ward Level	
Information	The extent to which medication related information is given or easily available for residents and nursing staff
Administration	The extent to which the administration of medicines to residents by nurses is organized and controlled
Preparation	The extent to which the preparation of the administration of medicines (reading from the medication chart and fetching from the drug stock) is organized and controlled
Resident Autonomy	The extent to which the resident is allowed autonomy in the management of his/her medication
Storage	The precautions taken for keeping medicines
Medication Records	The amount of and the maintenance of information on medicines in the nursing record.
Communication	The extent to which communication about medicines and residents' health is going on between nurses and physicians.
Formulary	The extent to which a drug formulary is available and promoted
Work Procedures	The extent to which the process of the medication distribution is explicitly described in written procedures

One week before the consensus meeting, all experts received an electronic copy of the PowerPoint presentation supporting the discussion as well as the questionnaire used during the interviews. In preparation of the meeting, a preliminary score was attributed by 2 members of the PHEBE team (2 pharmacists who had also assisted with the literature search, the elaboration of the questionnaire and with the interviews in the nursing homes). Their reasoning behind this score was also provided to the panel in the presentation. This method was used in order to initiate and facilitate possible discussions. On each topic, the panel discussed the given scores and reasoned until a consensus was reached. The whole scoring procedure took about 3 hours. The details are shown in Appendix 9.

3.3.6.2 Prescribing quality scores

The procedure described above provided information on the medications used by each individual resident and his or her relevant clinical diagnoses and care problems. With this limited amount of information it is possible to assess to a certain extent the quality of the process of prescribing medicines, focusing on the drug choice process of the physicians.

We used three existing sets of prescribing quality indicators, specially adapted to the setting of the elderly in general and the residents of nursing homes in particular:

- The BEERS criteria of potentially inappropriate prescribing in the elderly
- The ACOVE Criteria of underprescribing in the elderly
- The BEDNURS (Bergen District Nursing Home Study)

In addition, we added 2 other approaches to quality of prescribing:

- Chronic use of benzodiazepines
- Belgian medication with low benefit/risk ratio

We will describe in more detail the three international sets of prescribing quality indicators and how these were adapted for this project in Belgium, as well as the two other approaches.

The BEERS Criteria

Beers and colleagues developed in 1997 explicit criteria for potentially inappropriate drug prescribing in ambulatory older adults aged 65 and over. These criteria were widely used to estimate the prevalence of inappropriate drugs. At first, the Beers list of inappropriate medicines was a list of medicines which use should be avoided in elderly, whatever their indication. The Beers List was updated in 2002. Some medicines were deleted and other added to this list in the 2002 update with 48 individual medications or classes of medication that should generally be avoided in persons 65 years or older because they are either ineffective or they pose unnecessarily high risk for older persons and a safer alternative is available. In addition, for some medicines dose and co-morbidity were considered. For 8 medicines the inappropriateness of the medicine was conditioned by exceeding a maximal appropriate dose. The most important change was the production of a list of 20 medical conditions with a formal list of drugs that should not be used in patients having these conditions.

We experience a number of problems when adopting this list to the Belgian situation. First, 10 of the 48 potentially inappropriate medications were not registered on the Belgian market, and another 25 have a very limited consumption. Second, programming the list of contra-indicated medicines for some medical conditions proved to be cumbersome as some very broad or ill-defined classes of drugs were used. Examples of broad classes are “drugs with high salt content” or anticholinergic drugs. This is difficult to program for identification based on individual medicinal product packages. Examples of ill-defined classes are “anticholinergic antidepressants”. Some of the medical conditions in the updated list were not on our questionnaire of clinical data (e.g. atrial arrhythmia, bladder obstruction). Third, some of inappropriate medications registered in Belgium, are not registered in the US, and hence, not considered in the BEERS list (e.g. a number of long acting benzodiazepines, such as flunitrazepam).

Hence, we limited the use of the BEERS criteria to the potentially inappropriate medication with a substantial usage in Belgium. This approach makes our data on prescribing quality not suitable for international comparisons. However, the items we retained provide a partial but valid contribution to our attempt to quantify prescribing quality problems.

The ACOVE criteria of underprescribing

We wanted to include in our analysis of prescribing quality the dimension of underprescribing. For this purpose, we turned to the Assessing Care of Vulnerable Elders (ACOVE) project. This is a set of 203 quality indicators for care of 22 conditions (including geriatric syndromes and 11 associated diseases) and 6 domains of care (screening, prevention, diagnosis, treatment, follow-up, and continuity). Fourteen types of medical intervention were considered, one of which was medication (with 68 indicators pertaining to pharmaceutical intervention). Nine of these indicators were

related to underprescribing of medicines. All these indicators have the form of IF/THEN/UNLESS. IF specifies the clinical condition to which the quality indicator pertains. THEN specifies the medical act that should be performed. UNLESS lists the exceptions to the rule. An example of an underprescribing quality indicator is: if the patient has diabetes, then low dose aspirin should be prescribed, unless there is a contra-indication for aspirin. These criteria were designed to be assessed by pharmacists, performing a clinical review of the residents and their medication, with full access to the medical record of the patients.

We were able to program seven of the nine ACOVE underprescribing quality indicators. Two criteria could not be assessed because they pertained to patients with atrial fibrillation, a condition which was not on our checklist in the clinical questionnaire. The remaining 7 quality criteria were programmed for the IF/THEN conditions. The UNLESS statements (with the list of exceptions) were too complex to program and could not be assessed in a valid way, given the limited nature of the data we collected. Again, this limits the validity of our data for international comparison.

The criteria from the BEDNURS study

In this approach, the occurrence of potential medical problems is investigated using an extensive physician/pharmacist medication review. The study focused on cardiovascular and central nervous problems. It addresses indication, dosage and duration of treatment, as well as safety, drug-drug and drug-disease interactions, duplication and underprescribing.

We were able to program most (31) of the potential medication problems of the BEDNURSE approach into criteria, which could be generated by a computer analysis (see full list in results section). Dropped items were: Vitamin C for cystitis prophylaxis, nutritional supplements for iron deficiency anaemia. Some items were slightly simplified: use of antipsychotics in non-psychotic patients was simplified to use of antipsychotics, because we did not know whether our patients were psychotic or not. Concomitant use of central nervous system drugs was simplified to concomitant use of ATC class N05 (psycholeptics) and N06 (psychoanaleptics) in three different combinations.

Chronic use of benzodiazepines

All patients with chronic use of benzodiazepines (and related substances), whether used as sedative or hypnotic, were recorded. We decided to include a flag for usage of any benzodiazepine or derivative, as studies have shown increased risk for falls and/or hip fracture for benzodiazepines with very short, short half-lives as well as long-acting benzodiazepines, regardless whether these products were used as hypnotics or sedatives.

Belgian medications with low benefit/risk ratio

A list of medication with low benefit/risk ratio of the Belgian Drug Information Center was used. These are officially registered medicines in Belgium with poor evidence of efficacy, or with too many active substances combined. These medications can be recognized on the web site of the centre (www.bcfi.be), because no recommendations for posology are made for these medicines.

3.3.7 Statistical analysis

Data analysis was performed with the statistical package SPSS version 12.0. A p-value of $p < .05$ was used as the significance level. The conceptual framework of the analyses performed is shown in table 3.3.

3.3.7.1 Descriptive analysis

First, a general exploration of the databases was performed using descriptive statistical techniques. At the level of residents, inclusion for description of administrative characteristics and medication usage was limited to residents with administrative data

and a medication chart available. For description of quality prescribing parameters, only residents with clinical parameters available (i.e. medication form returned by responsible GP) and not in need for palliative care were included.

Before using analytic statistical methods, parameters of prescribing quality were carefully tested, investigating their internal relationship, their predictive value and their coverage of different aspects of quality (see table 3.2).

Table 3.2 : Operationalization of quality of prescribing in this research

VOLUME	Number of medications on the medication chart
	Number of systemic chronic medications
EXPENDITURES	Public expenditures for reimbursed chronic medication (RIZIV/INAMI)
	Co-payment for reimbursed chronic medication
	Payments for non-reimbursed medication (at ex-pharmacy retail price, VAT 6% incl.)
APPROPRIATENESS	SUMSCORE of Potential Prescribing Quality Problems

3.3.7.2 Univariate analysis

Univariate analysis was performed at the level of residents exploring the relationship between patient and institution characteristics and the quality of prescribing. Univariate analyses were also performed at the level of the institution and the level of the ward to investigate the internal dependency between patient and institution characteristics and their relationship with the parameters of prescribing quality. Also the relationship between characteristics of medication management and quality of prescribing was first explored using univariate statistical techniques (bivariate regression analysis, one-way ANOVA). We preferred to use the non-parametric Spearman Rank Correlation Test (indicated by rs) because of the semi-quantitative nature of the data (quality scores) or the skewness of their distribution (expenditures).

To answer the specific research question on the relationship between institutional medication management and the quality of prescribing, multivariate analysis at the institution level was performed using multiple regressions. In table 3.3 an overview is given of the regression analyses performed at the different levels of analysis in univariate and in multivariate approach.

Table 3.3 : Conceptual framework of the analysis

	RESIDENT LEVEL (N=2510 OR N=1730) UNIVARIATE	WARD LEVEL (N=112) UNIVARIATE	INSTITUTION LEVEL (N=76, 74 OR 72) UNIVARIATE MULTIVARIATE	
General Institutional Characteristics				
Size in Beds		Impact on prescribing quality and medication management systems		Impact on prescribing quality
Size in Wards				
Type			Impact on prescribing quality	
Stratum				
Province				
Price Competition				
Delivering Pharmacists				
Price Competition				
Monopoly in delivery				
percent RVT beds				
Percent billing private exp.				
Percent OCMW-patients				
Staffing characteristics				
CRA-activity		Impact on prescribing quality and medication management		Impact on prescribing quality
Number of GPs visiting				
Residents per nursing staff				
Residents per A1+A2				
Percent A1				
Medication management systems at the institution level				
Manag		Impact on prescribing quality		Impact on prescribing quality
Form				
Pharm				
Medication management systems at the ward level				
Procedures		Impact on prescribing quality		Impact on prescribing quality
Pharmacist				
Communication				
Medical record				
Storage				
Self Medication				
Preparation medication				
Administration				
Information				
SUMSCORE MMS				
Residents characteristics (Demographics and case mix)				
Age	Impact on prescribing quality			Impact on prescribing quality
Sex				
Dependency score (Katz)				
Dementia				
Number of diagnoses				
Number of care problems				

3.3.7.3 Multivariate analysis

Since differences in individual consumption and prescribing quality could be explained both by resident and/or nursing home characteristics, it is important to include both individual as well as organizational characteristics simultaneously in the analyses in order to disentangle both sets of variables on prescribing quality.

Multivariate data analysis techniques such as regression analysis allow to separate these effects and to identify their distinct impact on drug consumption. A number of

dimensions of prescribing quality (averages at nursing home level) will be used as endogenous variable in the regressions. The aim is to identify the impact of resident and nursing home characteristics on three dimensions of prescribing quality: volume of usage (average number of medications per resident, average number of chronic systemic drugs per resident); expenditures (average ex-pharmacy expenditures of reimbursed chronic drugs per month per resident, average co-payment for chronic reimbursed drugs per month per resident, average out-of-pocket payment of non-reimbursed drugs per month per resident, percentage of cheap drugs), and appropriateness of prescribing (average sum-score of prescribing quality problems).

Descriptive statistics of these endogenous (or dependent) variables (including Box plots and histograms and Box plots) and descriptives per stratum and province of these variables are reported in Appendices 11 and 12.

These variables are the result of an aggregation process of resident variables (expressing quality of prescribing) to the level of the institution. Per institution the mean of all residents per institution is given. Consequently these data cannot be considered as ratio variables (or integer or count variables). Hence, we opted for regression techniques based on Ordinary Least Square methods, and not on binomial or Poisson approaches.

We refrained from performing multivariate, multilevel regression techniques at the level of the residents, because most data on medication management systems were recorded at ward level and not at institutional level. Ward data could not be reliably attributed to the resident level, as there was no certainty that the resident belonged to either one of the surveyed wards.

In the following sections, the 7 outcome variables presented on the previous pages will be used as endogenous variables in regressions. Possible explanatory variables are listed in table 3.4. All regression models start with a full model in which all variables listed in the table are used as exogenous variables.

Table 3.4 Variables included in the full model

GENERAL INSTITUTIONAL CHARACTERISTICS	
LOCATION	Province
TYPE	Public / Private not-for-profit / private for profit
SIZE	Number of beds, number of wards
MEDICAL STAFF	Number of residents per visiting general practitioner, Percentage of residents treated by the coordination physician
DELIVERING PHARMACIST	Type of pharmacy, Single or multiple delivering pharmacies
NURSING STAFF	Number of residents per nursing staff, per nurse, per nurse bachelor level
BILLING TO RESIDENTS	Percentage of residents with separate bill for private expenditures
MEDICATION MANAGEMENT SYSTEMS	
	At management level (3 items), At ward level (8 items)
CASE-MIX	
Age	
Percentage of female residents	
Percentage of beds certified as highly dependent (RVT)	
Percentage of residents with dependency score C	
Percentage of residents with dementia	
Number of clinical problems, number of care problems	
Percentage of residents living on local social welfare	

The following procedure was used for all 7 outcome variables. First, a “Full model” was estimated (using Ordinary Least Squares (OLS)) in which all exogenous variables from

table 3.4 were included. Residuals were examined to detect possible bias due to misspecification of the model.

Examining individual significance of the variables included in these full model regressions revealed that a number of them were not estimated significantly different from zero and did therefore not contribute to explaining differences in the endogenous variable. These variables were iteratively omitted from the regression, starting with the least significant one (i.e. the variable with the smallest partial correlation with the dependent variable). After the removal of the least significant variable, the equation was re-estimated and the variable with the smallest partial correlation was considered next. The procedure stopped when there were no variables in the equation that satisfied the removal criterion (t-statistic smaller than 0.75 (in absolute value)). Thus the remaining variables in the equation all have t-statistics larger than 0.75 (in absolute values).

3.3.8 Ethical considerations

Before the start of the study, the project proposal was presented at the Regional Organizations of Nursing Homes and the provincial CRAs. The protocol of this study was submitted to and approved by the ethical commission of the scientific organization of general practitioners of Flanders (WVVH). Informed consent was asked to the directors of selected nursing homes and of treating physicians. All data were collected anonymously. It was the exclusive task of the CRA of the participating nursing homes to anonymize the data for the researchers and to unlock the identity of the GPs to send them the print out of the medication charts.

3.4 RESULTS

This study was performed in 76 randomly selected nursing homes located in the provinces of Antwerpen, Oost-Vlaanderen and Hainaut, including 2,510 residents with administrative data and a medication chart available.

3.4.1 Representativity of the sample

In Belgium, 1,722 nursing homes with 126,346 beds were registered in 2004. Among them 970 were nursing homes with at least 30 beds and with a mixed character having available both ROB beds (beds for healthy elderly) as well as RVT beds (beds for elderly in need for nursing care). Out of the latter group, institutions were randomly selected in 3 provinces using a stratification system based on size (less or more than 90 beds) and type (OCMW/CPAS or private).

In table 3.5, basic characteristics of the eligible Belgian institutions and the PHEBE participating institutions are compared, showing an acceptable fit between both.

Table 3.5: Comparison of basic characteristics of the sampled nursing homes with the population of Belgian nursing homes

Province	Number		Mean size (in beds)		% RVT beds		Type (OCMW-privé)	
	Total	In study	Total	In study	Total	In study	Total % private	In study % private
Antw	159	27 (17%)	104	108	49	48	65	52
OostVI	152	25 (16%)	100	105	45	46	57	56
Heneg	115	24 (21%)	102	115	50	51	61	70
Belgium	987	76 (8%)	97	108	48	48	61	58

*including only mixed ROB/RVT nursing homes with at least 30 beds

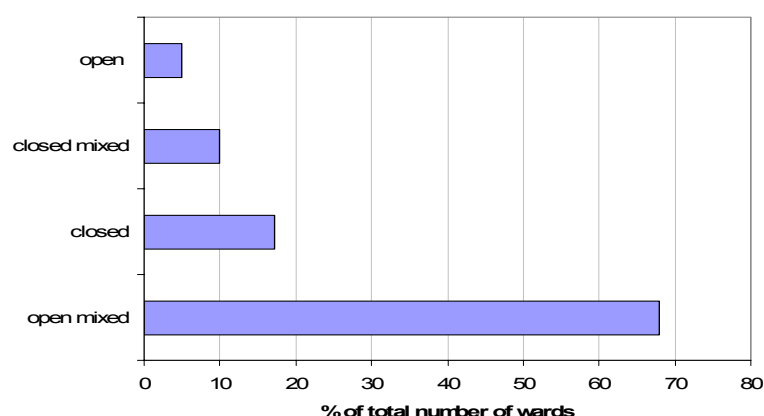
Approximately 8% of the Belgian population over 65 is living in a nursing home. In 2004, institutionalized elderly had a mean age of 84.9 and 76.9% of them were female. Included residents in our sample had a mean age of 84.8 and 77.4% were female.

Hence, we concluded that our sample of residents was representative for the population of residents in Belgian nursing homes. The size of our sampled institutions was slightly larger, private institutions were somewhat underrepresented in the province of Antwerpen and somewhat overrepresented in the province of Hainaut.

3.4.2 Description of participating nursing homes

The selected nursing homes had a mean capacity of 106 beds (range: 35 - 306) and a mean number of wards of 2.6 (range: 1 - 7). The distribution of the type of wards is shown in figure 3.1. The wards were mainly (68.0%) 'open mixed', meaning that they are open for all kinds of residents, even those with beginning dementia. The rest of the wards were 'closed' (=closed ward only for demented residents; 17.2%), 'closed-mixed' (=closed ward for demented as well as non-demented residents; 9.9%) or 'open' (=open ward only for non-demented elderly; 4.9%).

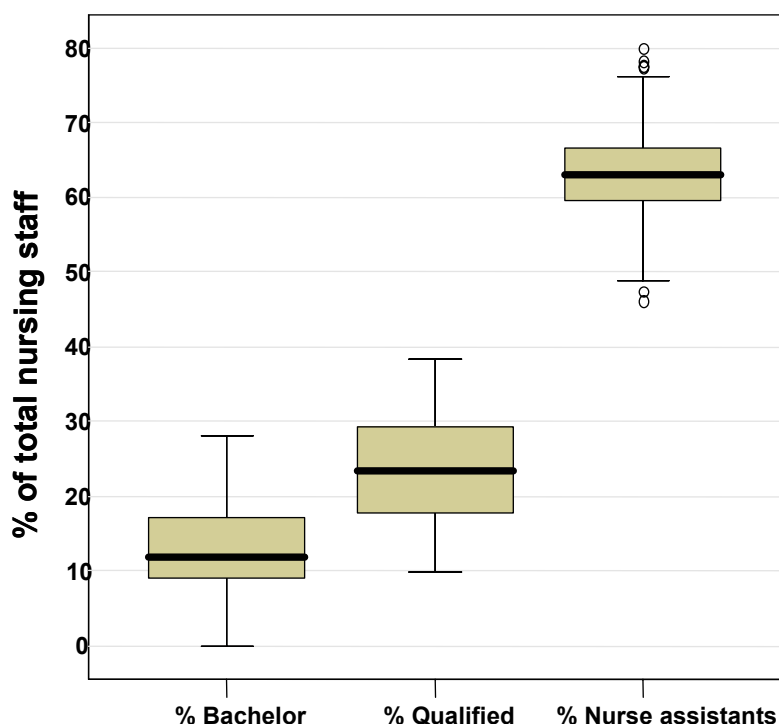
Figure 3.1: Distribution of type of wards in included nursing homes in Belgium (N=112)



Included nursing homes had 20 to 153 RVT beds (mean percentage of RVT beds 48%). Mean age of their residents was 85 (range 79-89) with 77% of females (range 59-86%). Case-mix according to the Katz score revealed that 20% of their residents had Katz 0, 15% Katz A, 20% Katz B and 45% Katz C.

Participating nursing homes had between 35 and 249 staff members including approximately 65% of nursing staff. Resident/nursing staff ratio ranged from 2.0 to 6.2 (mean 3.2 residents per nursing staff member). Only 37% of nursing staff was qualified as a nurse (13% bachelors and 24% qualified nurses). Distribution of nursing personnel according to qualification is shown in figure 3.2. Per nursing home, a mean of 31.8 visiting GPs was identified (range: 7 - 115). On average, the CRA was the treating doctor for 23.9% of the residents (range: 0 – 86.0%).

Figure 3.2: Mean proportional distribution of bachelors, qualified nurses and nurse assistants in included nursing homes (n=76)



3.4.3 Description of the medication management system at the level of the institution

3.4.3.1 Medication management

The vast majority of the nursing homes had a quality coordinator (88.2%) and a quality handbook (84.2%). A quality coordinator is responsible for good quality of services provided in the nursing home, by coordinating all quality related activities (care, medication, food and hotel services) and contributing to the development of a general quality handbook and work procedures. 81.6% (62/76) of the nursing home directors had made written agreements with their staff on the practical organization of the medication process. These agreements were written down (not necessarily signed) in the general quality handbook (64.5%) and/or in separate work procedures (53.2%). Table 3.6 gives an overview of the different aspects of the medication process whereof written agreements were made. The number of written agreements per nursing home was distributed as follows: 16.1% made 1 to 4 written agreements, 41.9% made 5 to 9 and 41.9% made 10 or more.

Table 3.6: Written agreements regarding the medication process

Topic	% of nursing homes that made written agreements on this topic
engagements with the delivering pharmacy	64.5%
engagements with the GPs concerning the prescription of medication or the modification of therapy	61.3%
the drawing up of medication charts	74.2%
the correct way to order medication	74.2%
the management and storage of medication	66.1%
the disposal of excess or expired medication	53.2%
the management of narcotics	67.7%
the dispensing of medication	80.6%
the administration of medication	79.0%
the administration of injections	54.8%
the administration of over-the-counter medication	66.1%
the administration of prescription medication in acute situations without consulting the GP	67.7%

To minimize the risk of medication related errors in nursing homes, a proactive evaluation of the medication process is advisable. However, only one in five (21.1%) of the investigated nursing homes evaluated the medication process on a regular basis (at least every 6 months). 39.5% of the nursing homes performed such evaluation annually, while 39.5% never (or less than once a year) evaluated the medication process. A self-reporting medication error system, whereby the staff records all medication errors throughout the entire nursing home, can be very useful to identify errors and unsafe conditions. Such self-reporting medication error system had been set up in 69.7% (53/76) of the investigated nursing homes and in most of these nursing homes (48/53) this resulted in actions taken to prevent these errors in future. Also about half (13/23) of the nursing homes not having a self-reporting medication error system, proclaimed to make interventions to reduce medication errors.

3.4.3.2 *Formulary*

A drug formulary tailored to the special needs of elderly patients can be a very useful tool to improve the quality of prescribing in nursing homes. Almost all of the selected nursing homes (94.7%) had a drug formulary, whereby the national formulary for nursing homes ('Nationaal RVT Formularium') was the most frequently used (78.9%). Surprisingly, 5.3% (4/76) of the nursing home directors declared not to have a formulary in their institution despite the fact that this is legally obliged and that every nursing home in Belgium annually receives a free copy of the national formulary for nursing homes. 31.6% of the nursing homes (24/76) used an electronic prescribing system, for about half of them (11/24) the formulary was electronically available and for one third (8/24) the formulary drugs popped up as first choice during the electronic prescribing process.

3.4.3.3 *Pharmacy*

Nursing homes purchased their medication from a community pharmacy (82.9%), a hospital pharmacy (13.2%) or a wholesaler (3.9%). 63.4% of the nursing homes purchasing medication in a community pharmacy worked with only 1 community pharmacy, 28.6% with 2 or 3, and 7.9% with 3 or more community pharmacies (see figure 3.3). For nursing homes working with more than 1 pharmacy, medication was

delivered by turns (81.8%) or simultaneously (18.2%) by the different pharmacies. For the purchase of prescription drugs, 22.7% of the nursing homes had made a public tender and 33.3% made an informal agreement with the pharmacy. For over-the-counter medication, these percentages were 22.7% and 34.8%, respectively.

The pharmacist delivered the medication packaged per resident with the resident's name on each box (which is the method described by law) (50%), in one bag for the ward with the resident's name on each box (43.4%), per resident without name (3.9%) or in one bag for the ward without names (2.6%) (see figure 3.4). In addition to dispensing medication, the pharmacist also provided an overview of the delivered medication (94.7%), provided drug information (63.2%), consulted with the nursing home management about the medication process (42.1%), assisted with the evaluation of the medication process (26.3%), gave advice about the medication process (38.2%), controlled the expiration dates of the drugs (11.8%) or provided other services (27.6%) such as the management of an emergency kit. This is shown in figure 3.5.

Figure 3.3: Type and number of delivering pharmacies

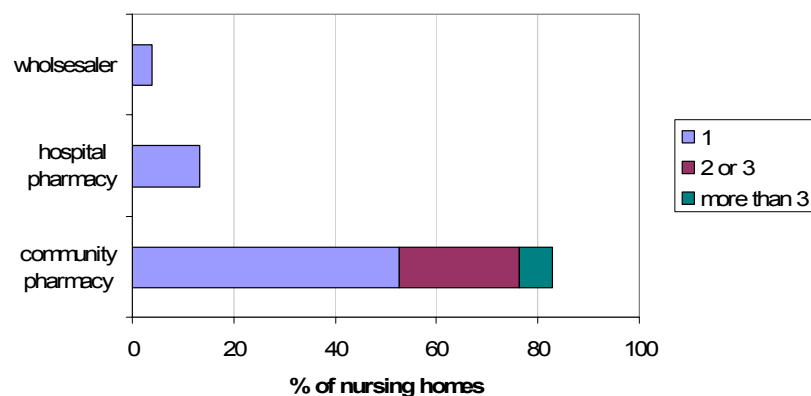


Figure 3.4: How is the medication delivered?

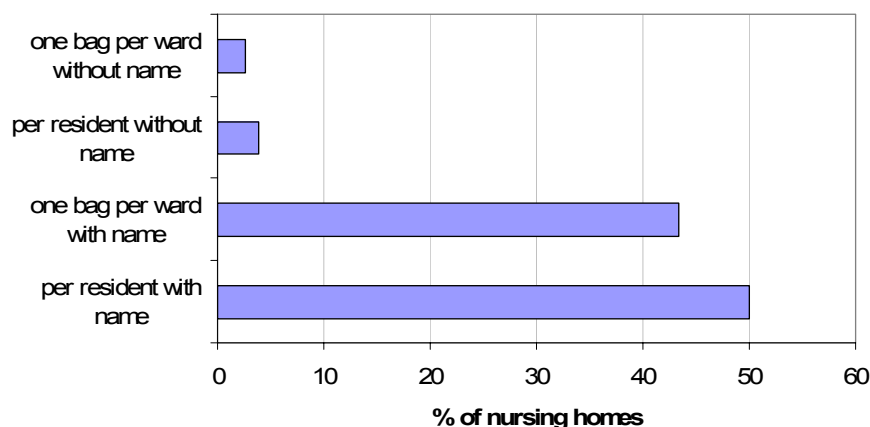
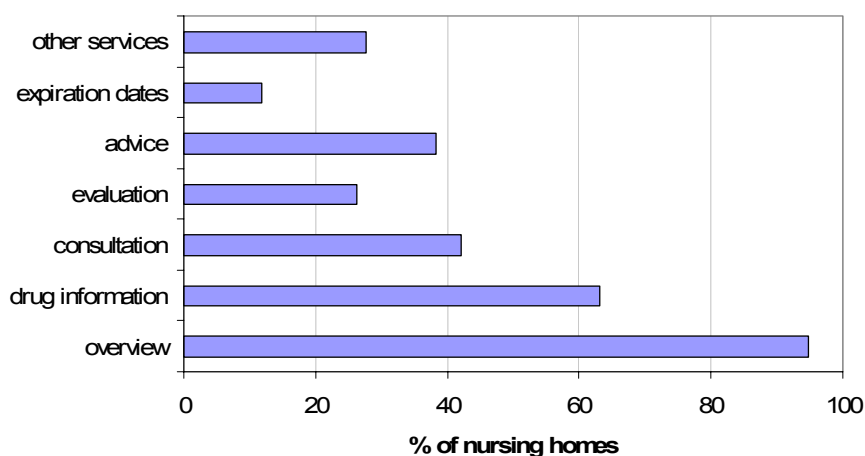


Figure 3.5: Services provided by the pharmacy

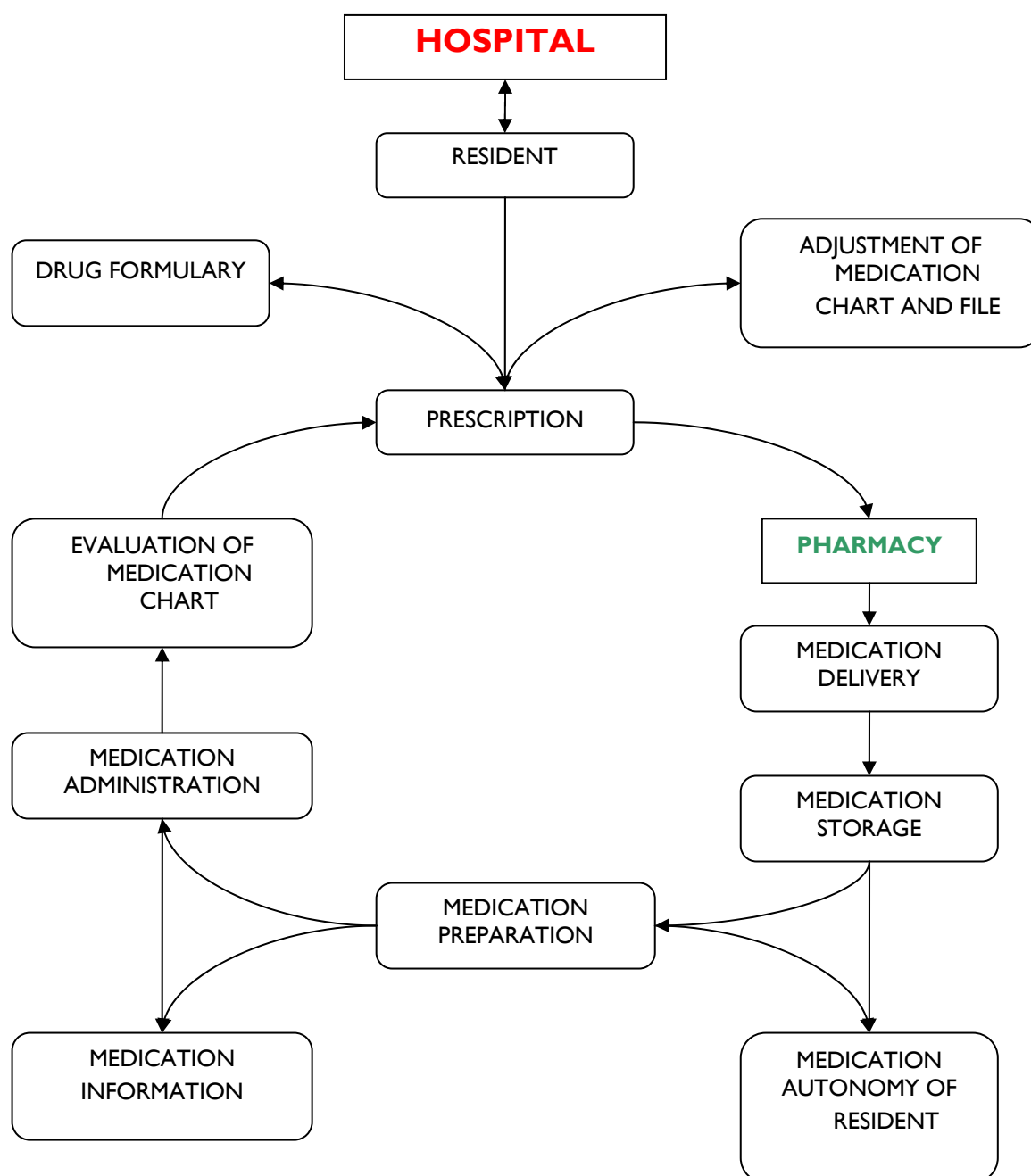
3.4.3.4 Autonomy of residents in medication management

More than half of the nursing homes (57.9%) forbade the storage of prescription drugs in the resident's room, with 74.9% of them *never* and 25.1% *sometimes* making exceptions on this prohibition. Regarding over-the-counter medication, only 30.3% of the nursing homes forbade storage in the resident's room.

3.4.4 Description of the medication management system at the level of the wards

The medication process is the process starting from the moment of prescription, through the purchase, storage, preparation and administration of medication, until the follow-up of pharmacotherapy. Figure 3.6 schematically describes the organization of the medication process in a nursing home. In order to provide a clear overview of all medication-related activities in the investigated nursing homes, the results of this survey are described per step in the medication process.

Figure 3.6: Schematic overview of the medication process in nursing homes



3.4.4.1 Drug formulary

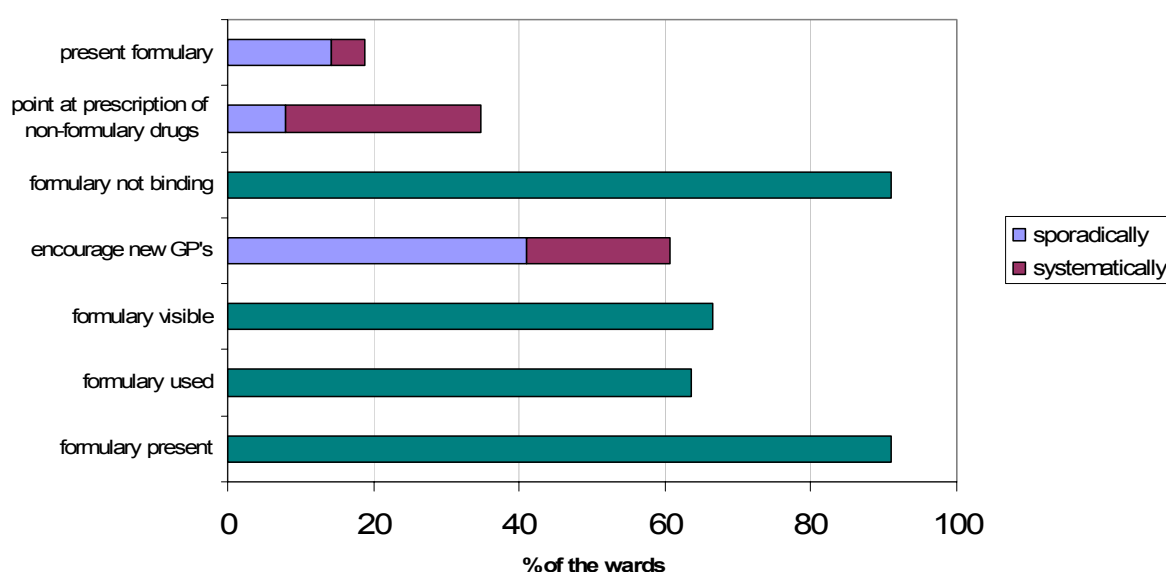
In order to ensure rational prescribing in nursing homes, the use of a drug formulary (for elderly) is advisable. According to the senior nurses, a drug formulary was *present* in 91.1% (102/112) of the wards, but was only *used* in 63.7% (65/102) of them. This formulary was visibly present at the place where the prescription was made in 66.6% (68/102) of the wards. Surprisingly, one of the interviewed divisional heads declared to use the formulary while no formulary was present on the ward.

Senior nurses *sporadically* (19.6%) or *systematically* (41.1%) encouraged new GPs to use the formulary. Such stimulation of formulary use seems advisable since nursing homes

are visited by numerous GPs, each having their own prescription pattern. In the majority of the wards (91.1%), the drug formulary was not binding, meaning that GPs can prescribe non-formulary drugs without having to motivate their choice. Nurses *sporadically* pointed the GP at prescription of non-formulary drugs in 26.8% of the wards. This happened *systematically* in 8% of the cases. At the moment of prescription, nurses actually presented the formulary to all GPs in 14.3% of the wards, while in 4.5% of the wards, nurses only presented it to GPs receptive to formulary use. The policy about drug formulary use is shown in figure 3.7.

After the prescription was made, the GP always handed over the prescription form to a nurse, who made sure that it was forwarded to the pharmacy. In about two thirds of the wards (69.6%), nurses did not wait for a prescription before ordering chronic medication implying that the doctor had to prescribe the medication *afterwards*. This can have severe consequences such as the continuation of not further indicated medication.

Figure 3.7: Policy about drug formulary use



3.4.4.2 Medication record

At admission of a new resident, an anamnesis of the used medication needs to be performed. This was the task of the head nurse (60.7%), the general practitioner (43.8%), the nurse responsible for the resident (43.8%), or another person (9.8%, mainly the nurse present at the admission time or the social services). This anamnesis was used to draw up a medication chart, which was done for every single resident in the nursing home on a standard form (the medication form was standardized in 98.7% of the nursing homes). This medication chart was still handwritten in 21.4% of the wards. The majority (88.6%) of the wards disposed of an electronic medication chart, which was a self developed model (e.g. Excel file) in one third of the cases or developed by a software company in two thirds. In 55% of the wards, the entire patient nursing record (including a copy of the medication chart and the nursing file, the care plan, a diary ...) was computerized.

Medication charts can contain up to 13 items: brand name, generic name, dose, galenic form, administration route, administration frequency (times per day), administration time, administration moment (before or after a meal), a blank for specific instructions, start date, stop date, the difference between chronic and acute medication, and PRN (pro re nata, "as needed") medication. 9 of these 13 items are legally mandatory, 4 (generic name, administration moment, the difference between chronic and acute

medication and the blank for specific instructions) are optional. In 30.4% of the wards, the chart contained less than the 9 mandatory items. The other 69.6% had even more items than the 9 mandatory ones on the medication charts. The most frequently omitted items were the generic name (absent in 71.4%) and the difference between chronic and acute medication (absent in 68.8%). Next to the daily oral medication, medication charts could also list medication that needs to be taken once a week (100%), ear or eye drops (92.9%), injections (99.1%), dermatologic preparations (67.9%) and rectal medication (93.8%). In 57.1% of the wards, medication charts were controlled on completeness and correctness by a third person.

At every new prescription, the GP filled in the prescribed medication in the medical file of the resident (in 93.8% of the cases) while the nurse did the same in the nursing file (95.5%). The medication chart was also adjusted at every new prescription. A new handwritten medication chart was filled in: at each change in the therapy (12%), weekly (12%), twice a month (8%), monthly (52%) or less than once a month (16%). A new electronic medication chart was filled in and printed out: at each change in the therapy (3.4%), weekly (17%), twice a month (33%), monthly (45.5%) or less than once in a month (1.1%).

3.4.4.3 Medication delivery

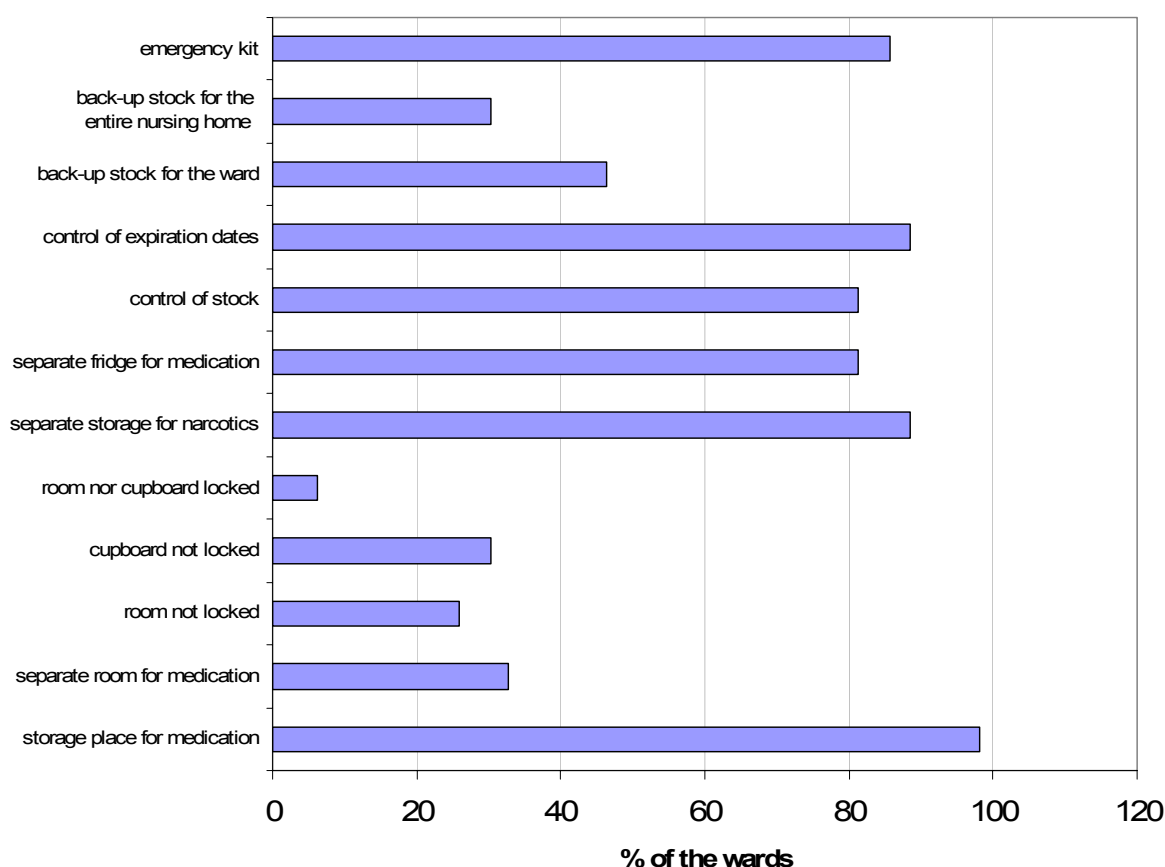
For more details on the dispensing pharmacy and on how the medication was delivered to the nursing home, we refer to subheading 3.4.3.3. The delivered medication was checked on correctness in 88.4% of the nursing homes. This happened mainly at the moment of delivery (79.5%), using either the order form (59.8%) or the prescription form (16.1%).

3.4.4.4 Medication storage

In 35.5% of the nursing homes, medication was stocked in one central location in the nursing home. By coincidence, this central location could happen to be on the interviewed ward, which resulted in 98.2% of the wards stating to have a storage place for the medication of the residents. In 32.7% of the cases, this was in a separate room only for the purpose of storing drugs. To prevent misuse, the medication should not be accessible for residents. In spite of this common sense, the medication room was never locked in 25.9% of the cases and in 30.4% the cupboard where the drugs were stored was never locked. In 6.3% of the wards, neither the storage room nor the cupboard was locked. Most of the wards had a separate storage place for narcotics at their disposal (88.4%) as well as a fridge used for drugs requiring cool storage (81.3%). The amount of available stock (81.3%) and the expiration dates of the drugs (88.4%) were controlled on a regular basis by nurses.

In 46.4% of the wards, there was a back-up stock of medication while 30.4% of the wards could use a back-up stock available for the entire nursing home. When such stock existed, there was a responsible in 79.1% of the cases. These stocks were originated from orders to the pharmacy (16.3%), excess medication (93%), free samples (3.5%) or from deceased residents (22.3%). In 24.4%, there was a logbook in order to register incoming and outgoing medication from this back-up stock. The amount of available stock and the expiration dates of the drugs were checked just as for the regular medication, in 59.3% and 94.2% of the wards respectively.

85.7% of the wards had an emergency kit containing life saving medication. In 93.8% of the cases, a responsible for this emergency reserve had been assigned. Emergency kits were composed by the medical coordinator ("CRA") (75.9%), the GPs (6.3%), the pharmacist(s) (20.5%) and the senior nurses (35.7%). The results of the topic of medication storage are shown in figure 3.8.

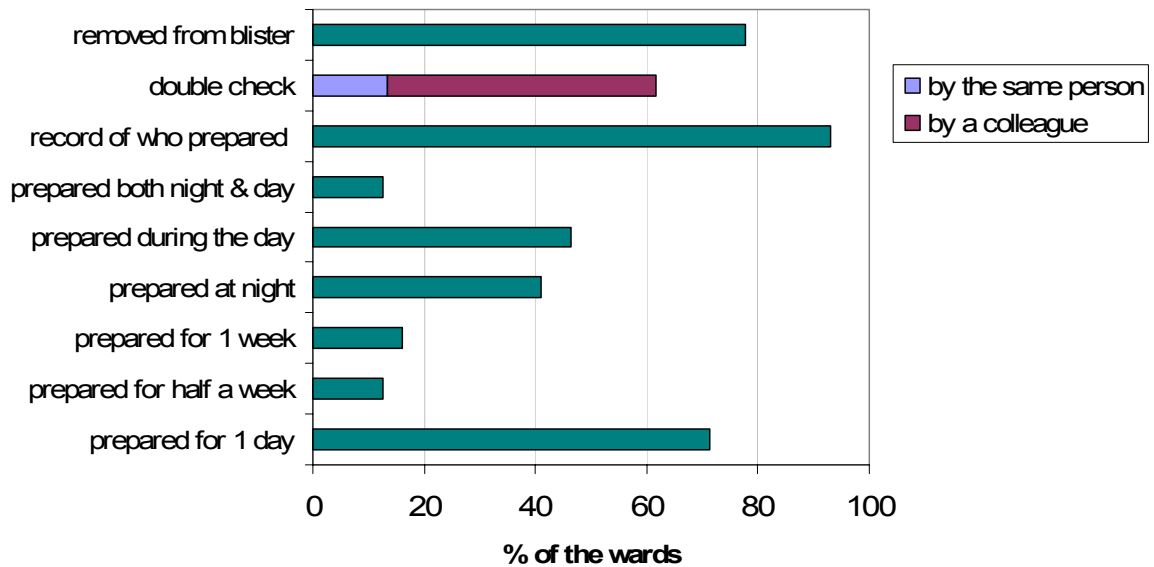
Figure 3.8: Medication storage

3.4.4.5 Preparation of the medication

Before dispensing to the residents, the medication was prepared (meaning that tablets were taken out of their packages and were put on a tray per resident in order to facilitate the administration) using the medication chart (94.6%) or a list copied from the medication chart (5.4%). The medication was prepared for 1 day (71.4%), half a week (12.5%) or 1 week (16.1%) by nurses (99.1%) and / or care aids (11.6%). Belgian law states that medication should be prepared maximum 24 hours before administration and that this preparation should always be performed or supervised by nurses. Preparation could happen at night (41.1%), during the day (46.4%) or both (12.5%). In 92.9% of the cases, the person who prepared the medications was recorded. In 13.4%, the person preparing medication also checked if the drugs were prepared correctly and in 48.2%, this control was performed by a colleague (see figure 3.9).

At the moment of preparation, tablets and capsules were already removed from their blister in 77.7% of the wards. However, some other galenic forms were prepared immediately before administration. This was the fact for solutions (84.8%), effervescent tablets (78.6%), powder bags (95.5%), and medication that requires cool storage (93.8%). This medication was checked on correctness by the same person (36.9%) or by a colleague (22.5%).

Figure 3.9: Medication preparation



3.4.4.6 Information about medication

To ensure correct medication use, nurses need to search information about a specific drug (administration route, crushability, ...). As drug information sources, 5.4% had the “gecommentarieerd geneesmiddelenrepertorium” (commented medication repertory) at their disposal, 20.5% had the “compendium of the pharmaceutical industry” (which is a compilation of scientific medicines packages inserts) and 71.4% had both. Internet was available in only 17% of the wards.

Other important sources of professional information were the caregivers regularly involved with the nursing home. Information could be asked at the pharmacist (85.7%) or at the GP or medical coordinator (“CRA”) (96.4%). 18.8% of the nurses kept the patient package inserts of medicines but did rarely use them. 8% kept the patient package inserts and used them on a regular basis.

Nurses did sometimes give information to mentally intact residents about their medication. On 48.5% of the wards, information about the indication and the intake was provided *systematically* to the residents. But the information about side effects was *restricted to certain drugs* (48.5%).

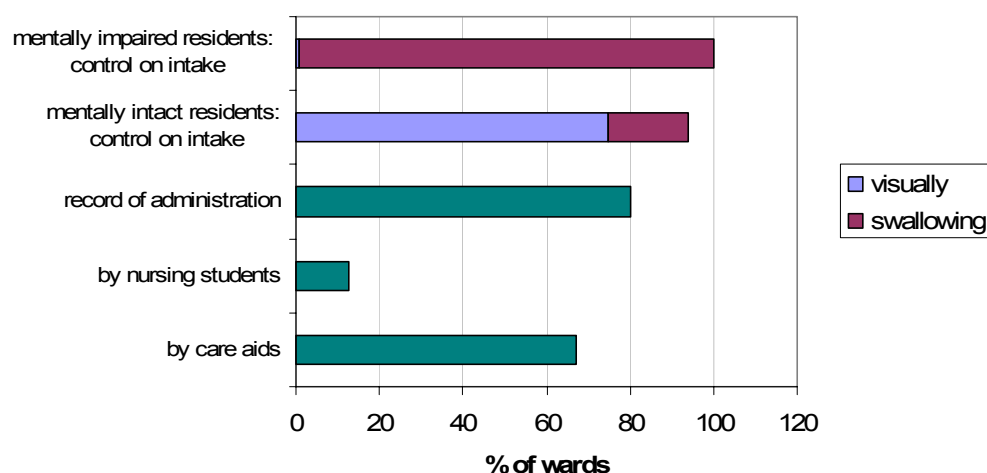
On almost every ward (99.1%), medication was crushed (mainly to facilitate the swallowing). Crushing of dosage forms can seriously alter the release pattern of the drug. For example, crushed enteric coated formulations release their drug in the stomach, while crushed sustained release formulations release all their drug at once (‘dose dumping’). However, nurses consulted information before crushing in only 21.4% of the cases. When the nurses *did* consult some information source, they consulted the medical coordinator (‘CRA’) (64.3%), the pharmacist (33%) or the package inserts of medicines (29.5%).

3.4.4.7 Administration of medication

Only nurses are legally allowed to administer drugs to the nursing home residents. On all of the wards, nurses were indeed involved with the administration of medications. However, the interviewed head nurses proclaimed that the medications were also administered to the residents by care aids (67%) or nursing students (12.5%). This administration was recorded in 80.2% of the wards.

For mentally intact elderly, the intake was visually controlled afterwards (i.e. control if the drugs had “disappeared”) for 74.7% and by swallowing (the nurse waited at the bedside of the resident until the medication had been swallowed) in 19.2%. For mentally impaired residents, these percentages were 0.9% and 99.1% respectively (see figure 3.10). The medication intake was most frequently recorded only in the case when the resident did not take the medications (83.9% for mentally intact and 82.1% for mentally impaired residents).

Figure 3.10: Medication administration



3.4.4.8 Evaluation of Pharmacotherapy

From time to time, nurses evaluated the medication chart in consultation with the GP. They assessed together if the medication was still indicated and appropriate, if the dose or galenic form needed to be adapted and if other drugs needed to be added. This happened *sporadically* (whenever therapy problems occurred) in 33.9% and *systematically* in 66.1% of the wards.

3.4.4.9 Resident autonomy in medication management

On average, 2.6% of the patients on the investigated wards (range: 0 to 17%) were completely autonomous regarding their medication: 14.6% of them (range: 0 to 98.5%) took their drugs *without* control on the intake and 83.2% (range: 0 to 100%) *with* control on the intake.

When there were autonomous people on the ward, 80% of them got a medication chart like all the other residents. The nurses also controlled the amount of available stock in the room of autonomous residents in 22% of the wards and the expiration date of the drugs in 24%.

3.4.4.10 Hospital

When a resident needed to be admitted to the hospital, the nursing home always (100%) provided an overview of the currently taken medication of that resident.

Keypoints

- A drug formulary was present in 91% of wards in the nursing homes but only 2 out of 3 wards were using the formulary effectively.
- In 79% of the wards the medication chart was electronically produced. Chronic medication was often ordered without a prescription of the GP which makes critical appraisal of polypharmacy and alterations unlikely. In 2/3 of wards, the appropriateness of medication was systematically assessed from time to time by nurse and GP.
- The correctness of medication delivery was checked in over 8/10 of nursing homes.
- On several points in the preparation and administration of medication, legal standards were not always followed. In the majority of nursing homes medication was also administered by other personnel than qualified nurses. About two third of wards met the legal obligations for medication management.

3.4.5 Assessment of the quality of the medication management system

3.4.5.1 At the level of the institution

The mean total score for the nursing home management was +0.05, with 39.5% of the nursing home management not meeting the legal obligations concerning the medication process, and half of them (51.3%) scoring positively. Best domain scores were obtained for the medication management (56.6% > 0), and worst scores for the pharmacy (36.8% < 0). The scores for the nursing home management ranged between -12 and +7. For further details, see table 3.7 below. The scores are also displayed as box plot in figure 3.11. Correlations between the different domains were also assessed.

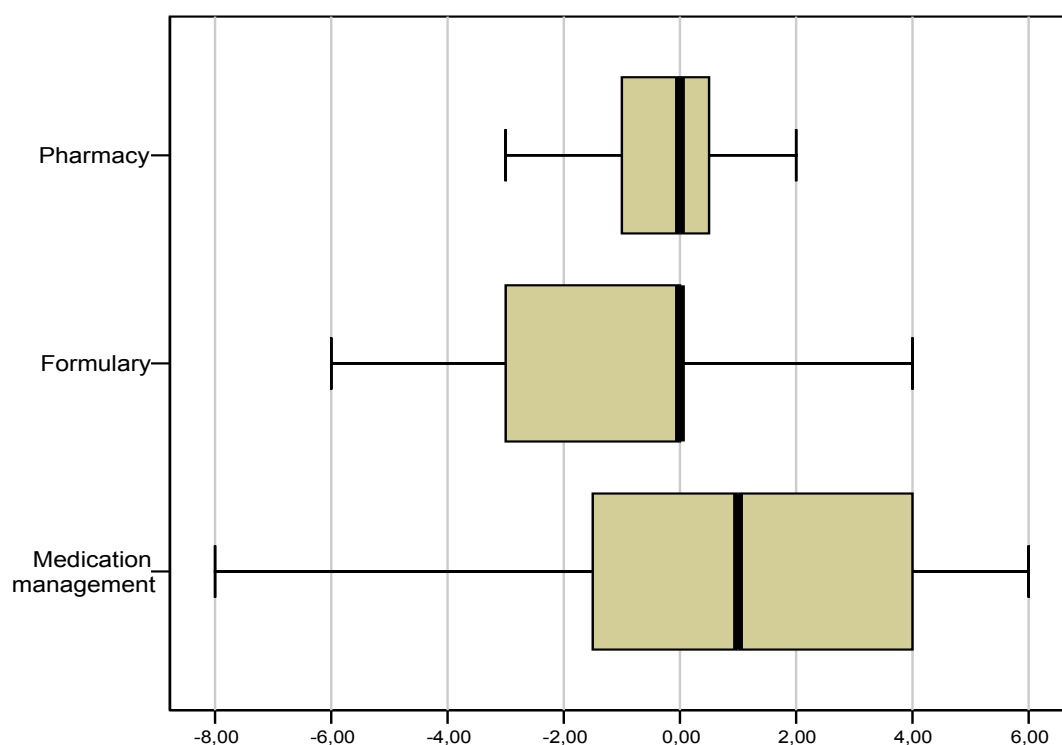
Table 3.7: Domain and total scores for the nursing home management

domain	mean	25th	75th	range		% <0	% >0
		percentile	percentile	min	max		
medication management	0,5921	-1.75	4	-8	6	32,9	56,6
formulary	-0,3947	-3	0	-6	4	26,3	15,8
pharmacy	-0,1447	-1	0.75	-3	2	36,8	25
TOTAL	0,0526	-3	4	-12	7	39,5	51,3

Note: %<0 indicates the frequency of institutions with less than legally obliged activities; %>0 indicates the frequency of institutions with more than legally obliged activities; all remaining institutions had a score of zero.

Figure 3.11: Box plots of the domain and total scores for the nursing home management

3.4.5.2 At the level of the wards



The mean total score for the wards was +2.81, with 32.1% not meeting the legal obligations. The most common shortages were situated at the domains “medication storage” and “medication preparation”, and “formulary”. 64.3% of the wards had a positive total score. The best scores were obtained in the domains of communication and information. The total scores ranged between -20 and +23. These results are detailed in table 3.8 and shown as box plot in figure 3.12 below.

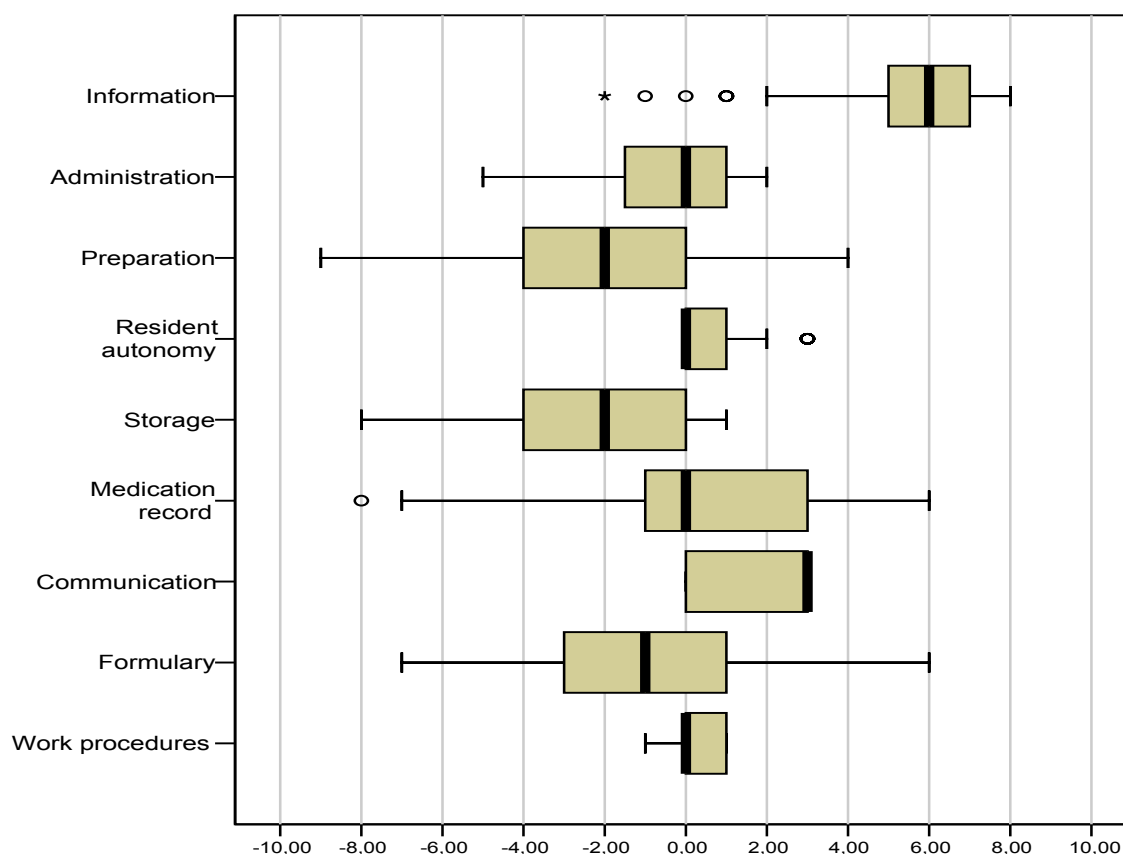
Statistically significant correlations were found between work procedures and formulary ($p=0.000$), preparation of medication and formulary ($p=0.003$) and administration of medication and information about medication ($p=0.008$). Unfortunately, these correlations have no logical or factor-related meaning.

Table 3.8: Domain and total scores for the wards

domain	mean	25th percentile	75th percentile	range min	range max	% <0	% >0
Work procedures	0,0893	0	1	-1	1	24,1	33
formulary	-1,375	-3	1	-7	6	59,8	29,5
communication	1,9821	0	3	0	3	/	66,1
medication record	0,3125	-1	3	-8	6	36,6	44,6
storage	-2,125	-4	0	-8	1	60,7	17
resident autonomy	0,5625	0	1	0	3	/	36,6
preparation	-1,9107	-4	0	-9	4	66,1	23,3
administration	-0,3571	-1.75	1	-5	2	33,9	36,6
information	5,6339	5	7	-2	8	1,8	97,3
TOTAL	2,8125	2	9	-20	23	32,1	64,3

Note: %<0 indicates the frequency of institutions with less than legally obliged activities; %>0 indicates the frequency of institutions with more than legally obliged activities; all remaining institutions had a score of zero.

Figure 3.12: Box plots of the domain and total scores for the wards



3.4.6 Description of selected residents

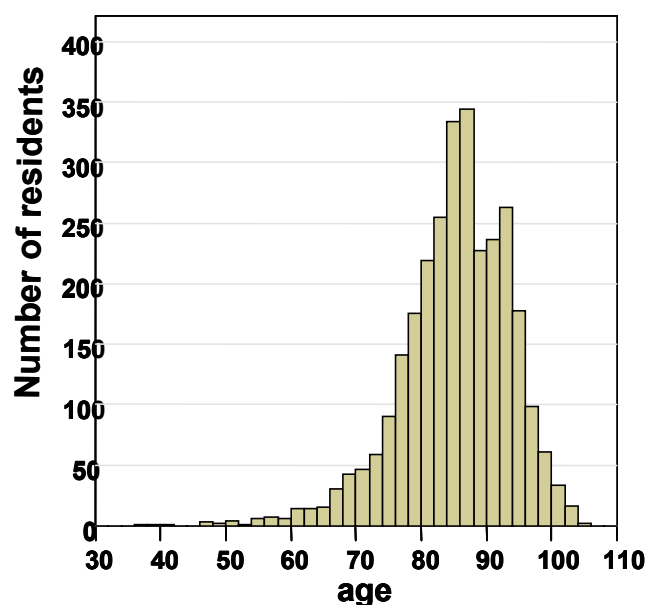
At residents' level, 2,510 subjects with administrative data and a medication chart available were included for analysis.

3.4.6.1 Age and gender

Mean age of residents was 84.8 years (range 36-104) with 77.4% women. In figure 3.13 we present a histogram of the age distribution of residents with a bimodal curve,

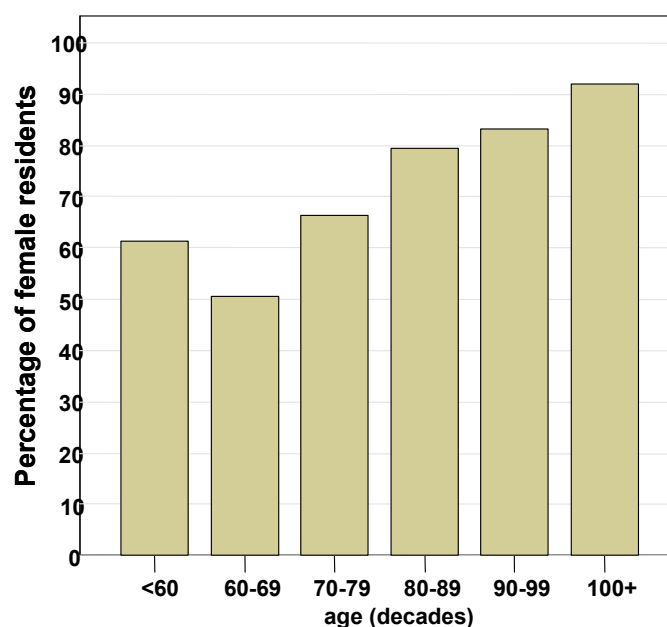
presenting a dip in the distribution in the age group 90 to 93 years old, due to the dip in nativity during World War I.

Figure 3.13: Age distribution of included residents (N=2510)



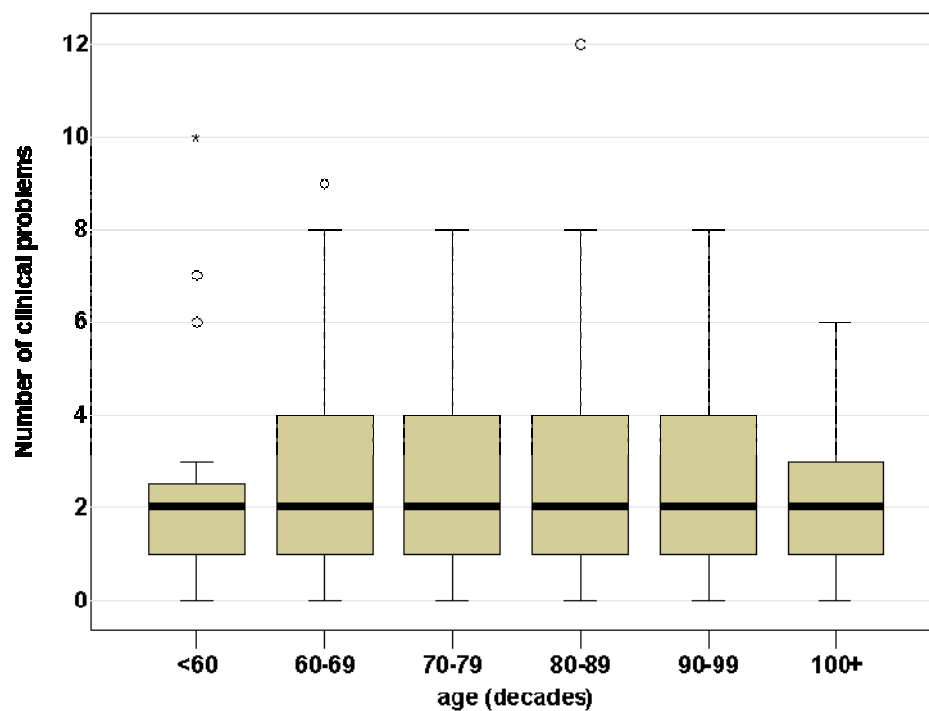
In figure 3.14 the increasing percentage of female residents with increasing age is presented. Among sexagenarians, 50% of the residents are female, while this percentage rises to 82% women in the residents of 90 to 99 years old.

Figure 3.14: Percentage of female residents according to age



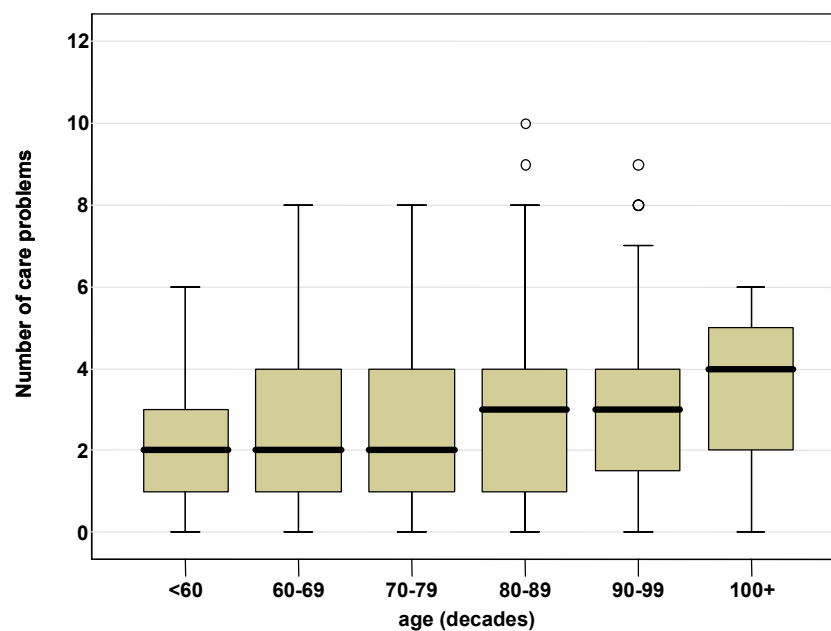
The median number of clinical problems was 2 in all age groups, with little difference between age groups in the distribution of the extent of pathology (see figure 3.15)

Figure 3.15: Number of clinical problems according to age



By contrast, there was a net increase of the number of care problems with age, with the median number of care problems progressing from 2 to 4 (see figure 3.16)

Figure 3.16: Care problems according to age



3.4.6.2 Administrative characteristics

Residents had a privileged reimbursement system for medication (WIGW/VIPO status with lower co-payment) in 60% of cases and 14% were dependent on Community Social

Welfare support (OCMW/CPAS) with out-of-pocket expenditures for medication paid by the local social security system.

3.4.6.3 Case mix

In Belgian nursing homes, a crude system for allocating case-mix categories to residents is used. This system is the basis for the determination of the per diem funding of nursing homes. It is based on a mixture of a four grade dependency scale and the presence or absence of dementia.

In table 3.9 the distribution of residents over these case-mix categories and their description is given.

Table 3.9: Distribution of residents over the Belgian dependency categories according to the Katz scale (N=2,520)

Belgian Case-Mix Class	Description	Percentage of residents
Katz O	Cognitive fit and physically independent	6.1%
Katz A	Minor physical dependency ^a , not dement OR dement and physically independent	15.0%
Katz B	Major physical dependency ^b , not dement OR dement and minor physical dependency	18.5%
Katz C	Full physical dependency ^c , not dement	12.0%
Katz Cd	Full dependency and dement	48.4%
Total		100.0%

^aMinor physical dependency: dependent for washing and clothing

^bMajor physical dependency: a + dependency for mobility and bathroom

^cFull physical dependency: a + b + dependency for incontinence and/or feeding

Poly-pathology was observed in most residents with clinical problems diagnosed by the GP ranging from 0 (9%) to 12 with a mean of 2.6 problems. Cardio-vascular pathology was most frequently observed (see figure 3.17). Additionally, residents had between 0 (11%) and 15 care problems with a mean of 2.7 care problems. The highest frequency was observed for fall risk, insomnia and constipation (see figure 3.18).

Figure 3.17: Frequency of pathological problems

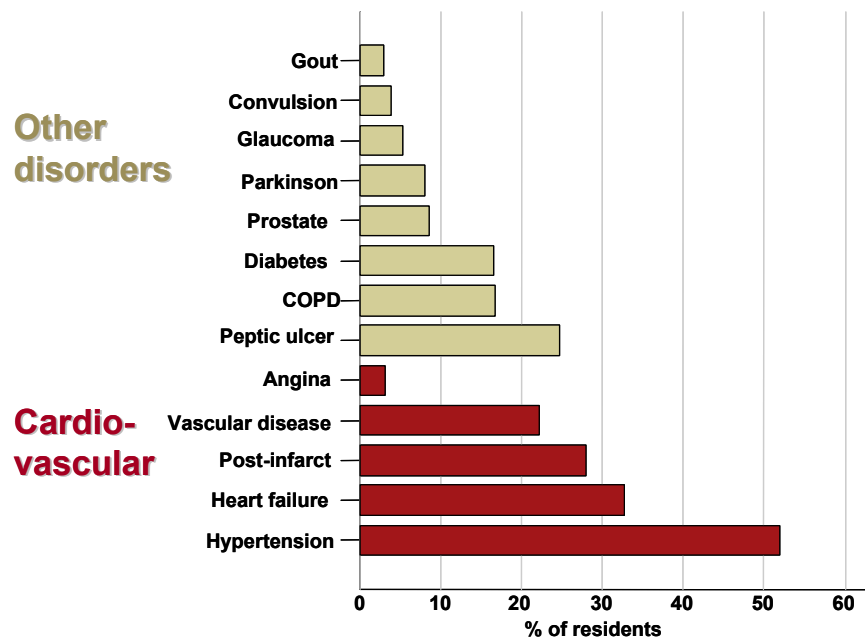
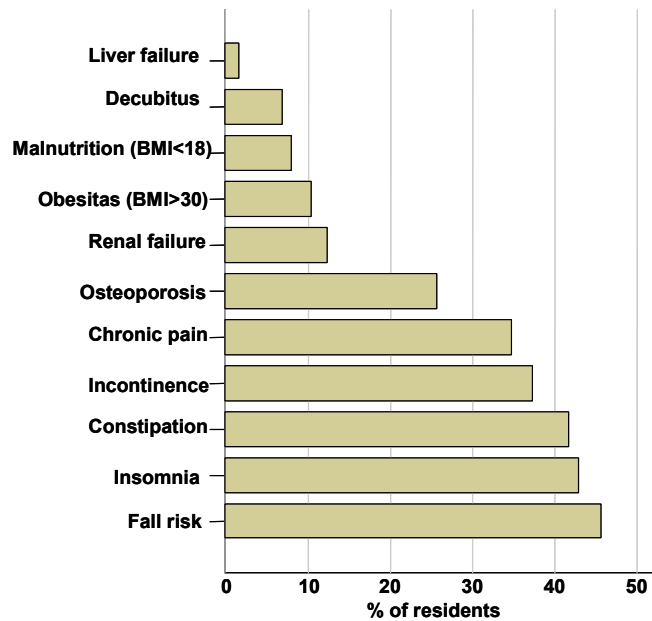
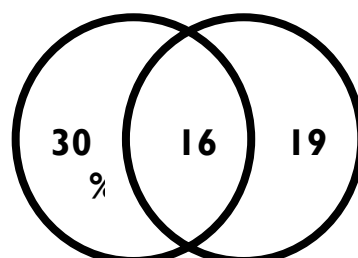


Figure 3.18: Frequency of care problems



The treating physician categorized 46% of the residents as demented, and 35% as depressed. The overlap between the two diseases is shown in figure 3.19. Only 35% of the residents were free of either dementia or depression, 16% suffered from both affections, 30% was demented without depression and 19% depressed without dementia.

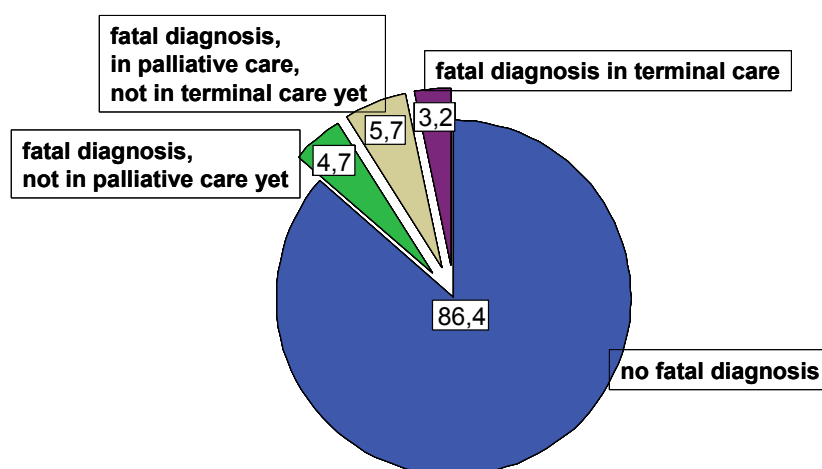
Figure 3.19: Venn-diagram of dementia and depression as assessed by the treating physician (N=1730)



Demente Depresse

14% had a fatal diagnosis with palliative care installed in 9% of residents, of which 3% were in terminal phase (see figure 3.20).

Figure 3.20: Distribution of palliative and terminal care patients (N=1730)



Keypoints

- The majority of the residents were females (77.4%) and had a mean of 2.6 clinical problems that was constant over all age categories. In contrast, the number of care problems increased from 2 to 4 depending on age.
- 6 out of 10 residents were eligible for lower co-payments (preferential treatment) and in 14% of residents out-of-pocket payments were dealt with by the OCMW/CPAS.
- According to the treating physicians, nearly half of residents had dementia and over 1/3 was depressed. 1 out of 10 was receiving palliative care.

3.4.7 Description of the medication used

We collected the medication charts of 2,510 residents with an average of 8.1 entries per medication chart, resulting in a total of 20,275 recorded entry lines (no entry lines for patients with no medication).

3.4.7.1 Crude consumption

Of the 20,275 entry lines on the medication charts, 88% were for chronic medication, 3% for acute medication, and 9% on an "as needed" basis. 94% of the entry lines were for officially registered medications. Of the 6% entry lines which were not officially registered medications, 3% were for magistral preparations, copying officially registered medications; 1.4% were for other magistral preparations; 1.4% for topical preparations not registered as medication; 0.1% for complementary medicines and 0.1% for parapharmacy.

Entry lines for oral medication accounted for 88% of the entries, entry lines for other systemic medication for 7%, and entry lines for topical or instillation medication for 5%. A prescription from the physician was needed for 71% of the entry lines, and 57% of the entry lines were for reimbursable medication. Of these entry lines for reimbursed medication (N=11,546), 19% were for brand drugs without generic alternative, 53% were for brand drugs with a generic alternative available, but priced above the reference price, and 28% for generics or brands below the reference price.

3.4.7.2 Medication usage per resident

Volume

Very few (0.9%) residents had no medication; 16.6% had 1 to 4 entry lines on the medication chart; 49.5% had 5 to 9 entry lines; 27.6% had 10 to 14 entry lines, and 5.5% had more than 14 entry lines (up to a maximum of 22).

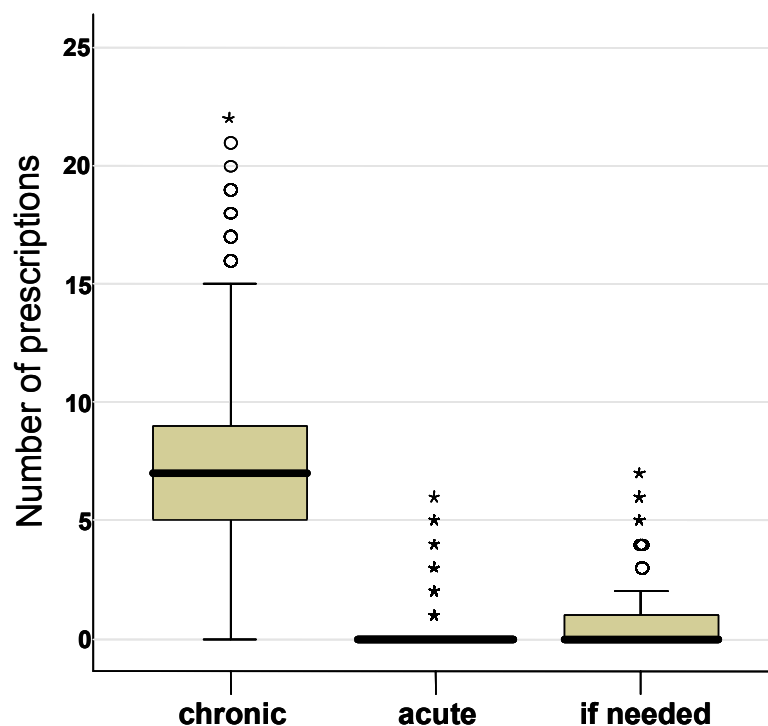
When the analysis was limited to chronic medication, these frequencies slightly changed: 1.1% residents had no medication; 22.7% had 1 to 4 chronic medications; 53.1% had 5 to 9 chronic medications; 20.8% had 10 to 14 chronic medications, and 2.1% had more than 14 chronic medications (up to a maximum of 22).

Only 15.1% of the residents were on a course of acute treatment at the moment of observation (10.2% on one acute medication, 4.8% on more than one acute medication, with a maximum of 6).

With regard to medication on an "as needed" basis, 44.7% of the residents had at least one such entry line on the medication chart (25.9% one medication, 19.9% on more than one acute medication, with a maximum of 7).

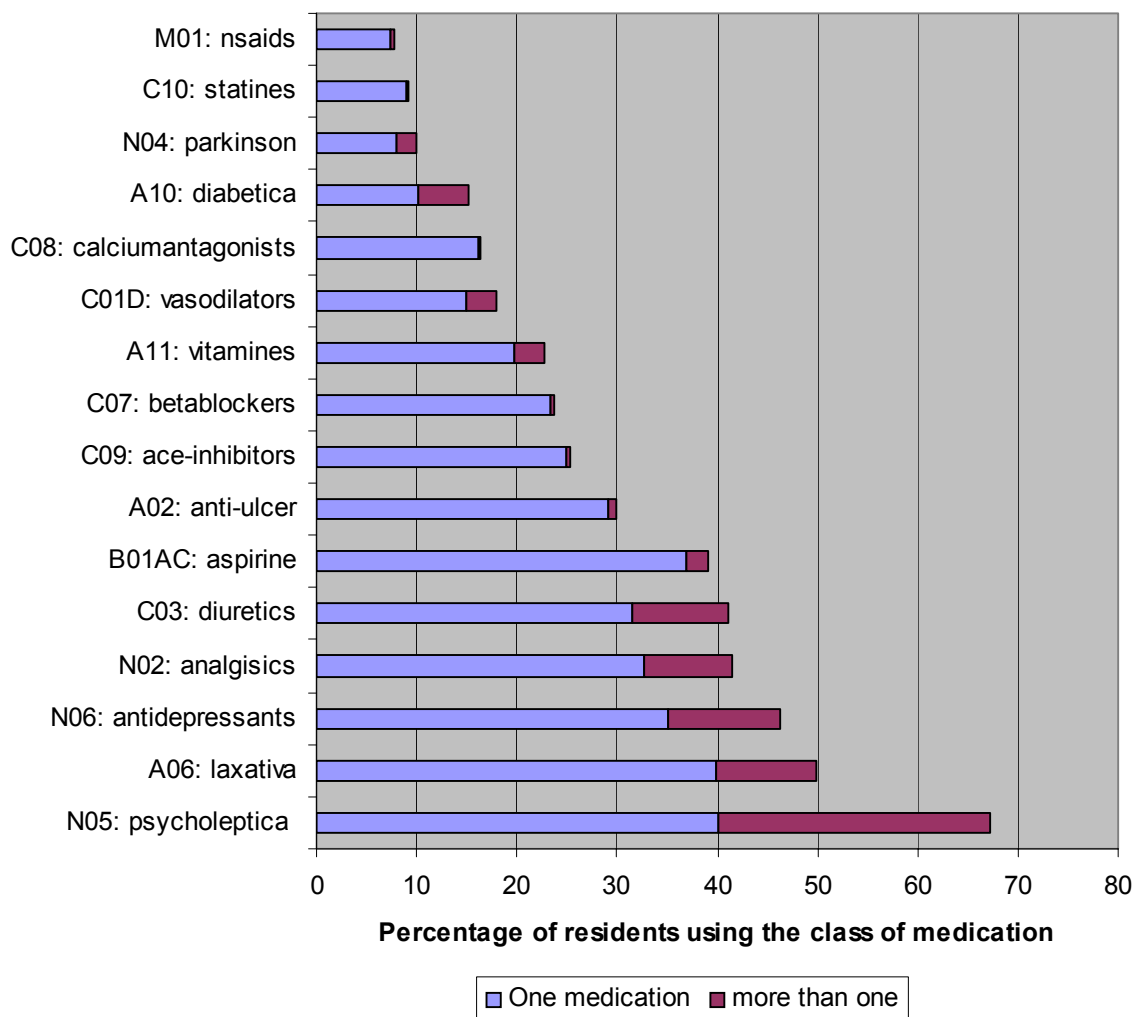
In figure 3.21, an overview in boxplots is given of these data on chronic, acute and "as needed" medication.

Figure 3.21: Number of medications per patient for chronic, acute, and “as needed” medication (N=2510)



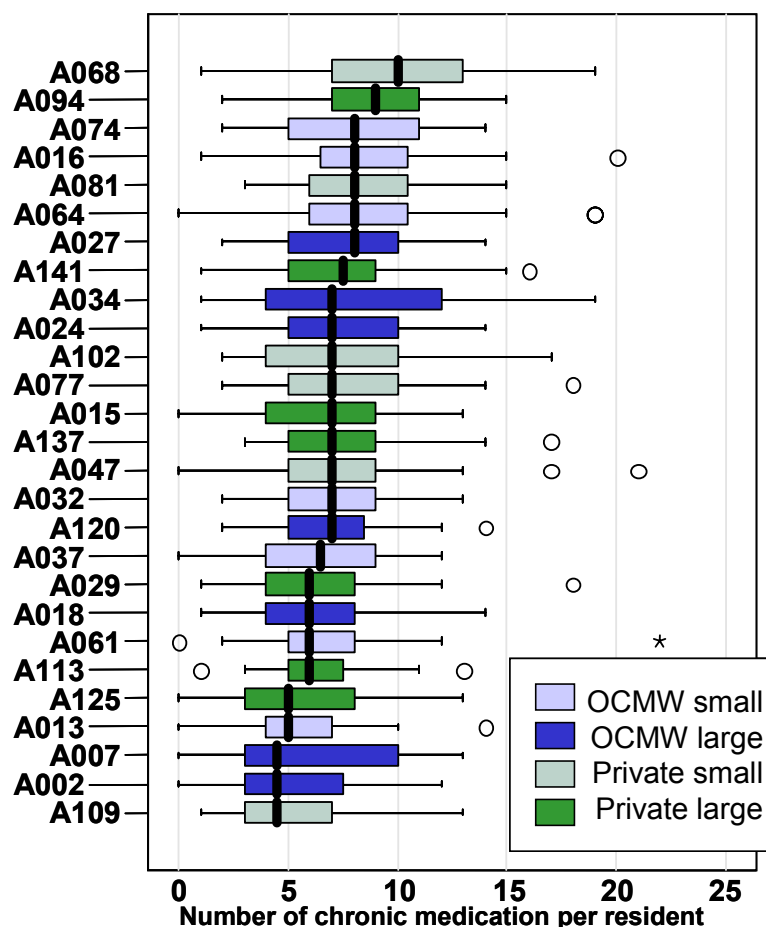
The median (P25-P75) number of entry lines on the medication chart was 8(5-10), of chronic medications 7(5-10), of oral and systemic medications (e.g. parenteral or transdermal) 7(5-9), of only oral medications 7(4-9), of only medications which need a prescription 6(4-8), of reimbursed medication 4(3-6). We calculated the prevalence of the usage of major therapeutic groups among residents of nursing homes in Belgium in figure 3.22.

Figure 3.22: Prevalence of medication usage per therapeutic group in Belgian nursing homes (N=2,510)



The variation in the consumption of chronic medicines among institutions was considerable. In figure 3.23, we present the results from one province (Antwerpen) to illustrate this wide variation with the median of the number of drugs per resident within each institution ranging from 5 to 13. The range of the percentages of residents treated with a specific therapeutic class was substantial for a number of classes, such as antidepressants (19% to 48%), NSAIDs (0% to 26%), Vasodilators (0% to 40%).

Figure 3.23: Consumption of chronic medicines per nursing home – Antwerpen



The number of chronic medication per resident was of course strongly correlated with the number of diseases listed for each resident, as there were more medications with increasing polypathology (Pearson Correlation Coefficient .534, $p = .001$).

Expenditures

The total mean expenditure per month and per resident for chronic medication was estimated at 140 (SD 125) € (see figure 3.24). Of this total, mean public expenditure for chronic reimbursed medication was 90 (SD 115) €, mean co-payment for chronic reimbursed medication was 23 (SD 17) € and mean out-of-pocket payment for non-reimbursed chronic medication was 27 (SD 30) € (see figure 3.25). In figure 3.26, an overview is given of the variation and extent of the 3 types of expenditures for chronic medication: public expenditures by the health insurer, co-payment for reimbursed medication by the patient, and out-of-pocket expenditures for non-reimbursed medication. 29% was cheap medication. Additionally, total mean expenditure for acute medication was 17 (SD 24) €.

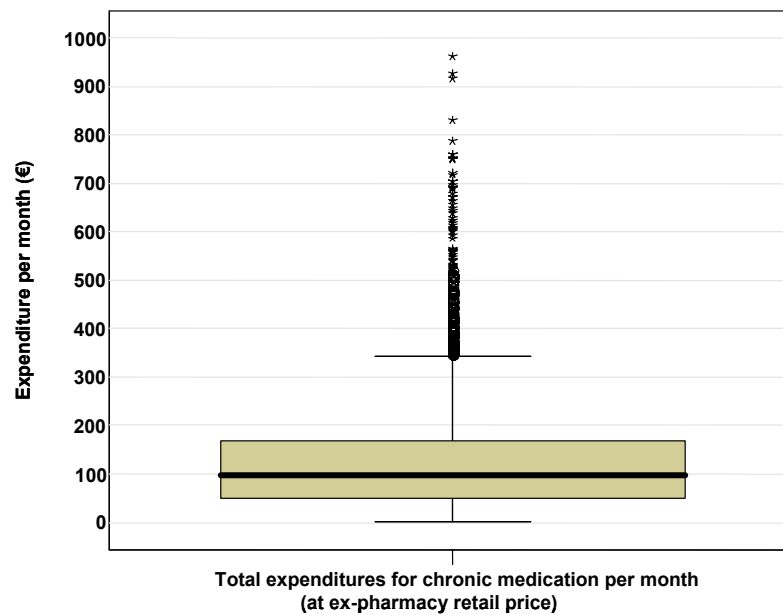
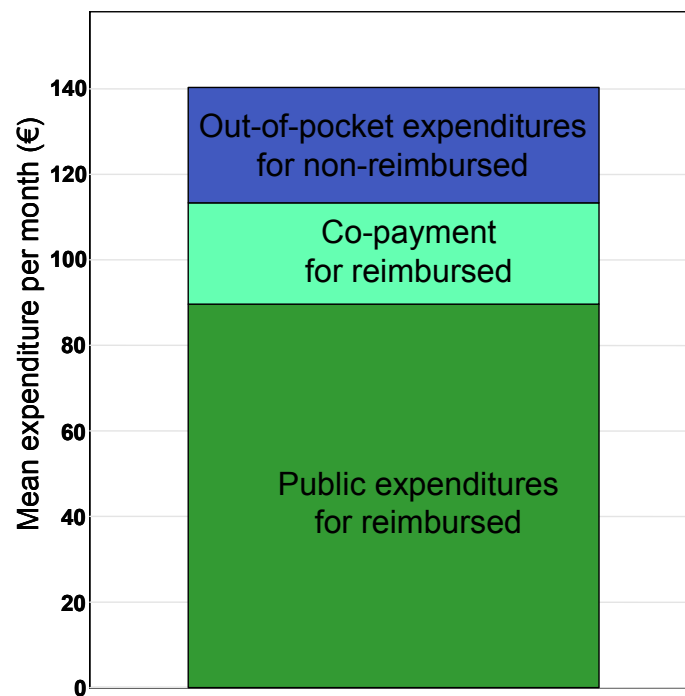
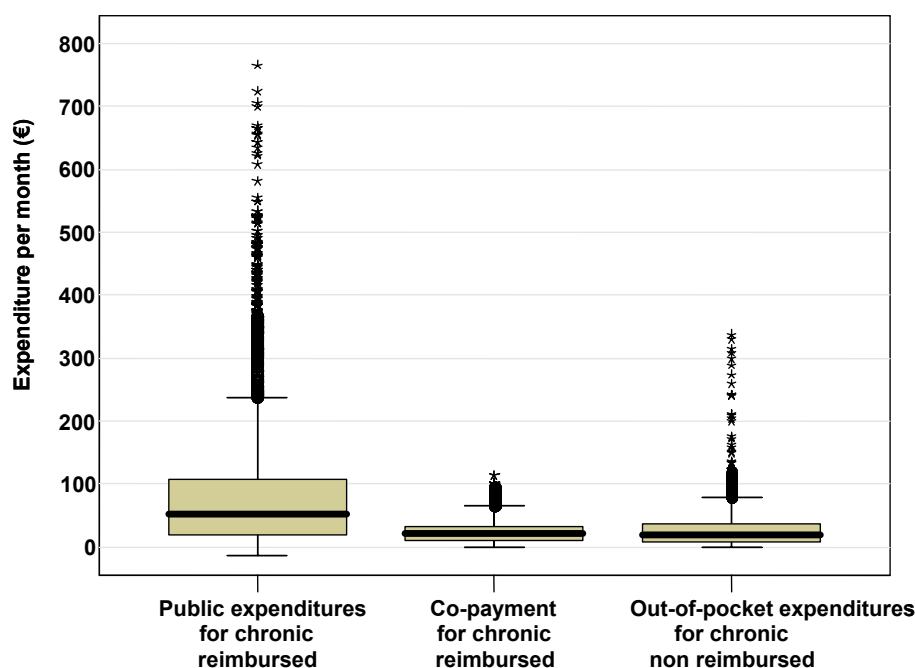
Figure 3.24: Total expenditure for chronic medication per resident**Figure 3.25 : Mean expenditures for chronic medication**

Figure 3.26: Expenditures for chronic medication per resident



Keypoints

- On average, a resident used 8 medications, ranging from no medication (less than 1% of residents) to 22 medications. Most medication (88%) was for chronic use. Most frequently used were psycholeptic and/or antidepressant agents (in 68% of residents), laxatives (50%) and cardiovascular drugs (47%).
- Expenditures per resident for chronic medication amounted to a mean public expenditure of 90 €, co-payment of 23 € and out-of-pocket payment for chronic non-reimbursed medication of 27 €.

3.4.8 Assessment of quality of medication prescribing

Our aim was to assess several elements of prescribing quality (underprescribing, misprescribing, overprescribing) with published sets of prescribing quality indicators, using a pragmatic approach. We limited ourselves to items which could be programmed on the basis of our clinical questionnaire and on the basis of the description of the medication on the medication chart.

We focused on three published sets (see Appendix 10):

- ACOVE Criteria of underprescribing
- BEERS Criteria of inappropriate drugs
- BEDNURS Criteria for nursing home residents

In addition, we programmed

- a list of relevant and prevalent drug-drug interactions, based on recent observational study
- a list of inappropriate medicines as indicated by the Belgian Drug Information Center
- identification of any chronic use of benzodiazepines and analogues

3.4.8.1 ACOVE criteria

A pragmatic selection of 7 criteria of underutilization was made. Identification of the disease (the IF statement) was based on the appreciation of the physician ticking a limited list of diseases on the questionnaire. With the diagnosis of heart failure, no information on the ventricular ejection fraction (indicating the pumping capacity of the heart) was available.

Identification of the medicine (the THEN statement) was based on the international ATC-classification. No distinction was made between selective and non-selective beta-blockers. Possible contra-indications for the medicines (the UNLESS statement) were disregarded, as the information was not available or too complicated to program. With a computer program, all residents were screened for potential cases of underutilization. The prevalence of potential problems is given in table 3.10, together with the prevalence of the condition in the population.

Table 3.10 : Most prevalent prescribing problems according to 7 ACOVE Criteria of underprescribing in Belgian nursing homes (N=1,730).

ACOVE Criteria	% of patients with the disease (N=1,730)	% of patients with underuse (N=1,730)
Heart Failure and no beta-blocker	32	23
Heart Failure and no ACE-Inhibitor	32	20
Myocardial infarction and no betablocker	27	18
Osteoporosis and no bisfosfanates/VitD/Calcium	26	15
Myocardial infarction and no aspirine	27	11
Diabetes and no aspirine	17	9
Osteoporosis with bifosphanates or VitD but no calcium	26	8

Substantial underutilization was observed with regard to cardiovascular risk in heart failure, myocardial infarction and diabetes. In a substantial number of residents with osteoporosis a potential for more aggressive treatment might be present.

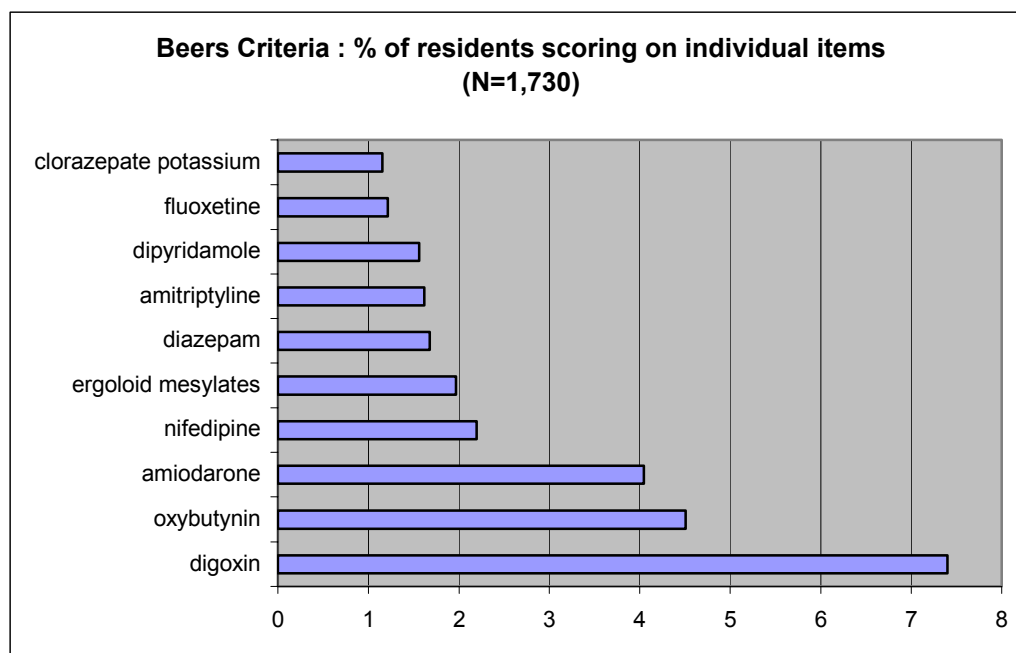
3.4.8.2 Beers criteria

The BEERS List consists in fact of a list of inappropriate drugs for the elderly, a list of inappropriate drugs when dosed too high, and a list of disease-drug interactions (or drugs used in contra-indicated conditions). For this project, only the inappropriate drugs were identified (regardless of their doses).

The programming of the disease-drug interactions was attempted but proved to be cumbersome, because the delineation of some classes (e.g. anticholinergic antihistaminics) was unclear, because information was lacking on details of Belgian products (e.g. medicines with high salt content), or because our questionnaire provided not enough detail (e.g. incontinence instead of a split in bladder output dysfunction and stress incontinence).

In figure 3.27, the prevalence of the use of potentially inappropriate drugs among nursing home residents is given. During the interpretation of this list, limitations should be considered.

Figure 3.27: Prevalence among Belgian nursing home residents of the use of potentially inappropriate drugs in 2005



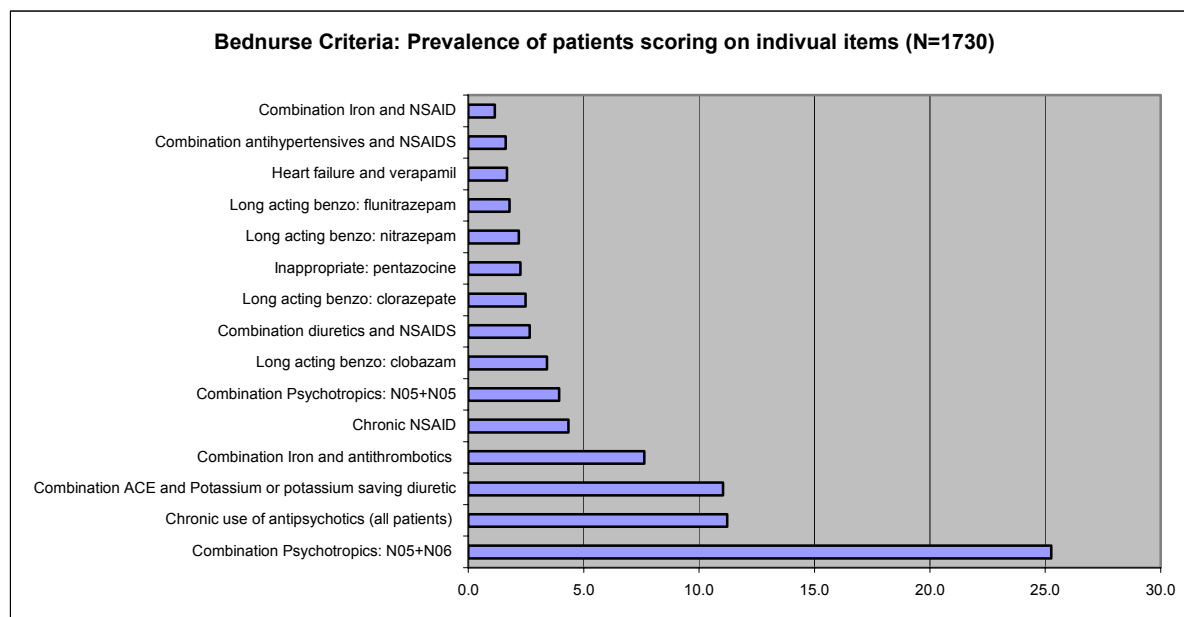
Limitations: Digoxin was scored even when the dose was reduced to .125 mg and when there was atrial arrhythmia / Oxibutyn and nifedipine were not restricted to short acting formulations. Short acting dipiridamole was removed from the 2002 criteria.

In Belgian nursing homes the prevalence of the use of potentially inappropriate drugs on the Beers list is rather low. Respecting the nuances in the Beers Criteria for potentially inappropriate drugs would further reduce these low prevalences.

3.4.8.3 BEDNURS criteria

Although intended for clinical review of individual residents by clinical pharmacists with full access to the medical record, these criteria proved to be relatively straightforward and simple to program. In this set of criteria, attention is given to the use of psychotropic medication, to NSAIDs, to drug-drug interactions, and to disease-drug interactions. Combinations of antidepressants with antipsychotics or benzodiazepines were observed in 25% of the residents, and the use of multiple antidepressants in 4%. 12% of the residents used antipsychotics. Combinations of medicines with a risk of hyperkalemia were the third most prevalent problem. Inappropriate combinations of NSAIDs with a number of other medicines were observed, as well as a high overall use of chronic NSAID. Five different long-acting benzodiazepines with a prevalence of more than 2% were detected (see figure 3.28).

Figure 3.28: Most prevalent prescribing problems according to the BEDNURS criteria in Belgian nursing homes in 2005



Limitations: Antipsychotic use was scored without excluding chronically psychotic patients / monotherapy of heart failure with diuretics was disregarded because of programming error.

3.4.8.4 Other criteria to assess prescribing quality

Our attempt to address problems of drug-drug interactions by programming a list of relevant and prevalent interactions based on a European observational study yielded little additional information for the detection of potential problems. The same held true for the programming of a Belgian list of non-recommended medicines. Finally, we flagged the chronic use of any benzodiazepine or analogue, whether it was used as a hypnotic or an anxiolytic, or as an antiepileptic.

3.4.8.5 The prescribing quality problem score used in this study

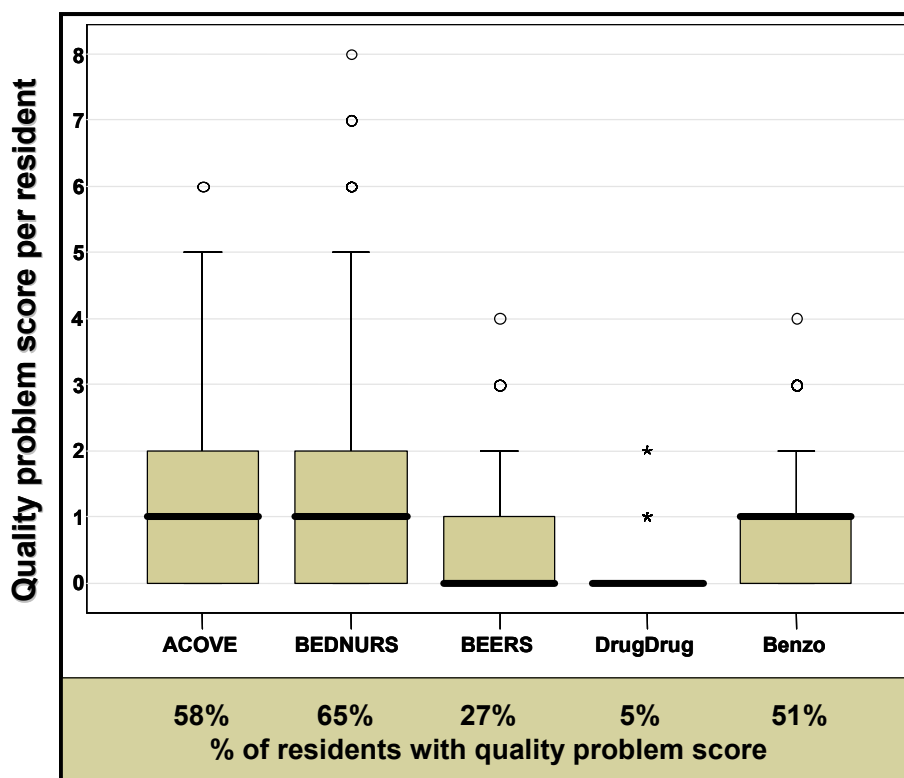
For each resident, we run computer programs to flag potential problems according to the three published sets of quality indicators and the three other approaches described above. All flags for one resident were added to a sum-score. The purpose of this sum-score was its use in an explorative analysis of the explanatory power of institutional characteristics with regard to the variability in the quality of prescribing within institutions. The purpose of this sum-score is not to make a reliable estimation of the individual level of quality of prescribing in the different institutions.

We made this sum-score because each set of quality criteria measured different aspects of prescribing quality ranging from under- and overprescribing to misprescribing. There was however some degree of overlap in the items of the different sets of prescribing quality indicators with regard to psychotropic drug use, some drug-drug interactions and some disease-drug interactions. The overall relationship between each set of quality criteria was limited and showed the highest correlation between the score for drug-drug interactions and BEERS criteria ($r_s=.334$) and between the chronic use of benzodiazepine and BEDNURS ($r_s=.304$). All other correlation coefficients were low ($r_s<.200$). No attempt was made to correct for this overlap.

In figure 3.29 the contribution of the different sets to the overall sum-score is described. Few residents scored on the drug-drug interaction set (5%) and on the set

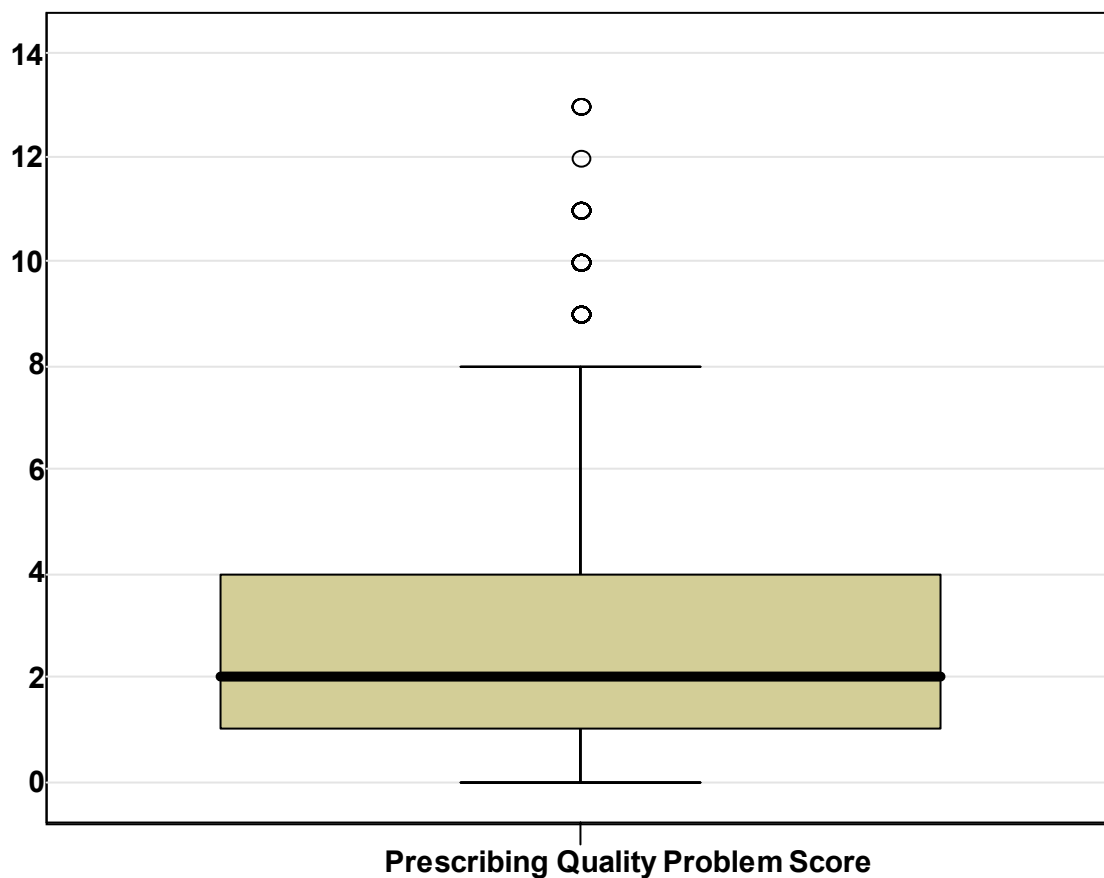
for obsolete drugs (8%). 27% of the residents had a flag on the set of BEERS criteria; 65% on the BEDNURS criteria and 58% on the ACOVE criteria.

Figure 3.29 Number of flags per resident on the different sets of prescribing quality indicators



In figure 3.30 the result of summing up all flags per resident is shown. The median (P25-P75) is 2 (1-4) with a range from 0 to 13.

Fig 3.30: Number of flags per resident on the overall Prescribing Quality Problem Score



There was considerable variation within institutions of this sum-score where the median number of flags per resident per institution ranged from a median of 1 to a median of 5 flags per resident between institutions. The Spearman rank correlation between this prescribing quality problem score and the number of diseases per resident ticked by the physician on the clinical questionnaire was .429 ($p < .01$).

Finally, we examined the prevalence of use of a number of active substances which were discussed in the study of the national aggregated data. The prevalence of usage of molsidomine was 10%, acetylcysteine 8%, anti-cholinergic anti-Alzheimer medications 5%, clopidogrel 5%, cetirizine 4%, anticholinergic spasmolytica 4%, betahistine (a medication marketed for vertigo) 3%, other anti-Alzheimer medications 0.2%, and piroxicam (a long-acting NSAID) 0.1%.

Keypoints

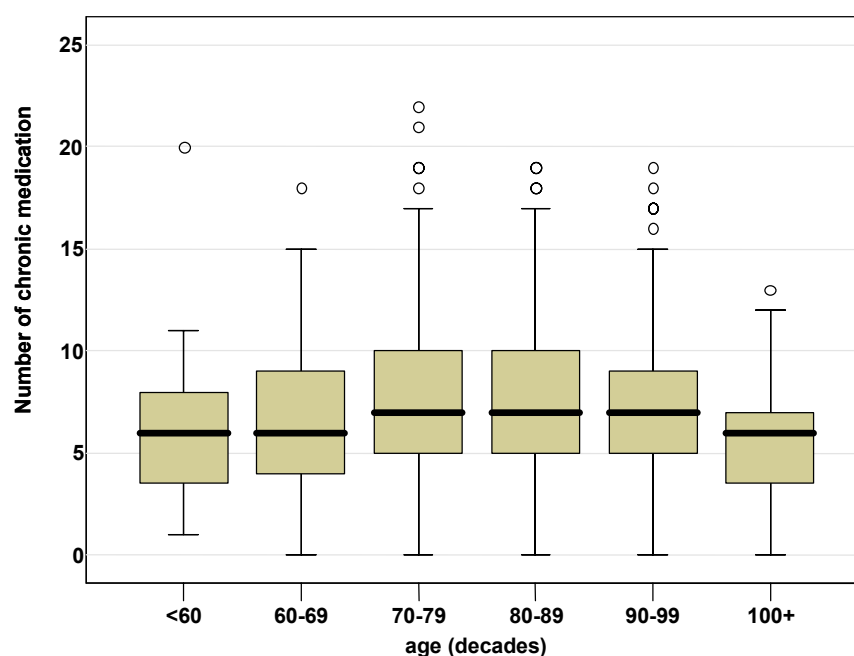
- Under-utilization was mainly observed for medication that reduces cardiovascular risk.
- Antidepressants were combined with benzodiazepines or antipsychotics in 1/4 of cases. Some combinations with a high risk for hyperkalemia and several inappropriate combinations with NSAIDs were prescribed.
- Only few residents received a combination that could lead to dangerous drug-drug interactions.
- The median number of quality problems was 2 per resident, ranging from 0 to 13. There was a considerable variation between institutions with a median ranging from 1 to 5.

3.4.9 Relationship between residents' characteristics and parameters of prescribing quality

3.4.9.1 Age and gender

There was no linear relation between age and medication use ($r=-.037$, $p=.062$). As shown in figure 3.31, the number of chronic medication increased to a mean of 8.4 in the age category 70-79 and decreased to a mean of 6.6 in the age category of 100 plus. No difference could be observed in the number of chronic medication and the total expenditure for chronic medication between males and females. However, the total quality problem score differed according to gender with a higher mean score for females compared to males of 3.1 (SD 3.3) and 2.7 (SD 3.0), respectively ($p<.001$).

Figure 3.31: Consumption of chronic medication according to age



3.4.9.2 Katz Scale

The number of medications used varied considerably according to the Katz score ($p<.001$) with the highest consumption observed in the Katz C group with a mean of 8.6 (SD 3.5) (figure 3.32). Total expenditures for chronic medication and the total quality

problem score followed the same trend. A linear decrease in chronic medication use was observed with increasing degree of dementia ($p < .001$) (see figure 3.33).

Figure 3.32: Consumption of chronic medication according to Katz scale

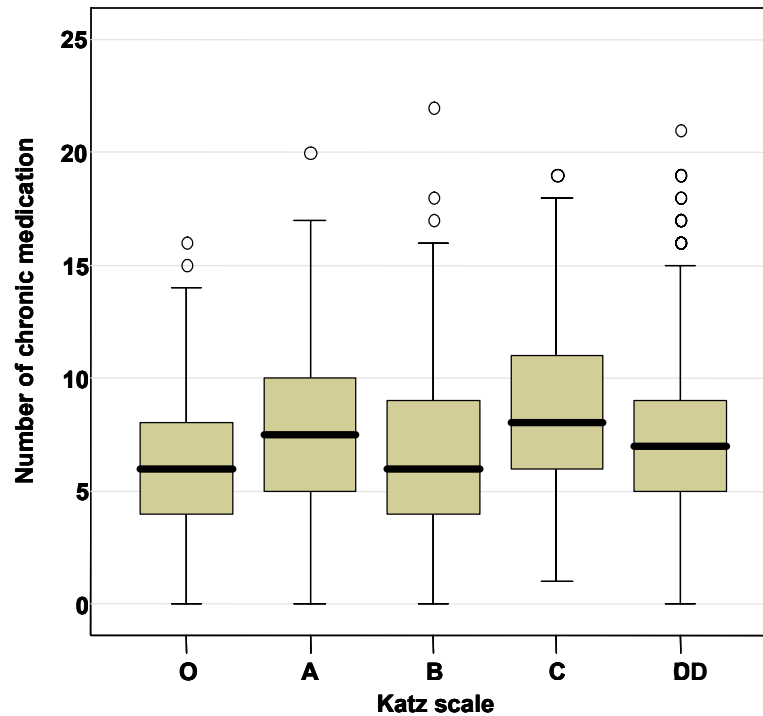
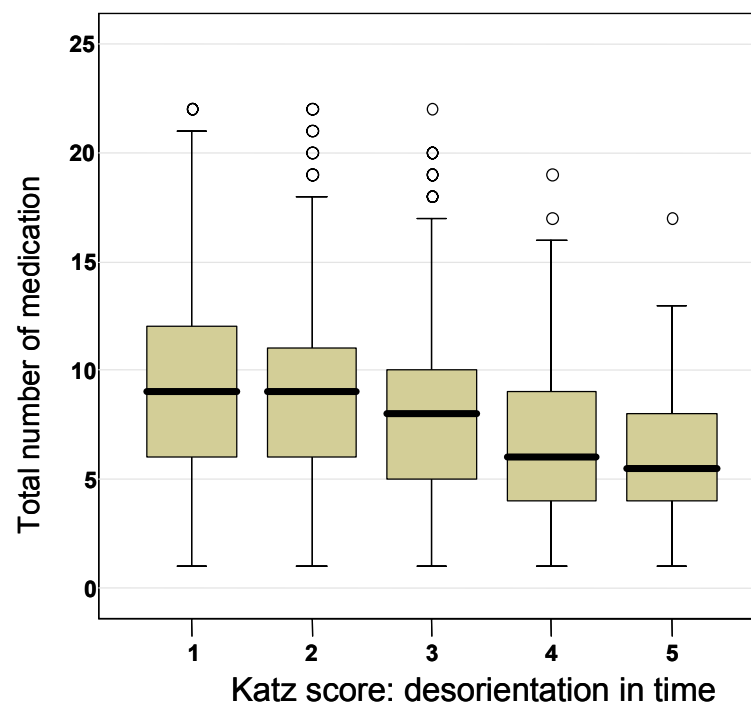


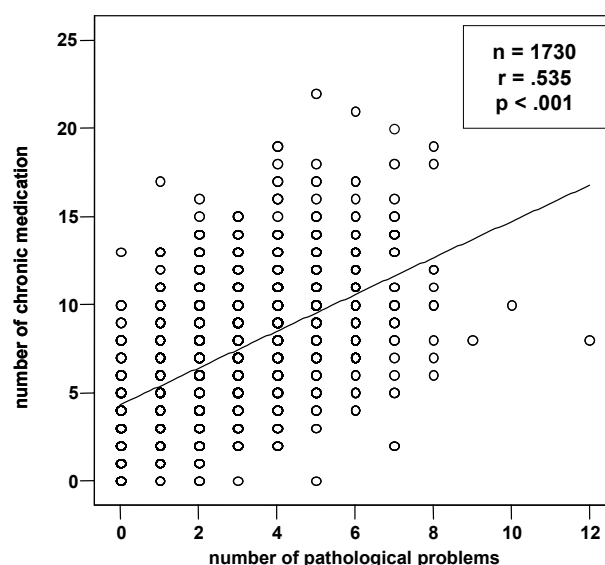
Figure 3.33: Consumption of chronic medication according to mental disorientation



3.4.9.3 Clinical problems

A high positive linear correlation could be observed between the number of pathological problems and the number of chronic medications used ($r=.535$, $p < .001$) (figure 3.34), total expenditures ($r=.313$) and the total quality problem score ($r=.409$). Albeit less pronounced, the same significant positive correlations could be observed between on the one hand the number of care problems and on the other hand chronic medication ($r=.326$), total expenditures for chronic medication ($r=.176$) and the total quality problem score ($r=.331$) (all $p < .001$).

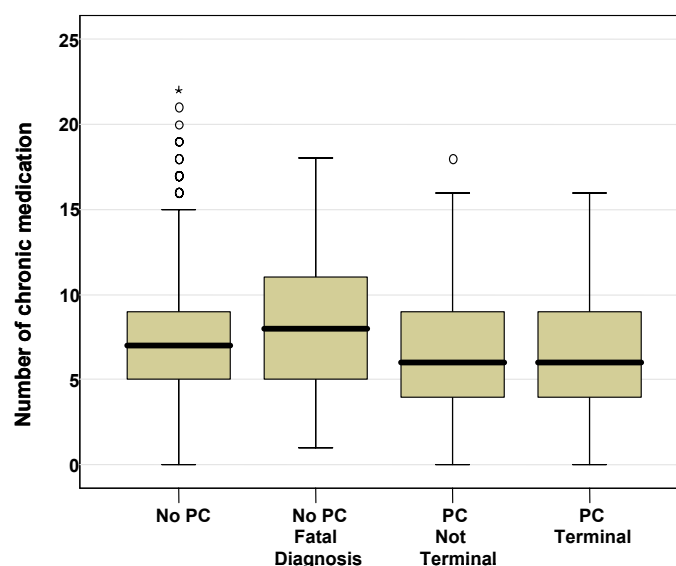
Figure 3.34: Relationship between polypathology and chronic medication



The clinical diagnosis of depression resulted in an increase in the consumption of chronic medication from a mean of 6.3 (SD 3.2) to a mean of 8.6 (SD 3.3) ($p < .001$) and an associated increase in total expenditures and total quality problem score (all $p < .001$). In contrast, the clinical diagnosis of dementia lowered the medication use, total expenditures and total quality problem score ($p < .001$, $p = .028$ and $p < .001$ respectively).

The evolution in the amount of chronic medication used in different stages of palliative care is shown in figure 3.35 with highest consumption in residents with a fatal diagnosis but not in palliative care as yet. Although medication use decreased in the palliative care phase, total expenditures for chronic medication did not.

Figure 3.35: Consumption of chronic medication according to degree of palliative care



3.4.9.4 Administrative characteristics of residents

The WIGW/VIPO statute of a resident did not influence the amount of chronic medication used, the total expenditure or the total quality problem score. Only the co-payment for chronic medication decreased with one third in residents with a WIGW/VIPO statute. At residents' level, also OCMW/CPAS dependency had no influence on consumption, expenditure or quality.

3.4.10 Univariate relationship between institutional characteristics and parameters of prescribing quality at resident level

3.4.10.1 Type of nursing home

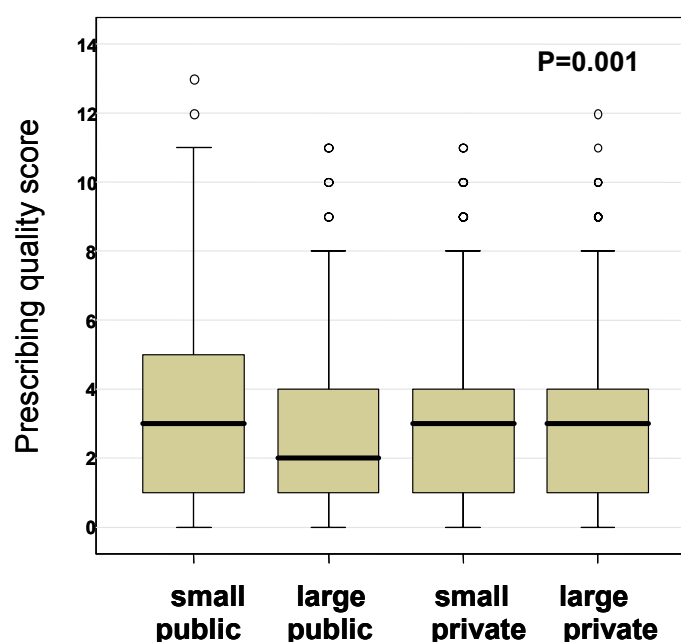
Large OCMW/CPAS nursing homes showed a significant lower consumption of chronic medication with a lower co-payment for this medication and a higher amount of cheap drugs (table 3.11 and figure 3.36).

Table 3.11: Parameters of prescribing quality according to type of nursing home

	OCMW small n = 548	OCMW large n = 562	Private small n = 638	Private large n = 762	p-value of difference
	mean (SD)	mean (SD)	mean (SD)	mean (SD)	
number of drugs	8,6 (3,9)	7,8 (3,9)	7,9 (3,7)	8,1 (3,7)	0,002
number of chronic systemic drugs	7,4 (3,5)	6,8 (3,4)	7,1 (3,5)	7,2 (3,3)	0,059
public expenditure for chronic reimbursed drugs	97 (128)	86 (102)	90 (114)	93 (121)	0,0780
co-payment for chronic reimbursed drugs	24 (17)	21 (16)	24 (17)	24 (17)	0,004
out of pocket exp. chronic non-reimbursed drugs	26 (25)	30 (41)	26 (27)	28 (29)	0,172
percentage of cheap drugs	28%	32%	30%	26%	0,036
	n = 401	n = 379	n = 463	n = 487	
quality problem score	3,6 (2,4)	3,3 (2,3)	3,3 (2,3)	3,4 (2,3)	0,354

In large public nursing homes less prescribing quality problems were noted (ANOVA $p=0.001$).

Figure 3.36 : Quality problem score according to type of nursing home



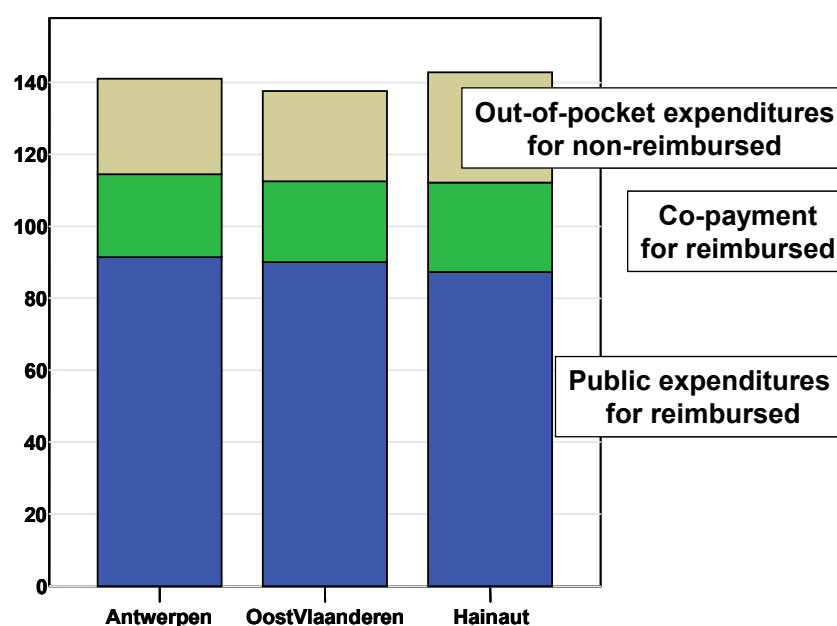
3.4.10.2 Province

A comparison of the parameters of prescribing quality between the 3 provinces included in the PHEBE project, revealed a significantly higher co-payment and a higher out-of-pocket expenditure in the province of Hainaut while the percentage of cheap medication was lower (table 3.12 and figure 3.37).

Table 3.12: Parameters of prescribing quality according to province

	Total n = 2510 mean (SD)	Antwerpen n = 946 mean (SD)	Oost-Vlaanderen n = 841 mean (SD)	Hainaut n = 723 mean (SD)	p-value of difference
number of drugs	8.1 (3.8)	8.1 (3.9)	8.1 (3.7)	8.1 (3.8)	0,804
number of chronic systemic drugs	7.1 (3.4)	7.2 (3.6)	7,0 (3.2)	7.1 (3.3)	0,760
public expenditure for chronic reimbursed drugs	90 (115)	91 (119)	90 (117)	87 (107)	0,777
co-payment for chronic reimbursed drugs	23 (17)	23 (17)	22 (16)	25 (17)	0,005
out of pocket exp. chronic non-reimbursed drugs	27 (30)	27 (29)	25 (32)	31 (31)	<0,001
percentage of cheap drugs	29%	31%	28%	27%	0,001
	n = 1730	n = 654	n = 572	n = 504	
quality problem score	3.4 (2.3)	3,2 (2.3)	3,6 (2.4)	3,4 (2.3)	0,001

Figure 3.37: Expenditures for chronic medication per province



3.4.11 Univariate analysis at institutional level

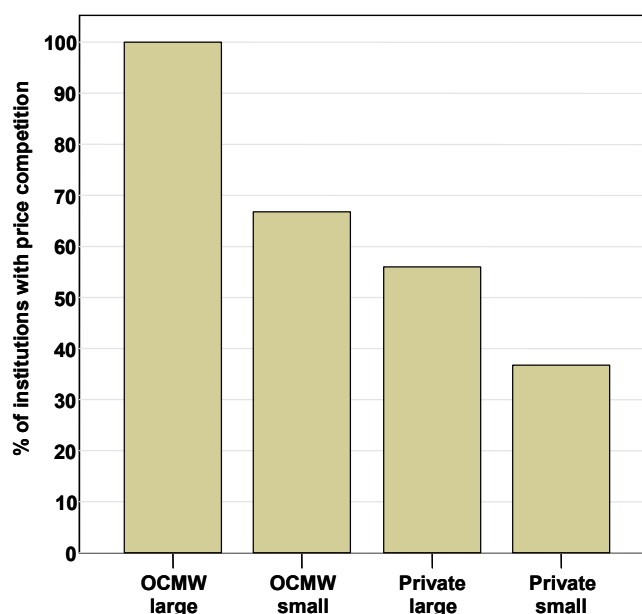
3.4.11.1 Institutional characteristics

Large differences in institutional characteristics could be observed between different types of nursing homes. Mainly large OCMW/CPAS nursing homes had an important percentage of their patients treated by the CRA (mean 36% versus about 20% for the other types). In contrast, particularly the large private homes had to work with a large number of family doctors (mean 44). Nursing staff ratios varied considerably between a mean of one nursing staff member (including bachelors + graduates) per 7.7 residents in small OCMW/CPAS homes to one per 10.2 residents in large private homes ($p < .018$). Differences in staff ratios disappeared if also nurse assistants were taken into account.

The percentage of nurses with a bachelor degree (in FTE) did not differ significantly between strata. The delivery of medication by a hospital pharmacist could only be observed in OCMW/CPAS nursing homes.

Price competition for medication delivery differed considerably between different types of nursing homes ranging from 100% of large OCMW/CPAS homes to only 37% of small private homes having competition (figure 3.38). In all private homes, residents received a separate bill for their medication. In OCMW/CPAS homes, this was the practice in 65% in the large and 80% of the small homes.

Figure 3.38: Price competition for the delivery of medication



The practice of having a large amount of patients treated by the CRA differed between provinces with a mean of 40% of patients treated by the CRA in Antwerpen, 18% in Hainaut and 11% in Oost-Vlaanderen. Nursing staff ratios were comparable in both Flemish provinces with on the average one staff member per 8.1 residents. In Hainaut, one staff member had to take care about a mean of 10.9 residents.

Hospital pharmacists were only active in the nursing homes of Antwerpen. Price competition was used in 85% of the homes in Antwerpen compared to half of the homes in Oost-Vlaanderen and Hainaut.

3.4.11.2 Case mix as part of the institutional characteristics

To determine the case-mix of the residents, residents' characteristics (age, gender, OCMW/CPAS dependency) as well as clinical parameters (pathology problems, care problems and dementia) were taken into account.

Case-mix of residents did not significantly differ between the different types of nursing homes. According to province of localization, significant differences in case-mix could be observed for mean age of residents (older in Hainaut), mean percentage of OCMW/CPAS dependency (higher in Antwerpen), mean percentage dementia (highest in Antwerpen) and mean number of care problems (highest in Hainaut).

3.4.11.3 Relationship between institutional characteristics and the quality of the medication management system

Some of the structural aspects of the nursing homes had a substantial influence on the quality of the medication management system. A positive relationship could be observed

with the presence of a hospital pharmacist and a better nursing staffing (less residents per staff member, more bachelors). A negative relationship was observed with the location in the province of Hainaut and with the practice of offering a separate bill for medication. Only the quality score for self medication forms an exception to these general trends. Here we noticed a positive relationship with location in Hainaut, a high number of residents and a high number of residents treated by one nursing staff member.

Clinical aspects of the case-mix did not show any significant relationship with the quality of the medication management system in the nursing homes. In contrast, higher percentage of females, older mean age and higher percentage of OCMW/CPAS dependent residents had a positive influence on the total quality score as well as some of the partial scores (table 3.13)

Table 3.13: Relationship between institutional characteristics and the quality of the medication management system

Institutional characteristics	Total quality score	Partial scores			
	rs	Procedures rs	Formulary rs	Preparation rs	Self medication rs
Structural					
OCMW nursing home					
Location in Hainaut	-0,243	-0,393	-0,195	-0,198	0,284
Total number of beds				-0,236	
Number of residents at the ward					0,313
Percentage treated by CRA					
Hospital pharmacist		0,291	0,366		-0,192
Price concurrence					
Separate bill for medication		-0,241	-0,319		
Ratio residents per nurse	-0,262	-0,229		-0,323	0,205
Percentage Bachelors				0,242	-0,230
Case Mix					
Mean birth year			-0,251		
Percentage female	0,299	0,255	0,190		
Percentage OCMW dependent	0,237		0,223	0,251	
Mean number of pathological problems					
Mean number of care problems					
Percentage dementia					

3.4.11.4 Relationship between institutional characteristics and the parameters of prescribing quality

As shown in table 3.14 structural parameters as well as case-mix were clearly related to the different aspects of prescribing quality. The presence of a hospital pharmacist and price competition had a positive influence on expenditure for medication. Quality problems decreased with high activity of the CRA and the presence of a hospital pharmacist, with higher percentage of OCMW/CPAS dependent residents and dementia. Quality problems increased with higher percentage of females and higher mean number of pathological and care problems.

Type and size of nursing home and ward, staff ratio and mean age of residents did not show any relationship with the parameters of prescribing quality.

Table 3.14: Relationship between institutional characteristics and the parameters of prescribing quality

	n of chronic medication	public exp reimbursed	co-payment reimbursed	percentage cheap	quality problems
Institutional characteristics	rs	rs	rs	rs	rs
Structural					
OCMW nursing home					
Location in Antwerpen				0,317	-0,384
Location in Hainaut			0,267	-0,299	
Total number of beds					
Number of residents at the ward					
Percentage treated by CRA				0,211	-0,265
Hospital pharmacist			-0,244	0,372	-0,213
Price concurrence		-0,218	-0,290	0,267	
Separate bill for medication				-0,410	-0,288
Ratio residents per nurse					
Percentage Bachelors					
Case Mix					
Mean birth year					
Percentage female					0,195
Percentage OCMW dependent			-0,197	0,285	-0,239
Mean number of pathological problems	0,509	0,356	0,428	-0,192	0,560
Mean number of care problems		0,250	0,210	-0,355	0,416
Percentage dementia					-0,385

3.4.11.5 Relationship between the quality scores of the medication management system and the parameters of prescribing quality

Univariate analysis of the relationship between the quality of medication management systems in the nursing homes and prescribing quality only delivered a limited number of significant results. A better score on the use of a formulary resulted in an increase in the percentage of cheap medication (table 3.15).

Table 3.15: Relationship between the quality of the medication management system and parameters of prescribing quality

	n of chronic medication	public exp reimbursed	co-payment reimbursed	percentage cheap	quality problems
Quality scores of medication management system	rs	rs	rs	rs	rs
Level of the ward					
Work procedures					
Formulary				0,392	
Communication					
Medication record					-0,207
Storage of medication					
Self medication					
Preparation					
Administration					
Information					
Total score at ward level				0,225	
Level of the institution					
Medication management					
Formulary				0,358	
Activities of pharmacist	-0,309				
Total score at institutional level	-0,217				

3.4.12 Multivariate analysis

This analysis was performed at the level of the institution and compared institutional characteristics (see method for the full list of the variables) and the exogenous variables of appropriateness of prescribing (see methods for operationalization).

The iterative omission of insignificant variables procedure (cfr. supra for a description) resulted in a “Final model”. Detailed regression results of the final models included estimated coefficients, their standard errors, t-statistics and p-values. Highly significant variables (p-values < 0.05) are printed in bold (see Appendix 11 and 12). All models explain between 53% and 78% of the variation of the outcome variables.

The average number of medication was mainly influenced by the degree of poly-pathology and the number of care problems of the residents. The average number of medication decreased with a more favorable resident/nursing staff ratio. Focusing on the average number of chronic systemic medication per resident, the same problem scores and staffing variables showed to have a significant effect. For chronic systemic medication, also the percentage of RVT beds in the nursing home was positively related to the number of chronic systemic medication.

The variation in public expenditures for chronic medication was mainly influenced by the number of care problems, the percentage of residents with OCMW/CPAS dependency, the resident/nursing staff ratio, the size of the institution and the number of residents treated by the CRA. The average amount of co-payment was mainly influenced by the percentage of women, the percentage of OCMW/CPAS dependency, the poly-pathology of the residents and the size of the nursing home. The percentage of cheap medication prescribed was negatively influenced by the monopoly position of the pharmacist. In contrast, price competition had a positive influence on the amount of inexpensive medication used.

The total score of prescribing quality problems increased with higher poly-pathology and in larger institutions. The problem score decreased with a higher number of residents treated by the CRA, a larger number of activities performed by the pharmacist, a higher mean age of the residents and a higher percentage of dementia.

Additional multivariate analysis with various aspects of the quality of the medication management system as dependent variables revealed that particularly the extent and the qualification of the staff played a role in explaining the variation among nursing homes (see Appendix 12).

In summary, focusing on institutional characteristics (and after correcting for case-mix) it is clear that resident/nursing staff ratios contribute substantially in explaining differences in outcome variables.

Other institutional characteristics (size, supply of drugs, medication management scores) seem to be of relative minor importance in explaining differences in the outcome variables: these characteristics were estimated significantly in maximum 2 of the 7 models.

Keypoints for 3.4.9 to 3.4.12

- Poly-pathology and a high number of care problems increased the number of prescribed medications as well as the number of prescribing quality problems.
- Large OCMW/CPAS nursing homes showed a significant lower consumption of chronic medication with a lower co-payment for this medication and a higher amount of cheap drugs.
- A significantly higher co-payment and a higher out-of-pocket expenditure in the province of Hainaut were observed while the percentage of cheap medication was lower.
- The presence of a hospital pharmacist and price competition showed a positive relation with expenditure for medication.
- Quality problems decreased with high activity of the CRA and the presence of a hospital pharmacist, with higher percentage of OCMW/CPAS dependent residents and dementia. Quality problems increased with higher percentage of females and higher mean number of pathological and care problems. Staffing played a role in the variation among nursing homes.

4 DISCUSSION AND GENERAL CONCLUSIONS

Authors: Robert Vander Stichele, Dirk Ramaekers, Carine Van de Voorde,
Monique Elseviers, Mirko Petrovic

4.1 STRENGTHS OF THE STUDY

In this report, for the first time, national aggregated data on medication use and expenditures of reimbursed medicines in rest- and nursing homes in Belgium are described, making it possible to assess the impact of this segment on the total health care budget. In the field study, a large representative sample of Belgian residents, stemming from a considerable number of institutions of 3 of the 10 provinces of the country, is investigated. Detailed information on the clinical and functional status of the residents was collected and a thorough analysis of prescribing quality was performed, using a range of internationally accepted sets of prescribing quality indicators, suitable for electronic evaluation. The close collaboration with the management of the nursing homes and with the coordinating physicians guaranteed the high response rate of the treating physicians, resulting in high quality and high clinical content of the data.

In the collaborating institutions the medication management system was evaluated in detail with an extensive questionnaire and a newly developed scoring system. Because we combined an extensive data collection of institutional characteristics with a thorough assessment of prescribing quality, we were able to study the relationship between both in univariate and multivariate analysis, at the level of the residents and at the level of the institutions.

4.2 LIMITATIONS OF THE STUDY

Drug utilization data based on aggregated national data are only crude consumption measures, sometimes difficult to interpret without clinical information. There is some imprecision in the consumption data from the nursing homes served by hospital pharmacists, because of practical problems with invoice data. Prudent interpretation of geographical variation of these aggregated data is warranted, because of the problem of ecological fallacy.

Data collection of medication usage in the field study was based on the medication charts as recorded in the nursing record. Detection bias is possible and more likely for “if needed” or acute medication. We did not attempt to collect expenditure data on the “if needed” medication because it was not possible to record their actual consumption in a cross-sectional study. The calculations of expenditures for acute medications were based on a crude estimation of duration of therapy. Volume was calculated with the Defined Daily Dose, which is based on the standard dose for the main indication of the drug in adults. Recommendations for dose reductions in frail elderly were not taken into account in these calculations and must be considered in the evaluation of the consumption of individual drugs.

For the construction of disease-oriented quality indicators, data were collected on the clinical diagnoses and care problems of the residents, based on the assessment of the treating physician, responding to a non-validated questionnaire. This is but an approximation of the full risk profile and co-morbidity of the residents.

We applied automated scoring algorithms for flagging potential prescribing quality problems, based on sets of prescribing quality indicators, originally designed for labour-intensive, individual assessment of residents by clinical pharmacists, having access to the full medical record. Individual chart review by clinical pharmacists allows for more accurate establishment of diagnoses, and specification of clinically acceptable exceptions to general rules of prescribing. These limitations may lead to a limited degree of false positive detections of quality problems. On the other hand, it was not possible to program all elements of the Beers Criteria, leading to underdetection of problems. This hampers the use of these data for international comparisons. We made a crude sum-

score of the flags detected by the different sets of quality indicators, because each set of quality criteria measures different aspects (misprescribing, underprescribing, overprescribing). However, there is a limited overlap between the different sets, and no attempt to correct for this overlap was made.

Our analysis of the complex relation of institutional characteristics with prescribing quality was hampered by the lack of information on an obvious determinant, namely the prescribing physician, and by the lack of information on true outcome variables such as mortality, hospitalization admission rates and quality of life. This was a cross-sectional study, with a single observation in time. Longitudinal research would give more insight in the dynamics of the functional status, medical condition and medication usage of nursing home residents.

We were able to conduct a multivariate analysis of the relationship between institutional characteristics and prescribing quality. However, studying multiple models for several dependent variables may increase the chance of erroneously finding significant results. In addition, considerable collinearity between the independent variables increases the difficulty of a correct interpretation of the results. The weight of dummy variables (e.g. private institution or not) may distort results, especially when the difference between for profit and non-for profit private institution is ignored or biased. Therefore, we performed a full and systematic univariate analysis first and made prudent conclusions on possible relationships, only based on correlations confirmed in both univariate and multivariate analysis. Because we were not able to aggregate the residents' data to the level of the ward, it was not possible to perform a multi-level, multivariate analysis.

4.3 MEDICAL DISCUSSION OF THE DETECTED PRESCRIBING QUALITY PROBLEMS

In both the study of the aggregated national drug utilization data and in the results of the field study a number of prevalent prescribing quality problems were identified. In the following sections we will discuss the clinical relevance of these problems, in the light of the available evidence in the medical literature.

4.3.1 Discussion on the national drug utilization data in rest and nursing homes

The scope of this research project did not permit us to perform a full systematic review or health technology assessment including a cost-effectiveness analysis for every single drug. However, a rapid literature search on several of the drugs frequently used in Belgian rest and nursing homes leads to numerous recent systematic reviews and some recent good quality clinical trials. The utility of certain frequently used drugs and the appropriateness of some prescription patterns can be questioned. Since we did not dispose of other variables like clinical patient characteristics per medication group it is in general not warranted to interpret the national data towards an under- or overuse and hence to appraise the drug utilization quality. However, certain prescription patterns can be discussed for those drugs that are linked to one or a limited number of indications and where the evidence clearly points towards possible quality problems related to effectiveness, appropriateness and safety.

Molsidomine, a so called nitric oxide donor and the number one in the group of cardiovascular drugs used in Belgian rest and nursing homes, is used for the treatment of patients with stable angina pectoris. It is commercialized in several European countries among which Belgium. Molsidomine features a similar pharmacological profile as the organic nitrates. With regard to pharmacokinetic effects, organic nitrates and molsidomine are similar.¹⁶¹ As the onset of action of molsidomine is comparatively slow, it is not used to treat acute cases of angina. Furthermore, due to its carcinogenic effect, molsidomine should only be considered when the treatment with organic nitrates is not sufficient, for example in the 'nitrate-free' interval. Pharmacokinetics and metabolism of molsidomine are impaired in elderly subjects. In patients with liver disease and congestive heart failure similar changes were observed. Clearance is also impaired in patients with liver disease, but the pharmacokinetics of molsidomine was not markedly altered by impaired renal function.¹⁶² The acute toxicity of molsidomine as well as the

organic nitrates are directly related to their therapeutic vasodilatation of orthostatic hypotension, tachycardia and throbbing headache.

The evidence concerning long-term effects of molsidomine is scarce.¹⁶³ There is no high quality evidence that molsidomine compared to placebo reduces the number of angina pectoris attacks, nor that it influences long term endpoints such as morbidity and mortality. Some studies showed a positive effect on a surrogate endpoint i.e. exercise tolerance. There is no evidence for the hypothesis that there is no tolerance development with the use of molsidomine.¹⁶⁴ In clinical practice guidelines, such as the recently updated guideline of the European Society of Cardiology, molsidomine is not mentioned in the algorithm for the medical management of stable angina.¹⁶⁵ There is only one reference to a study that studied the noninferiority of molsidomine 16 mg compared with 8 mg in institutions in Hongary, Poland and Belgium and that was written by employees of Therabel Pharma.¹⁶⁶

Since no detailed clinical data were available, it is impossible to appraise the antihypertensives prescription behavior. Geographical variations in antihypertensives show clear preferences towards either more diuretics (including thiazides) or towards more second line treatments such as amlodipine, ACE inhibitors and angiotensin II antagonists (sartans).¹⁶⁷ The recommendations of the NRKP/CNPQ favor diuretics over the other abovementioned classes as first line treatment. However, to interpret the differences in prescription behavior more epidemiological data and more longitudinal analyses of the sequence on prescribed antihypertensive agents based on e.g. the data of the sickness funds are needed.

In old age, depressive syndromes often affect people with chronic medical illnesses, cognitive impairment or disability. The number of prescriptions of antidepressants is huge in this elderly population in Belgium. Without detailed clinical data on the depressive disorders and the diagnostic process followed, it is impossible to suggest an underuse or overuse of antidepressants. The use of atypical antipsychotics is very popular in Belgian rest- and nursing homes. It is unlikely that they are often used for schizophrenia in this population, so that the most frequent indications are most likely behavioral and psychological symptoms of dementia (BPSD). The atypical antipsychotic drugs are being used with increasing frequency without clear evidence of the nature and extent of the clinical value of antipsychotic medications. Few high quality randomised trials have evaluated their use for BPSD and there have been concerns about adverse effects, significant risk for cerebrovascular events especially with risperidone, and increased mortality overall. Several of these newer atypical drugs are more expensive than the older 'typical' antipsychotics. Limited evidence supports the perception of improved efficacy and adverse event profiles compared with typical antipsychotic drugs.^{168, 169} Recently, in a government sponsored effectiveness trial¹⁷⁰, it was shown that atypical antipsychotic drugs were somewhat more effective but also more toxic than placebo in Alzheimer patients. There was no difference for the clinically highly relevant primary endpoint (drug discontinuation for any reason) as an indicator of the overall success of drug therapy. Although these findings do not invalidate therapeutic trials of these drugs in appropriately selected patients with Alzheimer disease, taken into account the volume and the large variations in the use of these drugs, they do suggest that their appropriate use urgently needs further investigation.

The use of acetylcholinesterase inhibitors for dementia, the so called anti-Alzheimer drugs, has been largely debated in the medical literature.¹⁷¹ A Cochrane reviewer of cholinesterase inhibitor trials explored the potential effects of several limitations and methodological flaws and concluded that the likely magnitude of the bias does not invalidate the beneficial findings of the studies.¹⁷² Donepezil is the most frequently used drug in this class in Belgium. People with mild, moderate or severe dementia due to Alzheimer's disease experience benefits in cognitive function, activities of daily living and behavior. The debate on whether donepezil is effective continues despite the evidence of efficacy from the clinical studies because the treatment effects are small and are not always apparent in practice.¹⁷³ There is no evidence to support the use of donepezil for patients with mild cognitive impairment. The putative benefits are minor, short lived and associated with significant side effects.¹⁷⁴ The cost-effectiveness of these expensive drugs is unclear and highly dependent on assumptions surrounding clinical effect and local cost

data.¹⁷⁵ Extracts of the leaves of the maidenhair tree, ginkgo biloba, have been used in traditional Chinese medicine for thousands of years for several purposes. Clinical trials of the effects on dementia show inconsistent results.¹⁷⁶ Several case reports describe bleeding complications with Ginkgo biloba, with or without concomitant drug therapy.¹⁷⁷

Mucolytics are the drugs most prescribed for respiratory disease in rest- and nursing homes. The most dominant drug in this class, N-acetylcysteine, was promoted to reduce the number of acute COPD exacerbations, supported by some systematic reviews.¹⁷⁸ However, there is insufficient evidence for the systematic use of acetylcysteine¹⁷⁹ and a recent large prospective multi-centre study (BRONCUS), reported that acetylcysteine in the regular dose of 600 mg daily is ineffective at prevention of deterioration in lung function and prevention of exacerbations in patients with COPD.¹⁸⁰

The more recently commercialized anti-allergic agent levocetirizine is an enantiomer of cetirizine, and is thus as such not a new compound, but part of an already known and cheaper preparation. Levocetirizine has not been shown to have any advantage over cetirizine with respect to clinical efficacy, adverse drug reactions or cost.

Clopidogrel, related to the older ticlopidine, and much more expensive than aspirin, is widely prescribed in Belgian rest and nursing homes for chronic treatment. In general, the use of antithrombotic agents has risen dramatically over the last years. In theory, it has however only limited indications, especially in those circumstances where aspirin is contraindicated or not tolerated and in a limited time interval following coronary stent implantation (e.g. 1 month following bare metal stents and 3 to 6 months following drug eluting stents). It can also be considered during the first few months following an acute coronary syndrome. There is evidence that long-term chronic treatment with clopidogrel plus aspirin is not more effective than aspirin alone for reducing cardiovascular (CV) events.¹⁸¹ On the other hand, it has been shown that bleeding risks with this combination antiplatelet therapy, which is a matter of concern in the elderly, is remarkably high.¹⁸² Since there is only a marginal benefit of clopidogrel over aspirin in cardiovascular high risk patients while the price is much higher, the cost-effectiveness of this approach for patients where low dose aspirin is not contraindicated should be questioned.

Statins are widely viewed as very effective and safe. Their benefits to coronary artery disease have been copiously documented and are incontrovertible. In addition, statins have been shown to benefit survival in a large study of middle-aged men with, or at high risk for, heart disease.¹⁸³ Nonetheless, all drugs have potential adverse reactions despite their potential benefits. Understanding these risks is vitally important, particularly in frail elderly patients in whom both risks and benefits differ relative to younger patients. Evidence suggests the balance of benefits to risks may be less favourable in frail elderly. Cholesterol becomes a less potent predictor of cardiovascular problems, and adverse reactions from drugs, including statins, may become more prominent. While patients at high risk for cardiovascular disease receive mortality benefit from statins in studies predominating in middle-aged men¹⁸³ no trend toward survival benefit is seen in elderly patients at high risk for cardiovascular disease.¹⁸⁴ A less favourable risk-benefit profile may particularly hold for patients older than 85, in whom benefits may be more attenuated and risks more amplified.¹⁸⁵ In fact, in this older group, higher cholesterol has been linked observationally to improved survival.¹⁸³

The rationale for venous thromboembolism prophylaxis is based on the clinically silent nature of the disease. In fact, most events cause few specific symptoms, and the clinical diagnosis is notoriously unreliable. Beyond the immediate complications of pulmonary embolism, which can lead to death, unrecognized and untreated DVT can cause long-term morbidity from chronic venous stasis (postphlebotic syndrome) and predispose patients to recurrent venous thromboembolism. Each institution should have guidelines for identifying patients at risk, as well as a policy for providing prophylactic therapy.

Non-pharmacologic prophylactic measures include compression stockings, leg elevation, and early mobilization. Aspirin may be appropriate for prophylaxis of arterial thrombosis, but is not adequate for prevention of venous thrombosis. Low-molecular-

weight heparins (LMWHs) are used for DVT prophylaxis and in the treatment of DVT. LMWH are mostly given subcutaneously. The bleeding risk associated with LMWH administration is similar to or slightly lower than the risk observed with unfractionated heparin and is related to dose and molecular weight.

Elderly patients who are candidates for prophylaxis include those with limited mobility, those with chronic conditions such as paraplegia, and those requiring permanent respiratory assistance. However, the true long-term risk of VTE in these patients is not well known; no studies have been performed that evaluate the benefit of prophylaxis with an appropriate duration of treatment in this population.

Most long-term care residents with atrial fibrillation would be at high risk for embolic stroke, a disastrous complication. Additionally, they are theoretically good candidates for adjusted-dose warfarin treatment for atrial fibrillation.¹⁸⁶ They should be accessible for monitoring and should have less dietary variability, a controlled medication list, and supervised medication administration. Balancing these features is at least a moderate risk of severe bleeding from anticoagulation based on age, co-morbidities, and polypharmacy. The decision to start warfarin will therefore be based on the individual's risks and potential benefits. The optimal intensity of anticoagulation is unknown for subgroups of patients with atrial fibrillation who have at least an intermediate risk of bleeding (e.g., adults older than 75 or 80 years), but there is no evidence that an INR lower than 2-2.5 is efficacious. Another option is to use aspirin instead of warfarin for patients at high risk of bleeding.¹⁸⁷⁻¹⁸⁹

4.3.2 Discussion of the prescribing quality problems detected in the field study

The quality of drug utilisation will be discussed starting from the different criteria and quality systems that were applied to the data generated by the field study.

PROBLEMS IDENTIFIED WITH THE ACOVE CRITERIA OF UNDERPRESCRIBING

Heart failure and no beta-blocker

Beta blockers should be considered standard therapy in patients with New York Heart Association class II or class III heart failure who are hemodynamically stable, who do not have dyspnea at rest and who have no other contraindications to the use of these agents.¹⁹⁰

Heart failure and no ACE-inhibitor^{191, 192}

Overwhelming evidence accumulated during almost 20 years of clinical experience has established the benefits of this drug, which blocks the harmful effects of angiotensin, a substance that causes blood vessels to narrow, said the study authors. Current guidelines recommend that all patients with systolic dysfunction should be getting ACE inhibitors, unless they have a contraindication to the use of these drugs. Physicians might be reluctant to prescribe ACE inhibitors in certain high-risk patients, such as those with kidney disease. Some health care delivery systems might lack the necessary structure, controls or resources to ensure that heart failure patients receive the best care possible. Or, some physicians possibly lack awareness about the potential benefits of treatment with ACE inhibitors.

Myocardial infarction and no beta-blocker¹⁹³

Although beta-adrenergic antagonists can significantly reduce mortality after a myocardial infarction, these agents are prescribed to only a small number of patients. Underutilization of beta blockers may be attributed, in part, to fear of adverse effects, especially in the elderly and in patients with concomitant disorders such as diabetes or heart failure. However, studies have shown that such patients are precisely the ones who derive the greatest benefit from beta blockade. Advancing age or the presence of potentially complicating disease states is usually not a justification for withholding beta-blocker therapy. With use of cardioselective agents and through careful dosing and monitoring, the benefits of beta blockers after myocardial infarction far outweigh the potential risks in most patients.

Osteoporosis and no VitD/Calcium/ bisfosfonates¹⁹⁴

Osteoporosis is caused by the cumulative effect of bone resorption in excess of bone formation. Multiple treatments are available and more are being developed.

Calcium and Vitamin D: less than one third of elderly residents take in the recommended amounts of calcium and vitamin D. Patients with malabsorptive problems, renal disease or liver disease may have further problems. Calcium and Vitamin D supplementation have been shown to reduce the risk of hip fracture in older adults. Calcium should be given with meals for optimal absorption and adults should take in at least 1000 mg/day (ideally 1500 mg/day in postmenopausal women or those with osteoporosis). Vitamin D (25 and 1.25 D3) can be checked, but if the serum calcium level is normal most would recommend empiric treatment with additional vitamin D of at least 400 IU. In frail older patients with limited diets and sun exposure, the required amounts are most likely much higher, at least 600-800 IU daily.

Bisphosphonates: these drugs act to decrease bone resorption. Multiple studies have demonstrated a significant benefit in the reduction of hip and vertebral fractures. It is important to remember that those at highest risk for fracture (the older patients and those with existing vertebral fractures) were the patients who derived the most benefit from treatment. Contraindications include renal failure and significant oesophageal erosions/disease.

Diabetes and no aspirin¹⁹⁵

Patients with type 2 diabetes mellitus have a markedly increased risk of cardiovascular morbidity and mortality. Guidelines of both the American and Canadian Diabetes Associations recommend the use of aspirin as antiplatelet therapy for all adults with type 2 diabetes. Aspirin is a safe, inexpensive, and readily available therapy that is effective for preventing cardiovascular disease, and patients with type 2 diabetes are particularly likely to benefit from such preventive therapy.

However, we found significant underuse of aspirin therapy among our study population. Low dose aspirin should be included and better promoted as a factor in high-quality, evidence-based diabetes management.

PROBLEMS IDENTIFIED WITH THE BEERS CRITERIA OF POTENTIALLY INAPPROPRIATE MEDICATION

Digoxin¹⁹⁶

The incidence of digoxin toxicity increases with age, largely because the two most common conditions that benefit from use of digoxin, congestive heart failure and atrial fibrillation, are markedly more prevalent in old age. Current reviews conclude that the drug still has beneficial effects in patients who remain symptomatic with appropriate treatment with diuretics and angiotensin-converting enzyme inhibitors.¹⁹⁷ Whether the elderly are more sensitive to the effects of digoxin because of age per se is unclear. However, several other factors render the elderly more susceptible to digoxin toxicity. These include an age-related decline in renal function and a decrease in volume of digoxin distribution. There is also an increase in the number of comorbid conditions, including cardiovascular and chronic obstructive pulmonary disease, which heightens susceptibility to digoxin toxicity. Moreover, treatment of these diseases with such interactive medications as quinidine and calcium channel blockers may increase the serum level of digoxin. Similarly, such electrolyte imbalances as hypokalemia and hypomagnesemia occur more frequently in the elderly as a result of diuretic therapy.

Oxybutynin¹⁹⁸

Oxybutynin is a tertiary amine with anticholinergic and spasmolytic effects on the bladder smooth muscle. It was developed specifically for overactive bladder and to suppress involuntary bladder contractions. Oxybutynin works by a direct antispasmodic action on smooth muscle and inhibits the muscarinic action of acetylcholine on smooth muscle. It is selective for muscarinic receptors on the detrusor and is more potent and more direct than atropine. Despite an improved anticholinergic side effect profile, side effects are still frequently dose limiting, or cannot be tolerated in the elderly. Anticholinergic effects are important causes of acute and chronic confusional states. Nevertheless, polypharmacy with anticholinergic compounds is common, especially in

nursing home residents. Recent studies have suggested that the total burden of anticholinergic drugs may determine development of delirium rather than any single agent.

Amiodarone¹⁹⁹

Beers criteria for safe medication use in older adults include also amiodarone. Amiodarone is considered a "broad spectrum" antiarrhythmic medication, that is, it has multiple and complex effects on the electrical activity of the heart which is responsible for the heart's rhythm. Amiodarone is used for many serious arrhythmias of the heart including ventricular fibrillation, ventricular tachycardia, atrial fibrillation, and atrial flutter. Although amiodarone has many side effects, some of which are severe and potentially fatal, it has been successful in treating many arrhythmias where other antiarrhythmics fail. In addition to being an antiarrhythmic medication, amiodarone also causes blood vessels to dilate. This effect can result in a drop in blood pressure. Amiodarone may interact with beta- blockers, or certain calcium-channel blockers, such as verapamil or diltiazem, resulting in an excessively slow heart rate or a block in the conduction of the electrical impulse through the heart. It is recommended that the dose of digoxin is cut by 50% when amiodarone therapy is started. Amiodarone can result in phenytoin toxicity because it causes a two- or three-fold increase in blood concentrations of phenytoin. Symptoms of phenytoin toxicity include unsteady eye movement (temporary and reversible), tiredness and unsteady gait. Amiodarone also can interact with tricyclic antidepressants (e.g. amitriptyline), or phenothiazines and potentially cause serious arrhythmias. Amiodarone interacts with warfarin and increases the risk of bleeding. The bleeding can be serious or even fatal. This effect can occur as early as 4-6 days after the start of the combination of drugs or can be delayed by a few weeks.

Nifedipine²⁰⁰

Calcium antagonists have long been used as first-line drugs for hypertension and angina. However, deleterious effects have also been reported in patients treated with calcium antagonists. A fall in diastolic BP and a rapid increase in heart rate can be associated with ischemic episodes without with nifedipine. Slow-release nifedipine may induce myocardial ischemia through a heart-rate increase and a decrease in coronary blood flow due to lower diastolic BP in patients with severe coronary artery disease.

Gastric ulcer and NSAID²⁰¹

Non-steroidal anti-inflammatory drugs including aspirin use is the second most common aetiological factor for peptic ulcer disease and a major factor for peptic ulcer complications. The use of non-steroidal anti-inflammatory drugs, including cyclooxygenase-2 inhibitors, may increase the short-term risk of complications and death in patients with bleeding peptic ulcers.

Fall risk and benzodiazepines

In our study, more than half of the nursing home residents with fall risk took benzodiazepines. Benzodiazepines have been recognized as an independent risk factor (IRF) for falls among the elderly. Benzodiazepines may produce inappropriate sedation and psychomotor impairment and are associated with an increased risk of falls and hip fractures.²⁰² A recent prospective, multi-centre study of approximately 8,000 hospitalized patients showed that benzodiazepines with very short and short half-lives were positively associated with falls during a hospital stay and that their use is an IRF for falls.²⁰³ The study also showed that patients were at a greater risk of falls if they were receiving other psychotropic agents or diabetic agents, if they had cognitive impairment, a high level of comorbidity, advanced age (>80 years), or if they stayed in the hospital for 17 days or more. Long-acting benzodiazepines have been shown to markedly increase the risk of falls and hip fracture.²⁰³ Up to 20% of older adults take benzodiazepines; benzodiazepine use is more common among women, whereas alcohol use and abuse is more common among men.²⁰⁴ Prescriptions for these agents should be carefully evaluated in institutionalized elderly patients.

PROBLEMS IDENTIFIED WITH THE BEDNURS CRITERIA

Combination of psychotropics^{205, 206}

Use of psychotropic medication is very common in nursing home residents. The prevalence of committant prescribing of psychotropic drugs in our study is substantial. This may be a potentially important and avoidable risk factor for drug-related illness in elderly people. It has been shown in the literature that abundant sedative drug use has been associated with high age, female gender, poor basic education, poor health habits (e.g., smoking), depression, dementia, or impaired mobility. Users also have poor self-perceived health. More studies are needed in this field. Physicians caring for nursing home residents require further education on the benefits and adverse effects of psychotropic drugs in frail elderly people.

Chronic use of antipsychotics²⁰⁷

Continuous use of antipsychotics in our study exceeds 10%. It has been shown in the literature that chronic use of antipsychotic has been related to both depressive symptomatology and sleep problems. If a patient initially has responded well, the following duration of treatment before attempting to taper and discontinue the antipsychotic has been recommended: delirium, 1 week; agitated dementia, taper within 3-6 months. Combinations with carbamazepine, tricyclic antidepressant and fluoxetine have been considered as contraindicated. Extra monitoring has been recommended when combining any antipsychotic with lithium, lamotrigine, or valproate or with codeine, phenytoin, or tramadol.

Combination of ACE-inhibitors and potassium or potassium-saving diuretics^{208, 209}

Combination of ACE-inhibitors and potassium or potassium-saving diuretics was found in more than 10% of the participants in our study. A potentially serious side effect of taking ACE inhibitors is increased blood potassium levels. Taking potassium supplements, potassium-containing salt substitutes or large amounts of high-potassium foods at the same time as ACE inhibitors is not recommended. Potassium sparing diuretics have generally been avoided in patients receiving ACE inhibitors, owing to the potential risk of hyperkalaemia. Nevertheless, a recent randomised placebo controlled study, the randomised aldactone evaluation study (RALES), reported that hyperkalaemia is uncommon when low dose spironolactone (≤ 25 mg daily) is combined with an ACE inhibitor. Risk factors for developing hyperkalaemia include spironolactone dose > 50 mg/day, high doses of ACE inhibitor, or evidence of renal impairment. It is recommended that measurement of the serum creatinine and potassium concentrations is performed within 5-7 days of the addition of a potassium sparing diuretic to an ACE inhibitor until the levels are stable, and then every one to three months.

Longacting benzodiazepines²¹⁰

Benzodiazepines with oxidative pathways and longer half-lives, such as chlordiazepoxide, diazepam, and flurazepam, are more likely to accumulate in the body and cause prolonged sedation. Long-acting benzodiazepines are not recommended for elderly patients because they increase the risk of impaired cognitive function, falls, and hip fractures. The prevalence of long-term benzodiazepine use among nursing home residents in our study does not exceed 5%. Nevertheless, this topic merits attention given that this segment of the population could be expected to grow and given that elderly persons are particularly prone to adverse reactions to benzodiazepines.

Neuropsychiatric symptoms of dementia are common and associated with poor outcomes for patients and caregivers. Although non-pharmacological interventions should be the first line of treatment, a wide variety of pharmacological agents are used in the management of neuropsychiatric symptoms; therefore, concise, current, evidence-based recommendations are needed. Recently a systematic review on this subject was conducted by Sink et al.²¹¹ They concluded that pharmacological therapies are not particularly effective for management of neuropsychiatric symptoms of dementia.

PROBLEMS WITH MEDICATIONS WITH LIMITED EVIDENCE BASE FOR EFFICACY

Piroxicam is a nonsteroidal anti-inflammatory drug (NSAID). Used for the management of several different symptoms and numerous conditions, NSAIDs as a group continue to be among the most frequently prescribed medications. Nevertheless, physicians generally recognize that the prudent use of NSAIDs requires cognizance of potential side effects. Clinical experience suggests that, although complications can occur early in the course of treatment, they are more likely to occur with chronic use. According to the revised Beers criteria piroxicam belongs to potentially inappropriate medications for the elderly.

Gastrointestinal toxicity is the most frequently encountered side effect associated with piroxicam and other NSAIDs and presents considerable concern. Approximately one half of all hospital admissions for a bleeding ulcer are attributed to the use of NSAIDs, aspirin, or the two taken in combination during the week prior to admission.²¹² The relative risk of gastric ulcer (4.7), duodenal ulcer (1.1 to 1.6), bleeding (3.8), perforation, and death are all increased by NSAID use when such patients are compared to those who do not take these products. Patients at increased risk of developing GI complications include those with a prior history of peptic ulcer and especially those with prior upper GI bleeding, regardless of the source. These patients had a relative risk of 13.5 for a recurrent complication.²¹³

Renal complications are the second greatest concern associated with piroxicam use. Renal side effects include fluid and electrolyte disturbances such as sodium and water retention and/or hyperkalemia. Acute renal failure, nephrotic syndrome with acute interstitial nephritis, and papillary necrosis may also occur.²¹⁴ Although renal events are uncommon, they can have profound consequences if the drug use is not stopped and appropriate care is not initiated.

The effect of piroxicam on the function of antihypertensive medications is another area of concern. Concomitant use of NSAIDs plus antihypertensive medication increases with age to greater than 50% among the elderly.²¹⁵ A large, case-controlled study of patients more than 65 years of age demonstrated that recent users of NSAIDs had a 1.7-fold increase in risk of initiating antihypertensive therapy when compared with non-NSAID users.²¹⁶ It appears that NSAID use reduces the antihypertensive effects of angiotensin-converting enzyme (ACE) inhibitors to the greatest degree while having lesser effects on beta blockers, diuretics, vasodilators, and calcium channel blockers.^{217,}
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Allergy to piroxicam and other NSAIDs occurs in approximately 0.3% of the population. A not uncommon side effect associated with piroxicam is interference with hemostatic disorders. Aspirin irreversibly acetylates cyclooxygenase and thereby inhibits synthesis of both TXA₂ and PGI₂. In contrast, NSAIDs reversibly inhibit cyclooxygenase. There is conflicting evidence as to whether aspirin and other NSAIDs are associated with increased bleeding from surgery.²¹⁸ However, where an association is suspected, the following factors may portend a high risk for bleeding complications: age older than 60 years, bleeding disorders, liver dysfunction, thrombocytopenia, and other risk factors such as alcohol use and use of oral anticoagulants.

Betahistine is advocated as a vestibular suppressant mainly for Meniere's disease. Betahistine was approved by the US FDA about 30 years ago for roughly 5 years, but later approval was withdrawn because lack of evidence for efficacy and because the major report of effectiveness contained deficiencies and misrepresentations.²¹⁹ Subsequently, four double-blind studies have been done reporting reduction of vertigo attacks with betahistine.²²⁰⁻²²³ Nevertheless, these studies may have been flawed and a recent review suggested that it is presently still unclear if betahistine has any effect in Meniere's disease.²²⁴ Betahistine was again reviewed by the FDA in June of 1999. Essentially, the conclusion seems to be that there is no evidence that it is harmful, but also little evidence that it has any therapeutic effect. It thus is similar in official status to an inert substance.

4.4 GENERAL CONCLUSIONS

4.4.1 The magnitude of medication use and costs for long-term residential elderly in Belgium

The national aggregated data on drug utilization in Belgian rest- and nursing homes clearly illustrate certain prescription patterns, habits and often large geographical differences for those drugs that are linked to one or a limited number of indications. The field study (PHEBE project) showed the high number of 8 chronic medications per resident among residents in nursing homes, highly related to the polyopathy of the residents.

Albeit only 1.4% of the Belgian population lives in nursing homes, the data from this study and data from national claims databases^{mm} indicate that 5.6% of the public expenditures on medication (pharmaceutical specialties) may be generated by nursing home residents (123 million € in 2004 in Belgium). Residents of nursing homes generate considerable public expenditures for pharmaceutical care (90 € per month), but also pay hefty amounts of personal money out-of-pocket for co-payment of chronic reimbursed medicines (23 € per month) as well as for payments to the pharmacy for non-reimbursed medication (27 € per month).

4.4.2 The medical needs of residents in nursing homes

We detected an average of 5 medical problems per resident (2.7 clinical problems and 2.6 care problems). The treating physician categorized 46% of the residents as demented, and 35% as depressed, with an overlap between the two diseases of 16%. At the moment of the survey, 9% of the residents were in palliative care, of which one in three was in terminal care.

The number of medical diagnoses does not increase with increasing age, in contrast to the number of care problems by resident, showing a significant increase in the very old.

4.4.3 Measurement of the quality of prescribing

The average number of potential prescribing quality problems per resident was high. A number of clinically relevant problems with a substantial prevalence could be identified as a possible target for prescribing quality improvement programs.

None of the existing sets of prescribing quality indicators provides a comprehensive view of the different aspects of evidence-based clinical practice, and all require further adaptation to local medical practices. The implementation of accepted sets of prescribing quality indicators requires more explicit specifications for the definition of drug classes in terms of the Anatomic Therapeutic Chemical Classification (ATC) of the World Health Organization. In addition, further validation of physician assessed lists of medical diagnoses and care problems is needed. Finally, validation is needed of the application of these sets of quality indicators in the context of automated analysis of medication charts.

4.4.4 The general characteristics of Belgian nursing homes and their medication management systems

Belgium has a well-established network of rest and nursing homes within its cities and villages, mainly run by community social services, by religious charities or by private for-profit corporations. Belgian residential homes for the elderly have a mix of residents where slightly and highly dependent patients and demented and non-demented patients live together in one institution. Many residents are still supervised by their former general practitioner, but in some nursing homes the coordinating physician is responsible for more than half of the residents of the home. The large majority of

^{mm} Public expenditures on pharmaceutical specialties amounted to 2,213 million € in 2004 (personal communication M De Falleur – RIZIV/INAMI).

nursing homes are served by community pharmacists, with little engagement in clinical pharmacy activities. About one in ten nursing homes is served by a hospital pharmacist.

The medication management systems in the nursing homes are poorly developed and focus mainly on the distribution process inside the institution, and less on the appropriateness of prescribing. Few residents manage to keep some form of autonomy with regard to medication, except in institutions with limited staff and poor distribution management.

Although a drug formulary is formally available in most institutions, the implementation of this formulary and its impact on the drug choice process of the visiting physicians seems to be limited. Nursing homes run by the local community social service (OCMW/CPAS) more often have a hospital pharmacist running the medication supply to the institution, more often have coordinating physician treating a high number of residents within the institution, and more often have more intense medication management systems.

4.4.5 Institutional characteristics associated with the quality of prescribing

In the field study, lower quality of prescribing was associated with the location of the nursing home in Hainaut, and with a lower number of residents per attending physician. Higher quality of prescribing was associated with higher activity of the coordinating physician, better implementation of the formulary, and greater activity of the delivering pharmacist. Higher expenditures were associated with the province of Hainaut and with the absence of price competition.

With regard to the impact of case-mix, we observed that the volume of medication usage did not increase in the very old. Dementia and end-of-life care seems to be associated with a decrease in the volume of medication usage.

4.4.6 Implications for research and practice

There is a need for reliable and feasible scales to assess the case-mix of institutions and the continuous functional assessment of individual residents. Given the imminent digital revolution in health care facilities, the transformation of the pharmaceutical and clinical data collection methods in this cross-sectional research to tools for continuous, automated data-collection based on computerized nursing records seems feasible. The effectiveness of collective feedback on prescribing quality indicators to the community of visiting physicians to a nursing home merits further investigation.

Interventions to enhance the quality and the affordability of medications in nursing homes will be more cost-effective when these interventions not only have an impact on the drug choice process for residents of nursing homes, but also on the drug choice process for all elderly patients on the list of the general practitioners.

Robert Vander Stichele	initiated and coordinated the project, conducted the literature review, participated in the design, data collection and data analysis and in writing and editing the manuscript.
Carine Van de Voorde	supervised the project, participated in the data collection and analysis of the national aggregated data on nursing homes and in writing and editing the manuscript.
Monique Elseviers	participated in the design, was responsible for the organization of the data collection in Dutch nursing homes, for the management of data-entry and databases, for the statistical analysis, and participated in the writing and editing of the manuscript.
Charlotte Verrue	participated in the design of the questionnaire and score for medication management systems, in conducting the literature review, in the data collection in Dutch speaking nursing homes, and in writing and editing the manuscript.
Kris Soenen	was responsible for the coordination of the data collection and data-entry and for communication with actors in the field.
Mirko Petrovic	participated in the design of the clinical questionnaire, in the choice of the prescribing quality indicators and in the interpretation of the results on prescribing quality.
Pierre Chevalier	coordinated the field study in the French speaking nursing homes and participated in the design of the clinical questionnaire.
Mike Smet	was responsible for the multivariate statistical analysis.
Tom De Floor	participated in the data collection in the Dutch speaking nursing homes.
Els Mehuys	participated in the design of the questionnaire and score for medication management systems, and in writing the manuscript.
Annemie Somers	participated in the design of the questionnaire and score for medication management systems.
Micheline Gobert	participated in the data collection and data entry in the French speaking nursing homes and in editing the manuscript.
Marc De Falleur	participated in the data collection and analysis of the national aggregated data on nursing homes.
Marc Bauwens	participated in conducting the literature review and in the data collection in the Dutch speaking nursing homes.
Thierry Christiaens	participated in the design of the clinical questionnaire and in the choice of the prescribing quality indicators.
Anne Spinewine	participated in the data collection in the French speaking nursing homes, in the interpretation of results on prescribing quality and in editing the manuscript.
Stephan Devriese	participated in the data collection and analysis of the national aggregated data on nursing homes and in writing and editing the manuscript.
Dirk Ramaekers	participated in the design and the project management of the study, and in the writing and editing of the manuscript and of the recommendations.

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