Pharmaceutical Care, the Future of Pharmacy

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Farmaceutische Patiëntenzorg

Theory, research, and practice

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Dissertation

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INTRODUCTION

The subject of pharmaceutical care appeared on the agenda of many pharmacists and policy-makers in the beginning of the 1990s under the influence of American philosophies. The concept was embraced by the FIP, the International Pharmaceutical Federation soon after its introduction. At that time society was (and still is) questioning the general role of pharmacists in the provision of medicines in many countries and as a result pharmacists are looking for new roles and ways to prove their added value to society. Moreover, individual patients increasingly demand attention and proper care from all health care professionals, including the pharmacist.

The basic reason for care by pharmacists around pharmaceuticals can be found in the fact that drugs are used in a certain context. Physicians, pharmacists, patients, in fact the whole community expect them to heal. But drugs are just chemical substances and must be properly used in order to have their full beneficial effect otherwise they turn into intoxicating substances, as already recognised in 300 BC.

> *'Medicines are nothing in themselves, if not properly used, but the very hands of god, if employed with reason and prudence.' (Herophilus approx. 300 BC, a Greek physician)*[*]

Pharmacists deal with medicines all the time. They help to select them, also in the management of self-limiting illness, and dispense them on physicians' prescriptions.

How can the pharmacist more fully contribute to patient care? Apart from very local or national attempts in different countries to extend clinical pharmacy, not many integral co-ordinated efforts have been made by pharmacy to contribute to the patient's well-being, apart from through the dispensing process.

Pharmaceutical care was the first integrated philosophy of practice to combine the expertise of pharmacists with influencing prescribing and evaluating drug regimens on one side and counselling on the other side to improve the patients' outcomes, including quality of life.

This dissertation consists of 4 parts. The first part introduces the different concepts of pharmaceutical care globally and explains why and how the topic emerged in the eighties in Dutch pharmacy. The second part describes the OMA and TOM projects. The third part describes pharmaceutical care practice and research from a more international point of view and the fourth part contains the conclusions of this dissertation. In the fifth part (the Appendices) some questionnaires and additional information for certain chapters are presented.

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[*] From: Compton's Reference Collection [CD-ROM] Comptons New Media Inc.;1996.

The TOM and OMA studies were financially supported by
- The Stichting Pharmaceutical Care (Pharmaceutical Care Foundation)
- The Dutch Pharmacist Organisations KNMP and VNA
- The Dutch wholesale companies Brocacef, Interpharm and OPG

Peak flow meters for the TOM study were provided by the generic producer Pharmachemie, and the evaluation study of PAS®, a system for coding pharmacists' activities which is briefly mentioned in this dissertation, was funded by the Dutch pharmacy-software company Pharmacom.

Paranimfen: Corinne de Vries
Roelof Bijleveld

In the epilogue all people who contributed to the research and content of this dissertation are mentioned.

OVERVIEW OF CONTENTS

Part I, Introduction

In *Chapter 1* the philosophy of pharmaceutical care is outlined and it an explanation is given as to why the definition (and the concept) of pharmaceutical care differs in different countries. This chapter has been accepted for publication in the Millenium Edition of the International Journal for Pharmacy Practice.

Chapter 2 deals with the history of the pharmaceutical profession in the Netherlands and answers questions about the professional development of pharmacists. It traces the merger of social pharmacy, clinical pharmacy and provision of drug information into a concept that is now called pharmaceutical care, or in Dutch, farmaceutische patiëntenzorg (FPZ). A slightly altered version has already been published in the Journal of the American Pharmaceutical Association in 1999.

Part II, The TOM and OMA projects

Chapter 3 considers the structure and methodology of two Dutch pharmaceutical care research projects, TOM and OMA, and outlines the pharmacist interventions and the research and intervention instruments used.

Chapter 4 and 5 provide the results of the OMA and TOM studies at the patient level. Both chapters deal with different aspects of the process indicators and outcomes of the interventions. Findings which did not match expectations, are reported together with the more positive results.

In *Chapter 6* the influence of pharmaceutical care on the health-care professionals e.g. GPs, pharmacists and assistant-pharmacists are considered based upon results from the TOM and OMA studies. Part of this chapter has been submitted for publication to the Pharmaceutisch Weekblad.

Part III, Pharmaceutical care in world-wide perspective

Chapter 7: Assuming that it is worthwhile to adapt pharmacy practice to the pharmaceutical care philosophy, the work presented in this chapter describes the implementation barriers in everyday pharmacy in a number of European countries.

In *Chapter 8* the results of a comparative study into community pharmacy provision around the world, conducted in co-operation with the community pharmacy section of FIP are presented. This section is especially aimed at looking at aspects, which might enhance or inhibit the provision of pharmaceutical care by community pharmacists in their respective countries. The best opportunities to develop pharmaceutical care currently seem to exist in the Netherlands, Japan and the United States.

In *Chapter 9* (and Appendix 5) the current situation with regard to pharmaceutical care projects and research in countries around the world are catalogued and discussed. In this chapter the activities of the Pharmaceutical Care Network Europe (PCNE) are also described.

Part IV, Conclusion and summary

Chapter 10 focuses on the conclusions that can be drawn from the totality of the research undertaken. Special emphasis is given to the challenges of research in practice, and the role of the definition of pharmaceutical care in the interpretation of both implementation and research projects.

In the *Summary* an overview of the total dissertation can be found, in an English and Dutch version. This section also contains the *Epiloque*.

Part V, Appendices

The appendices contain a number of questionnaires used during different projects and additional information on certain chapters.

This part also contains the curriculum vitae and a list of publications and presentations of the author.

SOME ADDITIONAL REMARKS

This dissertation is especially meant for researchers and practitioners who are interested in social pharmacy, pharmacy practice, and the evolution of the pharmaceutical profession and community pharmacy.

The dissertation is not a only a collection of published or unpublished scientific articles, but also a philosophical examination of the historical and future development of pharmacy within the primary care sector.

ABBREVIATIONS

To improve readability a number of abbreviations have been used throughout this dissertation. An alphabetical list of these abbreviations is as follows:

- AFTO Pharmacotherapeutic consultation between GPs and pharmacists in The Netherlands
- ATC Anatomic Therapeutic Chemical classification index
- COPD Chronic Obstructive Pulmonary Disease
- DDD Defined Daily Dose
- FIP International pharmacist federation
- FTO Pharmacotherapeutic consultation between general practitioners and pharmacists
- GP General practitioner (in Dutch: 'huisarts')
- HMO Health Maintenance Organisation
- HRQL Health Related Quality of Life
- ICPC International Classification for Primary Care
- LHV The Dutch association for GPs
- KNMP The Royal Dutch Association for the Advancement of Pharmacy
- MMSE Mini Mental State Exam
- OMA Elderly Medication Analysis, one of the projects described in this dissertation
- PAS® Problems-Assessment-Solutions tool for assessing and drug related problems
- PDD Prescribed daily dose
- PEF Peak Expiratory Flow
- Prn. Take when necessary
- PhC Pharmaceutical Care
- TOM Therapeutic Outcome Monitoring. TOM in asthma is one of the projects described in this dissertation
- WINAp The Dutch scientific institute for pharmacy

Throughout this dissertation the terms 'drugs' and 'medicines' are used indicating substances, which potentially heal or prevent disease. The terms 'physicians' and 'doctors' are both used for people who hold a medical `degree and who are practising medicine. The term 'professional' is used to indicate a health-care professional.

Contents

Part I

Introduction

1
PHARMACEUTICAL CARE, INTRODUCTION

Defining an activity like care in itself is difficult and on an international level it becomes hazardous. The concept of care is strongly influenced by national care concepts and local circumstances in health care practice.

This chapter deals with issues surrounding health systems and the definitions of pharmaceutical care. The place of pharmaceutical care within a general health system is defined and the scope on pharmacy and pharmaceutical care is used for explaining the development of different definitions. Different linguistic and cultural influences on the construct of the definition are given.

1.1 THE CHALLENGES OF DEFINING PHARMACEUTICAL CARE ON AN INTERNATIONAL LEVEL *

Looking at the literature, pharmaceutical care is a way of dealing with patients and their medication. It is a concept that deals with the way people should receive and use medication and should receive instructions for the use of medicines. It also deals with responsibilities, medication surveillance, counselling and outcomes of care. In some countries the concept also deals with the way people should obtain information about disease states and lifestyle issues. In exceptional cases even purchasing medicines by a pharmacy is considered to be part of the concept.

Observations of, and communications with, researchers in the field of pharmacy practice in different countries in Europe, Australia, New Zealand, and in the USA reveal many differences in the interpretation of the concept of pharmaceutical care and its outcomes. The different interpretations sometimes prohibit the exchange and comparison of the results of pharmaceutical care and pharmacy practice research. The differences are a result of international cultural factors in pharmacy practice (see also Chapter 8), linguistic difficulties, the national and social environment in which health care is provided and different interpretations of the terms 'managed care' and 'disease management'. Also different approaches towards outcomes may lead to misunderstandings. All these factors have contributed to a continuous development of the concept of pharmaceutical care internationally. The questions of how and why different definitions have developed and why the original American definition of pharmaceutical care[1] has been and perhaps should be further reshaped in other countries are discussed.

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* A slightly adapted version of this chapter has been accepted for publication in the December 1999 issue of the International Journal for Pharmacy Practice as: van Mil JWF, McElnay J, de Jong-van den Berg LTW, Tromp ThFJ. The Challenges of defining pharmaceutical care on an international level.

To be able to outline the place and function of pharmaceutical care, the terms managed care, disease management and pharmaceutical care will first be described, before identifying elements that might influence the concept and the definition of pharmaceutical care at a national level.

1.1.1 Sources of information

Initially a literature search was performed using Medline Silver Platter, from 1985 to 1993, using the keywords 'pharmaceutical care' as text in title and/or abstract and appropriate articles including definitions of the subject or discussions around the definition were selected. For the period between 1993 and 1999 additional searches were performed in a similar way. These latter searches did not offer important new viewpoints.

Although a large number of articles dealt with the elements, which might or might not be part of the pharmaceutical care concept, the number of articles discussing its definition is limited especially in Europe. Furthermore literature descriptions reflected the ideal situation rather than reality. Therefore the content of this chapter is also influenced by discussions with representatives of the international academic and professional pharmaceutical community, such as researchers united within the Pharmaceutical Care Network Europe Foundation (PCNE)[2] and peers meeting during the conferences of the International Pharmaceutical Federation (FIP). The results of a questionnaire survey on international pharmacy are also used. This questionnaire was compiled in 1997 in co-operation with the community pharmacy section of FIP. Information was obtained from the pharmaceutical societies of 31 different countries (response rate was 68%, see chapter 8). Most section member countries in Asia and Eastern Europe did not reply. South Africa is not represented in the FIP community pharmacy section.

Although the results of the survey have not yet been published, one of the questions in the questionnaire specifically asked for the definition of pharmaceutical care used nationally. Other information was obtained from the Internet, especially the PharmCare discussion list Pharmweb.

1.1.2 Pharmaceutical Care, Disease Management and Managed Care

In the European world of healthcare and pharmacy, the terms managed care, disease management and pharmaceutical care often seem to be used without much distinction. From discussions with peers it appears that many activities are labelled as managed care (especially in Switzerland) or disease management (sometimes in The Netherlands or Germany), where pharmaceutical care probably would be more appropriate. In the USA, where the terminology originated, there is a much clearer distinction between those terms.

..... (*playing consumer advocate*), who are we to withhold information about medication which someone else is taking? It is the right of the consumer to be fully informed about side effect etc. It is not our job to "filter" what the consumer is told, it is our job to interpret that information. As Janne Graham (Consumer Health Forum) would say, if you provide adequate directions on the pack label, give them the CPI and then the consumer throws all the info away, takes an overdose and dies, well that is the right of the consumer! They can accept or reject whatever we advise or provide, that is their decision. If we withhold information because we think the consumer may become scared, not use the medication or may not understand the info, then we are playing God. Remember that it is a pharmacist's duty of care to ensure the "safe and effective use of medication". If a pharmacist provides the info and counselling for that duty of care and the consumer decides to do something else, well that's their decision, the pharmacist has fulfilled all his/her responsibilities. Remember also, that although we may quite rightly feel that some CPI is rubbish, we must work with it because it does hold a certain legal status now. I believe that the content should be altered, and lets work to bring those changes about for all our sakes!

Mr Kim Bessell, President
Pharmaceutical Society of Australia (SA Branch)

Citation 1-1 Statement on position of patient in care[†]

There is a major difference between these different forms of care in a sense that the drivers and the subjects of the processes differ. Managed care, disease management and professional care (e.g. pharmaceutical care) are concepts, which are initiated by groups with specific interests. Many definitions have been advanced to indicate the differences between these forms of care or care activities, but none of them seems to be appropriate. One of the confusing examples of such definitions can be found in a Dutch article by de Smet *et al.*[3].

They define managed care as a framework and disease management as a process. But others see disease management as a framework for which the processes still must be defined in the form of protocols for the health care professionals. On the other hand, during a FIP-meeting in Germany, managed care was defined as a process[4].

Table1-2 Actors in care

CONCEPT	Patient	Pharmacist	Physician	Insurer
Pharmaceutical Care	++	**I**	+	+/-
Disease management	+	+	**I**	+
Managed Care	+/-	+/-	+	**I**

I = Initiator/driving force
+/- = Maybe important
\+ = Important
++ = Very important

[†] (Published with consent from the author)

The different parties in health care, being the patient, professionals, insurance companies and the health care industry, obviously have different approaches. The different parties have developed methods, systems and concepts. However, the role of the patient in these developments often seems to be rudimentary.

In the different concepts, systems or methods, functions are assigned to the different other parties in the field. Table 2-1 best illustrates this.

Managed Care is a market-driven framework for the provision of health-care, originally developed in the United States[5]. 'Health-care management' could be another term for this. The Managed Care Organisation (MCO), or a large employer initiates and controls the framework through a managed care plan either offered by a Health Maintenance Organisation (HMO) or by directly hiring health care professionals though a Preferred Provider Organisation (PPO). The physician plays the central role, within a large administrative organisation[6]. The role of the patient and his/her influence on the system is often almost absent. Pharmacists discussions on different internet platforms (the Pharmaceutical Care Discussion Group and the Pharmacy Mail Exchange), suggest that managed care's main purpose is reducing costs and providing care to a level which is just acceptable to society[7].

Managed care is the principal driving force behind health care in the USA. In Europe the influence of managed care on health care systems is limited although the UK National Health System could be seen as one large HMO.

In **Disease Management** the physician is the initiator of a framework which controls the treatment of specific diseases. Often the HMO drives the physicians' actions through a disease management programme. The role of the pharmacist and patient is usually acknowledged but the individual patient has no direct influence on the content of the care provided.

The pharmacists' role in disease management has become increasingly clear. Munroe *et al.* state that pharmacists have the unique expertise that is vital to ensuring the maximum benefit of pharmacotherapy to be able to deliver improved patient outcomes and lower costs[8]. Pharmaceutical care has some of the characteristics of disease management in the sense that attention is being paid to the patient and protocols are sometimes being used when disease specific pharmaceutical care is to be delivered. But the concept of disease management is usually only applied to groups of patients with 'expensive' diseases, certainly in Europe[9].

In **Pharmaceutical Care** the individual patient is the main subject and usually the pharmacist is the initiator and driving force of the process. Depending on the interpretation of the definition, the latter need not always be the case. By identifying, resolving, and preventing undertreatment, overtreatment or inappropriate treatment, pharmacists can prevent or reverse many adverse drug-therapy related events and also have an economic impact[10]. These activities can be protocollised to a certain extend. Sometimes the insurers seem to be interested in the concept, but distance themselves from it. Usually the profession itself supports the development of the concept through their professional organisations.

Pharmaceutical care is a form of professional care like nursing care or medical care, and therefore the core roles of the patient and the provider are vital.

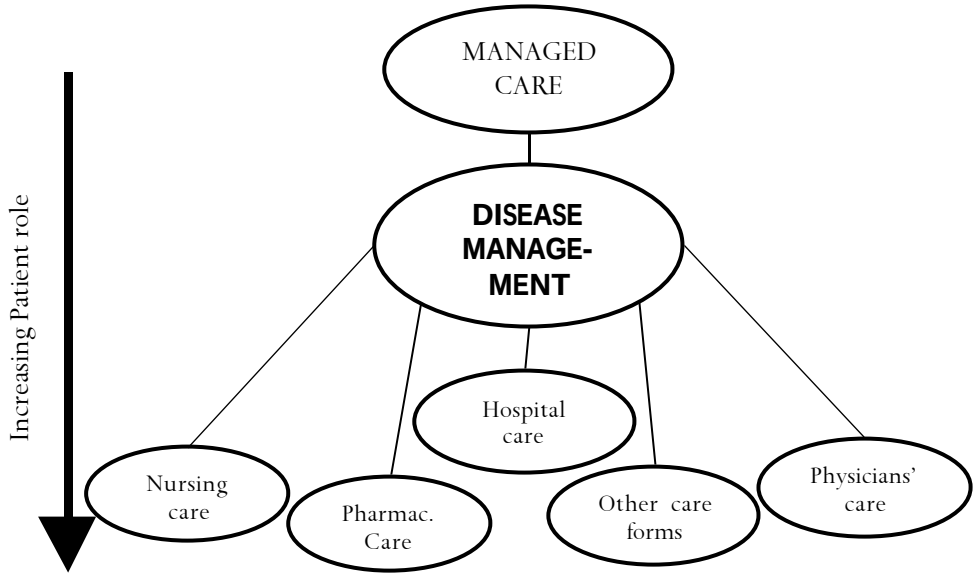

Figure 1-3 Relationships between care in a health system

1.1.3 Defining Pharmaceutical Care

In the complex field of care, as outlined above, it is necessary to define pharmaceutical care. One can regard the activities in a (community) pharmacy as separated into supportive pharmaceutical actions, (carried out in the back-office) and clinically oriented activities (disease or case oriented). In addition to these activities pharmaceutical care, aimed at the individual patient, can be carried out at the counter or in the consultation room. Figure 1-4 shows the relationships of those activities.

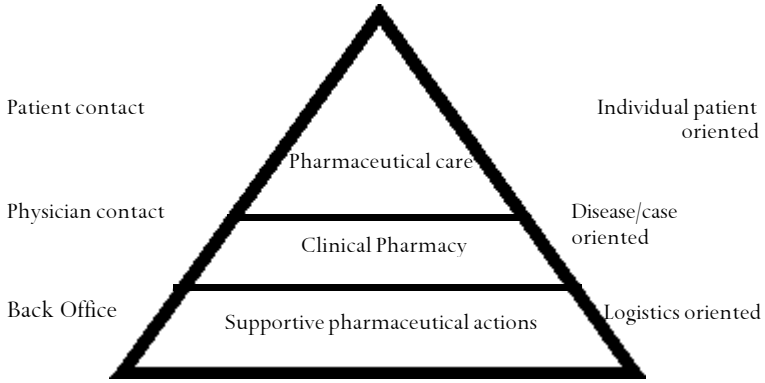

Figure 1-4 Pharmacy activities

Depending on the time and the country of origin, different definitions of pharmaceutical care are in use. In the United States, for example, the definitions have developed into their current form, starting in 1976, and since then pharmaceutical care has been often redefined. However, in the FIP questionnaire, which was evaluated at the University of Groningen. 6 out of the 30 responding countries indicated in that they use the Hepler and Strand (1990)[1] definition as their current working definition. Twelve countries did not give a definition of pharmaceutical care (including the USA) and 12 countries gave their own description or definition, which was in all cases significantly different from the Hepler and Strand definition. All definitions and descriptions have the same intent, namely care for individual patients.

A message on the PharmCare discussion list also suggests that a community level provision of pharmaceutical care is possible, especially in developing countries. In this case pharmaceutical care would focus on developing standard treatment guidelines, effective supervision of dispensing and effective use of support personnel[11]. Although these activities are extremely useful in certain circumstances, this structural group-approach is not common and currently is not regarded as pharmaceutical care according to all published definitions.

The American definitions

Clinical pharmacists generated the first definition for pharmaceutical care in the US, not unexpectedly if we look at the history of the pharmacy profession in that country. Mikeal *et al.* described pharmaceutical care in 1975 as 'The care that a given patient requires and receives which assures safe and rational drug usage'[12]. In the following years the term pharmaceutical care has been used a number of times for all actions which are needed for compounding and dispensing medicines. Brodie *et al.* were the first to give a more complete definition of pharmaceutical care in 1980. They stated: 'Pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only of the drugs required but also of the necessary services (before, during or after treatment) to assure

optimally safe and effective therapy. It includes a feedback mechanism as a means of facilitating continuity of care by those who provide it'[13].

In this definition for the first time a possible feedback-mechanism was suggested, a principle that Hepler later used in the work following his joint definition with Strand[14]. It also placed pharmaceutical care in a sociological context in which the role of the patient and his or her needs became important.

In 1987 Hepler formulated his first definition, in which the commitment to the patient became apparent: 'a convenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions (with appropriate knowledge and skill) governed by awareness of and commitment to the patients' interest'[15]. It is interesting to note that Hepler at the time of formulating this definition seemed to suggest that only a pharmacist could provide pharmaceutical care. This viewpoint is less clear in the widely accepted definition published in1990, which Hepler formulated together with Strand. That definition is the current cornerstone of many parties working in the field of pharmaceutical care, in hospital as well as in community pharmacy: 'pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient's Quality of Life'[1].

Strand, in 1992, published a new definition together with Cipolle and Morley, in which the patients' central position in the process receives even more emphasis. 'Pharmaceutical Care is that component of pharmacy practice which entails the direct interaction of the pharmacist with the patient for the purpose of caring for that patient's drug-related needs'[16].

In her address delivered when receiving the Remington Medal in 1997, Strand redefined pharmaceutical care as: 'A practice for which the practitioner takes responsibility for a patient's drug therapy needs and is held accountable for this commitment'[17]. It seems like Strand's approach has become more humanistic while Hepler's approach remains more process orientated in nature. Others, like Munroe, see pharmaceutical care as a service during which the clinical and psychosocial effects of drug therapy on a patient are systematically and continuously monitored i.e. a more clinical approach[18], which still can be recognised in the Australian interpretation of pharmaceutical care.

In summary, currently in the US there seems to be three approaches to pharmaceutical care: a process oriented one (Hepler), a humanistic one (Strand) and a clinical one (Munroe).

The Dutch definition, an example

When pharmaceutical care started to develop in The Netherlands in the beginning of the 1990s, the definition was formulated as follows: 'Pharmaceutical care (Farmaceutische Patiëntenzorg, FPZ) is the structured, intensive care by the pharmacist for an optimal pharmacotherapy in which the patient and his condition are the primary concern. The aim is to obtain optimal Health Related Quality of Life'[19].

Some typical Dutch aspects of community pharmacy practice are inherent to this definition e.g. continuity of care, protocols or critical pathways, documentation, high quality communication with patients, providing drug information, medication surveillance and communication with other professionals. These aspects therefore are not explicit in the definition. The new aspect for Dutch pharmacy was that the care now became targeted

directly at the individual, whereas before it was more of a technical professional approach originating from clinical pharmacy.

In 1998 the WINAp, the scientific Institute for Dutch Pharmacists, redefined pharmaceutical care as 'the care of the pharmacy team for the individual patient in the field of pharmacotherapy, aimed at improving the quality of life'. In this definition the role of the whole pharmacy team, pharmacist and assistant-pharmacists, is stressed and pharmaceutical care also became a possible activity when there was no *current* pharmacotherapy involved, thus including disease prevention or merely providing advice on drug related issues.

In both definitions the patient plays the central role and it is also clear that from the Dutch viewpoint pharmaceutical care is a practice philosophy solely for the pharmacy profession.

1.1.4 Language and cultural differences

Whenever someone comes up with a definition, be it for an object or a concept, words and meaning of words in a language play an important role. But the problem is not only linguistic. The framework of reference in which a definition is constructed is also important. This framework can be societal, as seen by any observer, but also professional as seen by practitioners close to the subject defined.

Language differences

As words may have slightly different meanings in different languages, translating definitions becomes a hazardous activity. The English word 'care' and the Dutch word 'zorg', as far as we can judge, have approximately the same meaning in the health care environment being personal and emotional care combined with professionalism and quality. But words like 'soin' (French), 'Fürsorg'(German), or 'omsorg' (Scandinavian languages)[‡] have a different meaning, with much more emphasis on the intrinsic emotional aspect. That is why the French would rather speak about 'suivi pharmaceutique' (meaning a pharmaceutical follow up) and the Germans speak of 'Betreuung' (meaning coaching). The Scandinavian countries have not found a more suitable word and tend to use the English expression.

An essential word like the English word 'outcome', which is used in the definition of Hepler and Strand, cannot be translated into the Dutch 'uitkomst' or 'resultaat'. It is a concept that covers both Dutch words.

The language difficulties noted above are one of the reasons why certain countries cannot adapt or translate the basic definition of Hepler and Strand.

Influence of health systems

In describing an activity like pharmaceutical care, the meaning of the words 'pharmacy', 'pharmaceutical' and 'care' must be interpreted with regard to the health system of the country of origin.

For the word pharmacy, an American will have the image of a shop where you can buy health related substances but also all kinds of other commodities like food, cigarettes,

[‡] Personal information Dr. Hanne Herborg, Danmarks Apoteksforenings Kursusenjendom and Dr. Christian Berg, Norske Apotekerforening

detergents, photo equipment etc., and somewhere in the back of this store you can go with your prescription. The British will have images, which depend not only on national but also regional differences. Someone who lives in a city may have the image of, for instance, a department store with mainly beauty-related products and a counter where you can buy OTC products or present a prescription for dispensing. Someone from a village in Great Britain has the image of the place to go for prescription medicines, a limited set of other health care products and perhaps veterinary products. In The Netherlands a pharmacy is the place where you usually only go to have your prescriptions filled, and perhaps purchase self care pharmaceutical products. The only common feature of the meaning of the word 'pharmacy' is therefore a place where you can go to have your prescription filled and where you can buy self care products. All other features are different between the countries mentioned.

Depending on the country, community pharmacies serve anywhere between 1500-18000 patients and the generated income in some countries depends heavily on the turnover from related products, rather than drugs. Pharmaceutical Care is the concept of a patient orientated activity in this broad range of pharmacies with a variation of driving forces.

Professional differences

If Dutch pharmacists describe Pharmaceutical Care from a professional viewpoint, they will relate to the pharmacy practice in their country. Since in The Netherlands professional aspects like medication surveillance, keeping medication records and giving patient-information leaflets are common practice in all community pharmacies, those activities are an implicit part of the definition. In Denmark and Sweden, where keeping medication records is largely prohibited because of privacy laws, certain activities which are standard practice in Dutch pharmacies are hard to conceive and their interpretation of the same definition will therefore show a conceptual difference. In Norway keeping medication records is now common practice in community pharmacies but medication surveillance by computer is not, and the provision of patient information leaflets is restricted to 'group' leaflets of the type used in The Netherlands about 10 years ago[§].

In most western countries the licensed team-members in a pharmacy fill and dispense the prescriptions. There is, however, an amazing difference in the amounts of prescriptions the team-members handle per day. According to the results of the FIP questionnaire, each licensed team-member in a pharmacy in Luxembourg fill on average 130 prescriptions per day, in Spain 107, in the USA 70, but in The Netherlands only 32. Although it is unclear how a prescription is interpreted (the total prescription or the numbers of different medicines on it), this suggests a difference in the professional content of the work of licensed team-members (mostly pharmacists).

Another major professional difference in The Netherlands, when compared with countries world-wide, is that the assistant-pharmacist[**] also may provide patients with prescription medicines, even when no pharmacist is on the premises. This is unthinkable in

[§] Personal information Swan Apotheke, Tromso

[**] A Dutch assistant pharmacist receives a 3 year non-university education in preparing and dispensing medicines

other countries, where a pharmacist always must be present during opening hours and supervise the pharmacist-assistants.

Additionally a pharmacist does not always have an academic degree. In most Scandinavian countries there are two types of so-called pharmacists, but with a different background. One is the university-educated person, the other is the prescriptionist (reseptar), who has not received a full academic pharmacy education but also is called a pharmacist. In a country like Brazil there even are two kinds of pharmacists with a different university education (three or five years after highschool).

The relationships between professionals, especially the physician and pharmacist, also are very different in different countries. In the United Kingdom and the United States it is quite customary for hospital pharmacists to attend the wards-rounds, but according to the FIP questionnaire, communication in the community setting is much less well developed although there have been advances in this area. In the Dutch setting the regular pharmacotherapeutic consultation meetings or the drug-formulary committees in hospitals between pharmacists and physicians ensure a reasonable easy communication between those two professions. In Germany and Switzerland the controversies between pharmacists and doctors about dispensing rights and professional responsibilities make relationships difficult but such relationships are slowly starting to improve as a result of developing communication between the professions[††].

What outcomes?

The concept of outcomes of pharmaceutical care, usually meaning final outcomes, may lead to confusion as well. The major fields of outcome in care a threefold: economic outcomes, clinical outcomes and humanistic outcomes (quality of life and satisfaction)[20].

The word 'outcomes' was deliberately not used in the Dutch definition because of conceptual difficulties, but also because there may be a potential conflict when outcomes are used in the double sense of Heplers' definition, e.g. 'definite outcomes which improve the patients' Quality of Life (HRQL)'. Certain desirable outcomes in a pharmaceutical sense may sometimes conflict with that main outcome of care i.e. to obtain an optimal Health Related Quality of Life. Nevertheless the outcome might be worth pursuing. This can be easily explained by the example of benzodiazepine use in an elderly population. As an outcome in general, decreased use of benzodiazepines in the elderly would be a possible target for a pharmaceutical care intervention, because elderly people in general should preferably not use this class of drugs[21]. Although in the long term HRQL may improve as a group effect in elderly patient if benzodiazepine use is discontinued, certainly not all elderly patients will benefit this way if examined at an individual level. That also explains why in both Dutch definitions, the 'individual patient' is mentioned.

Additionally economic outcomes may conflict with health status or quality of life. If all three types of final outcomes are to be taken into account, which one has priority? In the Dutch definition therefore an explicit choice has been made for the field of quality of life as (final) outcome, which needs to improve under the influence of the provided care.

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†† Personal information Dr. Martin Schultz, ABDA, Frankfurt

1.2 Conclusion and recommendations

The concept of pharmaceutical care is part of health care. There are essential differences between the concepts of pharmaceutical care, disease management or managed care, although there are also some relationships. The main difference can be found in the extent of influence of the patient on the process or concept of care and the initiator of the care concept. In some countries conceptual differences are overlooked and this leads to a confusing use of the terminology. From pharmaceutical care through disease management to managed care there is a decreasing chance for the patient to influence his/her own treatment. However, pharmaceutical care can be, and often is, part of disease management while managed care uses disease management strategies to control costs.

There are different definitions and interpretations of the term 'Pharmaceutical Care'. When defining pharmaceutical care, at least the culture, the language, and the pharmacy practice in the country of origin have to be taken into account. Even after 20 years of evolution of the definition of pharmaceutical care in different cultures, it is not absolutely clear whether pharmaceutical care is a service that could be provided by different health-care providers who have been trained, or a practice philosophy for pharmacy. The current different approaches in the USA by Strand and Hepler illustrate that differences in opinion can even be found within one country i.e. a process approach (Hepler) versus a humanistic approach (Strand). It is therefore amazing that the Hepler and Strand definition (1990) is so often used in other countries, apparently without taking into account the existence of differences in culture, language and the professional context. It is clear from the issues raised in this chapter that authors and presenters should include their working definition of pharmaceutical care when presenting or writing about the concept. A Cochrane review[22] in 1997 reached the same conclusion, based upon articles by Rupp *et al.* and Ilersich *et al.*[23,24].

Social and culturally bound activities like pharmaceutical care need rephrasing, depending on factors in the country of origin and the health care system developments over time. When literally translating definitions, one must also take conceptual language differences into account.

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2
CONCISE HISTORY OF COMMUNITY PHARMACY AND PHARMACEUTICAL CARE IN THE NETHERLANDS

The long history of the profession of pharmacy in The Netherlands has been filled with many important developmental issues. As is the case in many other countries, the profession developed from the extemporaneous preparation and selling of medicines to the dispensing of medicinal products coupled with patient counselling. One could ask if this is a logical development. Why have Dutch pharmacists during the last decade, become increasingly interested in care? Which forces have pushed the profession in this new direction and did these forces originate from outside or from within the profession?

In this chapter an attempt is made to identify the forces influencing the development of the profession and convergence, as a tool to help improve understanding of the current and future professional developments of pharmacy in The Netherlands. The same issues can probably be identified in other countries, although the pace of change may differ.

The separate development of the pharmacist's role in providing advice to physicians and patients, the development of clinical pharmacy and the emergence of social pharmacy are regarded as the core issues leading to the current trends towards the pharmaceutical care paradigm.[*]

The following definitions are used throughout the chapter.

- Social Pharmacy: The science addressing relationships between the drug and the society, including the professional pharmaceutical and medical community.
- Clinical pharmacy: The science addressing the pharmacodynamics and pharmacokinetics of drugs in relation to their effects on the human body.
- Pharmaceutical care: the care given by the pharmacy team (in the field of pharmacotherapy) to individual patients, aimed at improving their quality of life.†

2.1 HISTORICAL RESEARCH

To find an answer to the questions posed in the introduction, a literature review was conducted, supplemented by information from the Internet and personal communications

[*] A slightly reduced version of this chapter with the title has been published in J Am Pharm Ass (Wash) 1999;39:395-401 as: van Mil JWF, Tromp ThFJ, McElnay JC, de Jong-van den Berg LTW, Vos R. Development of Clinical Pharmacy and Pharmaceutical Care in The Netherlands: Pharmacy's Contemporary Focus on the Patient'

† Definition developed by the Dutch Scientific institute for Pharmacy (WINAp), 1998

with key figures in pharmacy practice. Recent developments in The Netherlands, especially during the last 5 to 6 years, were difficult to find in the published literature, because little has been written about this subject. Several textbooks on the history of pharmacy in The Netherlands were used as sources for the early developments. The *Pharmaceutisch Weekblad*, the weekly Dutch pharmaceutical journal and official journal of the Dutch Society for the Advancement of Pharmacy (KNMP) was reviewed (starting in 1945) for articles that indicated a new direction for the profession. Such indicators often appeared in the annual addresses by the chairmen of KNMP, usually one to several years after shifts began.

2.2 THE EARLY HISTORY OF THE PROFESSION

Thorbecke, one of the most important 19th century statesmen in The Netherlands recognised the social importance of drugs to society as early as 1865:

> *Het bereiden van artsenijen is een zaak van algemeen belang omdat de volksgezondheid erbij betrokken is. (Preparing medicines is a matter of general importance, because public health is involved)*

However, when studying the history of pharmacy, it appears to have taken another century before the providers of medicines recognised their impact on society. Although the profession of pharmacy has existed for centuries, until the 19th century there was no institutional separation between their medical role and their pharmaceutical role, a situation which still exists in some other cultures (for example, Korea and Japan). The pharmacists' role was social as well as medical, and included a broad spectrum of patient care activities, including diagnosing. Pre-1800, doctors and pharmacists were organised on a local level only and had very little contact outside the town or village where they practised. Major changes, however, started to occur in the 19th century. Not only were the first pure drugs produced industrially at that time (quinine being the first to be manufactured in The Netherlands in 1827), but legislation also changed and doctors, pharmacists and druggists acquired their own separate roles. In 1555 in 'Docter van Reydt' in Deventer was allowed to visit the local pharmacy for inspection twice a year but at the same time was denied the right to prepare remedies and medicines himself.[1] This limited the doctors' individual rights in favour of the pharmacist. But the major legislation which defined the role of the pharmacist more clearly, and in which the function of doctors was separated from the function of pharmacists, was not introduced until 1804.

It was also in the first half of the 19th century (1842) that the regional professional organization called *Nederlandsche Maatschappij ter Bevordering der Pharmacie* (NMP) was founded in Amsterdam. The year after its foundation this organisation allowed pharmacists from other regions of The Netherlands to become members, and thus it became the national pharmacists organisation[2]. The same organisation is now *called Koninklijke Nederlandsche Maatschappij ter Bevordering der Pharmacie* (KNMP, Royal Dutch Association for the Advancement of Pharmacy).

2.3 THE 20TH CENTURY

When drugs began to be produced industrially at the end of the 19th century, the pharmacist's professional role started to shift in many countries, including The Netherlands, with control of drugs and their distribution becoming the central focus in Western countries. Pharmacists increasingly occupied themselves with the art of dispensing and acquiring chemical knowledge about the drugs that they dispensed[3]. The commercialisation of pharmacy led to a decline in patient care and the level of social and ethical standards associated with pharmacy practice[4]. Even the preparation of medicines gradually disappeared from the scope of the pharmacists' activities; in 1996 only 6.3% of the medications dispensed in The Netherlands were prepared in the pharmacy[5]. In 1999 this share dropped further to 5.5%[6].

During the 1980s and 1990s, however, the pharmacy profession in most European countries returned to a more patient-focussed approach. Internationally the profession has begun to embrace pharmaceutical care, bringing increased attention to pharmacists' activities, including their patient advisory role, the clinical pharmacy movement and the emerging field of social pharmacy.

When did the focus of the profession really shift from preparing drugs to providing information, and when did the role of the patient become more important? In other words, when did the paradigm shift occur in which pharmacists became aware of the needs and expectations of their clients (again), and at what point did reprofessionalisation begin in The Netherlands?

2.3.1 The advisory role of the Dutch pharmacist to physicians

When the pharmaceutical industry started to advertise their drugs to prescribers, physicians and pharmacists increasingly started to question the ethical aspects of these advertisements. In the 1950s, discussion on this subject frequently appeared in the *Pharmaceutisch Weekblad*. The role of the pharmacist in advising physicians became more clearly recognised as a result of the increasing pressure of the pharmaceutical industry on the prescribing process[7,8]. Huizinga, a hospital pharmacist and professor of pharmacotherapeutics in Groningen, was the first (in 1957) to express the view that the pharmacist should be the pharmacotherapeutic advisor of the general medical practitioner (GP)[9]. One year later an initiative between the Royal Dutch Medical Association (KNMG) and the KNMP established this advisory role, which was the subject of the scientific meeting of the KNMP in 1958[8].

A consensus developed that to extend sufficient credibility to such a role, the pharmacist's knowledge of physiology and anatomy needed to improve. It is therefore not surprising that Martens, KNMP chairman, highlighted this educational need in his annual address to the members of the association in 1959[10]. KNMP subsequently took the step of supporting the individual pharmacist by publishing pharmacotherapeutic summaries in the *Pharmaceutisch Weekblad*. The first article, on blood pressure lowering agents, appeared in 1961[11]. By 1962 all four Dutch schools of pharmacy (Amsterdam, Groningen, Leiden and Utrecht) were teaching physiology and pharmacology[12].

Co-operation between physicians and pharmacists intensified with the establishment of the first community health centres in the late 1960s, and the formation of of

pharmacotherapeutic consultation groups (FTOs) in the 1970s and 1980s[13]. The first formularies were drawn up between pharmacists and GPs in the 1970s as a result of this increasing co-operation[14]. In 1985, several professional bodies, among them KNMP and KNMG, drew up a charter on the importance of regional medical-pharmaceutical meetings. This charter was, however, not well supported by practitioners in the field[15].

In 1991 the government initiated a structured approach to the discussion of pharmacotherapy between pharmacists and GPs, by publishing the Guidelines for FTO[16]. Moreover, the GP's had to be stimulated to participate in these meetings and were paid for their attendance (later this payment was included in their regular fees). The regional FTOs were, however, strongly supported by the professional organisations of both pharmacy (KNMP) and general practice medicine (*Landelijke Huisartsen Vereniging* [LHV]). A supportive network developed with the education and research department of the LHV (*Onderzoek & Onderwijs*[O&O]), in the leading role. From that time, the number of active FTOs grew and now almost all Dutch GPs attend the meetings. The Foundation for Appropriate Drug Provision (DGV), a co-operative foundation between KNMP and LHV, was established in 1994 to advise and support regional FTOs (and also support drug information meetings for the public). These regional pharmacotherapeutic meetings have resulted in the current close co-operation between pharmacists and physicians in Dutch communities.

2.3.2 Role of the patient in Dutch pharmaceutical history

As described in the few books available on the history of pharmacy in The Netherlands, patients were never considered as a serious factor in the work of pharmacists until the Second World War. The patient is rarely mentioned in these books -not even in the main work on the history of Dutch pharmacy, *Poeders, Pillen en Patiënten* (Powders, Pills and Patients) by Prof. Bosman-Jelgersma[1]. Of course, patients were customers, making them commercially important, as long as they could pay their bills. However, no insight as to the social relationships between pharmacists and their clients is evident in the major Dutch texts on the history of pharmacy.

In the beginning of the 20th century the NMP defined its pharmacy regulatory role, but again, patients were not highlighted. This is best recognised in the first of a series of 20 bills published in 1920: 'The Society has as most important task to improve the material welfare of its members, pharmacy owning pharmacists, under the proposition that the people are entitled to good pharmaceutical provision, accessible within reasonable distance and not more expensive than proper'[17]. No further description of pharmaceutical provision is given, but it seems reasonable to assume that time only the provision of pharmaceuticals was considered.

The development of the patient advisory role of pharmacists after the 1940s has its roots in pharmacist's increased knowledge of pharmacotherapy, which came about as a result of the increasing role of pharmacists in the provision of advice to GPs, as described earlier. But other societal factors drove this role as well. By 1957, Dutch pharmacists were worried about the influence of the pharmaceutical industry advertisements to the public,[7] and in 1961 they expressed concern specifically about the commercial influence of television on drug consumption[18]. In the same year members of the Dutch Study-Group for Social Pharmacy,

founded in 1958, described the group as 'a proactive organisation for optimal pharmaceutical help to the individual and the community'.[19] The members of this group, consisting of young pharmacists, were at that time pioneers in highlighting the professional responsibility with regard to the customer. It was also this group which stimulated the introduction of social pharmacy into the pharmacy curriculum. From 1972 onwards, social pharmacy has been taught as an independent subject at the Groningen and Utrecht schools of pharmacy, and these courses have contributed to an increased understanding in pharmacists of their role and the role of drugs in society. According to the inaugural lecture of Gerritsma, the role of the pharmacist in the late 1950s was compounding, advising physicians and patients, and the inspecting drugs.[20] In 1962 Martens, the KNMP chairman, mentioned the same roles in his annual presidential address. With the thalidomide disaster in the 1960 physicians, pharmacists, politicians and the public all came together in the realisation that there was more to a drug then just swallowing it.[21,22]

Nelemans, an academic expert on pharmacotherapy, was the first to mention the central role of the patient in the medical-pharmaceutical process in his 1962 article simultaneously published in *Medisch Contact* and *Pharmaceutisch Weekblad*. He stated, 'To my firm belief it should be the patient who is to be the core of everything'. He was the first author to clearly state that pharmacists should accept the pharmaceutical industry's assumption of the task of preparing drugs and that the provision of drugs should ultimately serve the interest of the patient. Although in retrospect this article was a landmark, it aroused little controversy at the time of publication.[23]

In 1964 the president of the KNMP asserted that the pharmacist should be allowed to give information to the public, which at that time was still a revolutionary viewpoint for the profession. It was another few years, however, before KNMP acknowledged that patient rights had to be taken seriously. It was not until 1973 that KNMP, together with KNMG and the Group of Sick Fund Organisations, sent a letter to the Dutch Ministry of Health and Environment stating their common view that the patient has a right to drug information[24]. This increasing importance of the patient's role was also a result of the demands of society for greater rights for the individual after the 'Paris Revolution' (1968) in Europe.

In 1976, the KNMP issued an official charter stating that the pharmacist was allowed to give drug information to the patient. This had been an ethical dilemma for the association and they risked a controversy with different physician organisations that claimed that is was the physician who had the right to decide what information was given to the patient. Finally, in 1977 the chairman of KNMP clearly recognised the prime position of the patient in his presidential address[25]: 'The patient now has arrived in the centre of our thoughts. The patient is a human being for whom we care, and for whom we feel the same responsibility as the physician.'

Recognising the importance of interprofessional co-operation, the charter on patient information was changed in 1980 to state that the pharmacist should provide information to the patient unless the physician clearly asked the pharmacist not to do so. In the latter case, the patient should be informed of the prescribers' preference. However, in the same year the chairman of the KNMP expressed the differing opinion that all patients have the right to

information about their medications, even if the physician denied the pharmacist's right to be the information provider[26].

During the following years, the right of patients to information and the means of information provision were a frequently debated in the *Pharmaceutisch Weekblad* and other forums.[27,28]

In 1985 Cox, chairman of the KNMP, officially confirmed the necessity of an active role of pharmacists and their assistants in the provision of drug information to the patient.[29] Three years later Tromp was the first to indicate the clear potential for tension in the relationship between patients and pharmacies. He outlined the possible problem areas, including the privacy of patients and the educational level and attitude of the co-workers in the pharmacy.[30] This concerns are now being addressed largely through the education of pharmacy staff, with an emphasis on personal commitment to pharmaceutical care.

2.3.3 Development of package inserts and patient information

Information leaflets have played a peculiar role in the development of Dutch pharmacy practice. Initially they were developed as package inserts by the manufacturers and written in scientific language to serve as an information source for physicians, although the physicians had rarely time to read them. By Dutch law these leaflets were removed from the package before dispensing and discarded before the pharmacists dispensed medication. In 1975, however, the law was changed, and pharmacists were not allowed to remove the inserts unless they dispensed only part of a package, which is common practice in The Netherlands.

Since 1974 KNMP and the KNMG have jointly published a series of informational leaflets on groups of drugs. These leaflets were all clearly patient-oriented instead of physician-oriented. In 1977 specific drug information leaflets were produced, which covered the field of generic drugs and were designed to overcome the lack of written information available to the patient on these agents. The pharmaceutical industry has been slow to follow the demand for special patient-information leaflets. In 1983 and 1984 the chairman of KNMP stressed that the manufacturers leaflets should be understandable to the patient, which is still not always the case[31,32].

These developments, among others described in this chapter, illustrate how the professionals, as well as the politicians, have attempted to satisfy patients' demands for more information about the drugs they were taking.

2.3.4 Clinical pharmacy and medication surveillance

The first integrated approach to drug use and patient care seems to have come about with the development of clinical pharmacy and, shortly thereafter, medication surveillance. The development of clinical pharmacy was first described in The Netherlands by van der Kleyn, a hospital pharmacist, and supported by van der Vlerk, a community pharmacist[33]. The clinical pharmacy movement started first in the United States in the late 1960s in The Netherlands in the early 1970s.[34] Interestingly, the development of clinical pharmacy in the United States resulted from the simultaneous desire by pharmacists to extend their professional roles and the shortage of physicians at that time.

The Dutch front runners in this field received remarkably little response from the professional organisations. This is illustrated by the annual speech of the chairman of KNMP and an article by Boiten published in the same year. In both, the main professional problem was purported to be the age-old controversy of trade versus professional ethics; no attention being given to the development of clinical pharmacy[35]. However, 4 years later, the inaugural lecture of Prof. Merkus at the University of Amsterdam in 1974, clearly demonstrated an appreciation by pharmacy faculty of the concept of clinical pharmacy[36].

In The Netherlands, clinical pharmacists initially viewed the patient very much as a number of tissue compartments into which drug penetrated and resided to differing extents (pharmacokinetics) while outcomes of pharmacotherapy (pharmacodynamics) were measured as biological or physiological responses. Obviously, this type of patient-oriented pharmacy still was not yet focussed on care or the social life of the patient. Currently clinical pharmacy internationally develops in the direction of individual patient and pharmaceutical care[37].

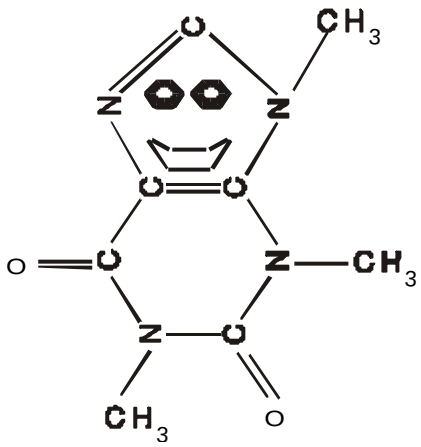


Figure 2 -1 The patient according to an old clinical pharmacist

The first opportunity for pharmacists in The Netherlands to truly intervene in patient therapy in a systematic way came in 1973, when the first medication-evaluation instruments were constructed (e.g. the translation by Merkus of Whiting's interaction chart)[38] and card-systems were developed containing prescription information in the pharmacy[39,40]. When computer software later became available to store patient medication records[41], medication surveillance became a realistic option for all community pharmacists. In 1976 Nieuwenhuis, the chairman of the KNMP, acknowledged the importance of medication surveillance but also stated that it still was at a preliminary stage and had to be developed further[42]. With this statement he encouraged the profession to accept this new role for the pharmacist.
Within the framework of clinical pharmacy, the approach to the patient was an indirect one. It often happened that if the pharmacist thought that the patient could benefit from a change in therapy, he would contact the physician and perhaps not inform the patient. Informing patients was still considered to be unethical. Slowly, by 1987, information

provision and medication surveillance began to merge into medication counselling in community pharmacy. Although the patient was considered to be an important subject, his or her active role in this process was still not fully acknowledged[43,44].

With regard to medication surveillance, since 1990 almost all Dutch pharmacies have had computer systems that maintain patient medication data and perform medication analysis[45]. These patient medication records are almost complete because until 1995 patients insured through sick-funds (approx. 70% of the Dutch population) always had to be registered in one specific pharmacy. Even in 1997, 93% of the patients still tended to go to one pharmacy. This factor makes the medication history, and hence the medication surveillance, very complete. On average, a pharmacy system now generates 0.4 to 0.5 surveillance message per prescription. Approximately 15% of these messages are on interactions, 25% on contra-indications, 27% on compliance and 12% on dosing.[§] As part of quality control, many pharmacies now have routines to handle the messages generated by their surveillance systems.

The Dutch organisation of GPs claims that its members, and not the pharmacists, should perform medication surveillance. In practice this would be rather difficult since Herings found in 1997 that GP records contain data on about 75% of the patients' medication only. In high-risk groups e.g. the elderly or people who receive complex pharmacotherapy, the study indicated that the GP has access to details on only approximately 50% of the medication records. Increasingly, however, GPs in The Netherlands now have on-line access to the medication data of the pharmacy[46], which they use to prepare renewal prescriptions and to complement their own patient data. Because Dutch pharmacists and their assistants also take Hippocratic oath when they graduate as professionals, this exchange of information can benefit the patient without violating principles of privacy.

The development of medication counselling from medication surveillance began in the mid-1980s, and the patient information leaflet became an integral part of this counselling activity. In 1988, a project was undertaken in which the idea of an individualised patient information leaflet was considered. The first versions of these leaflets were very readable, with the name of the patient and the individual directions for medication use integrated into the text[47]. This idea has now been developed further by Pharmacom® computer systems which selectively prints the different information blocks according to characteristics of the patient (e.g. sex, age, contraindications) and the other drugs he or she is using.

2.4 TRANSITION TO PHARMACEUTICAL CARE

By the end of the 1980s, the patient had largely become the focus of the pharmacist's professional attention. However, the mental switch had not yet been made, because pharmacists considered themselves primarily drug specialists who protected the public from drug misuse by performing medication surveillance and providing information. Their knowledge and abilities were not integrated into a patient-centred concept of comprehensive care. For this change to take place, catalysts were needed to merge the

[§] Unpublished data from an ongoing project at the Science Shop for Pharmacy, Rijksuniversiteit Groningen, The Netherlands

different developmental strands. The catalysts were the activities of Hepler and Strand[48], and the law on medical and paramedical treatment (WGBO).

The ideas articulated by Hepler and Strand for the development of pharmaceutical care were adopted quickly by the International Pharmaceutical Federation (FIP). In 1991 the executive committee of the community pharmacy section of FIP introduced the concept of including continuing education in its annual conference[49]. Pharmaceutical care was suggested as the central theme for this program, and Hepler was invited to chair the program committee. The first series of courses on pharmaceutical care was presented at the FIP conference in Tokyo in 1993. In the same year, pharmaceutical care was acknowledged by FIP as part of good pharmacy practice (GPP). In 1996 pharmaceutical care was further acknowledged by World Health Organisation (WHO) in a joint statement with FIP on GPP in community and hospital practice settings[50].

Members of the executive committee and Europharm Forum (a European professional pharmacy group related to WHO) introduced the subject of pharmaceutical care to The Netherlands in 1993. As already mentioned, Dutch community pharmacists were familiar with the field of clinical pharmacy and medication surveillance, the provision of information to patients and co-operation with physicians. With the definition of Hepler and Strand as a working definition at that time, the missing elements were the level of responsibility that the pharmacist should take regarding patient care and the central role that the patient should play in the patient-physician-pharmacist relationship.

In 1994 the KNMP positioned itself in the debate about the role of the pharmacist by emphasising cost containment as a means of achieving rational pharmacotherapy. This was an important political issue at that time[51]. However, further emphasis on the role of the patient followed in the wake of a public opinion survey on the role of the community pharmacists, conducted that same year. The public saw the main tasks of pharmacists as distributing medications and advising patients, other important professional roles, such as medication surveillance, advising GPs, and containing cost were barely acknowledged[52]. The publics' limited view on the role and tasks of pharmacists did not particularly please the pharmacists; however, at least society's opinion on pharmacists had changed dramatically from around 1900, when Ambrose Bierce, a U.S. writer and journalist wrote in his *Devils Dictionary*[53]

> *APOTHECARY, n. The physician's accomplice, undertaker's benefactor and grave worm's provider.*

The relationships between patients and many care providers in The Netherlands are covered in WGBO, but pharmacists are not mentioned in this law**. This omission prompted KNMP to sign an agreement in 1995 with the umbrella organization of patient organizations (NPCF), stating the right of the patient to receive care and information from the pharmacist. Partially as a result of that agreement, KNMP officially confirmed the central role of patients and their demands for care in the 1996 public statement *'Met het oog op de Patiënt'* (with the eye

** According to an agreement between the Minister of Health and the KNMP in October 1999, the pharmacists will now be incorporated in this law in 2000.

on the patient)[54]. This focus on the counselling and advising individual patients, and on the continuity of care, signifies the completion of the official paradigm shift for the profession.

This shift, however, still remains to be made at the individual pharmacy level, not only in The Netherlands but also in many other countries. Where medication surveillance and the pharmacist's obligation to provide care come together, in practice different forms of therapeutic outcome monitoring will emerge. However, pharmaceutical care is more than optimising outcomes. It is a practice philosophy in which the patient is the core of all professional activities of the pharmacist and his or her team. Many barriers continue to impede the full implementation of pharmaceutical care; time and money the most obvious ones. Other barriers can, however, be found in the field of behavioural sciences, and research is addressing these latter issues, especially in the United States[55].

2.5 Discussion and Conclusion

The recent movement of Dutch community pharmacy towards a pharmaceutical care model is the result of many discrete influences, including

- Development of the pharmacist-physician relationship;
- The development of the pharmacist-patient relationship;
- Advances in the education of pharmacist;
- Increased provision of information to patients;
- Improved medication surveillance and conceptualisation of clinical pharmacy;
- Development of social pharmacy.

Many of these influences were unrelated, making the development of pharmaceutical care in The Netherlands somewhat episodic and dependent on chance (Table 2-2). The convergence of various influences into the pharmaceutical care model required strong catalysts including the intellectual philosophy advocated by Hepler and Strand and the emerging demands of society for more information about medication therapy.
The sequence of events, however, is not surprising. Pharmacy is an open system that operates in the marketplace. As such it is sensitive to many outside influences.

In The Netherlands, the pharmacy profession appears to have been reactive to outside influences rather than proactive in planning for the future. Pressure of the pharmaceutical industry initiated the development of the pharmacists' advisory function of pharmacists. In the United States, the development of clinical pharmacy was initiated as a reaction to changes in the field of medicine. The demand for drug information came from consumer organisations, while the development of social pharmacy seems to have been initiated by the university community as a result of societal pressure.

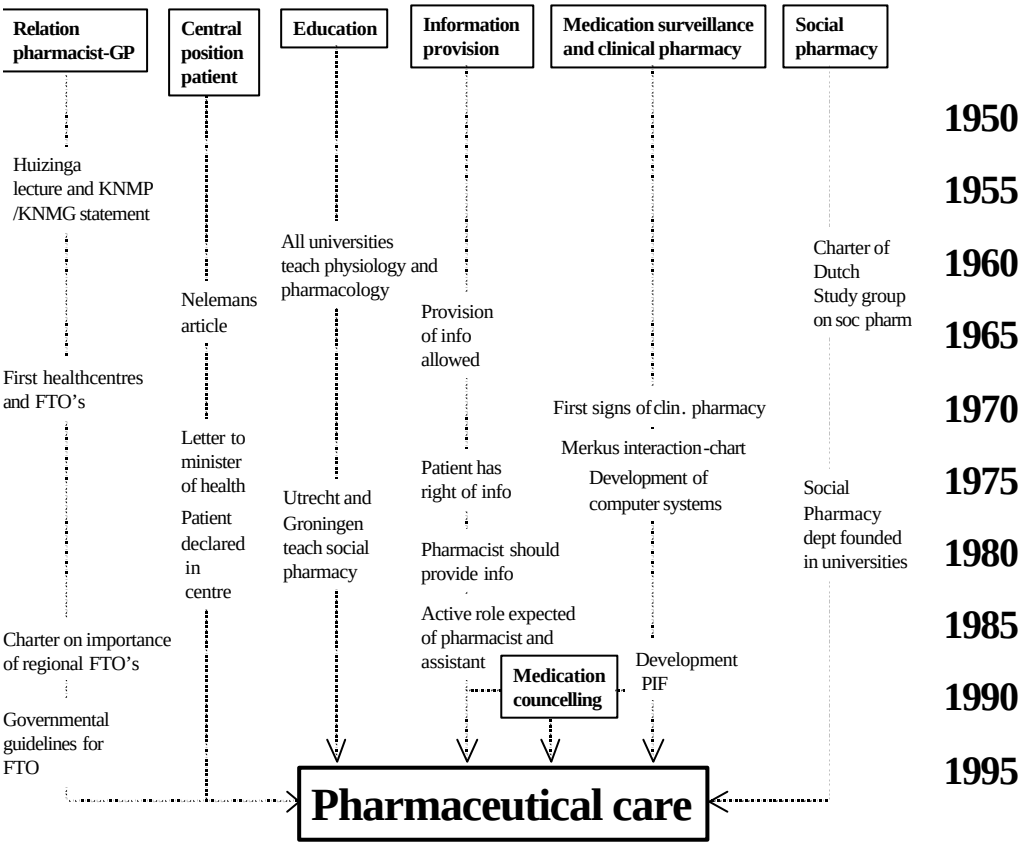
The development of the pharmacy profession in The Netherlands has depended much more on outside forces (government, industry, sick funds, patient-groups and computer developments) than on pressures from within the profession. It should be stressed, however, that pharmacy as a profession is not alone in this 'forced' evolution. Most other professions have followed a similar path of reacting to pressures from their 'clientele'.

Although the conservatism of pharmacy as a whole has been highlighted, the existence of a front-runner role of some pharmacists must be acknowledged.

Some professionals with vision pick up early signals and try to develop the professional activities that are required and desired by society. The rest of the profession eventually follows their pioneering work. This takes time and dedication due to the many barriers that have to be overcome. We are sure the profession is developing in the right direction, with ever-greater emphasis on the patient and societal needs. It is time, however, for the profession to become more proactive in setting its own agenda. The new discussion on the future of pharmacy in Great Britain (Pharmacy in a new age) and in Northern Ireland (Pharmacy 2020) are inspiring examples, which could usefully be followed by many other national pharmacist organisations.

A proactive attitude, not only from the front-runners, but also from the entire profession, is desirable if pharmaceutical care is to be incorporated into routine community pharmacy practice.

Table 2-2 History and development of Pharmaceutical Care in The Netherlands



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Part II

The TOM and OMA projects

3
PHARMACEUTICAL CARE RESEARCH, TOM AND OMA

DESIGN AND METHOD OF THE INTERVENTIONS INCLUDING CONSIDERATIONS

This chapter describes the development of the methodology of two intervention studies, TOM and OMA. Both studies are designed to prove the effect of the provision of pharmaceutical care. TOM studies the effects of pharmaceutical care in asthma patients, OMA studies the effects of pharmaceutical care in the elderly, using 4 or more different medicines.

The hypothesis that pharmaceutical care improves patients' Health Related Quality of Life (HRQL) can in principle only be proven by providing the first and measuring the latter in a controlled trial. The effects of the provision of pharmaceutical care by the pharmacist are best measured in patients receiving chronic medication, since care is a process over time and more drug related problems can evolve. This does not mean that a concept like pharmaceutical care has no place in over the counter (OTC)-medication or short-term use of prescription drugs e.g. courses of antibiotics or pain-relieving medication. But it is more likely that the benefits of pharmaceutical care can be proven in those patients who have a more or less steady medication-regime, since they visit pharmacies frequently and their medication gives the pharmacists different angles to apply their care, skills and knowledge.

The contents of pharmaceutical care can be such that many different approaches are possible (see Chapter 1). A basic pharmaceutical care circle can be applied, with an emphasis on therapeutic outcome monitoring (TOM) like Heplers' concept of pharmaceutical care[1]. This type of pharmaceutical care is suitable to be applied to patients with specific, drug sensitive diseases like asthma and diabetes. The medication can then adapted to the actual disease state of the patient. In those cases it must be possible to prove that the intervention results in a short time better control of the disease. But one can also imagine a more diffuse process in which the pharmacist performs drug use evaluations, keeping an eye on specific patient characteristics, interactions, other adverse drug related problems including compliance, where counselling is an almost continuous process like described by Cipolle, Strand and Morley in 1998[2]. In such comprehensive pharmaceutical care many pharmaceutical care circles may be present at the same time and influence each other. Preventive actions by the pharmacist will not directly be recognised by the patient or reflected in a better short-term disease control, for instance in hypertension. Such a type of pharmaceutical care can be applied in patients with some equal characteristics (e.g. age, gender) or multiple or complex diseases. In those cases the link between medication and effect is less clear but the same benefits may evolve like increased compliance, less side effects, better coping and presumably a better HRQL.

In both types the increased professional attention by the pharmacist in itself may already have an improving effect on several outcomes, or as Louis Nizer said:

'Words of comfort, skilfully administered, are the oldest therapy known to man'[3].

The first part of this chapter gives general information about the drug use and possible drug related problems in both populations. The second part outlines the study design, data-collection and the interventions, followed by some additional considerations and a table with an overview of the design.

3.1 INTRODUCTION

3.1.1 Asthma and drug use*

According to the Nederlands Astma Fonds, about 5% of the Dutch population have asthma, i.e. 700,000 people. Another 5% have chronic bronchitis or emphysema. The mortality rate as a result of asthma in The Netherlands is rather low in the age group 5-34 year: 0.3 per 100,000. This means that measuring changes in mortality as a result of an intervention will not render useful information, unless the sample size and duration of the project are very large. Obstructive airway diseases in The Netherlands are mainly treated by the general practitioner (80%), the rest by medical specialists. Inhalation therapy is the most common treatment method (86%).

In several projects it has been proven that many patients with asthma feel insecurity, fear, depression and anger. Part of these feelings probably originates from insufficient information and knowledge about the disease. It can be expected that more knowledge, better guidance of the treatment and improved pharmacotherapy will influence these feelings.

Many asthma and COPD patients still have questions about their disease and its treatment. As a result of a Dutch television program *Het leven gaat door* ('Life continues') in May 1997, a telephone team received 146 questions. Most questions (47%) were related to the aetiology of the diseases and drug use and 29% were related to drugs and drug use. Findings from van Ganse *et al.* show a suboptimal education and health status in a random sample of asthma patients and most patients expressed a negative attitude towards the use of inhaled corticosteroids, which is the cornerstone of the treatment[4].

It has been postulated that the measures of emotions are sometimes better predictors of the course of asthma than some medical parameters like PEF-values. But measuring these emotions is too complex for the purpose of a large-scale study. On the other hand, measuring HRQL, as will be performed in the TOM study, includes the emotional aspects of the disease. More practical and measurable parameters are frequency of awaking at night, presence of morning dip in peak expiratory flow rate (PEFR) and frequency of use of beta-agonists.

The perception of symptoms in COPD and asthma-patients is poor in general, but in asthma this perception is better than in COPD[5]. Usually it is found that in asthma there is

* Throughout this paragraph data and statements are also used from: Maillé AR, Kaptein AA. Omgaan met CARA. Sociaal wetenschappelijk CARA-onderzoek op weg naar de toekomst. Leusden, Astma Fonds, 1993. ISBN 90 668 014 0.

only a discrepancy between objective and subjective obstruction in 15% of the cases. Self-measurement of the peak-flow improves the signalling of bronchial obstruction, although keeping a symptom-diary might sometimes serve the same purpose. In the publication of Kendrick *et al.*, a high frequency of poor symptom perception of 60% was found in patients treated for asthma in general practice, however, in this study no proper difference between asthma and COPD was made[6].

In The Netherlands in 1993, when this study was designed, no self-management scheme was advised by the Dutch organisation of general practitioners (NHG), nor by the patient-organisation or the Dutch Asthma Foundation. Glaxo introduced a self-management program in March 1993, but it was not widely distributed at that time. In some regions lung-specialists started to introduce self-management in 1995 (i.e. Enschede). Although no well-designed controlled study has been published to date on the positive effects of self-management and self-treatment, results of other studies indicate that self-management improves asthma control[7].

According to a study published in 1989 only approximately 13% of the asthma patients show full compliance[8]. Better coaching of asthma patient therefore seems desirable, not only to prevent acute exacerbations of asthma but also to improve persistent pulmonary morbidity and prevent emphysema, of which the first is closely linked with the quality of life[9]. It is to be expected that application of pharmaceutical care will improve compliance. Improving communication and implementing self-management have positive effects on compliance. Some general practitioners as well as lung specialists and paediatricians in The Netherlands are becoming more aware of the improvements achieved in self-managed asthmatics[10], but the patient's lack of knowledge proves to be a barrier[11]. Occasionally special asthma-nurses and clinics are put in place. The TOM study uses these strategies, but originated and implemented by the community pharmacist. Self-management plans in themselves are known to significantly reduce the number of doctor consultations and the use of oral steroids/inhaled beta-mimetic agents, if properly implemented[12].

Asthma is a reversible obstructive airway-disease. The causes of the obstruction can be manyfold, ranging from emotions or effort to allergens or smoke. If obstruction occurs, there is always some form of inflammation process present in the airways, which can be treated with drugs in several ways. The acute treatment with short acting beta-agonist agents usually is the first step. The actual inflammation is not being treated by this class of drugs, but the dilatation of the airway by itself should last long enough for the cause to subside. What the next step should be, if occasional treatment with a beta-agonist agent by inhalation does not treat the condition sufficiently, depends on the protocol followed by the physician, but in general chronic use of inhaled corticosteroids is advised.

Protocols or critical pathways for the treatment of asthma differ over the world. Currently most protocols adhere to two international consensus reports on the treatment of asthma. The older one is very clear but does not include long acting beta-sympaticomimetic agents in the treatment schedule[13]. The newer one is more diffuse but allows for long acting beta mimetic agents to be used. The Dutch standardised protocols differ only slightly from the international consensus documents[14]. Since the start of the project a new Dutch standard has appeared with a slightly different approach, in which long acting beta-mimetic agents

are introduced into the treatment, but this standard has not been used as a basis for the study[15]. Anti-leukotriene drugs[16] are not yet included in any treatment-standard.

3.1.2 Drug use in the elderly

The use of drugs in the elderly has been subject of many research projects. Several forms of problems may occur when elderly people use different drugs, e.g. compliance problems, increased risk of adverse drug reactions and drug interactions, and drug misuse[17]. In general the researchers have found a significant overuse of drugs, estimated to be 25% by Lamy[18].

The use of drugs in the elderly is high. From a study in a group of independently living older people in a rural area in The Netherlands it was concluded that over 90% had used drugs in the four weeks previous to the interview, 87.4% on prescription and 12.6% over the counter (OTC). In a Swedish population of patients over 80 years old around 1995, Giron *et al.* even found that 94.1% had used drugs, during the period of 2 weeks before the interview[19]. Using a certain drug for a period longer than originally intended (55%, 'once a drug, always a drug'), appeared to be a major problem followed by incompatible combinations of drugs (22%)[20]. In an American study published in 1992, an average number of 5.6 drug-related problems per patient was found in the elderly over 60, who were responsible for taking their own medication[21]. From the results of these research projects it can be concluded that several factors are responsible for the high and/or incorrect use of medicines in the elderly. Firstly women tend to use drugs incorrectly more often than men do. The chance of incorrect use increases with the frequency of visits of the GP, the amount of help people need in handling their medication, the amount of information they have and the positive attitude towards the use of drugs in general. In general patients are quite satisfied with the provision of information but from the result of the first study it is surprising that people who read the information leaflets and get more oral information, also tend to show incorrect use more often. The latter findings might be due to a misinterpretation of information, or a bad quality of the information leaflets.

The principal groups of drugs being used in the elderly in The Netherlands are cardiovascular drugs, analgesics, sedatives, antacids and hypoglycaemic agents. According to a Dutch publication in 1993, drug use decreases from 2.5 to 2.1 drugs on average, when older people are admitted into a psychogeriatric ward[22]. This indicates that drug-use can decrease if it is properly monitored.

Data from the AFTO-database[†] show that in 1996 benzodiazepine hypnotics and sedatives are used by 33% of the Dutch population over 65 years (calculated on 10,334 patients of whom the date of birth was known). In the general population this figure is only 14.5% (calculated on 65,702 patients of which for 1.78% the date of birth is unknown.). This enormous overuse of benzodiazepines (they use 127% more then the average population) has to be taken into consideration when developing a pharmaceutical care project in the elderly, because this class of drugs has many unwanted effects in this population especially in higher dosages[23]. The figures found in the AFTO population are in the same range as the

[†] Figures generated by the AFTO-project June 1993. Rijksuniversiteit Groningen. Working Group Social Pharmacy and Phamacoepidemiology. Miss Corinne de Vries

ones found by van Hulten in his rural population in the North of The Netherlands (131.2% and 145.3% in 1992 and 1990 respectively)[24].

The pattern in the USA is somewhat different and therefore not comparable in detail. In a study published in 1992, using the database of the Established Populations for Epidemiologic Studies of the Elderly, 60-68% of the men and 68-78% of the women older then 65 use drugs on a doctors' prescription[25]. According to the results of the same project 52-58% of the men and 64-76% of the women used OTC-drugs. Users of drugs were especially found in the elderly with symptoms of depression. Also handicapped people, elderly people who were in hospital more often than average and people with little insight into their own health used more drugs than average. It is probable that this difference between the countries is a result of differences in insurance-systems.

3.2 TOM AND OMA, THE STUDY DESIGN

It was decided to study the effects of pharmaceutical care in asthma patients, where Therapeutic Outcomes Monitoring can be applied and self-management can be put in place[26]. This study is called TOM of Holland. In this patient group improved drug-use should result in better control of the disease, better coping behaviour and through these effects, a better HRQL. In spite of the relative clear-cut model of Therapeutic Outcome Monitoring, it was nevertheless expected that several pharmaceutical care circles would be present at the same time. Parts of the basics of the Dutch study are described by Jansman *et al.*[27]. Similar studies are under way in Austria, Belgium, Florida (US), Iceland, N. Ireland, Norway, Germany, and Canada. A TOM-asthma study was completed in Denmark in 1995, but to date the results have not been published in the international literature.

It was also decided to study the effect of pharmaceutical care in the elderly over 65, using 4 or more different drugs and living independently. This study is called OMA (which stands for 'Ouderen Medicatie Analyse') or Elderly Medication Analysis. In this patient group the increased rationality of the treatment and better control over side effects, together with the increased attention by the pharmacist should result in a better HRQL. Similar studies, based upon our protocol, are now under way in Denmark Germany, Ireland, Northern Ireland, Portugal and Sweden, co-ordinated through a Biomed grant.

3.2.1 The hypothesis

The hypothesis for both the TOM and OMA study was: A specified process of pharmaceutical care does improve the HRQL of the patients involved, the satisfaction of patients, pharmacists and GPs involved, the knowledge on drugs and diseases, the drug use and the use of medical resources of the patient. Derived from this hypothesis, the outcomes to be monitored in the studies are the following.

- Health Related Quality of Life of patients;
- Satisfaction on the provided care of the patients;
- Satisfaction on the provided care of the GPs;
- Satisfaction on the provision of care of the pharmacists;
- Disease state;
- Patients' knowledge of disease state and medications;

- Drug use (including compliance);
- Use of medical resources.

3.2.2 Reference groups

Both studies are designed as controlled (cohort) studies, because pharmaceutical care is in a rapid development (see Chapter 1 and 2) in The Netherlands. External reference groups for both studies were selected from randomly chosen pharmacies.

Crossed design, internal reference groups

What happens if a pharmacist starts providing pharmaceutical care to a specific group of patients? Would there also be a general influence on the way other patients, with other characteristics than the intervention group, are treated in this pharmacy? Would there possibly be an influence on the attitude of the pharmacist at the counter or the provision of information? To study these effects it was decided to include a second reference group, the internal reference group. Table 3-1 outlines the connection between the TOM and OMA-study. The reference patients were all selected in the same manner as the intervention patients.

N.B. In the TOM-pharmacies, the elderly were the internal-reference group; in the OMA-pharmacies the asthma patients were the internal-reference group.

Table 3-1 Cross links between TOM and OMA-study

	Intervention patients	Reference patients for TOM	Reference patients for OMA
TOM pharmacies (n=18)	+	-	+
OMA pharmacies (n=21)	+	+	-
Ext. Reference pharmacies (n=15)	-	+	+

3.2.3 Patient selection

The TOM project

To be able to measure the changes in all domains of HRQL with one of the selected instruments, the SF-36, a minimum of approximately 300 patients was required (see section 3.6). Therefore an attempt was made to find 20 pharmacists all over The Netherlands, who would each recruit 25 patients, to allow for a dropout rate of 40%.

The intervention pharmacies for the TOM study were directly requested to co-operate by the research team, on the basis of a shown interest for the research. The pharmacists of those pharmacies were already active in the field of providing information and actively involved in medication surveillance. Patients were selected by means of the automated prescription database in each participating pharmacy. To be able to have a population with mild to moderate asthma, the pharmacists were asked to provide a list of all patients who had

received both beta-mimetic agents and corticosteroids per inhalation in the previous 6 months[‡]. Excluded were:

- patients younger then 20 (less likely to co-operate);
- patients over 45 (more likely to suffer from COPD);
- patients using continuous oral prednisolone or more then 3 courses of oral antibiotics or prednisolone per year (more likely to have chronic bronchitis or severe asthma);
- patients using ipratropium bromide (more likely to suffer from COPD).

These selection criteria later proved to resemble those of Osborne *et al.*[28] and are more elaborate than those mentioned by van der Molen[29]. The selection criteria were tested in one pharmacy by checking with the GP if the selected patients indeed had asthma. In 95% of the cases this proved to be the case, according tot he GP. When the same therapeutic selection criteria in this pharmacy were applied to 45-50 year old patients, 73% of this group had COPD according to the GP.

After the initial selection in the pharmacies, the research team randomly assigned a new sequence to the list and the pharmacists were asked to ask the patients in the given sequence by telephone if they would like to co-operate. Then an information leaflet was provided through the pharmacist and a preliminary registration form. This form was sent back to the research team. Pharmacists continued until they had 30 positive responses and 30 registration forms were received. Informed consent-forms were signed at intake. Control patients were recruited in the same way, in randomly chosen control pharmacies and the pharmacies participating in the OMA project.

The OMA project

In the elderly group a higher dropout rate was expected than in the TOM-group. To be able to measure the expected changes in most domains of HRQL with one of the selected instruments, the SF-36, a minimum of approximately 300 patients was required (see section 3.6). Twenty pharmacists throughout The Netherlands were needed who would each recruit 30 patients, thus allowing for a dropout rate of 50%.

The intervention pharmacies were recruited by means of an article in the weekly Dutch pharmacist journal the *Pharmaceutisch Weekblad*. Most of the pharmacies included were already active in the field of providing information and actively involved in medication surveillance. Patients were selected by means of the automated prescription database of each participating pharmacy. Pharmacists were asked to provide a list of all patients who were 65 or older and used 4 or more different drugs on prescription. Patients living in nursing homes were excluded from the study. The research team then randomly assigned a new sequence to the list and the pharmacists were asked to ask the patients by telephone if they would like to co-operate. The research team then provided an information leaflet via the pharmacist and a preliminary registration form. This form was sent to the research team. Pharmacists continued till they had 30 positive responses. Informed consent forms were signed at the intake.

[‡] The possible number of patients per pharmacy was estimated by a small test-run in 5 pharmacies, in which all users of corticosteroids and beta-mimetics were listed per age-group of 5 years. This usually generated between 50 and 60 patients in the age group between 25 and 40.

When people are filling in a HRQL questionnaire, they are supposed to be able to express their opinions and feelings and have a reasonable possession of perceptual functions. In the case of the elderly this might not always be the case and therefore it was decided to include an instrument for measuring the mental state, the Mini-Mental State Examination (MMSE)[30] into the OMA study. This instrument is a brief screening test that quantitatively assesses the severity of cognitive impairment. The MMSE seemed the most appropriate because its contents are highly verbal, which suits research purposes in the field of care. It has been well validated[31,32,33] and used all over the world. It has been translated into Dutch[§]. Although the Dutch MMSE is not fully validated, it has been in use for a long time[34,35]. Some authors state that the MMSE scores are also sensitive to changes in drug use, especially CNS drugs. This was, however, not confirmed in a recent study by Janzing *et al.*[36]. The cut off point (19-23) depends on age, education and social status[37]. After the intake a final selection by the research team excluded all patients with a MMSE score < 20. The MMSE was administered face to face. In the elderly intervention group the pharmacists administered the MMSE while in the reference group it was administered by paid volunteers or the staff of reference pharmacies. The research team trained all interviewers.

Control patients for the OMA study were recruited in the same way, in randomly chosen control pharmacies and the pharmacies participating in the TOM project.

3.2.4 Length of the studies and time schedule

Pharmaceutical care was expected to be a lengthy process. To allow for the process and the outcomes to be studied as completely as possible it was decided to design two-year studies. Because it was also known that changes in HRQL have the tendency to return to the original value, intermediate assessments were planned.

The selection procedures started in September 1994 and were completed in November 1994. Both studies therefore started around December 1994. The time-schedule for the collection of the different data can be found in table 3-2. In the same table it is recorded who was responsible for the collection of the data and where the data should be collected. Data collection was concluded relatively late in May 1997, due to the fact that some intervention pharmacies experienced delays in performing the intakes and that there was a delay in getting the data to the research centre.

3.2.5 Training of the pharmacists

To enable the pharmacist to provide pharmaceutical care optimally, three one-day education sessions were organised before the start of the projects. During the projects one-day education and evaluation sessions were organised every 6 months (see section 3.5).

3.3 Data Collection

Three sources were used for collecting data: the patient, the pharmacists and general practitioners. Information from pharmacists and GPs was obtained by mailed questionnaires. Information from the patients was obtained in two ways.

[§] We obtained the Dutch version in September 1994 from Prof. Dr. T.J. Heeren, H.C.Rümke groep, Zeist, The Netherlands

- Through pharmacists, at the intake and the half-year consultations;
- Through mailed questionnaires, telephone assisted and directly sent back to the research team (e.g. HRQL, satisfaction).

Answers to questions in our questionnaires could in general be given in either a 2 point (yes/no) scale or a 5-point Likert scale (global frequencies, opinions). Validated instruments were not altered and the appropriate scales were used. Since similar projects are now being or have been conducted in other countries, the use of international instruments for measurements of final outcomes, if available, was preferred to be able to compare results. This applies especially to the field of HRQL assessment.
In the table 3-2 the main items on which data were collected, when they were collected and by whom, are summarised.

Table 3-2 Time schedule TOM/OMA incl. sources of data

	Months					To be collected at/by#		
	0	6	12	18	24	Patient	Phcist	GPs
Demographics	☐					R,P	R	
HRQL	☐	☐	☐		☐	R		
Satisfaction with care provision	☐	☐	☐		☐	R	R	R
Drug use	☐	☐	☐	☐	☐	R,P		
Use of medical resources	☐	☐	☐		☐	R		
Severity of symptoms*	☐	☐	☐		☐	R,P		
Peak flow data*	☐	☐	☐		☐	R		
Knowledge about diseases and	☐	☐	☐+		☐	R		
Compliance with drug use	☐	☐	☐		☐	R,P	R	
Time investment of pharmacist		☐	☐		☐	R	R	
Opinion on PhC		☐	☐		☐	R	R	R
Contents of consultations		☐	☐		☐	R	R	

* Only in TOM project
# P=Data collected by pharmacist. R=Data collected by research team directly
+ During the studies it was decided to omit the 12 months knowledge assessment

3.3.1 Dealing with Bias

If data were sensitive to bias as a result of the relationships between the pharmacists and other parties, those data were asked for in the mailed questionnaires that should be sent back to the research centre directly. Some items were to be double-measured because self-reported data sometimes differ from data reported by others (e.g. compliance, health status, the contents of consultations, time investment).

3.3.2 Collection of demographic data

To be able to interpret the results, *demographic data* were collected from the patient (age, gender, life-style, etc.) by questionnaires and patient interviews by the pharmacists. Basic data about the pharmacists and his/her pharmacy (size and location of the pharmacy, age and interests of the pharmacist, number of workers, computer systems) were collected through interviews by the research team.

3.3.3 Collection of data on process, intermediate and final outcomes

Although *Health Related Quality of Life* is by definition the final outcome of pharmaceutical care (see Chapter 1 and 2), not only this outcome was measured but also other possible effects of pharmaceutical care, for instance on the use of health service and drug use. In the field of HRQL it was decided to use the SF-36 as generic instrument[38] and the Asthma Quality of Life instrument devised by Juniper and Guyat[39] (see also section 3.6). To avoid possible bias when the intervening or other pharmacists administer those questionnaires, it was decided to use mail versions to be returned to the research team. It was also decided to provide the patients with independent telephone assistance for filling in questionnaires because HRQL instruments (and our questionnaires) are lengthy and sometimes complex.

The patient's *satisfaction* with the care provided is of course of paramount importance. According to Robert satisfied patients get well more quickly[40]. This satisfaction was measured by straightforward questions in the questionnaires, but also by asking opinions on the role and skills of the pharmacist and other health care professionals. Satisfaction-questions were always asked directly to the patient by the research team.

In view of current and future developments also *the satisfaction of pharmacists and general practitioners* can not be neglected. The professional satisfaction of the pharmacists, with the provided care, and of the GPs involved, about the provided care, was also asked directly in a self-reported questionnaire.

The *data on drug use* were collected, 6 months before the intervention as well as during the intervention. The analysis was concentrated on the use of beta-agonists, inhaled and oral corticosteroids and the antibiotic use in the TOM patients. In the OMA project the use of benzodiazepines and diuretics was concentrated upon. The latter group can be used as a parameter for compliance.

The *use of medical resources* was measured in the patient completed questionnaires, to be able to get an impression of the possible financial benefits involved in the provision of pharmaceutical care.

Questions on the *severity of symptoms* and *peak flow data* were only applicable in TOM-patients. During the intake questions were asked by the pharmacist to estimate the severity of asthma. Some questions concerning asthma symptoms were also asked directly tot the patient. In the TOM-project the pharmacist were asked to collect 3-day *peak-flow data* from all TOM-patients at intake and at each consultation. Peak-flow meters were centrally distributed[**], including diaries and instructions for use.

[**] Peak flow meters for the project were provided by Pharmachemie, Haarlem.

Since increased *knowledge* also plays a role in coping capability (certainly in asthma it helps with the illness adaptation[41]), it was decided also to measure the development of knowledge in the patients. The knowledge questions were asked via the pharmacists about either asthma-related subjects (TOM) or heart disease related subjects (OMA). Currently no validated Dutch instrument to measure knowledge exists. Therefore it was tried to develop a sensitive instrument that would both measure actual knowledge as recalled knowledge. A sample of the questionnaire can be found as Appendix 6 to this dissertation.

Changes in *compliance* with the medication were also expected, but measuring the concept of compliance is a complicated matter, because compliance has different meanings depending on the interpreter[42,43,44,45]. Sometimes the term 'adherence' is used, meaning adherence to professional advice. Improving compliance is also a complicated activity. From the 13 randomised clinical trials evaluated by Haynes through the Cochrane collaboration, only one showed significant improvements as a result of counselling and written information. Six studies showed an improvement in treatment outcomes[46]. Usually the patients' viewpoint is not taken into account and therefore the term 'concordance' has been used, meaning that there should be a concordance in the intentions of patient and physician as to the way a treatment should be implemented[47]. Hippocrates, who gives his opinion very much from the physicians' viewpoint, best describes the dilemma:

> *'Keep watch also on the fault of patients which often make them lie about the taking of things prescribed'*[48].

Nevertheless, compliance may influence outcomes. There are different ways of measuring compliance[49,50], and for these projects it was decided to use two indirect methods because of their relative simplicity. Firstly to ask the patients if they ever skip a dose or take a dose extra. And secondly to study the computer medication-data for delays or overlap in getting the refills for certain drugs. But there may still be a difference in information from the pharmacists automated prescription data and the actual advice received by patients from professionals who are treating them.

Data on *time investment* were mainly asked to the pharmacists. Some questions concerning the length of the consultations were also asked to the patients, as a control. Of course these data were not yet available at the intake. Time investment data can be used for the economical evaluation. Pharmacists were therefore also asked how much time they spent on other matters concerning the provided care (preparation, performing drug use evaluations). The *opinion on pharmaceutical care* could of course only be asked at people with experience, meaning the intervention patients, the intervention pharmacists and the GPs of the intervention patients. Such data may help to explain the satisfaction data.

The *contents of the consultations* were assessed as a process outcome, to be able to analyse if the proposed intervention had taken place.

3.4 THE CONTENT OF THE OFFERED CARE

In both studies only pharmacists would provide the full scope of pharmaceutical care and the assistant pharmacists would only play a marginal role. However, in the OMA-study

assistant-pharmacists were allowed to conduct a small part of the protocol. The contents of the care offered was as follows (see also table 4-4):

- An intake to get to know the patient and initiate data collection for the study and pharmacist's documentation;
- Frequent pharmacist-patient contact, every time a prescription is dispensed. These frequent contacts should establish a relationship based on mutual trust and thus enable patients to access the pharmacist more easily whenever they have medication related problems or just want to discuss their pharmacotherapy;
- Every half-year a consultation with the pharmacist, in which extra attention will be paid to medication related problems, a drug use evaluation will be performed according to the guidelines as described in Appendix 1 to this dissertation[51];
- An intervention of the pharmacist regarding the patients' medication, whenever there is a reason. These interventions will always be discussed with the patient, before contacting the GP if necessary.

3.4.1 Additional care in the TOM study

Additionally in the TOM study the pharmacists were asked to provide following:

- Installation of a self-management program in co-operation with the GP and regular evaluation of the PEF-measurement results, at least once every 6 months;
- Regular inhaler instruction based upon an article by van Mil *et al.*[52].

The self-management protocol

In the British Thoracic Society Asthma Self Management Protocol, dating from 1990, an action by the patient is required if the PEF-value is less than 75% of their maximum consistent PEF-value, i.e. doubling the steroid dose over a certain period with no change in bronchodilator-therapy[††]. If the PEF is less than 50% of the maximum consistent PEF-value, contact with the physician is required. Under 25% the patient must go to hospital without delay. Charlton and others have described a similar project in general practice in which the limits were 70%, 50% and 30%[53]. That study was carried out in a nurse-run asthma-clinic. Collins *et al.* have adapted that study to a set of instructions of their own, which were used within the Australian Asthma Management Plan[54]. They used limits of 80%, 70% and 60%.

In the international consensus the limits are 80 and 60%. Between 80% and 100% (the green zone) no action has to be taken. Between 60 and 80% (orange zone) doubling the inhaled corticosteroid dosage is required until the peak flow has returned to its 80% value and then one week more, possibly without consulting a doctor. Below 60% (red zone) medical intervention is necessary[13], and the patient is advised to contact his physician immediately.

As the pharmaceutical industry is handing out PEF-meters more or less freely, portable peak-flow meters can be obtained. Use of the same brand of meter for all participating patients has to be ensured. Charlton selected the cheap and accurate Mini-Wright peak flow

[††] This protocol has been used in a study in 300 patients, by Dr. K. Jones, Department of Primary health Care of the Medical School in Newcastle upon Tyne. The follow-up period was 6-9 months. In July 1993 the study was in its evaluative phase.

meter[12] as has the Dutch Asthma-Fonds. It is the most popular PEF-meter to date certainly for use in adults and its accuracy has been properly evaluated [55,56].
Although Miller has doubts about the error-profiles of the different meters available (and advises the development of a self-management scheme on the basis of the PEF-meter that is going to be used) he also used the Mini-Wright instrument[57].
On basis of the international consensus it was therefore decided to use the 60-80% limits in the TOM study and because of its proven accurateness, the Mini-Wright[‡‡] PEF-meter.

3.4.2 Additional care in the OMA study

In the OMA study, pharmacists were asked to additionally provide the following:

- House visits when the patient was unable to come to the pharmacy for the six monthly consultations or whenever necessary;
- An effort to decrease the use of benzodiazepines in the target group.

Influencing benzodiazepine use

Influencing the use of benzodiazepines is not an easy task for pharmacists. Support from the GP, and support of the GP by the pharmacist is certainly necessary. Several studies indicated that reducing benzodiazepine use in the elderly in general is a difficult, but not impossible task.

The withdrawal from benzodiazepines is a complex procedure. On top of the dependency, which must be broken, there is also a high probability of recurring anxiety-related symptoms and frequent sleep-disturbance. Success rates of gradual withdrawal programs vary between 50 and 70%[58], but no specific data in large populations of elderly are available. Ashton reports that in younger patients the success rates of her program were better than they were in the elderly. She reported a success rate of 70% in the younger population in the UK. All patients in the program were referred to a clinical pharmacologist [59]. Schweizer *et al.* found almost the opposite. Their elderly patients (over 60) showed significantly less severe withdrawal symptoms during gradual tapering than younger (under 55) patients, and did as well regarding outcomes[60]. Both groups were rather small, however, (19 and 22 patients respectively) and were outpatients under psychiatric surveillance. Reasons for these conflicting results might be found in the programs used in the population studied. Schweizers' study was performed in a university psychiatry unit and his success rate was, after 4 weeks, only 50% in both the elderly and younger group. Ashton's population was not primarily a clinical psychiatric one.

Most withdrawal or detoxification programs describe a gradual dose reduction, but the rate at which the withdrawal is obtained and the dosage schedules used, differ substantially. The usual withdrawal period is 1-3 months. Ashton, an experienced worker in this field, suggests leaving the control over the rate of dosage tapering to the individual patient[61], an idea very much supported in view of the desired outcome. Swantek *et al.* described the use of carbamazepine to treat benzodiazepine withdrawal symptoms in only 4 elderly patients[62]. The results are vague and are not likely to be reproducible in a non-hospital setting. It

[‡‡] Because of unforeseen circumstances the selected peak-flow meter was changed during the study.

should be questioned whether the approach of replacing one drug by a drug from another class, with its own side effects and interactions, is such a good idea.

Holton studied a population of 41 patients and has been looking into factors, which may predict the long-term success of a benzodiazepine-withdrawal program[63]. Unemployed men, under the age of 50 with little or no premorbid personality disturbances will usually do very well. Conversely older women with considerable anxiety related symptoms, even when taking benzodiazepines and with personal disturbances, are unlikely to do well.

According to a panel of GPs, stopping the use of benzodiazepines was indicated in 43% of the chronic users in their practice[64]. Only in 10 % of those 100 users the GPs actually managed to let the patients stop. A recent article by Hijzeldoorn *et al.* described a 19% reduction in chronic benzodiazepine use through a pharmacist supported GP intervention. The only intervention was that the GP informed the patient of the dangers of benzodiazepine use when writing a repeat prescription. During the study the use of this class of drugs in a reference group increased with 19%[65]. Coolen and Sitters describe a new project and different examples of reducing the use of benzodiazepines in co-operation with GPs in The Netherlands in1998[66]. The results of this project will be available in 2001.

In the OMA study the pharmacists were advised to try to gradually decrease the dosage by 10% in one-week steps, after consultation with the patient's GP.

3.5 THE EDUCATION OF THE PHARMACISTS

Although pharmacists are academic professionals, this does not necessarily mean that they have all knowledge, attitudes and skills to provide pharmaceutical care ready to use. The pharmacists also needed to have some insight in the research method. Therefore the TOM and OMA pharmacists received four half-day training sessions on different topics before the projects started. During the projects additional half-day training sessions were provided, each dealing with specific topics they had come across while providing care.

Topics for the pre-intervention training for TOM pharmacists included asthma and pharmaceutical care, the treatment of asthma, asthma treatment standards and self-management, communication with GPs and patients, the content of the protocol, and the selection of patients. During the project, every six months, half-day training sessions were given on performing medication analysis, giving inhaler instructions, the relationships and communication with patients and physicians, the mechanisms and treatment of asthma, self-management, and the patient's view on the meaning of suffering from asthma.

Topics for the pre-intervention training for OMA pharmacists included the elderly and pharmaceutical care, medication problems and the elderly, communication with GPs and patients, the content of the protocol, and the selection of patients.

During the project, every six months, additional half-day training was given on drug use evaluation and medication analysis, relationships and communication, benzodiazepine use and withdrawal, and heart diseases and their medications.

3.6 RESEARCH AND DOCUMENTATION TOOLS AND THEIR USE IN PHARMACEUTICAL CARE

During the TOM and OMA study a number of instruments were used or developed for documenting the care. The main problems of pharmacy practice research and thus pharmaceutical care research in the field of strategy are the facts that experimental conditions can hardly be influenced by the researchers and that there is a large possible variety in outcomes. It is therefore essential that the intervention is described in detail and that the process be monitored well. Odedina and Segal have developed an instrument to measure the pharmacists' activities, but this instrument was not yet available at the beginning of the TOM and OMA study[67]. The outcomes of care are partially subjective and include a large array of human variables. This implies that many instruments should be used to measure outcomes, or a limited number should be chosen in the knowledge that not all results of the application of pharmaceutical care, or the fulfilment of all pharmaceutical needs of patients, will be measured.

During our studies the Problem-Assessment-Solution (PAS®) system was developed, to document elements of the consultation process[68]. The system can also be used to analyse the occurring drug related problems using statistical methods[69] and has been added as Appendix 2 to this dissertation. In 1999 the Pharmaceutical Care Network Europe started the development of a new documentation system, which is partially based upon the PAS® concept.

The ICPC-code[70], a documentation tool to register diseases and complaints, was adapted to the needs of pharmacists providing pharmaceutical care. The results of that adaptation were published[71].

For documenting and analysing the patients' drug use, the ATC and DDD coding was used[72], not only because it is a good system for pharmacoepidemiology, but also because Dutch drug files for pharmacy computer software includes the ATC-codes of drugs.

The choice of quality of life instruments

Health related quality of life is the main outcome of all forms of care. In pharmacy the concept became important with the definition of pharmaceutical care. Health related quality of life (HRQL) as a research subject in relation to medicines became important as a marketing tool for the pharmaceutical industry in the beginning of 1990. Today most registration-authorities demand HRQL evaluations within the registration files to be submitted.[§§]

A simple survey in Medline-advanced® on the keywords 'Pharmaceutical Care' or on 'Quality of Life' *and* 'Pharmaceutical Care' (see Figure 3-3) shows an increasing number of hits for pharmaceutical care, starting in 1991. This simple fact is a good indication of the increasing importance of the pharmaceutical care concept in biomedical literature, although not much has been published yet about pharmaceutical care and health related quality of life combined.

[§§] Remark of Prof Ingela Wiklund, Astra Sweden during the 2nd Symposium on Pharmaceutical Care, November 1996, Utrecht

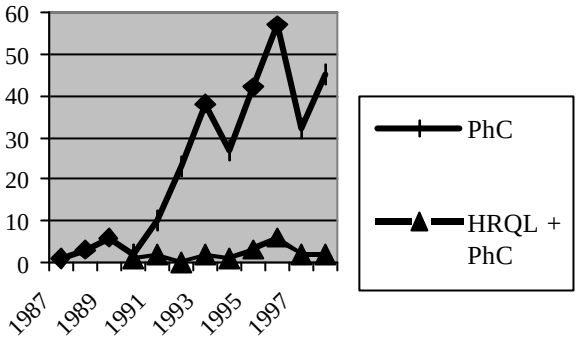

Figure 3-3 Hits in Medline for HRQL and pharmaceutical care

The selection of a quality of life instrument has been described frequently in literature. Both Guyatt and König-Zahn have written excellent articles about this topic[73,74]. Based upon their criteria it was decided to use the SF-36 as the generic instrument in the TOM and OMA study[38]. Additionally in the TOM study it was decided to use the Asthma Quality of Life Questionnaire, based upon the criteria mentioned in the articles by Mallié *et al.* and Juniper[75,9,39].

3.7 Power calculation for the TOM and OMA study

Since Quality of Life is the major outcome of pharmaceutical care, the power calculations for both studies were based upon the two least sensitive domains of the SF-36, the major HRQL instrument. These domains are Physical Role and Emotional Role, and when the instrument is applied to detect a 5-point difference over time within one group, 300 patients are needed. The number of patients calculated per group would also be sufficient to measure a 5-point difference in the 6 other domains (Physical Functioning, Bodily Pain, General Health, Vitality, Social Functioning and Mental Health), when applying this instrument to measure differences over time between two experimental groups in a repeated measure design. A 5-point difference is clinically and socially relevant.
For showing a 10-point difference (moderate differences) the maximum sample sizes is only 118, but such differences were not to be expected in this study[38,76].

3.8 Summary of the intervention

The interventions in the TOM and OMA study were developed based upon a number of considerations, described in this chapter. Although the interventions were complex, and difficult to monitor, they reflect the situation in everyday pharmacy practice in Dutch community pharmacies. The interventions find a firm base in the standard experience of the almost all Dutch pharmacists, who give drug-information to their clients and in the general presence of automated prescription databases, including medication surveillance.

Based upon the considerations and discussions in this chapter the following table (3-4) reflects the interventions for the TOM and OMA study.

Table 3-4 Summary of the interventions in the TOM and in the OMA study

TOM	OMA
- The intake - Regular drug use evaluation - Pharmacist-patient contact when drugs are collected in the pharmacy - Half yearly consultations and evaluations with the patient - Improving knowledge of and adherence to medication - Installing and coaching of self-management in co-operation with the GP - Regular inhaler instruction	- The intake - Regular drug use evaluation - Pharmacist-patient contact when drugs are collected in the pharmacy - Half yearly consultations and evaluations with the patient - Improving knowledge of and adherence to medication - House visits if patient is unable to come to the pharmacy - Attempt to decrease the use of benzodiazepines

The results of both studies are described in chapters 4,5 and 6 of this dissertation.

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Most data were entered and analysed using SPSS, version 7.5. Drug data were entered into an Access database, and analysed with the help of SPSS, Excel and Dbase V. Unless otherwise stated, a difference was assumed to be significant at a level of 95% probability or higher. Most comparisons of means have been made with the help of the Student t test, in the appropriate format as offered by SPSS. If other tests have been used this is explicitly mentioned in the text.

4.1 THE POPULATION, INCLUSION AND DROP-OUT

The OMA-project was started with 21 intervention pharmacies. Two pharmacists initially provided patients, but did not perform the intake. Those two pharmacies were then included in the external reference-pharmacy group (13+2). Ten internal reference pharmacies were selected. The beginning of the study was defined for intervention patients by the date of the intake, for the reference patient the dates of the reception of the first questionnaire at the research centre.

Before the beginning of the OMA-study 512 potential intervention patients, 212 internal reference and 264 external reference patients were selected. From these 788 patients, 141 patients did not sign the informed consent-form in time or did not receive an intake and 8 patients had a Mini Mental State Exam (MMSE) score below 20. As established in the protocol, they were excluded from the study. The study was therefore started with 839 patients, mean age 74.45 (65-94, sd 5.6). The study was concluded with 416 patients, the total drop out rate thus being 50.4%.

Patients dropped out in different phases of the study. Table 4-1 shows the remaining numbers of patients throughout the study at 6, 12 and 24 months after the start.

Table 4-1 Number of patients participating in OMA study, between brackets the percentage of drop-outs

	0 month	6 months	12 months	24 months
Intervention	423	340 (19.6)	286 (32.4)	196 (53.7)
Ext. reference	231	174 (24.7)	142 (38.5)	111 (51.9)
Intern. reference	185	158 (14.6)	132 (28.7)	109 (41.1)
Total	839	672 (19.9)	560 (33.3)	416 (50.4)

4.1.1 The characteristics of the population

Sex and age distribution

The total study-population includes more female patients (54,6%) than men. The distribution of the sexes in the intervention group and reference groups was not significantly different. The age-distribution in all three groups is similar. The overall mean age at intake was 74.5 (range 65-94, sd 5.6). There is no significant difference with regard to age between the three groups.

Other characteristics

Some other characteristics of the three groups at intake, which might *a priori* influence results, are summed up in Table 4-2.

Table 4-2 Other characteristics of the OMA population at intake

	Intervention (n=423)	Int. Ref. (n=185)	Ext. Ref (n=231)	Total (n=839)
Number of pharmacies	19	10	15	44
Highest completed education (%) *	50.4 pr.sc 42.8 sec. sc. 6.8 univ. (n=369)	58.0 pr.sc. 32.0 sec.sc. 10 univ. (n=100)	56.6 pr.sc 35.7 sec.sc. 7.8 univ (n=103)	53 pr.sc. 39.5 sec.sc. 7.5 univ. (n=598)
MMSE score (mean)	26.59 SD 2.28	26.89 SD 2.41	26.09 SD 2.28	26.53 SD 2.43
Freq. of visiting the pharmacy (yearly means)	11.45 SD 9.15	14.73 SD 12.45	12.56 SD 10.78	12.51 SD 10.51
Familiarity with pharmacist (% of patients)	63.5	69.2	59.8	63.9
Patients not visiting other pharmacies (%)	94.1	95.1	94.3	94.8

* Pr.sc.= primary school; sec.sc.= secondary school/highschool; univ.= university/technical college

At intake there is a significant group difference between the internal reference and intervention group with regard to the frequency of visiting the pharmacy. This difference cannot be explained from other factors like e.g. the mean hospital admissions (around 1,2 yearly). There are no significant differences between the two reference groups (Student t test). Data about the highest level of education completed were not available from all patients, but the available data show no significant differences.

4.1.2 Drop out

The analysis of drop-outs showed a number of possible reasons for not concluding the study. For 3.1 % of population, the reason for drop out was unknown, and 15.4% did not return the final questionnaire. Of the intervention group 17.5% dropped out at the end because the pharmacist did not perform the final evaluation because of research fatigue. More detail can be found in Table 4-3.

There are no significant differences between the drop-out patients in the internal reference), external reference and intervention group (Student t test, all $p>0,05$). The remaining patients showed no significant differences with regard to age, gender, MMSE and highest completed education at the 6, 12 and 24 months evaluation.

4.1.3 The reasons for drop out, from a process perspective

Some of the reasons for drop out can also be found in the process. Of the 19 initial OMA pharmacies, one did not develop any activities (no 19). The 18 remaining pharmacists

received a self completed questionnaire at 6,12 and 24 months during the study, but not all questionnaires were returned and one pharmacy never returned any questionnaire (no 6). In some pharmacies more pharmacists participated. Table 4-4 indicates the mean number of contacts patients reported during the study and the numbers of patients in the study according to the project administration, and some data about the pharmacy size. The rate of retention is the number of patients at the end of the project divided by the number of patients at intake. The frequency of contacts clearly decreased during the project.

There is a significant positive correlation (Pearsons correlation coefficient, r_p=0.52, $p<0.05$) between the total number of consultations during the first year and the rate of retention of patients. For the second year this correlation is not significant. There are no significant correlations between the retention rate and the number of pharmacists or the total staff members per pharmacy in relation to the pharmacy size (as a proxy for the workload).

Table 4-3 Reasons for drop out in the different patient groups

	Intervention (%, n=227)	**Int. ref** (%, n=76)	**Ext. ref** (%, n=120)
Died	21.2	7.0	12.0
Too ill	6.2	11.3	10.3
Did not feel like continuing	8.8	15.5	12.0
Too old	0.4	0	0.9
Failing memory	1.8	1.4	0.9
Moved	8.0	8.5	6.0
Reason unknown	8.0	5.6	3.4
No final evaluation or questionnaire received	45.5	50.7	54.7

4.1.4 Discussion about the population and drop out

The analysis of these basic data shows no significant differences between the characteristics of the intervention and reference groups at the start of the study. The high and unexplained drop out rate at the end of the study is possibly a result of the 'research fatigue' of pharmacists and patients, who repeatedly indicated that filling out questionnaires was rather bothersome.

Because there are many missing data for highest completed education, it cannot be established that there are statistically significant differences between the three groups. Nevertheless it can safely be assumed that the characteristics of the three patient groups are similar. There is no selection bias in sex, age, education or reasons at any of the evaluation moments. It should be pointed out that the reason for drop-out for those patients for which we have no final questionnaire or evaluation, is also unknown.

When the two reference groups are merged there are no significant differences between intervention and reference group for the major characteristics mentioned, including the MMSE score ($p>0.05$). At the start of the project and during the project there were no major

differences between the internal and external reference group in the mental health and physical functioning domains of the SF-36 (see section 4.2). The two reference groups therefore have been merged for most of the statistical analysis to increase the power of the calculations*.

Table 4-4 Mean pharmacy-patient contacts, retention rate and pharmacy size in OMA study

Phcy No.	Contacts 0-12 months mean	Contacts 12-24 months mean	Patients at intake	Patients at end	Rate of retention	No of phcist	Pharmacy size (# of patients (range)	Total prof. staff
13	6	4	19	14	73.7%	1.4	8000-9999	5.9
1	3	1*	29	21	72.4%	2	18000-19999	13.5
8	7	4	18	13	72.2%	1.6	6000-7999	5.1
16	>8	4	27	19	70.3%	1.8	12000-13999	8.4
7	>4	5	30	21	70.0%	1.0	10000-11999	5.9
12	7	4	22	15	68.2%	1	8000-9999	5.8
5	8	5	28	19	67.8%	2	12000-13999	9
14	5	2	24	14	58.3%	1.5	12000-13999	9.5
3	5	5	23	13	56.6%	2	12000-13999	9.8
4	6	3	26	14	53.8%	1.6	10000-11999	9.6
18	4	5	17	9	52.9%	1.2	10000-11999	6.7
21	>2	1	29	11	37.9%	2	6000-7999	7
2	3	1	16	3	18.8%	3	14000-15999	15.0
17	2*	2*	25	4	16.0%	1	12000-13999	7.5
11	7	>5	26	3	11.5%	2	10000-11999	9.5
20	2	3	26	0	0%	1.0	12000-13999	6.2
15	2*	2*	16	0	0%	2	10000-11999	8.3

* estimated on bases returned intake forms/evaluations

The results of this section also indicate that the workload of a pharmacy had no relation with the amount of attention spend on the patient and that the amount of attention for the project patients was a better indicator for retaining patients in the project. The more attention the patients received, the more chance there was that the patient would not drop out. The retention rate of pharmacies 2, 11, 15, 17, 20 and 21 is less than 50%. Nevertheless in the 'real' word such performance has also to be taken into account, and therefore their patients have been included into the analyses if data were available.

* Statistical analysis has been performed by J.S. Slis and described in the paper 'Farmaceutische PatiëntenZorg, het effect op de levenskwaliteit van de patiënt. Rijksuniversiteit Groningen 1998

4.2 QUALITY OF LIFE

During the OMA study the SF-36 was used repeatedly at the zero assessment and at the three evaluation assessments (after 6, 12 and 24 months) to measure changes in the quality of life. The SF-36 is an instrument for the assessment of quality of life, which has been developed in the United States[1]. It has been translated and validated in the Dutch language[2]. The arguments for its selection for the OMA study are given in Chapter 3.

The SF36 consists of 8 domains, which are Physical Functioning (PF), Role Physical (RP), Bodily pain (BP), General health (GH), Vitality (VI), Social functioning (SF), Role emotional (RE) and Mental health (MH).

4.2.1 Method

The questionnaire was administered by mail, with pharmacist and research centre independent telephone support 5-7 days after sending the questionnaire, by a marketing research organisation. Different statistical strategies have been applied to evaluate the changes in quality of life with the help of SPSS and for all tests a 5% level of significance has been applied.

The Health Institute of the New England Medical centre, where the SF-36 has been developed, published a manual and interpretation guide[3]. This manual was also used for the evaluation and interpretation of the data.

The changes for the different domains, apart from the health transition, have been analysed including all available data (Intention To Treat analysis), or only including the patients who concluded the study (Per Protocol analysis). There was no difference between the results of both analyses and therefore only the results of the ITT analysis are given.

A major obstacle in the analysis of the data proved to be the non-normal distribution of the scores. This probably was a result of the relative low scores in most of the domains. Therefore the Sign test and the Wilcoxon signed rank test were applied to discover potential significant differences between the intervention and reference group.

Although the responses in the domains at the different assessments do not show normality, the domain scores are strongly interrelated, all positive and significantly different from zero (one sided $p < 0.001$) according to the Pearson's correlation test, Spearman's rho and Kendall's tau. Because of this correlation, statistical evaluation of the data has sometimes been limited to two domains, the physical functioning (PF) and mental health (MH). Their correlation is the smallest and their level of measurement is the highest since they have a wider range of scores than most other domains (21 for PF and 26 for MH).

For the evaluation of the results at the pharmacy level, a minimum of 10 valid measurements (couples) were used.

4.2.2 The zero-assessment

The scores for the zero-assessment have been compared to the Dutch norm values for the elderly people with a comparable age-profile (see figure 4-5), obtained from the Dutch cancer institute, which is the Dutch centre of the International Quality of life assessment project[4]. The OMA population scored less, and often much less than the norm. The

difference was maximal for the domain role physical. There were no significant differences between the domain scores (n=367) and the reference groups (n=339).

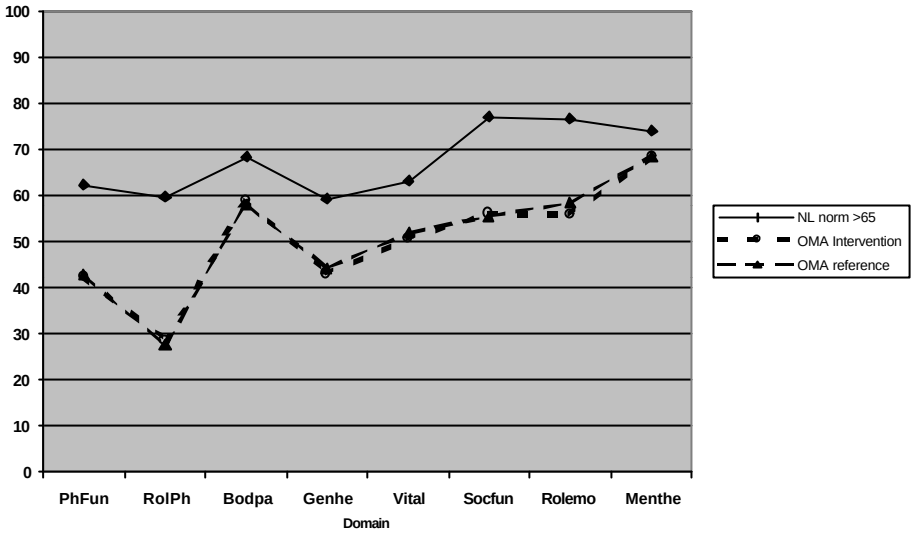

Figure 4-5 HRQL domain scores at 0-assessmet compared to Dutch norm

4.2.3 Changes during the study

General level

During the OMA study the quality of life in most domains of the SF-36 went down in both groups. The scores on health transition also illustrate this. The chi-square test sgows that the distribution of the answers of the health transition domain is significant uneven (asympt. Sign <0.000) in favour of a negative development of the health. The change in the intervention group seems more outspoken.

According to both the Wilcoxon signed rank test and the sign test, the HRQL as measured by the PF abd the MH domains both decreased significantly in the intervention and the reference group between t=0 and t-3 (24 months). As for other domains, a significant decrease in the Vitality domain was noted for the intervention group between t=0 and t=1 only.

If only patients were analysed who scored the mean value (PF 42.9 and MH 68.8) or lower in both domains PF and MH (intervention n=101 and reference n=107), the composition of both groups changed. The proportion of women became approximately 2/3. The available data were again subjected to Sign-tests[5]. Analysis of this subgroup in the first part of the study showed a significant increase of the PF and MH-domain scores for the intervention group and much less or no significant increase in the reference group. See table 4-6a and 4-6b.

Table 4-6a Two sided p-values for domain Mental Health <= mean (decrease in scores)

		t1 – t0	t2 – t0	t3 – t0
Intervention	Sign test	0.000	0.012	0.243
	Wilcoxon	0.000	0.006	0.213
Reference	Sign test	0.045	0.281	0.360
	Wilcoxon	0.019	0.455	0.758

Table 4-6b Two sided p-values for domain Physical Functioning <=mean (decrease in scores)

		t1 – t0	t2 – t0	t3 – t0
Intervention	Sign test	0.036	0.003	0.268
	Wilcoxon	0.001	0.002	0.446
Reference	Sign test	1.000	0.677	0.626
	Wilcoxon	0.514	0.577	0.919

Pharmacy level

Five out of the 19 pharmacies did not retain 10 or more patients in the study. The patients of one pharmacy showed a significant increase in the PF domain during the first 6 months of the study, based on the Wilcoxon test (p=0.016). In none of the pharmacies there was a significant decrease between measurements at the different times of assessment, but for all pharmacies the mean HRQL of their patients decreased overall between the zero assessment and the end of the study.

4.2.4 Discussion and conclusion on quality of life

There is a large difference between the mean HRQL of the OMA population (intervention and reference) and the normal values for a comparable age group. This is not surprising, since the OMA group is using 4 or more different medicines and will therefore suffer from multiple diseases. The mean HRQL of the intervention group and the reference group dropped during the study in a similar manner, based on both the PP and the ITT analyses. This is also a logical result of the population characteristics. Multimorbid elderly will seldom show an increase of the HRQL when ageing.

In general a significant difference between the changes in the intervention group and those in the reference group could not be detected. Only in the beginning of the study the intervention group showed a positive difference for people scoring average or below average in the domains physical health and physical functioning, compared with the reference group. This could indicate that people with a relatively low HRQL might initially improve somewhat when they receive pharmaceutical care, but could also be the result of regression to the mean.

On the other hand, when the intervention patients were asked, at the end of the project, if they had the impression that their health was better due to the provided care, 14.0% stated

that their health was much better and 30.1% stated that their health was better, 55.4% did not perceive any difference and 1 patient out of the 186 answered that his/her health was actually worse due to the intervention.

If the results are analysed on a pharmacy level, the number of data points available for reaching significant differences was greatly reduced. It is therefore remarkable that one pharmacy managed to produce a significant increase in the physical functioning domain by providing pharmaceutical care during the first 6 months. This pharmacy was one of the most active partners in the study.

Provision of pharmaceutical care has not had an effect on the patient's quality of life as measured with the SF-36. Insufficient data on the process have been obtained to analyse the effects on a pharmacy level. Nevertheless, about half of the patients felt that their quality of life had improved because of the provided care, when the question was asked directly. This could also be a reflection of the high satisfaction amongst the patients.

4.3 SATISFACTION WITH, AND OPINIONS ON, THE PHARMACEUTICAL CARE PROGRAM

During the OMA study the satisfaction of patients with the provided care, as described in Chapter 3, was measured only in the intervention group. The opinions about the expertise, role and functions of the pharmacists (and the GP) were asked in the intervention as well as the reference group. A sample of a questionnaire used in the TOM project (final round) can be found as Appendix 6 to this thesis. The questionnaire of the OMA project was similar.

4.3.1 Method

The intervention patients were asked if their opinion on the provided care was positive, neutral or negative with also an option of saying that they did not know (yet). The option 'don't know' was omitted at the 24 months evaluation to force patients to give an opinion.

The intervention patients were also given a number of statements, with which they could fully disagree, disagree, agree of fully agree. This method resembles somewhat the method used by Larson, to assess the patients' satisfaction with the delivery of products and information[6].

In another section of the questionnaires the intervention and reference patients were asked to indicate if they found different professionals (pharmacists, assistant-pharmacists and GPs) or their family members experts in the field of medicines. Patients could choose between 'certainly not expert, not expert, somewhat expert, expert, very expert and don't know'. At 24 months the possibility of answering 'I don't know' was omitted. All questions were asked in a self-administered questionnaire, which had to be returned to the research centre.

It was difficult to analyse the data on a pharmacy level, due to the very small numbers of patients at the end of the project for some of the pharmacies. No data were obtained from the final questionnaire for the patients of one pharmacy, because in this pharmacy the project was terminated after the 12 months assessment.

4.3.2 Results, the satisfaction and opinions of the patients

During the project an increasing majority of the patients was positive about the care provided (see table 4-7). There is no special drop-out effect for patients who were initially negative about the provided care.

*Table 4-7 Opinion about new form of care of OMA patients **

	6 months (%)	12 months (%)	24 months (%)
Positive	67.1 (73.4)	77.9 (79.4)	87.0 (87.0)
Neutral	12.9 (10.9)	10.7 (10.3)	13.0 (13.0)
Negative	0.6 (0.5)	0.7 (1.0)	0
Don't know (yet)	19.4 (15.2)	10.7 (9.3)	No option

* Between brackets the per protocol analysis.

During the project the percentage of intervention patients who stated that they can communicate well with their pharmacist increased from 90% (6 months) to 100% (24 months); 95% of the patients stated that they could communicate well with their GP throughout the project. An increasing number of intervention patients (from 6 to 18%) stated that it was difficult to access the pharmacists, if they wanted to speak with them. This percentage is about the same as for GPs (15-20%).

The percentage of intervention patients who indicated that they would first approach their pharmacist if they wanted to know more about medicines increased from 70 at 6 months to 84 after 24 months. The number of patients who agreed with the statement that the pharmacist knows more about medicines than the patient used to think, increased from 76% to 89%.

Table 4-8 Opinions of the patients at 24 months assessment, OMA study

Statement	% agree or fully agree	
	Intervention	Reference
I do not care if I speak to the pharmacist or the assistant pharmacist*	48.9	70.9
It is easier now to contact the pharmacist when I have questions about my *disease**	55.8	34.1
I think I can communicate well with my pharmacist	100	81.5
The pharmacist knows nothing about my disease*	17.2	40.6
It is easier now to contact the pharmacist with questions about drugs	90.6	68.9
With questions about drugs I first think of the pharmacist	83.6	59.3

* Significant difference between pharmacies

Table 4-9 Opinions of the patients at 24 months assessment, on which there were no significant differences between intervention and reference groups

Statement	% agree or fully agree
I think I can communicate well with my GP	96.1
I think they have all the details about my drugs in the pharmacy	96.5
The GP closely watches my drug use	87.3
The pharmacist knows more about drugs than I used to think	85.8
Repeating prescriptions can be done directly by the pharmacy	69.2
The GP is poorly accessible if I want to speak with him/her	17.3
The Pharmacist is poorly accessible if I want to speak with him/her	15.4

Table 4-10 Opinion on expertise of pharmacist, GP and assistant-pharmacist (% of patients)

		0 months		6 months		24 months	
		Expert & Very expert	Very expert	Expert & Very expert	Very expert	Expert & Very expert	Very expert
Pharmacist	Intervention	51.2	19.1	80.7	29.2	98.5	50.8
	Reference	60.8	21.0	61.1	20.7	90.1	23.3
Assistant pharmacist	Intervention	37.7	7.4	49.2	5.2	52.1	9.2
	Reference	40.4	4.7	37.9	6.6	44.2	5.1
GP	Intervention	74.2	27.8	79.1	32.6	80.2	32.1
	Reference	75.1	27.2	77.4	25.1	79.0	24.5

The opinions on those matters were also compared after 24 months with the reference group, which initially did not show significant differences with the intervention group. This lead to the following results (see table 4-8). In the table only the statements which had significant differences (Pearsons chi square test) are given. In addition significant differences between the groups of patients belonging to different intervention pharmacies are indicated. On the statements in table 4-9 there were no significant differences between the intervention and reference patients after 24 months.

When the intervention patients were asked whether they thought that the pharmacist could improve the provided care, 8.9% said yes but there was no relationship with this question if their health had improved, nor with their opinion on the provided care. A total of 30% of patients at the end of the project did not answer this question.

The opinion of the intervention and reference patients at 0 months, 6 months and 24 months on the expertise of the different professionals in the field of medicines is given in table 4-10. There is a statistically significant increase in the perceived expertise of the pharmacist, if 'expert' and 'very expert' are combined. However, a similar increase can be

seen in the reference group. If we only look at the 'very expert' responses, the difference between intervention and reference patients at the 24 months assessment becomes clear. A slight increase can also be seen for the assistant-pharmacists for the combined answers of expert and very expert. The perception of the expertise of the GP in the field of medicines has hardly to changed.

4.3.3 Discussion and conclusion on satisfaction and opinions

There is a clear and statistically significant increase in satisfaction about the provided pharmaceutical care amongst the patients, and at the end of the study there is no negative opinion. About 12% of the population remained neutral but throughout the project they are a changing group of patients. As for the accessibility to care there seems to be no difference between the ease of access to the pharmacist or the GP in The Netherlands.

It is also clear that in the intervention group the opinion on the expertise of the pharmacist in the field of medicines grew during the project, although there were some inter-pharmacy differences.

Since it was the pharmacist him/herself who provided the care during the OMA project, the difference in the expertise of pharmacists and assistant-pharmacists became clearer in the intervention group. Providing pharmaceutical care to this population clearly increased the perception of the patients that the pharmacist is expert in the field of medicines.

4.4 The knowledge about diseases and drugs

The participating pharmacists made an assessment of the possible knowledge changes in the patients during the OMA study between intake, 6, 12 and 24 months.

A questionnaire was compiled to assess knowledge changes about diseases frequently occurring in the elderly (hypertension and angina pectoris). Because of the structure of the knowledge questionnaire i.e. the fact that the questionnaire would give raise to discussion and was therefore part of the intervention, only the intervention patients completed this section at the time of the evaluations at intake, after 6 months and 24 months.

Fully completed baseline knowledge assessments were returned by 371 participants in the OMA study. Baseline assessments and either the 6 months assessment and/or the 24 months assessment were obtained from 298 participants. These participants were included into the analysis. The final number of evaluated knowledge assessments at 24 months is higher than the number of patients in the study at the end (105.6%), because some of those patients did not return their final questionnaire and therefore were considered to be part of the drop-out group.

4.4.1 Method of analyses and coding

The knowledge about diseases section of the assessment form consisted of 33 items, divided into 5 questions (see patient questionnaire in appendix 6 as an example) .

- Characteristics of hypertension 1 question, 8 items;
- Causes of hypertension, 1 question 6 items;
- Heart attack, 1 questions, 6 items;
- Angina pectoris, 1 question, 6 items;
- Benzodiazepines, 1 question, 7 items;

During the study it became clear that filling in this part of the questionnaire placed a burden upon the pharmacists and the patients. Therefore the planned 12 months assessment with this questionnaire was omitted.

The questions were scored as follows: 2 = spontaneous correct, 1 = after questioning correct, 0 =don't know and -1 = after questioning incorrect. The 5 red herring items (see chapter 3) were scored in reverse: -2 = spontaneous incorrect, -1 = after questioning incorrect answer, 0 = don't know and 1 = after questioning correct answer.

The range for the total score per patient is therefore –38 to 61. The data were analysed on the level of overall mean scores per assessment and changes in mean scores per patient. In an attempt to reduce the data and recognise other underlying factors which could explain the variance in the results, a principal axis factor analysis with Oblimin rotation (Kaiser normalisation, delta=0) was performed on the scores of the zero assessment.

4.4.2 Results of the knowledge assessment

Some pharmacists only completed this part of the assessment with only a few of their patients e.g. pharmacies 17, 18 and 20. The participants were divided over the pharmacies as shown in Table 4-11, which also gives the mean scores per pharmacy at the different evaluation points.

Total scores of disease knowledge

The scores of the knowledge per assessment show a large variation per patient. The scores for the zero assessment range from 0-48 (mean 20.39, sd 9.53), for the first evaluation from –13 to 54 (mean 19.81, sd 11.30) and the second (last) evaluation from –4 to 43 (mean 20.80, sd 10.70). Although there is a clear correlation between the scores of the three assessments per participant (r_p = 0,7), there is only a significant (negative) difference for the mean total knowledge between the zero-assessment and second evaluation (mean difference –1.2512, p= 0.024).

There is a weak correlation between the total knowledge score per patient of the zero-assessment and the MMSE score (r= 0,153). There is a weak positive correlation between the date of birth of the patients and the total scores of the different assessments (r_p = 0.163, r_p =0.251 and r_p =0.170).

Since the individual scores are variable, it was decided to look also at score changes. There is a significant negative change in the mean for the score changes between the zero assessment and first evaluation and the first and second evaluation (mean -1.2512, 95% confidence interval: -2.3376 to –0.1649).

Table 4-11 Number of evaluated knowledge questionnaires per pharmacy and their mean scores per pharmacy

Pharmacy	No of questionnaires			Mean knowledge score		
	0-assesment	0 and 6 months	0, 6 and 24 months	0-assesment	6 months	24 months
1	25	22	20	23.6	24.9	27.1
2	8	8	4	22.8	10.9	18.3
3	22	22	18	23.4	24.7	28.2
4	25	22	15	20.3	17.4	26.6
5	24	24	21	11.5	9.6	11.7
6	6	6	4	24.5	23.7	18.5
7	27	26	21	9.9	7.6	5.6
8	14	14	14	19.8	16.5	11.0
11	2	0	1	16.5		9.5
12	22	22	17	37.1	40.3	37.4
13	17	17	16	22.7	15.9	22.2
14	19	19	19	11.9	12.8	17.4
16	22	21	18	21.7	23.1	22.2
17	13	12	4	24.9	24.2	28.6
18	15	15	4	20.5	25.2	19.8
20	19	19	0	18.1	21.5	
21	18	17	12	22.0	20.2	22.5
Total	298	286	207	20.4	19.8	20.8

Changes at the patient level

Per question the proportion of patient-answers in a certain category changed. The number of patients answering spontaneously correct increased during the study. However, the overall percentage of patients that responded correctly after questioning decreased more than the increase in spontaneous correct answers. This pattern was consistent between all three assessments (see Tables 4-12 and 4-13).

Between the zero and last assessment, the major positive changes occurred in the knowledge about the following items:

- Q21c: A high systolic pressure is a mark for hypertension (mean change 0.25, SD 0.82)
- Q21e: A high diastolic pressure is a mark for hypertension (mean change 0.23, SD 0.86)
- The major negative changes in knowledge occurred with the following items:
- Q21b: Dizziness may occur as a result of hypertension (mean change –0.11, sd 0.99)
- Q22f: High blood pressure can be a result of physical exercise (mean change –0.13, sd 0.89)
- Q23f: Anxiousness may occur as a result of a heart attack (mean change –0.15, sd 0.95)
- Q25e: Benzodiazepines are bad for everyone (mean change -0.125, sd 0.82)

Table 4-12 Mean change (% of respondents, n=288) total items per domain between questionnaire 0 and 1 OMA project(0 and 6 months)

	Spont. Correct (%)	After questioning correct (%)	Don't know (%)	After questioning incorrect (%)
Hypertension	+2.6	- 2.5	-1.7	+2.1
Hypertension causes	+3.0	- 3.9	-1.2	+3.3
Heart attack	+0.6	- 3.7	+0.1	+2.8
Angina pectoris	+3.7	- 4.6	+0.3	+1.2
Benzodiazepines	+1.4	- 5.2	+1.3	+2.0
Average overall change per item	*+1.9*	*-3.9*	*-0.3*	*+2.2*

Table 4-13 Mean change (% of respondents, n=219) over total items per domain between questionnaire 0 and 3 (OMA project, 0 and 24 months)

	Spont. correct (%)	After questioning correct (%)	Don't know (%)	After questioning incorrect (%)
Hypertension	+4.4	-2.6	-1.0	-0.4
Hypertension causes	+3.6	-3.8	-0.8	+1.4
Heart attack	+0.2	-3.4	+3.1	+0.2
Angina pectoris	+4.5	-5.5	+1.3	+0.3
Benzodiazepines	+3.2	-5.8	+3.5	-0.3
Average overall change per item	*+2.7*	*-4.1*	*+1.2*	*+0.2*

Dealing with inter pharmacy differences

Between the zero assessment and the first evaluation there is a significant difference between the mean of the total score per pharmacy and the mean changes in total score per pharmacy (both elements one way ANOVA, $p < 0.0005$). Since the scores show such differences on the pharmacy level it was decided to analyse the changes in scores per pharmacy rather than the scores themselves.

The mean change of knowledge achieved in some pharmacies is mainly negative. From questionnaires returned by the pharmacists of the participating pharmacies some insight into the amount of time spent with patients was obtained. There were no clear relationships between those data and the changes in knowledge.

4.4.3 Factor analysis

Just over half of the variance (55.6%) of the total matrix was explained by 8 variables (Eigenvalues >1). In the total matrix factor 1 explained 25% of the variance, factor 2 explained 8% and factor 3 explained 4.7%. Further analysis showed that 3 factors were responsible for 55% of the variance when 16 items were selected on the basis of the higher communalities (>40). The factor loadings showed that factor 1 consisted mainly of the questions dealing with angina pectoris (Q24c, Q24d and Q24e), factor 2 combines all red herring questions (Q21d, Q22d, Q23d, Q24f and Q25f) and factor 3 deals mainly with the questions about systolic and diastolic pressure (Q21c and Q21e). The factor analysis was repeated for the selected items on the second and third measurement. The factor loadings were consistent across the three assessments in a paired sample analysis of the factor scores. It would be interesting to assess the correlations between the diseases experienced by the patients and the results of the variance, but clear data on the morbidity of the patients are not available. On the basis of this analysis the reduction of 33 items into 3 domains with 10 items seems reasonable, without loosing too much detail.

If the different items are arranged according to the most impact on variance on the basis of the factor analysis, three fields emerge: questions on angina pectoris (3 items), the red herrings (5 items) and measures for hypertension (2 items). The mean scores can be found in Table 4-14.

Table 4-14 Mean scores per domain knowledge questionnaire after factor analysis

	0 assessment n=298	**6 months** n=286	**24 months** n=219
Factor 1: Angina domain	0.76 (sd 0.,55)	0.72 (sd 0.63)	0.74 (sd 0.58)
Factor 2: Red herring domain	0.14 (sd 0.35)	0.16 (sd 0.37)	0.12 (sd 0.31)
Factor 3: Measuring hypertension domain	0.65 (sd 0.76)	0.79 (sd 0.89)	0.85 (sd 0.82)

When comparing the within subject contrasts (SPSS repeated measures analysis of covariance), only the increase in the knowledge about measuring hypertension was significant ($p<0.05$).

4.4.4 Discussion and conclusion of disease knowledge analysis

According to the participating pharmacists, the lack of fully completed knowledge questionnaires is a result of the occasional resistance of the pharmacists or patients, to perform that part of the questionnaires. For this reason the knowledge questionnaire was also deliberately omitted at the second evaluation round of the project (after 12 months). In the final pharmacist evaluation the knowledge questionnaires were considered to be the most bothersome element of the project by most pharmacists. Patients sometimes reacted to questions saying that they did not suffer from the mentioned disease and did not fully understand the nature of the questionnaire.

The differences between the mean overall scores per pharmacy indicate that there were large differences between the way of documenting by interviewing pharmacists, in spite of the instruction session preceding the distribution of the first questionnaires. This indicates that the interviewers need to be trained more thoroughly and that the analyses of this type of data should be carefully planned.

The differences between pharmacists could also point to differences in implementing pharmaceutical care, but the registration of the invested time (as a process indicator) does not correlate with the knowledge changes.

Some changes seem to have occurred in the knowledge of the patients. The most important being that some knowledge seemed to be more up-front in the memory. The changes in knowledge are related to the MMSE score and in some cases also to the participant's age. After regrouping of the items with the help of factor analysis, a significant increase of knowledge was found in the 'Measuring Hypertension' domain.

According to the factor analysis, the knowledge about diseases in the elderly concentrates around angina and hypertension, but is rather limited. As for the latter domain, Kjellgren *et al.* also found quite a limited knowledge, when they interviewed 33 hypertensive patients directly after a medical consultation.[7]

Conclusion

The knowledge about diseases seems not improved by the provision of pharmaceutical care, but slightly decreased. This is probably due to the increase in age of the intervention patients. Some knowledge however, came more up-front in memory by the provision of pharmaceutical care, especially knowledge about the measurement of hypertension.

The lack of a reference sample for this part of the questionnaire seems paramount, since in this age group (mean age 73.4) there may be a rather rapid loss of knowledge over time and hardly ever a spontaneous increase. The time scale for this study did not allow for further analysis of this finding.

The changes in knowledge in the population may have been a result of the interview-effect and the discussion about the assessment during the consultation, since spontaneous retrieval increased but aided recall decreased.

The questionnaire itself also needs improvement to prevent influences of the interviewers on the score, and to improve its sensitivity.

4.5 Drug Use Behaviour, Dispensed Drugs and Compliance

Because one of the major interests in the OMA study lies in the effect of pharmaceutical care on compliance and on the use of benzodiazepines, it was decided to concentrate on changes in the use of diuretics and the use of minor tranquillisers in the population. The hypothesis is that through the pharmaceutical care intervention, the overall use of benzodiazepines would decrease compared with the reference group. The compliance to the use of diuretics would increase, assuming that compliance is low in general. Patients were also asked after their drug-use behaviour.

4.5.1 Method

Drug use behaviour

Patients were asked in different sections of the final questionnaire if they were ever non compliant, deliberately or non-deliberately. The questionnaire was sent back to the research centre directly.

The analysis of drug data

All available drug data on diuretics (ATC-group C03) and of benzodiazepines and closely related substances (ATC-groups N05BA and N05CD and amitryptillin in a daily dose <=25mg) from computerised medication histories of intervention and reference-patients were entered into a Microsoft Access database using the ATC code, the numbers dispensed and the prescribed daily dose (PDD)[8]. The participating pharmacists provided the data usually from 6 months before the study until the end of the study, unless the patient had dropped out. The analysis of the drug data was therefore undertaken as a 'per protocol' analysis. If no daily use was indicated, it was assumed that the patient took the defined daily dose (DDD) as indicated by the ATC-DDD classification index. If the drug use for benzodiazepines was indicated as 'prn.' with a certain maximum, then the maximum indicated dose was assumed.

For both drug-groups the dispensed numbers of drugs were studied in 4 periods of 6 months after the intake for intervention patients or the date of reception of the first patient-questionnaire (the zero-assessment) for reference patients and compared with the period of 6 months before the intake. See table 4-15.

Table 4-15 Periods used in drug analysis

Period 0	6 months before intervention
Period 1	0-6 months after start intervention
Period 2	6-12 months after start intervention
Period 3	12-18 months after start intervention
Period 4	18-24 months after start intervention

If, from the data provided by the pharmacy, it was clear that not the whole 6 months period was covered, the period was set to missing. The data were processed using Microsoft Excel conversion, Dbase V for windows programs, and then analysed using SPSS version 7.5.

Diuretics

To be able to compare the compliance for the users of diuretics, only those patients were compared who had diuretics dispensed before and during the intervention, receiving one or more prescription per ATC code per period of 180 days with 45 or more unit (tablets or capsules). Patients using diuretics on a prn. basis were excluded. The percentage of compliance was calculated per period of 6 month, based upon the number of units (tablets, capsules) dispensed and indicated prescribed daily dose (PDD) as follows:

$$Compliance(\%) = \frac{noofunits \times strength}{PDD \times 180} \times 100$$

In a number of cases the indicated PDD clearly was not correct resulting in a compliance in period 0 of more than 150%. Those patients have been excluded. If a patient received more than 1 diuretic (range 1-5), the compliance rate for each diuretics was calculated.

Benzodiazepines

To study the use of benzodiazepines, the number of days dispensed were analysed for the 5 periods of 6 months mentioned above, based upon the number of units dispensed and PDD. The numbers of days dispensed were calculated as follows:

$$Daysdispensed = \frac{noofunits \times strength}{PDD}$$

Patients were included into the analysis ('users') if they had used a benzodiazepine anywhere in the total study period. Many patients used more than 1 benzodiazepine at the same time, which have been added up for this analysis.

4.5.2 Results drug use

Drug use behaviour

In the final questionnaire 22.3% of the intervention patients and 11.9% of the reference patients stated that they sometimes took more or less of a prescribed medicine (deliberate non-compliance). In the same questionnaire it was asked in a different way if patients ever forgot to take their medicine. Of the intervention patients 20.4% answered yes to this question and 20.6% of the reference patients (accidental non-compliance).

When both types of non-compliance were merged 31.4% of the intervention patients and 26.8% of the reference patients were non-compliant. The difference is not significant.

Compliance with diuretics

The available drug file contained 4977 prescriptions for diuretics. The major diuretics prescribed were frusemide (n=2260) and a combination of hydrochlorothiazide and a potassium sparing diuretic (n= 853). See Table 4-16.

115 Intervention patients (58%) and 101 (46%) reference patients who completed the study used a diuretic, according to the data provided by the pharmacists. Taking the criteria into account mentioned in the method section, only 33 intervention and 24 reference patients used a diuretic continuously, with an acceptable indication of daily use. Table 4-17 gives the mean compliance rate for intervention and reference patients during the different study periods.

Table 4-16 Most frequently occurring diuretic prescriptions in OMA-research population

ATC	Drug	% of patients using diuretics
C03CA01	Frusemide	41.3
C03EA01	HClthiazide+ potass. spar. agent	16.2
C03CA02	Bumetanide	9.9
C03AA03	Hydrochlorothiazide	9.9
C03DB02	Triamterene	6.3

Table 4-17 Mean compliance rates and differences in compliance per period compared with period 0 per patient for diuretics in the OMA study

	Intervention (n=33)		**Reference** (n=24)	
	Mean rate (n=33)	**D with Period 0**	**Mean rate** (n=24)	**D with Period 0**
Period 0	102.6%		89.6%	
Period 1	91.9%	-10.7%	111.8%	+22.2%
Period 2	123.0%	+20.4%	110.8%	+21.2%
Period 3	116.3%	+13.7%	107.1%	+17.5%
Period 4	128.2%	+25.5%	99.2%	+9.6%

Table 4-17 also reflects the difference in compliance rate for period 1,2,3 and 4 compared with period 0. In the intervention group the differences for period 1,2 and 4 were significant. In the reference group the differences for period 1,2 and 3 were significant (Paired Student t-test).

The use of benzodiazepines

The available file contained 3076 prescriptions for benzodiazepines and related substances. From the 19 different benzodiazepines and related substances prescribed, oxazepam (n=1461) and temazepam (n=1309) were the most frequently dispensed. The latter is usually used as a hypnotic agent, the first as a sedative agent, although no information is available as to the indications for drug use. See table 4-18.

It is interesting to note that amitryptilline, which basically is an antidepressant agent but has been promoted in the past as a hypnotic (dosage up to 25 mgm/day) is still prescribed in this population. This drug was excluded from further analysis.

Table 4-18 Most frequently occurring benzodiazepine prescriptions in pp OMA-research population

ATC	Drug	% of OMA patients using benzodiazepine
N05CD07	Temazepam	28.3
N05BA04	Oxazepam	27.4
N05CD02	Nitrazepam	11.1
N05BA01	Diazepam	9.3
N05CD01	Flurazepam	8.2

For the 'per protocol' analysis of benzodiazepine use, data from 15 intervention and 21 reference pharmacies were available. The intervention pharmacies provided prescription data for 100 users (51% of the final number of intervention patients) in the study period. In the 6 months period before the intervention those patients received an average supply of 97.28 days of benzodiazepines (min. 0, max 310, sd 83.22). The reference pharmacies provided prescription data for 92 users (42% of the final number of reference patients). In the 6 months period before the date of the first questionnaire those patients received an average supply of 98.42 days of benzodiazepines (min. 0, max 390, sd 83.59). Many patients received more than one benzodiazepine during the period studied, either simultaneously or in sequence. The number of dispensed days per 6 months period ranged from 0 to 420, with a mean of 97-106 per patient per period.

Table 4-19 Mean number of days and mean difference of numbers of days dispensed compared with period 0 per patient for benzodiazepines over 6 months periods in the OMA study

	Intervention*		Reference*	
	Mean no days	D with Period 0	Mean no days	D with Period 0
Period 0	97 (n=98)		98 (n=90)	
Period 1	93 (n=82)	+1 (n=80)	109 (n=88)	+9 (n=87)
Period 2	96 (n=89)	+5 (n=87)	101 (n=82)	-1 (n=80)
Period 3	103 (n=77)	+6 (n=76)	109 (n=86)	+9 (n=84)
Period 4	98 (n=92)	+5 (n=91)	102 (n=91)	+5 (n=76)

* Between brackets the number of patients with valid data in periods, included into the analysis

The results of the analysis can be found in Table 4-19. The table also reflects the difference in mean numbers of days dispensed for period 1,2,3 and 4 compared with period 0. A paired Student t comparison between the period before the intervention (0) and the different periods after the intervention (1,2,3,4) showed no significant differences.

There also were no significant differences between the number of intervention patients (14) and reference patients (15) who fully stopped the use of benzodiazepines after the start

of the intervention. Between the beginning and the end of the study 13 intervention patients and 10 reference patients started to use a benzodiazepine. But for this analysis only data from 55 intervention patients and 68 reference patients were available. The remaining patients had missing data in any of the period studied.

4.5.3 Discussion

The dispensed numbers of pdd's of diuretics increased in both the intervention group and the reference group. No conclusions can be drawn from these data. When interpreting such data one must keep in mind that in The Netherlands diuretics usually are prescribed on a 3 monthly basis. Already before applying the selection criteria as mentioned in the method section, the mean number of prescriptions per patient covered in the pre-intervention period of 6 month is low (2.98 ± 1.53). Although the standard deviation diminishes by applying the selection criteria, the number of patients available for analysis also decreases. Additionally one can see from the original database that the indicated daily dose probably is not correct, and that more is dispensed than justified by the indicated daily dose. Dosage changes are clearly not reflected in the registered pdd in the pharmacy when drugs are provided for 3 months periods at a time. The chosen method is not suitable for showing minor changes in compliance under these circumstances. The increase of the dispensed numbers of diuretics in both intervention and reference group is probably due to an increase in heart failure in the population during the 30 months the drug-data were collected.

Additionally the 'compliance rate' shown by the drug data in the intervention population proved to be already high at the beginning and the overall self-reported non-compliance of both intervention and reference patients (28.9%) was low, compared to other studies. Especially a similar study by Sturgess *et al.* showed a much higher self-reported degree of non-compliance (73.7%). They used the same questionnaire, which was translated for the Dutch OMA project.[9] The reason for this difference is not clear, because the wording for the questions was exactly the same. Either the Dutch really are much more compliant with their medication then the people in Northern Ireland, or the Dutch are less truthful. Based upon these self-reported data, it is not amazing that the compliance found in the drug analysis mounts to 88-95% in the beginning of the study. When a patient mentions to forget to take a drug, that does not necessarily mean that he/she forgets to take the drug frequently and that it will show up in the dispensed numbers of ddd's.

The provision of pharmaceutical care, with the emphasis on reduction of the use of benzodiazepines and related substances, has not had an effect on the total number of daily doses of benzodiazepines provided to the intervention patients per 6 months period.

4.5.4 Conclusion on the drug use of the OMA patients

In general, in the Dutch setting the use of medication-data from pharmacy computers for calculating compliance rates, especially for chronic medication, seems not very reliable in 6-month periods. Moreover, at least for research purposes but certainly also from the pharmaceutical care viewpoint, it is necessary to be more precise in matters of daily use on the drug-labels produced in the pharmacy. Additionally the number of missing periods in the analysis was high, resulting in relatively small numbers available for comparative

analysis. Such a situation could possibly be improved by downloading drug-data directly from the computers of the participating pharmacies.

The attempts of the intervention pharmacists to help the patient to decrease or stop the use of benzodiazepines have had no effect.

4.6 DRUG RELATED PROBLEMS

The assessment of drug related problems (DRP's), is the core of pharmaceutical care. However, it is also the aspect which is the most difficult to measure. The main reason is the fact that here are pharmacotherapeutic problems, problems with side effects of drugs and practice problems and these problems are interrelated. The number of DRP's is not a final outcome of care, but it is to be expected that it affects morbidity and mortality and as such is a proxy for those final outcomes[10].

The pharmacist in co-operation with the prescriber usually solves pharmacotherapeutic drug-related problems, after consultation with the patient. This is especially the case in The Netherlands, where major DRP's are usually already solved when filling a prescription together with the prescriber, due to the standard medication surveillance being performed in every Dutch pharmacy. Practical issues, e.g. problems with taking medicines, usually are only considered to be a problem when the patient shows a lack of compliance due to this type of problem and when the lack of compliance affects the treatment outcomes.

4.6.1 Method

In the European study regarding the effects of pharmaceutical care in the elderly, the assessment of drug use problems was also included. The specific questions in this field were only added to the Dutch questionnaire at the final evaluation because they were not available earlier. Cohen's kappa was used to measure the agreement between the occurrence of mentioning the different categories of specific problems with medicines.

During each evaluation session the pharmacist inquired after drug related problems with the patient. The number of problems was recorded and an assessment of the character of the problems was registered in the form of a PAS® coding[11]. The PAS codes were not analysed in depth because the PAS®-coding system proved to be difficult to use and interpret[12].

4.6.2 Results of the drug related problems

Practice problems

During the final evaluation the patients indicated practice problems as listed in table 4-20. The response to this section of the questionnaire (8 questions) was on average 77.2% (n = 425). Only 35.5% of the intervention and 40.8% of the reference patients reported not to have any problems with using medicines. The mean number of reported problems was 1.3 in the intervention group (sd 1.4, range 0-7) and 1.18 in the reference group (sd 1.3, range 0-6). There was a certain amount of agreement for most of the answers on a patient level. Many patients who had trouble reading information leaflets, also had trouble reading labels (κ=0.59, $p<0.0005$). Patients who had trouble opening containers, also had trouble using strips (κ=0.31, $p<0.0005$). Patients having problems with the taste of medicines had more

problems with the swallowing medicines (κ=0.27, p<0.0005) and also reported more frequent to have troubles with side effects (κ= 0.21, p<0.0005).

Table 4-20 DRPs reported by intervention and reference patients OMA study

Problem	%
Swallowing medicines	11,0
Opening containers	12,6
Using strips	16,1
The taste of medicines	14,3
Remembering to take medicines	20,5
Reading labels	15,2
Reading information leaflets	22,0
Side effects of drugs	31,2

According to the results of this section of the questionnaire, men have significantly fewer problems opening containers then women (Mann Whitney test, p=0.01) and significantly fewer problems with side effects (Mann Whitney test, p=0.045).

Patients with a higher level of education have significantly more problems with opening containers (Kruskal Wallis test, p=0.003) and less problems with reading labels (Kruskal Wallis test, p=0.007). Neither the patients age nor pharmacy seems to have a significant influence on the extend or profile of the problems reported.
There were no significant differences in the number of reported problems between the intervention and the reference group.

Problems discussed with the pharmacist

During the study the pharmacists recorded the number of problems patients had with their medication, at intake and during the evaluation-assessments. These data are therefore only available of the intervention patients.

Analysis of these pharmacist data showed a decrease in the number of patients who mentioned having problems with their medication during the consultations after the first half year. The maximum number of problems mentioned per patient per evaluation form and the mean number of problems mentioned also decreased (see table 4-21).
Of the 130 patients registered as having drug related problems at intake, 100 problems were coded with the PAS® system.

The main problem codes obtained from the pharmacists were P11 and P12, which stand for problems with the effects and side effects of certain medicines. According to the pharmacists these problems, as the patients expressed them, were mainly problems due to the occurrence of side effects. Giving information and/or referral to the GP and/or giving instructions for use solved the problems.

Table 4-21 Problems mentioned during OMA intake and assessments

	Intake (n=324)	6 months (n=259)	12 months (n=217)	24 months (n=202)
% of patients mentioning problems	37.7	38.6	18.4	11.9
Max. no of problems per patient	12	10	4	2
Mean no of problems if problems mentioned	1.84	1.46	1.26	1.04

There is a low but significant correlation (r_p= 0.31, p<0.0001) between the number of drugs used by the patient and the number of drug related problems registered by the pharmacist. An increased number of drugs clearly gave rise to an increased number of drug related problems.

4.6.3 Discussion and conclusion of the drug related problems

Since the questions on problems with medicines experienced by the patients were only added to the last questionnaire, no final conclusion can be drawn on the effect of pharmaceutical care. However, it appears that according to the patients the provision of pharmaceutical care has had no influence on the prevention of this type of drug-related problems. Of all patients, 37% have more problems, in more fields simultaneously. The major problems are difficulties with side effects of drugs, compliance and reading information leaflets. There are clear relations between the difficulties in reading (labels and leaflets), between getting medicines out of their different kind of packages, and amazingly between the taste of medicines and side effects. There is no indication in the pharmacists' evaluation notes, that they have addressed this type of patient-experienced DRP's, apart from the side effects.

Analysis of the evaluation data from the pharmacists also shows that side effects are the most common drug-related problem in the group of elderly over 65, using 4 or more different medicines. The occurrence of drug-related problems correlates with the number of drugs taken by the patient. The pharmacists tried to solve the problems mainly by giving information and/or by referral to the GP.

According to the pharmacist' data they were successful in using this strategy. The maximum number of problems as well as the average number of drug related problems decreased in the intervention group during the study. It is clear, according to those data, that it takes some time (> 6 months) before the problems are solved. However, the pharmacists' documentation did clearly not reflect the problems experienced by the patients and expressed in responses to the direct questionnaire.

4.7 USE OF OTHER HEALTH CARE RESOURCES

During the OMA-study the drug regimen of the elderly was reviewed and they received information about their drug use and their diseases. It was expected that this form of pharmaceutical care would decrease the frequency of the use of other health care resources such as general practitioners, specialist or hospitals. Therefore the pharmacists asked the

intervention patients about these issues during their evaluation sessions and documented their responses in the evaluation questionnaires.

4.7.1 Method

The pharmacists at intake obtained data (about the previous year), at 6 and 12 month (about the previous 6 months) and after 24 months (about the previous year). The frequency of GP and specialist visits and hospitals admissions were recalculated on an annual basis, and the means per year were compared using the paired samples Student t test. The analysis was performed for all patients completing the protocol, but due to some missing data for the first year (one pharmacy did not perform the 12 months assessment) the compared means are somewhat different from the overall means.

4.7.2 Results health care resources

Table 4-22 contains the means of the frequencies of the different contacts with health care providers according to the ITT analysis.

Table 4-22 Contacts with health care professionals of OMA population

	1 year before intake	First year of intervention	Second year of intervention
GP-visits or home visits	5.82	5.73	4.58
Specialist visits	4.76	5.02	4.09
Hospital admissions	0.73	0.95	0.62

When comparing the different years using PP analysis, the following changes where significant. The mean number of GP visits decreased by 1.29 visits per year from 5.87 to 4.58 between the year before the intervention till the second year of the intervention. The mean number of specialist visits decreased by 0.72 visits per year from 4.81 to 4.09 between the year before the intervention till the second year of the intervention.

Hospital admissions increased by 0,24 admissions per year from 0.71 to 0.95 between the year before the intervention and the first year of the intervention. However, this frequency decreased again after the first year.

4.7.3 Discussion and conclusion on the use of health resources

The mean number of GP-visits per annum is similar to the mean numbers found for people over 65 by van der Werf *et al.* (5.6 visits) in a large Dutch population.[13]

It is surprising that in this study the frequency of GP-visits shows only a slight difference with the frequency of specialist visits. In the Dutch healthcare system the GP is the key person, and serves as a kind of filter. One would have expected a lower frequency for specialist visits.

In spite of the fact that it could be expected that the frequency of the use of health care resources would go up because of the increasing age of the intervention patients, there has

been a clear overall downward change in this population, being statistically significant for GP and specialist visits. The data on GP and specialist visits during the first year of the intervention can be affected by the referral by the pharmacist. There is no clear explanation for the sudden rise of hospitalisations in the first year of the study but it may be a result of the increase of the GP and specialist visits.

The lack of sufficient data from the second evaluation (168 cases evaluated instead of 196) probably has influenced the general outcome. For a clearer evaluation more patients are required because the changes to be expected are small. Because reference patients had no direct contact with their pharmacists, no data could be obtained in a similar manner from that part of the population and comparison with the reference group therefore was not possible.

4.8 Overall conclusion to this chapter about the OMA study

The provision of pharmaceutical care, as described in Chapter 3, led to a high satisfaction amongst patients. However, no major influence was seen on knowledge or quality of life (according to the SF-36). There was no clear picture with regards to the influence on compliance, due to low numbers and the narrow pre-study period of drug data and no influence could be established on the dispensed numbers of benzodiazepines. Some other outcomes have changed in the expected sense, but not to a statistically significant degree.

The picture with regard to drug-related problems is mixed. Although the pharmacist recorded a decreasing number of problems while providing care (mainly problems dealing with side effects), according to the patients at the end of the project there was no difference between the intervention and reference groups with regards to the problems with medicines they experienced.

The overall picture shows some similarities to the result of a recent diabetes project in Great Britain, during which the care and communication were deliberately improved for a group of patients[14]. Although the satisfaction with the provided care in the intervention group was paramount in that study, no significant positive influence could be seen on the knowledge or the coping capabilities of the patients.

In general the provision of pharmaceutical care has led to some statistically significant expected positive changes and some tendencies towards positive changes, but there was a lack of a clear change in the final outcome of care, being quality of life.

On further consideration the latter is not surprising. First of all the final size of the research population did not add up to the desired size for measuring changes with the SF-36. Secondly a generic instrument, by definition, is not very sensitive. And thirdly, if changes occur (and the patients themselves confirmed positive change), then changes as a result of the provision of pharmaceutical care will probably be small and diffuse. It is to be expected that it is easier to measure changes in HRQL after one single, clear-cut intervention than during a 2-year continuous intervention, because patients adapt their expectations over time to their general health status.

The OMA study has not given all the expected results. This was certainly partially due to the bad process control and incomplete documentation, which will be discussed in the final conclusions of this dissertation (see Chapter 10).

4
RESULTS OF PHARMACEUTICAL CARE IN THE ELDERLY, THE OMA STUDY

The OMA study into the effects of pharmaceutical care in the elderly was carried out between the beginning of 1995 and the end of 1997. In this chapter the results of this study, based upon the methodology described in Chapter 3, are discussed. Several outcomes and indicators are analysed and discussed after a description of the population.

The intervention group received education about drug and non-drug management over a period of 24 months. Compliance with the drug regimen was regularly discussed. In the mean time the pharmacist evaluated the drug use and possible drug-related problems and gave suggestions for improvement to the patient. When necessary the pharmacist made recommendations to the physicians regarding pharmacotherapy. Additionally the pharmacists tried to decrease the use of benzodiazepines by the patients.

During the whole study the separation of an internal and external reference group was maintained. However, as will be shown in this chapter, there were no major differences between the developments in the two reference groups during the study, and therefore in some of the analyses the two groups are merged to increase the statistical power.
For the analysis the results were used from different sources, as follows:

- intake data and evaluations (after 6,12 and 24 months) by the pharmacists;
- replies to questionnaires which were sent to intervention and reference patients at the start of the projects and after 6,12 and 24 months;
- drug-prescription data of the intervention and reference patients, from the computers of the participating pharmacists.

Not all patients answered all parts of all questionnaires, therefore the evaluated numbers per item (and per paragraph) may differ from the total population and this will be mentioned in the appropriate paragraph.

Two kinds of comparisons are common throughout this chapter: comparisons between the intervention and reference group(s) and comparisons of the developments within the intervention group over time. The method chosen depends on the availability of data, because questions about the process and the content of the provided care could not be asked in the reference group since they received no special care.

The analyses have been performed according to the 'per protocol' principle (PP) as well as the 'intention to treat' principle (ITT), depending on the character of the available data. The target was to include as many patients as possible, but because of the high drop-out rate during the study the ITT principle could not always be followed and sometimes it was not appropriate.

4.9 REFERENCES TO CHAPTER 4

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within the age limit at intake. Some were not included because the intervention pharmacy dropped out before the whole intake procedure was finalised (2 pharmacies).

During the study a high percentage of the population dropped out, especially in the intervention group. The reasons for dropping out of the TOM study were difficult to assess. Usually the patients did not attend their meetings with the pharmacist, or did not return their questionnaires to the research centre without further explanation. The available reasons for drop out have nevertheless been analysed. Table 5.1 shows the composition of the study-population, and the drop-out numbers during the project.

Table 5.1 Study population TOM and drop-out

	Intervention	Internal reference	External reference
Patients at intake	191	157	105
Drop out during study	121 (63.4%)	28 (17.8%)	24 (22.9%)
Patients at end of the study	70	129	81

In the intervention group the initial drop out, between the 0-assessment and the first evaluation was 28.5%, another 22.8% dropped out between the first and second assessment. At the end of the study we received 100 patient-assessments from the pharmacists, however, only 70 of those patients also returned the final questionnaire. Some other characteristics of the patient groups at intake can be found in table 5-2.

Although the frequency of pharmacy visits shows a remarkable difference between the intervention and both reference groups, this difference is not significant. The difference in familiarity with the pharmacist is significant (Student t test), which can be explained by the different ways the intervention and external reference pharmacists were recruited (see Chapter 3).

Table 5-2 Characteristics of TOM study population at intake

	Intervention	Int. Ref.	Ext. Ref
Number of pharmacies	16	17	13
Male (%)	41.4	32.5	34.3
Mean age	34,3	34.0	32.6
Mean score symptom domain Asthma Related Quality of Life	4,98 (response 99%)	4,92 (response 99%)	4,95 (response 72%)
Freq. of pharmacy visits (yearly means)	7.9	9.4	9.6
Familiarity with pharmacist (%)	48.4	50.6	35.9
Patients not visiting other pharmacies (%)	94.7	86.5	93.2

5.1.1 Analysis of drop out

The major reason for drop out was the fact that no final evaluation was performed and/or no final questionnaire was returned. This accounted for over 95% of the dropouts in all three groups. In each group one patient moved, and in the intervention group three patients (2.5%) stated that they did not feel like continuing; another 3 patients found themselves too ill to continue.

In the external reference group a relatively high proportion of women dropped out (75%), compared to the original composition of that group. The resulting groups, however, were not significantly different from each other in this respect.

There also has been some bias on the basis of the age of the patients. The mean age (at the start) of the patients who completed the study went up by 0.5-2 years. With regard of the age limits in the study (20-45), this can be ignored but it is possibly an indication that younger patients had more difficulties to adhere to the study and attend the evaluation sessions.

5.1.2 Discussion and conclusion on the population in the study

The intervention, internal and external reference patients in the TOM study did not show significant differences at the beginning of the study, which might influence the results. The mean score for the symptom domain of the Asthma Quality of Life Questionnaire also showed that the severity of the asthma of the included patients is the same[1]. The external reference group is less familiar with their pharmacist than the intervention or the internal reference group. For the study itself and the interpretation of the results this has only minor consequences because satisfaction data about the pharmacist were only evaluated if the patients knew the pharmacist.

If dropout rates are compared, then the relative high rate of the intervention group is striking but not much can be said about the reasons for drop out in the TOM study. It appeared that there was not enough motivation left at the end of the study to fill out the final evaluation by the pharmacists and for the patients to fill out and return the final questionnaire. The intervention pharmacists reported that it often took a great deal of effort to even make an appointment with the patients included into the study. Most of the patients were at work during the daytime and not inclined to visit the pharmacist in the evening. But another reason could be that the patients found that they had learned enough to handle their own asthma after a limited number of consultations, and did not need to see the pharmacist anymore.

There is no reason to assume that the slight increase in the age of the remaining patients at the end of the study will influence results.

In general the intervention and reference population showed no important differences at intake and that no selection bias occurred which could influence the outcomes of the TOM study.

5.2 Quality of life

Because the main objective of pharmaceutical care is to influence patient quality of life, in this study a generic (the SF36) and a disease specific asthma questionnaire (the Asthma Quality of Life Questionnaire, AQLQ) were used (see Chapter 3 for the selection

arguments)[12]. After 24 months the intervention patients were also asked in a self-completed questionnaire if they felt better because of the received care during the TOM project.

5.2.1 Method

All intervention and reference patients received the mail version of the SF36 and the AQLQ at baseline and after 6, 12 and 24 month. Both questionnaires were administered by mail, with pharmacist and research centre independent telephone support, 3-5 days after reception of the questionnaire, by a marketing research organisation. The results were entered into SPSS, and domain scores were calculated. Scores of the SF-36 were compared according to the SF-36 manual with the help of SPSS, ver 7.5. Scores for the AQLQ were compared according to the procedures described by Juniper *et al.*[1]. The four domains for evaluation of the latter questionnaire are: activity limitations, symptoms, emotional function and exposure to environmental stimuli.

The list of activities offered to the patients in the AQLQ is well balanced and quite exhaustive. Therefore, if there were 1-4 missing activities amongst the first 5 questions of the questionnaire, the patient was expected to have no limitations in other activities than those mentioned and the missing scores for question 2-5 were defined as 7 (not at all limited). If no activity was mentioned at all, the scores for the first five questions were left as missing. Domain scores (means) were only calculated if not more than 75% of the scores per domain were missing, according to the indications given by the author of the questionnaire.* Missing data for the SF36 were dealt with according to the rules given in the manual[2].

Different statistical methods were applied to detect differences in the development between the intervention, internal reference and external reference patients. Internal and reference patient-groups were often merged to increase the statistical power because no clear difference between those groups could be established. Mainly one approach has been chosen for evaluation of the patients who had completed the whole study (Per Protocol, PP), because the interest of the study lies in the application of pharmaceutical care over time. Drop out analysis did not show any significance of drop out, as far as data were available.

5.2.2 Results Quality of Life

The analysis of the SF-36 data showed no significant changes in any of the domains (for detailed descriptions of the possible analysis of the results of the SF-36 see Chapter 4).
In case of the AQLQ there were no significant differences between the domain scores for the intervention and the reference groups at intake (Student t test for independent samples). In both the intervention group as well as the reference group there were significant score-increases for some of the domains, but the increases in the intervention group were always larger (Student t test for paired samples, see table 5-3).

In spite of the differences between the mean increase in the intervention and reference group, the GLM procedure in SPSS 7.5 did not indicate that the increases in the domains differed significantly between the intervention and reference group.

* Personal information (Email received from E. Juniper, Dept. of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, Canada. 13th November 1998.)

Table 5-3 Score and score changes in TOM study, PP analysis AQLQ (n=257)

	Mean score 0-assessment		Mean increase (D) of score over study period (24 months)	
	Intervention (n=70)	Reference (n=187)	Intervention	Reference
Activity	5.30 (sd 1.18)	5.19 (sd 1.14)	0.14 (n.s.)	0.05 (n.s.)
Symptoms	4.87 (sd 1.34)	4.92 (sd 1.17)	0.43 ($p<0.01$)	0.19 ($p<0.005$)
Emotional functioning	5.39 (sd 1.21)	5.45 (sd 1.18)	0.44 ($p<0.0005$)	0.26 ($p<0.001$)
Environment stimuli	4.56 (sd 1.33)	4.62 (sd 1.26)	0.52 ($p<0.0005$)	0.34 ($p<0.0005$)

n.s. = change not significant. If P values are mentioned then the change is significant

Of the 70 intervention patients remaining at the end of the project, 46% expressed in a questionnaire that they were feeling better or much better because of the received care. There was no clear correlation between this opinion and the changes in quality of life according to the AQLQ.

5.2.3 Discussion and conclusion of the quality of life

On the basis of the results of the AQLQ there is a clear indication, that the asthma related quality of life in the intervention group increased more than in both reference groups, although the difference was not significant at a 0.05 level. This increase was also found in the ITT analysis. The mean domain scores at the start of the project were similar, but somewhat lower than those found by van der Molen in a Dutch population with moderate asthma[3].

The question remains if the increase could be clinically significant. Juniper *et al.* described the minimal important difference in score to be 0.5, which should be consistent across the domains.[4] There is a continuous debate on the relationship between clinical findings and quality of life and their statistical and clinical significance, so it is hard to reach clear conclusions at this stage[5]. In another article, in which she described seven clinical symptoms, correlation of score changes with several clinical measures ranged from 0.30 to 0.6 (symptoms domain), from 0.26-0,56 (emotions domain), from 0.2 to 0.45 (activities domain) and 0.17 to 0.44 (environment domain).[6] Apparently different issues are being measured.

In the TOM study, especially in the fields of symptoms and emotional functioning the change in the intervention group came close to 0.5, but there was also a score increase in the reference group. The increase in HRQL in both groups could be attributed to effects of illness adaptation and increased coping-capabilities of all patients, an effect that has been described by Padilla *et al.*[7]. Part of the increase in both groups could also be attributed to environmental differences, which are season dependent and can not be corrected for (except by including a reference group in an asthma study, as was the case here).

Nevertheless with regard to the impact of emotions and feelings involved in asthma, which are reflected by a HRQL questionnaire, according to the TOM data there is a clear indication that a patient's quality of life improves from receiving the pharmaceutical care as described in Chapter 3. All scores went up, be it not statistically significant at a level of $p<0.05$ when compared to the reference group. This increase is especially clear in the field of symptoms, emotional function and exposure to environmental stimuli.

Apparently, the patients were not always aware of the improvement because there was no clear correlation between their opinion on their improved wellbeing and the results of the AQLQ. Since the Asthma Quality of Life questionnaire is well validated [1,4,11] , asking patients if they are feeling better clearly is not a good way of evaluating their asthma related quality of life.

Although in previous studies it has been demonstrated that the SF-36 is a suitable instrument to identify changes in the quality of life in asthma patients, our study does not confirm these findings[8,9,10]. The SF-36 scores in this study showed no significant changes. But according to Juniper the SF-36 is not well suited to use in longitudinal clinical trials and also correlates poorly between quality of life and clinical improvements in asthma[11]. Therefore in the case of the longitudinal evaluation of additional care for asthma patients the SF-36 is probably not a good instrument to measure changes in the quality of life. V.d. Molen also found in his PhD-dissertation that the most sensitive instrument to measure changes in asthma status is the AQLQ, and even advises against the use of a generic instrument[3].

5.3 Satisfaction, Content and Character of Communication, a Process Evaluation

The communication process is an important element of pharmaceutical care. During the TOM study different aspects of the communication process were studied because the major topics for the consultations were well defined: inhalation technique, drug use and self-management and because the consultation itself is even more important than in the (more diffuse) OMA project. If the communication process is optimal and important topics in the field of asthma have been discussed, then the chances for a good result are optimal. The satisfaction of the patients will partially depend on the satisfaction with the care provided during the consultations, and partially on the experienced changes in quality of life and physical improvements, which are discussed elsewhere.

5.3.1 Method

The intervention patients were questioned on the contents and the 'emotional' character of their communication during the consultations in the questionnaires at 6, 12 and 24 months. Not all intervention patients responded to all questionnaires. At 6 months 72.8%, at 12 months 76.4% and at 24 months 36.6% of the patients at intake responded to this section of the questionnaire.

Of the responding patients (n=140) one patient had not spoken with the pharmacist during the first 6 months of the study. Of the patients responding during the second round of questionnaires (n=146), 39 patients reported that they had not spoken with the pharmacist between the 6 and 12 month evaluations. Of the patients responding at 24

months (n=70), two patients stated that they had not spoken with the pharmacist during the previous 12 months. The given results are based upon the patients who responded that they had spoken with the pharmacist in the period concerned.

5.3.2 Results satisfaction and communication

Patients were asked to indicate how often and where they had spoken with the pharmacist. All consultations took place in the pharmacy.

During the first year the mean number of consultations (including the intake) was 3.8 (range2-15, sd 2.1). During the last year the average frequency was 2.07 (range 1-10, sd 1.46). Figure 5-4 clarifies the distribution.

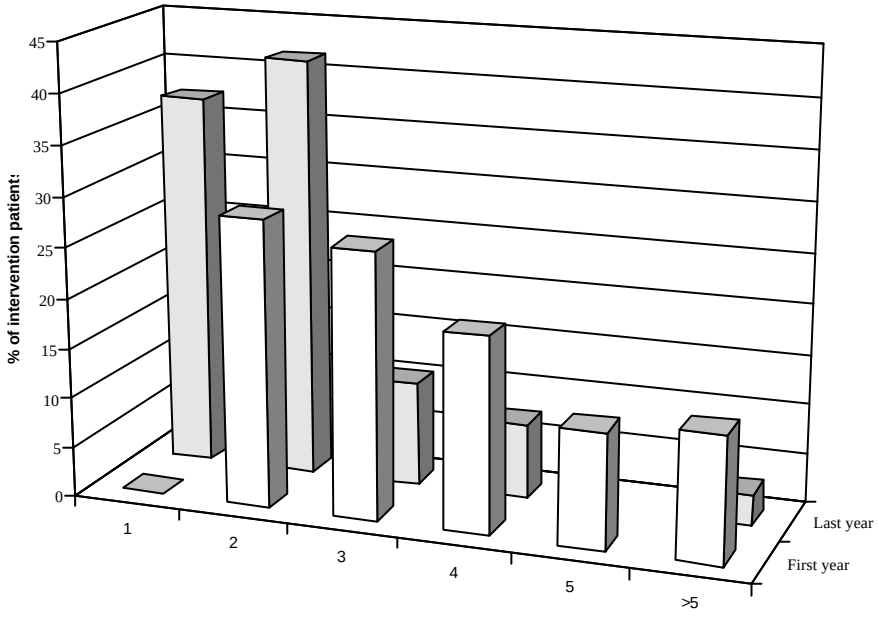

Figure 5-4 Frequency of consultations TOM study

From the available data it is difficult to estimate the average time spent on consultations. According to the pharmacists, the intake took about 45 minutes (range 30-60 minutes). Consequent evaluations took 20-30 minutes (range 15-45 minutes).

The patients mentioned average times per consultation ranging from 3 to 90 minutes, with a mean of approximately 28 minutes. After the first six months, most patients (60%) had only 1 consultation with the pharmacist as shown in table 7-5. This consultation was most probably the session at which the evaluation assessment was carried out. There were no differences between the individual pharmacies for the amount of time spent or the frequency of the consultations.

The intervention patients who responded and who had spoken with the pharmacist reported that they had always or mostly spoken about the topics mentioned in table 5-5.

The patients mentioned no additional topics. In general women indicated less often to have spoken about all those topics than men. The difference was significant for lifestyle, hobbies, family and health/disease in general.

Table 5-5 The topics discussed during consultation according to patients (% of responders)

	6 months n=139	12 months n=107	24 months n=68
Correct use of medicines	82.9	77.1	79.1
Action of medicines	82.1	81.3	76.1
Asthma self-management	81.0	82.8	80.0
Inhaler technique	69.8	63.5	65.4
Patients' disease(s)	66.7	77.4	67.2
Side effects of medicines	45.3	28.3	35.4
Life style issues	40.6	38.7	35.8
Health/disease in general	34.1	51.6	37.9
Relationships with doctors	19.6	19.2	14.9
Patients' hobbies	13.9	14.3	12.1
Family circumstances	10.1	5.6	7.5
The pharmacy	8.7	2.3	7.8
OTC	6.6	6.6	9.2
Home delivery of medicines	3.6	7.0	4.7

The character of the consultations was analysed for those patients giving an opinion as outlined in table 5-6. The opinion of the intervention patients hardly changed during the project. The indicated ranges are the minimum and maximum mentioned in any of the 4 assessments. No influence of gender could be recognised on these issues.

At the final evaluation the meaningfulness is correlated (Spearman's rho, r_s) with other positive opinions about the consultations, like clarifying (r_s=0.70), informative (r_s=0.62), pleasant (r_s =0.44) and personal (r_s =0.41), all $p<0.0005$. Patients who found the consultations annoying often found the consultations too long (r_s =0.41) or badly structured (r_s =0.47).

The positive opinion of the intervention patients with the new way of coaching increased slightly from 62 % after 6 months to 75.7% after 24 months. The remaining 24.3% of the patients at the end indicated to be neutral. No negative opinion was expressed. If patients were asked in what period they had benefited most of the provided care, 66% said during the whole period and 27% said during the first 6 months (n=52).

Intervention patients, who had spoken with the pharmacist about medicines, were also asked for their opinions on the interest of the pharmacist for their well-being and the

privacy offered. Before the intervention 64% of the patients who expressed an opinion (n=25) thought that the pharmacist was interested in their well-being and at the end of the intervention 87% (n=52). Before the intervention 56% of the patients who expressed an opinion (n=25) thought there was enough privacy in the pharmacy, after the intervention 92% (n=52) had this opinion. In the reference group there was no important change on these opinions (see table 5-7 and 5-8)

Table 5-6 Patient opinion on the character of the consultations

Suggested character of consultation	Range of patients sometimes or always agreeing
Too long	4-7%
Useless	5-12%
Badly structured	6-10%
Annoying	6-7%
Too short	10-15%
Professional	60-70%
Pleasant	80-86%
Personal	84-86%
Clarifying	89-97%
Friendly	94-99%
Meaningful	97-100%

Table 5-7 Opinion on enough privacy in the pharmacy and response rates in TOM study

Privacy	Intervention				Reference			
	Yes	No	Don't know	Response rate	Yes	No	Don't know	Response rate
Before study	56%	6%	13%	13.3%	47%	47%	5%	8.2%
End of study	92%	6%	2%	74.2%	67%	33%	0%	10.1%

Table 5-8 Opinion on the pharmacists' interest in the wellbeing of the patient and response rates in TOM study

Interest	Intervention				Reference			
	Yes	No	Don't know	Response rate	Yes	No	Don't know	Response rate
Before study	64%	12%	24%	15.1%	48%	24%	28%	8.2%
End of study	87%	0%	4%	74.3%	62%	0%	38%	10.1%

The increase in the reference group was in both cases clearly due to an increased positive opinion of the internal reference group. The numbers of responding patient were, however, to low to justify further statistical analysis on this aspect.

5.3.3 Discussion and conclusion of the satisfaction and process evaluation

It is difficult to assess how often patients and pharmacists spoke with each other. Apart from the first 6 months after the intake, most patients saw the pharmacist at least once every 6 months. In spite of this low frequency, patients had almost similar opinions about the character of the consultation at all three assessments, and are quite positive. Although their questionnaires were directly returned to the research centre, social desirability may explain part of this positive attitude. If patients did not like the consultations, they found them too long, useless or not so friendly.

Medicines and their use in asthma, including inhaler technique and self-management appeared to be the major topics which patients remembered to discus during the consultations. These topics remained approximately the same throughout the project. This might partially be explained by the fact that during the evaluations the content of the consultation was largely dictated by the evaluation questionnaire and that the pharmacists were asked by the research team to focus on inhaler technique and self-management.

Only the patients' diseases, and health and disease in general were more frequently discussed between 6 and 12 months. This indicates that such subjects apparently need more understanding between the partners in pharmaceutical care before they can be discussed.

During the study it became also more clear to the intervention patients that the pharmacist had an interest in their wellbeing and that there was enough privacy for consultations. In the reference group there was also a slight increase, but based upon much lower numbers because the patients in those groups had less contact with the pharmacist. In this respect there was an indication that the internal reference pharmacists (e.g. the pharmacists in the other pharmaceutical care study) performed increasingly better than the pharmacists in the external reference group, although the frequency of contacts with the pharmacists did not increase.

In general it is clear that patients liked the consultations (even when they dropped out), which is also reflected by the high satisfaction about the care provided. Based upon the fact that satisfaction in both the ITT and PP analysis were similar throughout the project, there is no indication that more patients with a negative or neutral opinion about the provided care dropped out of the project than patients with a positive opinion.

5.4 KNOWLEDGE ABOUT ASTHMA AND RELATED DISEASES

An assessment was made of the possible knowledge changes in relation to asthma and related diseases during the TOM study at intake, after 6 and after 24 months. The planned 12 months assessment was omitted because during project evaluation sessions the assessments about knowledge proved to be quite a burden on the participating pharmacists (and patients).

The structure of the knowledge questionnaire was similar to the one used in the OMA study (see Chapter 3). Because of the structure of the knowledge questionnaire and the fact that the questionnaire would give raise to discussion and was therefore part of the intervention, only data from intervention patients were collected. To avoid influencing the knowledge in the reference patients, they did not complete knowledge questionnaires.

Fully completed 0-month knowledge questionnaires were obtained from 190 participants in the TOM study. From 100 participants we received the 0-assessment and either the 6 months assessment and/or the 24 months assessment. These participants were included into the analysis. The final number of evaluated knowledge questionnaires at 24 months was 43% higher than the number of patients in the study at the end because some of those patients did not return their final questionnaire and therefore were considered to be part of the drop-out group.

5.4.1 Method of coding and analyses

The questionnaire consisted of 29 items, divided into 4 domains.

- Genesis of asthma 1 domain, 9 items;
- Reasons for an asthma attack, 1 domain, 8 items;
- Chronic bronchitis, 1 domain, 6 items;
- Emphysema, 1 domain, 6 items.

The questions are coded as follows: 2 = spontaneous correct, 1 = after questioning correct, 0 =don't know and -1 = after questioning incorrect. The 5 red herring items (see 3) are coded reversibly: -2 = spontaneous incorrect, -1 = after questioning incorrect answer, 0 = don't know and 1 = after questioning correct answer.

The possible range for the total score per patient therefore was minus 33 to plus 54. The data were analysed on the level of changes in mean scores per domain by different statistical methods, using SPSS for Windows.

5.4.2 Results knowledge TOM study

A high percentage (>80) of the patients knew from the beginning of the study that asthma means shortness of breath, wheezing, coughing, constriction of the bronchi, and that it has an allergic origin. They also knew that house-dust, pets and skin particles, smoke, and exercise may provoke an asthma-attack. More than 80% knew that chronic bronchitis also meant shortness of breath and involves a lot of mucus production. The knowledge about emphysema was much more limited. The development of knowledge on questions where less than 80% of the patients knew the correct answer has been performed per domain with table 5-9 as result.

5.4.3 Discussion and conclusion, the knowledge

From the results of the zero assessment it is clear that patients in general are quite well informed about asthma and etiological factors. They knew less about related topics like chronic bronchitis and emphysema.

Although there is no indication that the knowledge on asthma and precipitating factors has improved, it is clear that after 6 months and at the end of the projects more patients knew about chronic bronchitis and emphysema. The last aspect is important, because under-treated asthma may result in emphysema at a higher age.

The erratic knowledge changes in the two asthma domains indicate that it is not very useful to assess knowledge on well-known topics with this type of questionnaire. Furthermore, during the analysis of similar data from the OMA project, it became clear that

the type of questionnaire for assessing knowledge has to be developed further (see section 4-2 of this dissertation).

Table 5-9 Knowledge change in different domains TOM study

Domain	Compared assessment with intake	% Patients with increased scores	% Patients with decreased scores
Asthma genesis and effects	6 months	29	51
	24 months	42	39
Asthma attack, generating factors	6 months	46	36
	24 months	39	48
Chronic bronchitis	6 months	44	34
	24 months	48	37
Emphysema	6 months	53	34
	24 months	56	25

5.5 Drug use behaviour, Dispensed Drugs and Compliance

As already discussed in Chapter 3 of this dissertation, the drug use by asthma patients usually is not optimal. Especially the lack of compliance with regard to inhaled corticosteroids may result in decreased asthma control. Additionally, when self-management has been put in place, patients hesitate to increase their use of corticosteroids as a response to decreased peak flows[12]. The major interest during the TOM study in relation to medicines was on the effect of pharmaceutical care on asthma related medication. An improved use of preventive medication (inhaled corticosteroids of cromoglycates) leads to a decreased use of reliever-medication (betamimetics and anticholinergic drugs) and a decreased incidence of the use of rescue medication (courses of oral corticosteroids and antibiotics).

It was also expected that the knowledge about asthma medication as a whole increased, possibly leading to a better use of medicines. Therefore patients were asked the colour of preventive and relieving drugs (which is standardised in The Netherlands) and the sequence in which they would take this medication. Data on inhaler technique have not been analysed.

5.5.1 Method

Intervention (n= 70) and reference patients (n=230, internal and external reference group combined) were asked in different sections of the final questionnaire, which was sent back to the research centre directly, if they were ever non-compliant, deliberately or non-intentionally (reported behaviour). A sample of such a questionnaire can be found as an appendix 6 to this dissertation.

In the field of knowledge about their medication patients were also asked in which sequence they would take the blue (reliever) and the brown (preventer) drug. Intervention patients were asked what the different colours of drugs stood for: blue for relievers, brown for

preventers and green for longer-term relief (long acting β-stimulants like salmeterol and formoterol.

All available prescription data on drugs involved in asthma treatment from intervention and reference-patients were entered into a database using their ATC code[13]. Table 5-10 lists the drugs included, with their ATC code, based upon the commonly used drugs in airway diseases in The Netherlands, and identified in the population. Salmeterol and formoterol were not included because their role in asthma-treatment during the study was unclear and not yet described in any treatment standard. Theophylline and derivatives are hardly used in asthma treatment in The Netherlands anymore and therefore were not included. Ipratropium is occasionally used as reliever medication.

Table 5-10 ATC-codes of drugs included in TOM analysis

Corticosteroids (oral)*		**Beta-mimetics****	
H02AB06	Prednisolone	R03AC02	Salbutamol
H02AB07	Prednisone	R03AC03	Terbutaline
Antibiotics*		**Corticosterods inhaled*****	
J01AA02	Doxycycline	R03BA01	Beclometasone
J01CA04	Amoxicillin	R03BA02	Budesonide
J01CE05	Pheneticillin	R03BA05	Fluticasone
J01CR02	Amoxicillin +enzyme inhibitor	**Anti-asthmatics, other*****	
J01DA08	Ceflaclor	R03BC01	Nedocromil
J01EE01	Cotrimoxazole	R03BC03	Cromoglicic acid
J01FA06	Roxithromycin	**Anticholinergics****	
		R03BB01	Ipratropium bromide

* Rescue medication
** Relievers
*** Preventers

The participating pharmacists provided data usually from 6 months before the study until the end of the study (24 months after intake), unless the patient had dropped out. The dispensing frequency and the number of prescribed daily dosages (pdds) dispensed were analysed in periods of 6 months and then compared to the period before the intervention. The five available periods were: period 0 (6 months before intake), period 1 (6 months after start intervention), period 2 (6-12months after start intervention), period 3 (12-18 months after start intervention) and period 4 (18-24 months after start intervention). For the reference patients the starting date was the date of distributing the zero assessment questionnaires.

If, from the data provided by the pharmacy, it was not clear that the whole 6 months period was covered, the period was set to missing. The data were processed using Microsoft Excel conversion, Dbase V for windows programs, and then analysed using SPSS version 7.5.

Reliever medication

To study the use of reliever medication, the number of days dispensed were analysed for the 5 periods of 6 months mentioned above, based upon the number of units obtained at refills and the pdd. The numbers of days dispensed were calculated as follows:

$$Days dispensed(\%) = \frac{No of units \times strength}{PDD} \times 100$$

Preventive medication

For the preventive medication (inhaled corticosteroids and cromoglycates) compliance was analysed. The percentage of compliance was calculated per period of 6 month, based upon the number of units dispensed (tablets, capsules, inhalations) and PDD as follows:

$$Compliance = \frac{no of units \times strength}{PDD \times 180}$$

Rescue medication

The number of prescriptions for rescue medication (courses of antibiotics and oral corticosteroids (≤20 days)) were compared per period of 6 months.

Only those patients of whom drug data were available during more or less the whole study-period have been evaluated, being 62 intervention and 191 reference patients. If data in certain periods were incomplete, this period was marked as 'missing' in the analysis. The data were processed using Microsoft Excel and Dbase V for windows, and then analysed using SPSS version 7.5.

5.5.2 Results

Reported behaviour

At the time of the last questionnaire 66% of the reference patients and 84% of the intervention patients said that they sometimes did not take their medicines according to the instructions on the label, but took more or less than indicated. There was no clear correlation between this finding and responses dealing with self-management (see also the section 5-6).

Knowledge about medication

At the start of the project 70% indicated that they took their sympaticomimetic drug before their inhaled corticosteroid. At the end 92% of the intervention patients would follow that sequence whereas the percentage in the reference group did not change.

The percentage of intervention patients, who correctly named the action of the blue medication (short acting beta-mimetic agents), increased from 77 to 95%. For the brown medication (inhaled corticosteroids) the percentage went up from 68 to 92% and for the

green medication (long acting beta-mimetic agents, which were relatively new at the time of the project) from 11 to 24%. No data on this aspect were available from the reference group.

Drug use, inhaled reliever medication

Data on the use of reliever medication was available for 62 intervention (88,6%) and 191 reference patients (90,1%). Table 5-11 reflects the mean number of reliever dosages dispensed, over the period recorded. Between intervention and reference patients there was no significant difference at all periods. However, the decrease in dispensed reliever medication was significant for the intervention patients (Student t-test for paired samples) between the period 0 and 1 ($p=0.01$) and between the period 0 and 3 ($p<0.01$). An ANOVA-procedure showed no significant differences throughout.

Table 5-11 Mean no of days of dispensed reliever medication, TOM patients with valid data in period

Reliever medication	Period 0	Period 1	Period 2	Period 3	Period 4
Intervention (n_{total} =62)	151 (n=50)	116 (n=47)	118 (n=51)	113 (n=42)	106 (n=61)
Reference (n_{total} =191)	142 (n=180)	149 (n=188)	144 (n=181)	134 (n=186)	142 (n=159)

Drug use, inhaled preventive medication

Data on the use of preventive drugs were available for 53 intervention (90%) and 189 reference patients (90%). Table 5-12 reflects the mean overall compliance (%) of the calculated daily dose per 6 months period. In the period after the intake the difference between intervention and reference patients was significant at a 0.1 confidence level (Student t-test) in favor of the compliance of the reference group. In neither group changes between the different periods were significant at a 99% confidence level (Student t-test for paired samples).

An ANOVA-procedure also did not indicate significant differences.

Table 5-12 Compliance (%) of calculated daily dose with preventive medication TOM patients with valid data in period

Preventive medication	Period 0	Period 1	Period 2	Period 3	Period 4
Intervention (n_{total}=53)	69.6%	55.4%	67.4%	65.0 %	64.3%
Reference (n_{total}=189)	70%	73.7%	67.8%	63.3%	70.6%

Drug use, rescue medication

According to the drug data, 567 short courses of antibiotics or oral corticosteroids (<=20 days) were given to 42 different intervention patients (60%) and to 129 reference patients (61.4%) over the total period. Table 5-13 shows the mean number of courses per patient.

The difference in the mean number of courses between intervention and reference group in period 1 (0-6 months after intake, $p<0.06$, asymptotic Student t test) and in period 2 (6-12 months after intake, $p<0.09$, asymptotic Student t test) was significant. Although the decrease of the mean number of courses in the intervention group is clear (Student t test for paired samples), this decrease is only significant at a 0.4 level between the period 0 and 1. The changes in the reference group were not significant. An ANOVA-procedure showed no significant differences.

Table 5-13 Mean number of courses of antibiotics and/or oral corticosteroids and number of patients with valid data per period in TOM study

Courses of antibiotics or corticosteroids	Period 0	Period 1	Period 2	Period 3	Period 4
Intervention (n_{total}=42)	0.65 (n=40)	0.47 (n=36)	0.46 (n=37)	0.61 (n=38)	0.49 (n=41)
Reference (n_{total}=129)	0.70 (n=121)	0.77 (n=126)	0.74 (n=121)	0.73 (n=126)	0.79 (n=103)

Discussion and conclusion on the drug use

Optimal drug use in asthma patients is difficult to assess from pharmacy records. First there is a number of possible biases in the databases themselves, mostly dealing with erroneous data concerning the daily use[14]. Secondly it is difficult to assess what the optimal drug use for an individual patient should be. This could be quite different for different patients and certainly can change almost daily for reliever medication. Thirdly, like in every drug use process, the patient's adherence with taking the medication as prescribed can be questionable. Also, with inhaled medication, it is quite difficult to assess if the patient uses the right inhaler technique. And last, but certainly not least, the way Dutch pharmacy computer systems record the number of dispensed dosages and the daily use of medication of inhalers is not uniform. This gives rise to possible errors in the calculations of the dispensed daily dosages but has been corrected during the data-entry.

In this study, a large proportion of the patients admitted to not being fully compliant with the use of the medication, as it was indicated on the label. This is in line with findings of others in The Netherlands[15]. However, it can be questioned if this in itself is problematic, because an increased use of preventive medication would improve asthma control and result in a decreased use of rescue and reliever medication. Moreover patients nowadays are encouraged to regulate their own asthma medication, often with the help of a peak flow meter. However, 'non-compliant' patients did not indicate that they used self-management more often than 'compliant' patients did.

The analysis of the relieving medication in the intervention group shows a decreased use, compared with the reference group, significant for two distinct periods. This is an important finding. One should keep in mind that reliever medication is often still prescribed with a fixed daily dose, instead of prn. use. That may upset the type of analysis where the PDD is an element of the calculations.

Evaluation of the compliance with the preventive medicines was calculated on the basis of the available data concerning refills and daily use according to the prescription. Although the relatively low compliance in the first 6 months period for the intervention group is remarkable it was not statistically significant. In general there seems to be little difference between the intervention and reference group regarding compliance with preventive medication throughout the study.

The number of short courses of antibiotics and oral corticosteroids, and the use of reliever medication in the intervention group decreased. This was a clear indication of a better asthma control in the intervention group.

5.6 Other effects of the provision of pharmaceutical care

Although the main emphasis, when evaluating pharmaceutical care, is on the quality of life, other factors are also important. Several different items have also been included into the study such as the familiarity with the pharmacist and the pharmacy staff, opinions on the image and professional aspects of the pharmacist, the pharmacy staff and the physician, and the understanding of patient information leaflets.

5.6.1 Method

Data were collected through questionnaires sent to intervention and reference patients directly by the research centre before intake, and after 6, 12 and 24 months. Because there were hardly any differences between the internal and external reference group if those groups were combined for these analyses. Opinions were collected using either a 4 or 5 point Likert scale. In the final questionnaires, after 24 months, the option 'don't know' was omitted, to force respondents to formulate either a positive or negative response.

The image in the field of medicines of the pharmacist, GP and pharmacist assistants was measured by asking respondents to give an opinion on the expertise of those professionals with the options to reply 'not at all expert', 'somewhat expert', 'reasonably expert', 'expert' and 'very expert'. The proportion of respondents finding any of the professionals expert or very expert is given.

Intervention and reference patients were given a number of statements at the end of the project to which they could respond with 'strongly agree', 'agree', 'disagree' or 'strongly disagree'. Data were analysed, after merging positive and merging the negative responses using the Chi-square test in SPSS for Windows, version 7.5.

5.6.2 Results

At the beginning of the study 48.4% of the intervention patients and 46.4% of the reference patients personally knew the pharmacist of the pharmacy where they usually got their medicines. At the end of the project the proportion for the intervention patients was 97% and for the reference patients went down to 35.4%.

Whether a (professional) relationship between GP and pharmacist existed was still not clear to 38% of the intervention patients (and 59% of the reference patients) at the end of the project.

The image of the pharmacist and other professionals

Table 5-14 outlines the results of the questions on the expertise of the pharmacist, GP and pharmacist assistants as a reflection of their image in the field of medicines.

Table 5-14 % of TOM patients finding professionals expert or very expert in the field of medicines

		0-month	6 months	24 months*
Pharmacist	*Intervention*	40.0	83.9	95.6
	Reference	41.5	44.8	82.4
Pharmacist assistant	*Intervention*	29.6	35.0	50.0
	Reference	45.0	41.8	52.9
GP	*Intervention*	71.9	75.5	82.4
	Reference	75.8	74.5	75.8

* Option 'don't know' omitted

Opinions of intervention and reference patients at the end of the TOM project differed significantly on the statements mentioned in table 5-15. There were no differences between the internal and external reference patients. Only patients who indicated that they had spoken with the pharmacist during the previous year were included.

Table 5-15 Proportion of intervention or reference TOM patients agreeing with quoted statements at end of the project

Statement	Intervention (n=70)	Reference (n=207)
If I want to know something about medicines, the pharmacist is the first person I think of	74%	53%
The pharmacist is badly accessible if I want to speak with him/her *	10%	20%
I now access the pharmacist more easily with questions about medicines than 2 years ago	84%	57%
The pharmacist knows nothing about my diseases *	11%	26%
I find I can communicate well with my pharmacist	96%	61%
I now access the pharmacist more easily with questions about diseases than 2 years ago	51%	28%
I do not care if I speak with the pharmacist or the pharmacist assistant	47%	81%

The response to other statements (see table 5-16) showed no significant differences.

Table 5-16 Proportion of patients agreeing with quoted statements at end of the TOM project

Statement	Agree
I find I can communicate well with my GP	93%
As for me, repeating prescriptions can be done directly through the pharmacy	79%
I think they have all information about my drug use in the pharmacy	96%
The GP carefully watches my medicine-use	65%
The pharmacist knows more about medicines than I used to think	58%
The GP is badly accessible when I want to speak to him/her	17%

More asthma-related results

At the start of the project, 25% of patients used a peak-flow meter for the assessment of the severity of their asthma, mostly when the GP told them. After 1 year 75%, and at the end of the project 81% of the intervention patients used the peak-flow meter and in the reference group 20-21% of the patients only.

The reasons for using the meter were very similar in the intervention and the reference group: 7% used the meter daily, 47% if they were short of breath, 25% by request of the pharmacist and/or GP, and the remaining 21% for other reasons.

In both groups 77% of those patients who used the peak-flow meter also adapted their medication according to the peak-flow readings.

Table 5-17 Asthma control of users of peak-flow meters at end of the project

	Intervention (n=56)	Reference (n=43)
At least once a week problems with wheezing or tightness of the chest (p=0.06)	54%	72%
Failed to attend school or work because of asthma during the last year (n.s.)	27%	36%
Awakes during the night because of wheezing or tightness of the chest at least once a week (p=0.19)	42%	67%

The increased use of the peak-flow meter in the intervention group and/or the overall provision of pharmaceutical care resulted in the tendency towards an improved control of the asthma at the end of the project (see table 5-17). The same tendency concerning asthma control can be seen when all patients in the intervention and reference group are compared at the end of the study. The improved asthma control did not show from the plain reported yearly frequencies of having tightness of the chest.

No influence of the pharmaceutical care provision could be seen on smoking behaviour. In both the intervention and reference group, approximately 30% of the participants smoked at the end of the study. However, in the intervention group 56% lived in a 'cleaned environment' while in the reference group the corresponding value was only 23%.

5.6.3 Discussion and conclusion

It is clear from the results that the professional image of the pharmacist improved because of the care provided. Intervention patients clearly agreed more than reference patients did with statements concerning the professional content of the interaction with the pharmacist, with one exception. During the project over 50% of all patients came to think that the pharmacist knows more about medicines than they used to think. This can be the result of the effect of completing the questionnaires over the years or of the ongoing public relations campaign of the Dutch professional pharmacist organisation KNMP and which started around 1995[16].

The proportion of patients using a peak flow meter, and who adjusted their medication accordingly, increased because of the care provided. The project resulted in better asthma control for those patients. No changes have occurred in patients' smoking behaviour, however, this aspect did not receive special emphasis during the project.

5.7 Overall conclusion to this chapter about the TOM study

The general picture of the results of the TOM project is positive. More patients have started to use the peak-flow meter and became involved in self-management. In addition more patients were now using the reliever medication before their preventive medication. There was a better asthma control in the intervention group, which is clearly supported by the findings of the drug analysis. There is also an indication that the quality of life (according to the AQLQ) improved as a result of the provided care. The knowledge about fields related to asthma, e.g. chronic bronchitis and emphysema improved. There is no indication that a selection bias occurred as a result of the drop-outs from the study. Patients were satisfied with the provided care and found the regular consultations useful.

It is clear that the patients' image of a pharmacist changed and they now have a more positive opinion of the capacities of pharmacists to help them with their drug use and coping with their disease.

Clear pharmacoeconomic data could not be obtained, due to the relative low number of intervention patients retained at the end of the study

The overall picture resembles the results of the TOM asthma study in Finland, Germany and Denmark[17,18,19,20]. Major peer-reviewed publications for both studies are still pending. Non peer-reviewed publications suggest however that in both cases there was a better process-control than in the Dutch study.

In Germany significant improvements were found in the field of the severity of the asthma (subjective and objective), compliance and knowledge, the asthma related quality of life and even in the general quality of life as measured by the SF-36.

In Denmark the improvements in the field of asthma symptom status, days of sickness, quality of life (using the Nottingham Health Profile), knowledge and inhalation technique were significant. A publication on the cost-effectiveness of this TOM-asthma program will soon appear[21]. The evaluation of the costs of the programme shows cost-effectiveness ratios between 0.18 and 0.56. The pay off time for the programme is 23 months (range 9-24 months in the sensitivity analysis). The authors conclude that community pharmacists can contribute to identify and solve drug-related problems in a cost-effective way with positive

impact on death from asthma and the clinical and psychosocial outcomes, although the program is time consuming and intensive for all participants.

Recently a report appeared from a similar Austrian study (co-ordinated by the Pharmcare Network) in which the outcomes were addressed more directly at a patient level than in the Dutch study[22]. Patient stated that they noticed positive changes in their knowledge (71%), asthma related problems (50%), quality of life (47%), the use of their inhaling devices (57%) and the use of their peak-flow meters (53%). No significant negative changes were reported.

The Danish program and experiences from the other asthma studies in Europe have led to the development of a protocol and guidelines for pharmacy-based asthma services. This manual will be applied by pharmacy organisations all over Europe, guided by Europharm Forum[23].

The provision of (pharmaceutical) care during which there is an emphasis on the compliance with preventive medication, the proper use of peak-flow meters, inhaler technique and self management improves the patients' asthma control, knowledge and satisfaction with care in all studies published to date, including the Dutch TOM-asthma study.

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5
RESULTS OF PHARMACEUTICAL CARE IN ASTHMA, THE TOM STUDY

The TOM study into the effects of pharmaceutical care in asthma patients with moderate asthma was carried out between the beginning of 1995 and the end of 1997, according to the description in Chapter 3 of this dissertation.

The intervention group received education about asthma, drug and non-drug management and the self-management of asthma over a period of 24 months. Compliance with a preventive drug regimen was regularly discussed. In the mean time the pharmacist evaluated the drug use and possible drug-related problems and gave suggestions for improvement to the patient. When necessary the pharmacist made recommendations to the physicians regarding pharmacotherapy. In this chapter some of the results of the TOM study are presented and discussed. For the analysis the following data sources were available:

- the intake data and evaluations (after 6,12 and 24 months) by the pharmacists;
- the replies to questionnaires which were sent to intervention and reference patients at the start of the projects and after 6,12 and 24 months;
- drug-prescription data of the intervention and reference patients, from the computers of the participating pharmacists.

The data on knowledge about diseases have been evaluated differently from the OMA data (see Chapter 4) to explore different possibilities for data evaluation and presentation.

Like in the OMA study, not all patients answered all parts of all questionnaires, therefore the evaluated numbers per item (and per paragraph) may differ from the total population. An additional problem when analysing the data for this project was that the number of patients at intake and the number of patients who fully concluded the study was relatively low compared to the power calculations.

Most data were entered and analysed using SPSS, version 7.5. Drug data were entered into an Access database, and analysed with the help of SPSS, Excel and Dbase V. Unless otherwise stated, a difference was assumed to be significant at a level of 95% probability or higher. Most comparisons of means have been made with the help of the Student t test, in the appropriate format as offered by SPSS. If other tests have been used this is explicitly mentioned in the text.

As in the previous chapter, both the Intention To Treat as the Per Protocol have been used, depending on the character and availability of the data.

5.1 THE POPULATION, INCLUSION AND DROP-OUT

For the TOM-study 527 asthma patients with mild to medium severe asthma and aged 20-45, consented by telephone to take part in the study. However, 74 of these patients did not sign the informed consent form, did not return the baseline questionnaire, or proved not to be

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6
PHARMACEUTICAL CARE AND THE PROFESSIONALS

One can wonder what health care professionals think of the provision of pharmaceutical care. Not only pharmacists themselves will have their opinions, but also the GPs of the patients who receive care. Do GPs appreciate the pharmacists providing care, do they notice a change in their patients, do they see the pharmacist as a care provider? Can Pharmacist deal with the workload, do they enjoy giving pharmaceutical care?

Although many articles can be found, also in in Dutch literature, concerning the roles of the different health care professionals in the health care system (especially in the professional journals like *Huisarts en Wetenschap* or the *Pharmaceutische Weekblad*), not much has been written about the roles of pharmacists and GPs in relation to the possible co-operation, apart from referral models.

In the starting phase of the pharmacotherapeutic consultation (FTO) in The Netherlands in 1989 Paes published his dissertation on the GP-pharmacist co-operation[1]. In 1998 de Vries published a dissertation on co-operation between GPs and pharmacists in the field of the FTOs (pharmacotherapeutic consultation sessions in The Netherlands)[2]. She concludes that the partners in collaboration need to come to agreements about their roles before the co-operation can become successful. Apparently, in spite of a development of over 10 years between those studies, the roles still are not well established, which affects the quality of the co-operation.

Although participating pharmacists in the TOM and OMA study (see Chapter 3) were advised to discuss the projects with the GPs before the start, only few have done so extensively. The opinions discussed in this chapter therefore reflect the results of a model, more or less imposed upon the local health care system. If the GPs and pharmacists want or can continue their tango without stepping on each other's toes remains open for discussion.

6.1 SATISFACTION OF THE PROFESSIONALS

During the TOM and OMA study not only the satisfaction of patients with the provided care (as described in Chapter 3, 4 and 5) was measured, but also those of participating pharmacists and the GPs involved. Opinions about the role and functions of the pharmacists and the GP were asked. A sample of the questionnaires (final round) can be found as appendix 6 to this dissertation.

To get some additional insight into the division of tasks related to care between GPs and pharmacists, a small explorative qualitative study was carried out into the effects of the quality of the relationship between those professionals on the acceptance of the professional roles. This study is described in a section 6-2.

Pharmacists, patients and GPs are not the only ones involved in pharmaceutical care. Certainly there is also a role for the assistant-pharmacists. Therefore, opinion of pharmacists on the divisions of tasks between pharmacist and assistant-pharmacists is described in section 6-3.

6.1.1 Method

In a questionnaire after 6, 12 and 24 months during the TOM and OMA project, the pharmacists and the GPs of the intervention patients were asked if their opinion on the provided care was positive, neutral or negative with also an option of saying that they did not know (yet). The option 'don't know' was omitted at the 24 months evaluation to force them to give an opinion. Moreover they were given a number of statements, with which they could fully disagree, disagree, agree or fully agree. All questions were asked in a self-administered questionnaire, which had to be returned directly to the research centre.

The assessment of the change in opinions of the individual GPs over time was a difficult task, because often the GPs did not provide their identification when returning the questionnaires. Only a limited number of GPs returned an identifiable questionnaire at all assessments.

The data were analysed using SPSS for Windows, version 7.5. For correlations the Spearman correlation coefficient (r_s) was calculated.

6.1.2 Results; satisfaction and opinions of the GPs

Returned questionnaires and identified project patients

As stated in the method section, only 17 of the initial 184 GPs in the TOM and OMA project returned the questionnaires in an identifiable way throughout the project. The development of individual opinions therefore could not be followed. The data from the questionnaire at 24 months are the main source for the data in this section (an example can be found in Appendix 6 to this dissertation).

The response rate of the GPs during the project was 60-70% in general. At the end of the project 82 OMA-GPs returned questionnaires and 42 TOM-GPs, but not all questions were always answered.12 GPs indicated that they had no patients in any of the groups in the project anymore. According to the project administration the remaining OMA patients visited 76 different GPs (response rate 93%) and the remaining TOM patients visited 38 different GPs (response rate 89%). The 112 returned questionnaires of GPs who said they had patients in the projects, have been evaluated. The age of the responding GPs ranged from 35 to 67 (mean 46.5, sd 5.7).

Only 41% of the GPs knew to identify some or all of their patients who participated in the project. All responding GPs knew about the projects, but 57 % did not know about the content. They received the project information from the pharmacist (65%), from the patient (6%) or from both the pharmacist and the patient (29%). Most GPs (90%) had a good or excellent relationship with the pharmacist and 84% took part in the same pharmacotherapeutic consultation group as the pharmacist of the patient(s).

Noticed effects of the study by the GPs

After 6 months 49.2%, after 12 months 49.2 % and after 24 months 57% of the responding GPs had noticed an effect of the provided care in the OMA group. In the TOM-group this percentage was around 65% at all assessments. What they noticed at the 24 months evaluation can be found in table 6-1.

Table 6-1: Effects of Pharmaceutical care noticed by GPs at 24 months assessment **

Item	No of GPs noticing effect TOM (n=22)	No of GPs noticing effect OMA (n=50)
Better patient disease control*	13 (62%)	15 (30%)
Increased patient compliance*	12 (57%)	16 (32%)
More contact with pharmacist	10 (48%)	38 (76%)
More referral through pharmacy	10 (48%)	37 (74%)
Increased assertiveness of patient	8 (38%)	15 (30%)
Better contact with pharmacist	6 (32%)	24 (49%)
More contact with patient	5 (24%)	10 (20%)
Thwarting of treatment plan*	7 (23%)	6 (12%)
Thwarting formulary agreements*	4 (18%)	0
Less bothersome patients	2 (9%)	1 (2%)

* Significant difference between TOM and OMA group
** Between brackets the percentage number of GPs noticing that effect

We also asked the GPs if the *use of medication* by the patient had changed because of the activities in the field of pharmaceutical care. In the OMA project after 6 months 12% of the responding GPs had noticed a change and 12% did not know (n=78). After 12 months 14% had noticed a change and 16% did not know (n=63). After 24 months 17% had noticed a change in medication and 30% did not know (n=71).

In the TOM project 28% of the responding GPs had noticed a change in the use of the medication and 22% did not know (n=32). After 12 months 15% had noticed a change and 19% did not know (n=26). After 24 months 8% had noticed a change in medication and 27% did not know (n=37). The main changes noticed were the number of drugs and the way and the time of using the drugs.

Satisfaction and opinions of the GPs

The GPs must have formed an opinion about the pharmaceutical care regardless of whether they noticed anything changing. Table 6-2 gives an impression of their opinion after 2 years of pharmaceutical care. On average10% of the 112 GPs did not answer certain statements of these questions.

There are many significant ($p<0.001$) correlations between the different statements indicating that the GPs are quite consistent in their answers and have a clear opinion about

the role of the pharmacist and pharmaceutical care. If GPs find the intensified counselling useful, then they also think that the pharmacist may expand his/her activities (r_s=0.58), that the patient likes the counselling (r_s =0.48), that they do not necessarily want to be consulted about the pharmacists' activities (r_s =0.40), that they see less of project patients in their practice (r_s =0.37) and that they get more time (r_s =0.34).

If they find that the pharmacist takes his/her chair, then they find that the pharmacist does not know enough about diseases (r_s =0.50), they also find that the pharmacist affects their key-role in health care (r_s =0.44) and they think they (as GPs) are more able to counsel the patients about drug use (r_s =0.40).

Table 6-2: Opinion of GP on different aspects of pharmaceutical care provision at 24 months assessment

Statement (n=112)	**(Fully) Agree**
I think patients like the counselling by the pharmacist	84.6%
I think the intensified counselling of patients on drug use by the pharmacist is useful	81.7%
The pharmacist does not have enough knowledge about diseases to provide pharmaceutical care	54.7%
As far as I am concerned the pharmacist may expand his/her activities	52.8%
I think the pharmacist comes on my territory with his activities	49.5%
I cannot change medication as suggested by the pharmacist, because it has been decided by a specialist	40.2%
I think I am more able to counsel patients about drug use than the pharmacist	40.4%
Pharmacists affects my key-role in Dutch health care with their activities	15.7%
Because the pharmacist counsels the patients, I get more time for my core activities	13.2%
There is no need for the pharmacist to consult me about his activities	13.9%
I see project patients less in my practice*	9.2%

* Significant difference between TOM and OMA GPs in favour of TOM

There is no significant correlation between those statements and the gender of the responding GPs. There is a slight indication that younger GPs are more positive about the role of the pharmacist and pharmaceutical care (r_s =0.2, $p<0.05$)

The majority of the GPs (90.5%) stated that they found the pharmacist competent to counsel and coach patients on their medication use. The development of the GPs opinion about the project-activities of the pharmacist in the TOM and OMA project is given in table 6-3. One must however keep in mind that there is no way to ensure that the responding GPs have been the same at the different assessments.

Table 6-3: Opinion of GP on Pharmaceutical Care (TOM and OMA project)

	6 months (%)		12 months (%)		24 months (%)	
	TOM n=27	OMA n-64	TOM n=27	OMA n=47	TOM n=40	OMA n=72
Positive	59	50	37	53	38	47
Neutral	7	33	44	31	45	51
Negative	15	5	7	0	18	1
Don't know (yet)	19	22	11	15	*Option omitted*	

In spite of the sometimes-low numbers of GPs per pharmacy, there was a significant difference between the pharmacies. Out of the 72 GPs belonging to 19 pharmacies, five pharmacies in the OMA project scored only negative or neutral (by 10 GPs). Out of the 40 GPs belonging to 11 pharmacies, 4 pharmacies in the TOM project scored only negative or neutral. The opinion on the provision of care could be related to the relationship between pharmacist and GP. However, there seems to be no relation between these opinions and the opinion about the relationship with the pharmacist.

6.1.3 Results: Satisfaction and opinions of the pharmacists

The pharmacies, participating in the TOM and OMA project, were comparable as to size and workload (expressed in number of patient per staff-member). The mean number of pharmacists was 1.7 (range 1-3) and the mean number of assistant pharmacists was 6.5 (range 3.5-12). There were large differences in the included number of patients per pharmacy and in the pharmacists' capacity to keep the patients in the projects till the end. As was shown in Chapter 4, in the OMA project the calculated workload is not the important factor for retaining patients in the project, but the frequency of consultations.

All pharmacists found that their counselling sessions had been useful most of the time and 37% (6 months) to 53% (24 months) of the pharmacists estimated that their counselling had led to changes in the drug use of their patients. The major changes identified by pharmacists include the way of the use of drugs, compliance and the time and frequency of use. Only a few estimated that they had had an impact on the number of drugs and/or the use of OTC medicines.

By at the end of the project most pharmacists had noticed certain practice related events while providing care (see table 6-4).

At the 24 months evaluation, 3/4 of the responding pharmacists (n=24) thought they had contributed to a better quality of life of patients, by implementing the projects.

The pharmacists also were asked for their opinion on a number of statements. The results after 2 years of providing pharmaceutical care can be found in Table 6-5.

Table 6-4: Effects of Pharmaceutical care noticed by TOM & OMA pharmacists (n=24) at 24 months assessment

Effect (in columns the number of pharmacist)	**Not noticed**	**Noticed**
Increased understanding of drug use in patient	2	22
Better control patient over disease	3	21
Disseminating effect in pharmacy	4	20
Increased understanding diseases by pharmacist	5	19
Increased assertiveness of patient	6	18
More referral to GP	6	17
Better contact GP-Pharmacist	13	11
More contact GP-Pharmacist	12	10
Thwarting of formulary agreements*	16	8
Thwarting of pharmacy policy	23	1

* Mainly noticed by TOM pharmacists

Table 6-5: Opinion of TOM & OMA pharmacists (n=24) on different aspects of PhC provision at 24 months assessment

Statement	**Number agree or fully agree**
I think I can communicate well with the patient	23
I think the patients like a better coaching of their drug use	23
The intensive counselling of patients is useful	24
Project patients now ask more questions	21
I have sufficient time to provide PhC	19
The intake is an essential part of PhC	19
Because I provide PhC now to project patients, I also will provide it to other patients	16
I find that I should personally inform the GP when I provide PhC to his/her patients	18
Because I provide PhC I feel committed to the patient	18
Because I provide PhC I am also more active in my pharmacy	16
It is difficult to get access to specialists about medication	10
I come on the territory of the GP when I provide PhC	9
It is not necessary to inform the GP when I want to provide PhC	6
My knowledge of diseases is insufficient for proper medication counselling	3
When I provide PhC I damage the key-role of the GP in health care	0

There is negative correlation ($p<0.01$) between the statement about the usefulness of the consultations and the feeling of damaging the key role of the GP in health care ($r_s = -0.63$) or getting access to specialist physicians in healthcare ($r_s = -0.55$). There is a positive correlation ($p<0.05$) between the statement about communicating well with patients and that the opinion that the intake is an essential part of pharmaceutical care ($r_s = 0.46$) and about patients liking the increased attention ($r_s = 0.47$). Pharmacist who find that patients ask more questions, also find that the patients like the increased attention ($r_s = 0.42$) and think that they will provide it to other patients as well ($r_s = 0.48$) (both $p<0.05$). The opinion on the knowledge about the diseases does not correlate significantly with any of the other opinions. At the end of the projects, 56% of the pharmacists indicated that they were providing pharmaceutical care to others than the project patients only. Out of 24 pharmacists 8 pharmacists provided pharmaceutical care to other asthma and to COPD patients, 8 to diabetes patients, 8 to patients suffering from incontinence and 6 pharmacists provided pharmaceutical care to other groups of patients.

The pharmacist rated their satisfaction with pharmaceutical care in the same manner as the patients and the GPs. The results can be found in table 6-6.

At the 24 months evaluation 62% of the pharmacists indicated that they found the project period (2 years) too long in relation to the needs of the patient, 74% found the project too long in relation to the project (university) workload. Two OMA pharmacists found the project too short.

Table 6-6: Opinion of TOM & OMA pharmacists on pharmaceutical care (n=24)

	6 months (%)	12 months (%)	24 months (%)
Positive	58	87	67
Neutral	16	7	13
Negative	5	0	20
Don't know (yet)	21	7	Option omitted

Major barriers for the pharmacist, in relation to the project can be found in time restraints (17 out of 24) and difficulties in preparing the documentation properly (6). As for the latter, 13 out of 24 pharmacist had a special Electronic Pharmaceutical Documentation system (EPD) but some of them also mentioned documentation problems as barrier. Only 9 out of the 24 pharmacists used a documentation system regularly (at least once a week),

6.1.4 Discussion and Conclusion

Most GPs knew about the elderly and asthma project and about 40% had discussed the project with the patient. However, from the opinion section of the questionnaire it becomes clear that their attitude towards the pharmacist's new role is quite mixed, although the relationships in general are good. The major worry seems to be the (assumed) lack of knowledge of the pharmacists in the field of diseases. The more the GP worries about the pharmacists' knowledge on diseases, the less he/she thinks that the pharmacist may expand

his/her activities. This may well be one of the key elements of the acceptance of pharmaceutical care by the GPs. If pharmacist can show their expertise in the field, the acceptance by the GPs of the care by the pharmacist will increase. About half of the GPs are really positive towards pharmaceutical care at the end of the project.

As for the pharmacists, the majority was satisfied, although in general they found 2 years too long for the project. It is interesting to note that the more pharmacists find that they are doing a useful job, the less they find that they attack the core role of the GP in the health system. Half of the pharmacists also learned about the way patients deal with their medication from providing care.

From other data (see Chapter 4 and 5) it becomes clear that the patients were most satisfied about the provided care. Half of the GPs are satisfied and one was negative about the care. Amazingly in the pharmacist group the satisfaction decreased during the last half of the project, but this clearly was due to the length of the project.

It is also remarkable that only 3 out of 24 pharmacists found they did not have enough knowledge about diseases, whereas more than half of the GPs was of this opinion. There is also a clear difference in opinion on the degree to which the pharmacist comes on GP territory.

As to the effects of the provided care, pharmacists were more aware of a possible better control of the patient over his/her disease than the GPs.

The results of the OMA project give an interesting perspective on the relationships between GPs and pharmacists around the provision of care. GPs doubt whether the pharmacists have enough specific disease-knowledge to provide care. If the pharmacist thought they were doing a useful job, they did not think they invaded the GPs territory.

6.2 THE RELATIONSHIP BETWEEN PHARMACISTS AND GPS

From the previous section it appears that the relationships between pharmacists and GPs were diverse, although good in general. The relationship clearly influences the GPs opinions about the provided care. Additionally there seems to be some lack of trust in the professional abilities of pharmacists. In an attempt to clarify this finding and to find out what the reasons were for the difference in the relationships, a small qualitative survey was set up at the end of the TOM and OMA projects.

6.2.1 Method

Two TOM pharmacists and three GPs participated in a structured interview about their personal relationships with each other. The GPs co-operated with one of the pharmacists in the pharmacotherapeutic consultation (FTO). One pharmacist and one GP constituted group 1. The other pharmacist formed group 2 with two GPs.

In group 1 the relationship between the GP and pharmacist were described by the pharmacist and GP before the interview as not so good. In group 2 the relationships were called good by all three participants.

To facilitate the interview, the inhaler instruction for asthma patients (who gave it and why) was used as topic. The answers to the questions were compared group-wise.

6.2.2 Results, the co-operation on care issues

In both groups, with different relationships, pharmacists and GPs gave inhaler instructions, but from the answers it was clear that only in group 2 there had been a discussion on who should give the instruction and when.

When both GPs and pharmacists were asked to give an opinion about the quality of the instruction of the other, group 2 was clearly very positive. For GPs and pharmacist in group 2 the judgement about the given instructions was good because 'I have noticed no problems'.

The GP in group 1 wondered if there was enough privacy in the pharmacy and what would happen if not the patient, but a relative, came to the pharmacy to pick up the medicines. In this group the GP and pharmacist had no idea about the quality of each other's inhaler instructions.

The chances to discuss the division of roles in group 1 was very limited, pharmacist and GP spoke to each other maybe three times a year. The GP also stated he felt hindered in the relationship with the pharmacist and also wondered in general if there still was a role in health care for a pharmacist at present. Although this pharmacist and GP co-operated(?) already for approx. 5 years, they stated not to know each others first name. Neither the pharmacist nor the GP were open to a more personal and more frequent relationship. They both doubted somewhat their professional knowledge. The GP found that the pharmacist was only limited available for questions. The pharmacist thought the same about the GP. Especially the GP stated that the pharmacist was the cause of their limited relationship and did not trust the motives of the pharmacist. The pharmacist did not find that the GP was limiting their relationship.

In group 2 the pharmacists and GPs had a (much) more frequent contact, at least weekly. The GP opinion of the pharmacist was positive, contacts were described as merely professional, not personal. Pharmacist and GPs knew each other by the first name. They acknowledged the presence of sufficient knowledge on each other's territory. There were no limitations in the relationships mentioned. In professional sense pharmacist and GPs were always available for each other.

6.2.3 Discussion and conclusion about co-operation

From the results of this small explorative qualitative research it appears that the two groups have different relational, professional and personal characteristics. Group 1 has no clear role division for inhaler instruction. In Group 2, where relationships are better, there is more insight in each others role. It seems important that the two parties, GPs and pharmacists at least try to discuss their roles before pharmaceutical care is started, especially in fields that touch upon the territories of both parties.

Defining the role is not so easy, as can be seen in another pharmaceutical care project in the field of asthma and COPD in The Netherlands, the 'CARA Check'. A description of this discussion about roles and trust between the professionals can be found in an article by van der Ven *et al*[5]. After extensive discussions the roles in the field of inhaler instructions were

defined in a group of pharmacies and GPs. In appendix 3 the results of such a discussion can be found*.

From this overview it becomes clear that GPs have no common opinion on the kind of tasks that this particular group of (active) pharmacists can be trusted with. It seems like the pharmacists in this case could only safely claim tasks where their medication history and knowledge of pharmacoepidemiology comes in handy. According to the majority of the GPs, the real treatment related tasks they should mostly perform, although sometimes in co-operation with the pharmacist. It should be noted that most GPs wanted to do most tasks all by themselves. Only three regularly mentioned that they wanted a continuous co-operation. A similar picture can be seen in the report of an FTO on pharmaceutical care by Schoonhoven *et al.*[4]. During this discussion session only tasks typical for teaching the correct application of medicines were regarded as pharmacists' territory. As soon as it came to other issues in the field of care, the GPs claimed them.

It would be interesting to search for the motives behind the GPs opinions. Are they political or formed by experience? From our qualitative survey it becomes clear that a better relationship between the two professionals leads to more trust, so experience is certainly an important factor. On the other hand, Dutch GPs defend their key-role in healthcare with ardour and one must also keep in mind that age-old controversies about money and the doubt about the professional versus commercial role of the pharmacist still may play a role in the GPs mind. For political reasons currently the latter image of pharmacists is continuously being emphasised by the Dutch GP organisation LHV towards their members and the Dutch health care authorities. This resulted in 1998 in an article by Eekhof *et al.*, in which even the well-established task of Dutch pharmacists in the field of medication surveillance was challenged[5]. The former staff-member of the LHV Rob Oudkerk, who now is a member of parliament for the Dutch social-democrats (PvdA), depicted the Dutch pharmacists at all possible occasions in 1997 and 1998 in public as a plain money-maker, thus also influencing their public image. So apart from experience, the GPs opinion about the professionalism of pharmacists must also have been formed by political messages.

The opinions of GPs in the United Kingdom are quite different and do not seem to depend so much on the presumed lack of knowledge about diseases or professional distrust. A large proportion of the questioned GPs in a study by Bleiker *et al.* found, for instance, that the pharmacist were ideally placed to provide health education, because they are in that country the first point of contact for many people[6]. However, one should realise the different situation of pharmacists and GPs in healthcare in the United Kingdom, and the effects of their health care system.

Although there might be other factors involved, it is probable that a better relationship and co-operation between pharmacists and GPs results in more clarity about the allocation of tasks. The results suggest that better communication is also necessary to clarify the purpose and content of pharmaceutical care between pharmacists and GPs. It is clear that a better co-operation also results in a better care for the patients and hopefully a better control over the patients' medication. However, it is often difficult for a GP to change

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* Personal information from the Anjer Apotheek in Zevenaar

medication, certainly if more physicians (specialists or consultants) have been involved in the total package of pharmacotherapy, as is illustrated by Veehof *et al.*[7].

6.3 The role of the Dutch assistant pharmacist in Pharmaceutical Care

When performing pharmaceutical care in a pharmacy, there are many tasks. A part of those tasks is clearly patient or medication related. Other tasks (i.e. documenting) need to be done to ensure continuity or for administrative purposes. One of the major barriers for providing pharmaceutical care according to the pharmacist, is the amount of time involved. We conducted a study to find out the opinion of Dutch pharmacists on which members of the pharmacy staff could perform the patient and medication-related tasks and thus relieve the pharmacist (partially) of his duties.

In a questionnaire pharmacists could give their opinion on the possibility of letting the patient and medication related tasks being performed by their trained staff, in The Netherlands being the assistant pharmacist. Dutch assistant pharmacists have a 3-year non-academic training, which mainly focuses on preparing medicines, filling prescriptions and dispensing but also on counselling. They are authorised to dispense independently, but under distant supervision of a pharmacist who needs not always to be present at the time of dispensing. But at the end he remains the responsible professional. The individual role and tasks of pharmacists and their personnel vary in different countries. This section discusses the distribution of patient-related pharmaceutical care tasks in a pharmacy in The Netherlands.

6.3.1 Method

From a consultation round with pharmacists in the TOM and OMA study, the tasks that are part of the provision of pharmaceutical care were assessed. We then asked in a questionnaire the opinion of 2 categories of pharmacists: pharmacists providing structured Pharmaceutical Care, participating in the Dutch TOM or OMA studies (Group 1 TOM/OMA, n=34) and a random sample of pharmacists, not providing structured Pharmaceutical Care in those projects (n=34). The response rates to this questionnaire were 24 in the TOM/OMA group (70.5%) and 20 for the reference group (58.8%).

The tasks were put up for scoring in 1997, at the end of the TOM/OMA project. We asked the pharmacists which aspects of pharmaceutical or patient care could be performed by all assistants (score 1), by experienced assistants only (score 2) or not by the assistants at all (score 3). The distributed questionnaires were almost equal, apart from one question concerning the pharmaceutical care intake. This question was only posed to those pharmacists involved in the projects. We assumed that pharmacist, who were never involved in structured pharmaceutical care, would have no insight in the full scope of a pharmaceutical care intake.

From the results also we calculated the mean score per group per item, called the rank, thus obtaining an indication if the emphasis of the group was more towards all assistant pharmacists (AA), experienced assistant pharmacists (EA) or no assistants (implying the pharmacist only) (AP). The higher the rank, the emphasis moves to pharmacists only,

according to the respondents. Differences between intervention and reference group were calculated using the Mann Whitney U test. For correlations Spearman's rhoo was calculated (r_s). Statistical analysis was performed with the help of SPSS, version 7.5.

6.3.2 Results of the role assessment

In table 6-7 the opinions of the pharmacists about performing the tasks related to the provision of pharmaceutical care can be found.

Table 6-7: Opinions of pharmacist about performing pharmaceutical care related tasks

Item	TOM-OMA pharmacies (n=34)				Reference Pharmacies (n=34)			
	AA %	EA %	AP %	Rank	AA %	EA %	AP %	Rank
Dispensing medicines	100			1.00	100			1.00
Responsible advising in OTC medicines*	100			1.00	85	10	5	1.20
Giving advice/information on the correct use of medicines	88	13		1.13	95	5		1.05
Answering questions about medicines, side effects and interactions	58	38	4	1.46	50	20	30	1.80
Answering questions about diseases	46	38	17	1.71	30	40	30	2.00
Discussing compliance+	38	29	33	1.96	26	26	47	2.21
Performing an intake	22	17	57					
Discussing possible changes in medication with the patient	17	21	63	2.46	15	15	70	2.55
Conducting a consultation+,+++	5	14	82	2.77		16	84	2.84
Performing medication analysis++,*		22	78	2.78			100	3.00

* Significant difference between intervention en reference pharmacists ($p<0.05$)
+ No answer from one reference pharmacist
++ No answer from one intervention pharmacist
+++ No answer from two intervention pharmacists

There is a correlation between the opinion of the combined group of pharmacists concerning answering questions about medicines on one side, and on the other hand concerning answering questions about diseases ($r_s=0.45$, $p<0.005$), discussing compliance ($r_s=0.35$, $p<0.05$) and performing medication analysis ($r_s=0.32$, $p<0.05$).

6.3.3 Discussion and conclusion

In general, pharmacists with no direct experience in the field of pharmaceutical care (in the TOM and OMA project) have a tendency to ask for more experience in pharmaceutical care tasks then pharmacists with this experience. Amazingly this situation was just the reverse before the projects started in 1994. The correlations between the different aspects indicate that pharmacists regard the domain where advanced drug and disease-knowledge is needed, as one.

At the end of the projects there was a significant discrepancy in opinion between intervention and reference pharmacists when it came to field of performing a medication analysis and advising in OTC medicines. In general, according to the pharmacists, an assistant pharmacist (experienced or inexperienced) should preferably not perform following tasks:

- Performing medication analysis (a drug use review);
- Conducting a consultation ;
- Performing an intake;
- Discussing possible medication changes.

An experienced assistant pharmacist can do following:

- Discussing compliance with a patient;
- Discussing medication changes with the patient;
- Answering questions about medicines and their effects.

About 'answering questions about diseases', there was a clear discrepancy between the two groups of experienced pharmacists. The OMA-pharmacists, who themselves need an overview over many diseases because of the character of their project, meant that only pharmacists should answer those questions. The TOM pharmacists think those questions can also be answered by experienced assistant pharmacists.

Following tasks can certainly be performed by all assistant pharmacists:

- Dispensing medicines;
- Responsible advising in OTC;
- Giving advice/information about the correct use of medicines.

Traditionally those last tasks already are part of the work of the assistant pharmacist in The Netherlands.

A general tendency can be recognised. Those pharmacists, who have less experience in providing pharmaceutical care, demand more knowledge and skills for the different tasks to be performed than those who do have gained experience during the TOM and OMA studies. This finding is not amazing. Those who have not yet given a structured form of pharmaceutical care or are afraid to do so, are bound to overestimate the duties of this form of care.

We also can conclude from this survey that, since most pharmaceutical care tasks should be performed by an experienced assistant pharmacist or a pharmacist, there will be organisational demands to be met before a pharmacist initiates structured pharmaceutical care in the pharmacy. The right tasks must be divided over the right staff members.

6.4 Overall conclusion to this chapter about the professionals

It is not amazing that the intensity of co-operation between pharmacists and GPs in the field of care depends largely on the quality of their relationship. Apart from professional aspects, personal aspects of the relationship also seem to influence the co-operation.

When pharmacists provide pharmaceutical care, currently the major worry of GPs seems to be the assumed lack of knowledge of the pharmacist in the field of diseases. However, the more pharmacists are involved in pharmaceutical care, the less they doubt their own knowledge in this field.

For both the TOM and the OMA project, where medication sometimes had to be changed, the necessity to co-operate with the GPs is apparent. Campagna and Newling described the key factors influencing the pharmacists' drug therapy decisions, and defined attitudes, economic structure, expertise, laws and regulations, motivation, personality, practice settings and public expectations as the key factors that determine the pharmacists' behaviour. The individual factors (personality, attitudes, expertise and motivation) seemed the most important determinants[8]. Especially the expertise element can be recognised in the current worries of the GPs about the pharmacists' ability to provide care. In 1995 Campagna already described the levels of performance in the field of the pharmacists' drug therapy decisions as submissive, corrective, consultative or prescriptive[9]. Only submissive performance does not create resistance. In general one can say that Dutch community pharmacists are performing in a corrective manner due to frequent medication surveillance signals for which they contact the GP, and this may provoke resistance amongst the physicians.

In 1998 Bradshaw *et al*. also published findings on the opinion of physicians about the extended role of the pharmacist. Favourable attitudes were recorded in that study for the pharmacists' activities such as monitoring drug use, counselling patients, advising physicians and recording OTC drug use. A less favourable attitude was seen with regard to activities on a closer level to the physician, such as suggesting drug regimens alterations, discussing therapeutic equivalents with patients or changing dosage forms[10].

One can however imagine forms of pharmaceutical care where this co-operation is not absolutely necessary, as long as there is no necessity to change pharmacotherapy and the pharmacist sticks to tasks like giving extensive instructions for use of medicines or OTC counselling. Therefore, if the relationship is poor, that should be not an excuse for pharmacists to abstain from providing any form of care to the patient.

Overall the perception of the GP about the current task of pharmacists in care is probably best illustrated by the following imaginary pronouncement on the following page.

From the task-division scheme in the CARA-check project it is also clear that in spite of the pharmacists' extensive knowledge in the field of pharmacotherapy, the GP still claims the right to prescribe. That knowledge therefore can currently only be used to indirectly influence prescribing through the FTO's.

When it comes to incorporating the tasks of providing pharmaceutical care in the Dutch pharmacy organisation, according to the pharmacists, the real core of the work still should be done by the pharmacists themselves, although some side-issues and part of the patient-contact can also be delegated to the assistant pharmacist.

'Oh yes, it is certainly useful that the pharmacist provides pharmaceutical care, and my patients are really happy about it. But I sure want to know what he or she does with my patients. And I am not sure if I like the pharmacist to expand these activities, I would say he'd rather has to learn a bit more about diseases, before I would allow him to do so.

It is not that I have noticed much of what he did, and certainly he is capable of providing pharmaceutical care and I also think this project was great, but I have the feeling he is after my position a bit. Well, actually, that is nonsense isn't it? He certainly is not threat to my current focus role in Dutch health care.'

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Part III

Pharmaceutical care in world-wide perspective

7
IMPLEMENTATION BARRIERS TO PHARMACEUTICAL CARE

In the previous three chapters of this dissertation and also in many other studies it has been proven that the provision of pharmaceutical care has the expected positive influence on part of the outcomes of patient care. Although such studies have not yet been published in the major biomedical journals, it has clearly been established that the provision of pharmaceutical care has its value in the case of general ambulatory care[1,2,3], psychiatry[4], HIV infections[5], asthma[6,7], diabetes[8], hypertension[9], and hyperlipaedemia[10]. In spite of this evidence, it remains to be seen if all pharmacists are willing to implement pharmaceutical care in their daily practice.

7.1 Introduction

Many implementation barriers have been mentioned in response to the open question in the final pharmacist questionnaires of the TOM and OMA project, described in Chapter 3 (see table 7-1).

The fact that documentation scored relatively high on this list, is partially due tot the research-documentation which was required from the participating pharmacists. Fifteen out of the 22 pharmacists stated that the worst part of their project (TOM or OMA) was either filling out the questionnaires or collecting and sorting the data needed by the project team.

Time, lack of trained staff and lack of remuneration are most probably strongly interrelated; if there would be enough money the pharmacist could hire additional staff and thus free up time for providing care.

Although one pharmacist saw the lack of communication skills as a barrier, 15 pharmacists found especially the patient contact, thus communication, the most rewarding part of the studies. Two pharmacists even mentioned that they found the outcomes of the provided care motivating. So there are definitely also attractive sides to the provision of pharmaceutical care for pharmacists.

Implementation barriers for pharmaceutical care are also discussed in literature[11,12]. As Odedina, Segal an Hepler already described, there are even differences between pharmacists in one country, in the sense that there are 'providers' and 'non providers' of pharmaceutical care[13]. These differences can be found in direct patient care dimensions as well as attributes relative to the provision of pharmaceutical care. What some pharmacists perceive as a barrier to the provision of pharmaceutical care, is not regarded as such by others or has been overcome. This is also illustrated by the fact that over half of the barriers mentioned by the project pharmacists in the TOM and OMA studies are only mentioned once and probably not so relevant to others (although this was an open question in the questionnaire).

Table 7-1 Implementation barriers mentioned by TOM/OMA pharmacists (n=22)

Barrier	Frequency
Time	16
Documentation	7
Lack of (trained) staff	3
Can/should not offer to all patients	2
To get started	2
Responsible pharmacist not always on premises	2
Lack of clinical knowledge	2
Lack of computer support	2
Coaching staff	2
The GP's	2
Timing with patients	2
Assuring continuity	1
Lack of clinical data	1
Working structured	1
Difficult if family is involved	1
Patients don't want it	1
Pharmacist only can do it	1
Lack of stimuli to act	1
Motivating staff	1
Training staff	1
Lack of peer support	1
Lack of communication skills	1
Lack of remuneration	1
Don't see an effect	1

The implementation barriers found in the results of the TOM and OMA studies are not specific for The Netherlands. In other countries that are moving towards a pharmaceutical care model of community pharmacy the same barriers can be identified although their local importance shows some differences.

7.2 EUROPEAN BARRIERS TO THE IMPLEMENTATION OF PHARMACEUTICAL CARE*

7.2.1 Introduction

Although pharmaceutical care concept is sweeping over the pharmaceutical world, in daily community pharmacy practice not much has been implemented yet. It is clear that pharmacists perceive a number of barriers for the implementation. Moreover, the readiness towards the implementation of the concept is different, even per pharmacy[14].

The structure of pharmacy (and health care) in Europe is far from homogeneous. The results of a questionnaire of the University of Groningen together with the community pharmacy section of FIP show that pharmacies serve on average anywhere between 1500 (Greece) and 18000 (Denmark) people[15]. In some countries pharmacies have a well-trained staff but in other countries only shop assistants help the pharmacist. Also sometimes non-pharmacists can employ pharmacists and thus influence the professional activities and possibilities. Because of these differences it is not very likely that the barriers for the provision of pharmaceutical care will be the same in the different European countries.

In order to get some overview of the barriers perceived by European pharmacists for implementing pharmaceutical care, a semi-quantitative research project was carried out through structured interviews. To be able to obtain a higher level of aggregation, representatives of pharmacists' organisations or researchers in the field of pharmaceutical care were interviewed instead of individual practising pharmacists.

7.2.2 Method

From discussions with practising pharmacists during the continuing education sessions of the international pharmacy federation (FIP) and from the results of the Dutch TOM and OMA studies, a list of 25 possible barriers was compiled and structured into domains. See table 7-2.

During a structured interview, representatives from 11 different European countries, involved in pharmaceutical care at national pharmacist organisations (n=6) or in pharmaceutical care research (n=5), were first asked to identify spontaneously the barriers for pharmaceutical care in their country. The different countries and the nature of the interviewee are listed in table 7-3.

Then all unmentioned barriers from the list were screened and the subjects were asked to confirm or deny if those barriers played a role in their countries. Finally, the identified national barriers were presented and the subjects were asked to give them a ranking between 1 and 5 as to their importance, with 5 being very important in their country. An absolute ranking (the number of times a barrier was mentioned multiplied by their ranking factor) was calculated as well as a relative ranking (the absolute ranking divided by the number of interviewees considering the item as a barrier).

Pharmaceutical care was presented as a form of pharmacy practice during which the pharmacist assumes responsibility for the patient outcomes. Essential elements being

* Research performed for the Pharmaceutical Care Network Europe by the University of Groningen and the Quality Institute for Pharmaceutical Care, Kampen; publication pending.

documentation, the need to perform medication assessment (medication surveillance) to detect and resolve drug-related problems, the co-operation with the patient. The co-operation with physicians or other health professionals was described as not absolutely necessary but desirable.

Table 7-2. Barriers for pharmaceutical care

Resources
Lack of money (reimbursement)
Lack of time
Lack of space in pharmacies
Lack of software for medication assessment
No clinical patient data available
Lack of trained staff
Lack of protocols or consensus-reports for treatments
Attitude and opinions
Attitude/opinion of staff
Attitude/opinion of other professionals
Attitude/opinion of practising pharmacists (product orientation)
Attitude of pharmacy owner (the boss)
Lack of vision on professional development
Education
Lack of clinical education
Lack of education in communication skills
Lack of education in social pharmacy
Lack of education on health systems/public health
Skills
Lack of skills for medication assessment
Lack of communication skills of pharmacists
Lack of documentation skills of pharmacists
Lack of management skills
Environment
Legal barriers
National health care structure in general
Inertia of pharmacists as a group
Privacy problems

7.2.3 Results

Some of the interviewees mentioned another barrier than the barriers on the list (table 7-2) but this happened only occasionally. Such barriers were e.g. 'Pharmacists are afraid' or 'Pharmacists are not used to make judgements on soft data' or ' lack of recognition of pharmaceutical care by the university'.

Table 7-4 gives the 10 most important barriers in Europe, according to their absolute ranking, meaning that many respondents have recognised the barrier, or that the item is seen as an important barrier by several of the interviewees.

Table 7-3 Participating countries and interviewees

Country	Nature interviewee
Denmark	Representative
England	Representative
Finland	Representative
Germany	Researcher
Ireland	Researcher
N-Ireland	Researcher
Netherlands	Researcher
Norway	Representative
Spain	Representative
Sweden	Researcher
Switzerland	Representative

Table 7-4 Barriers in absolute ranking

Barrier	Abs. ranking
Lack of money (reimbursement)	43
Lack of time	42
Attitude/opinion of other professionals	38
Lack of communication skills	37
Health care structure in general	34
Lack of clinical education	34
Attitude/opinion of pharmacists	33
Lack of education in communication	33
Lack of management skills	28
Lack of vision on professional development	28

Table 7-5 gives the 12 most important European barriers according to their relative ranking, thus taking into account the numbers of respondents mentioning the barrier for their country.

According to the interviewees of Finland, The Netherlands, Norway, and Sweden, money is not a major barrier in their countries. For Spain money has not been identified as a barrier at all. In almost all of the European countries, the following barriers are perceived to a different degree of severity:

- Lack of time (all countries)
- The attitude/opinion of other professionals (all countries)
- Lack of communication skills (10 out of 11 countries)
- Lack of clinical education (10 out of 11 countries)
- Lack of money (10 out of 11 countries)
- Lack of education on communication (10 out of 11 countries)

Table 7-5 Barriers in relative ranking

Barrier	Rel. ranking
Lack of money (reimbursement)	4.3
Attitude of pharmacy owner (the boss)	4.2
Lack of time	3.8
Health care structure in general	3.8
Lack of documentation skills	3.7
Lack of communication skills	3.7
Attitude/opinion of pharmacists	3.7
Lack of software for medication assessment	3.7
Lack of management skills	3.5
Lack of vision on professional development	3.5
Lack of protocols or consensus-reports for treatments	3.5
Lack of education on health systems/public health	3.5

The least important barriers in the European countries, according to the respondents are the privacy problems, legal problems, the training of the staff, the lack of skills for medication assessment and the inertia of pharmacists as a group.

There is no significant correlation between the lack of time, money and space.

7.2.4 Discussion

The difference between the absolute ranking and the relative ranking indicates that, although some barriers were not perceived in some countries, they are important in those countries where they do play a role e.g. the attitude of the pharmacy owner (the Boss).

Time and money are the major barriers for the implementation of pharmaceutical care in all European countries studied, just like in the USA[16]. Other important factors can be found in the health care environment and the pharmacists' education. Although the correlation is

not clear from our date, there should be a relation between the lack of money and lack of time. If there would be enough money, pharmacists could employ staff-members for the provision of pharmaceutical care but most of the remuneration systems are turnover dependent.

Money (or the reimbursement issue) is the most important perceived barrier preventing pharmacists in all but one questioned European countries from starting pharmaceutical care in their pharmacies. The attitude and opinion of other professionals is a barrier that is spontaneously mentioned by all interviewees, but it is not a major one.

The lack of clinical education is another barrier in almost all countries. It is therefore amazing that the lack of skills for medication assessment only plays a role in 2 countries. Apparently the respondents trust the pharmacists to perform medication assessment if only the clinical knowledge were in place.

In countries where pharmacists are usually employed, the boss is perceived as the second major barrier, after the reimbursement. It is also interesting to note that legal barriers, the lack of protocols and the lack of education in health systems and public health, are only regarded as barriers in two out of the 11 countries.

Implementation barriers for pharmaceutical care are also discussed in literature[17,18]. The perceived barriers found in this study show a large resemblance to the results of two publications by Odedina *et al*.[19, 13]. In these analyses the authors studied the factors that influence implementation of pharmaceutical care and the discrepancy between the behavioural intent of pharmacists and the low provision of pharmaceutical care in the US. They find a number of barriers for implementation of pharmaceutical care that are experienced by pharmacists, but also note that the same perceived barriers nevertheless lead to different behaviour. They suggest that this discrepancy may be due to the low perceived social norm by physicians, the low perceived behavioural control, the low self-efficacies with respect to the means involved in the provision of pharmaceutical care and the low affect toward the means involved in the provision of pharmaceutical care.

The list of barriers mentioned in table 7-2 seems to cover almost all possible barriers for the implementation of pharmaceutical care in Europe, and could therefore possibly be used on a national level for a more thorough investigation of implementation barriers in a selection of individual community pharmacists.

Methodological remarks

The method used to identify the barriers in the research described here may cause some bias because not the pharmacists were interviewed but people who were supposed to have some overview over pharmacy practice and pharmaceutical care in their countries. Additionally, per country only one person has been interviewed. Furthermore the attribution of the values as impact factors is artificial and basically a ranking procedure. Calculating European overall scores therefore does not represent a highly balanced picture. Nevertheless it seems a useful approach. The numbers of pharmacies per country have not been taken into account and the results therefore can be regarded on country level only.

There is a chance that the opinion on the *current* role of pharmacists in society of those who were interviewed affect their view on the barriers, as the community pharmacists in the field

would perceive them. In other words, if the interviewed were rather disappointed in pharmacy in their country, they might mention more barriers than pharmacist's experience in practice. However, the reverse seems more probable. The respondents in general were strong supporters of the extended role of pharmacists in society and certainly were convinced of the importance of the implementation of pharmaceutical care.

As Odedina, Segal an Hepler already described, there are differences between pharmacists in one country, in the sense that there are 'providers' and 'non providers' of pharmaceutical care. These differences can be found in direct patient care dimensions as well as attributes relative to the provision of pharmaceutical care. What some pharmacists perceive as a barrier to the provision of pharmaceutical care, is not regarded as such by others or has been overcome.

7.2.5 Conclusion

Time and money are perceived to be major barriers for the implementation of pharmaceutical care in the European countries studied, both in the absolute and relative ranking method. Both issues are interrelated.

From this survey it is clear that the European Pharmaceutical Associations must pay attention to remuneration issues when they would like pharmaceutical care to advance in their countries. But it is also clear that they need to work continuously on a change of attitude amongst pharmacists and try to influence the opinions of other health care providers. The latter could not only be reached by public relations initiatives, but also by supporting researchers in publishing the results of their projects.

Important barriers have also been identified in the educational domain. More and/or better education of European pharmacists in the field of clinical pharmacy, communication skills, documenting skills and management skills therefore seems necessary.

7.3 Conclusion of this chapter

There are a number of successful research projects into the effects of pharmaceutical care described in literature and there are more concluded projects or on their way. By now (1999), there is sufficient scientific evidence that pharmacists can improve outcomes of (pharmaco)-therapy and thus improve the quality of the care for the patient (see also Chapter 4, 5 and 6 of this dissertation).

But as long as the positive effects of pharmaceutical care on health outcomes have not been published in peer review journals, the other members of the health care team will not readily embrace the concept and stimulate pharmacists to incorporate pharmaceutical care in their daily practice. Therefore it will take time before the attitude and opinion of other health care professionals, one of the major implementation barriers, will disappear. Additionally, the payers of health care will not contribute financially to this form of care for the same reason and the second implementation barrier (money) can not be broken down.

On the other hand, the very high level of satisfaction of the public with pharmaceutical care shown in all research projects to date does stimulate many pharmacists in different countries to start providing pharmaceutical care to their clients in spite of the perceived barriers.

In many countries the professional organisations of pharmacists now have adopted policies to stimulate their members to provide pharmaceutical care. Although it is not within the scope of this dissertation to describe such projects, many standards, protocols and implementation strategies are being developed on a national scale. The content of those protocols and strategies depend on the status of medical and pharmacy practice in each individual country.

Although developing standards and protocols for providing pharmaceutical care certainly seems necessary it seems more appropriate to start to eliminate as many other implementation barriers as possible, according to the research described in this chapter. The lack of consensus reports and protocols has only been identified as a barrier in 2 countries.

The provision of pharmaceutical care in practice demands a number of skills and a level of knowledge that apparently is not being taught in several countries at present. It is therefore a major challenge to academia to adapt their curriculae in order to enable pharmacists to deliver pharmaceutical care.

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8
THE CHANCES FOR PHARMACEUTICAL CARE

In community pharmacy around the world there is a role for the pharmaceutical care although there are some barriers for its implementation, as described in previous chapters of this dissertation. Especially the community pharmacy section of the International Pharmaceutical Federation (FIP) has advocated pharmaceutical care as a new role for pharmacist. In 1996 FIP itself secured that role in its joint statement on Good Pharmacy Practice (GPP) in community and hospital practice settings, together with the World Health Organisation (WHO)[1]. Currently that new role is more obvious in some countries than in others. How do different aspects of pharmacy practice enable or hinder the introduction of pharmaceutical care in a country and how much is actually happening? Do the barriers, found in the previous chapter, really inhibit the implementation of pharmaceutical care?

In this chapter it is analysed if some practice aspects, probable preconditions to the provision of pharmaceutical care in community pharmacy, are present in various countries around the world.

8.1 INTRODUCTION

This analysis is a result of the data obtained from an international survey conducted together with the community pharmacy section of FIP. The survey was performed to investigate the international differences in pharmacy practice, possibly affecting the chances for the implementation of pharmaceutical care. Countries with a good chance of introducing and promoting pharmaceutical care into daily community pharmacy practice are identified in this chapter.

In 1997 a questionnaire was sent out to the national boards of community pharmacist organisations in co-operation with the community pharmacy section of the International Pharmacy Federation (FIP) on different aspects of pharmacy practice[*]. The responses resulted in the FIP-database. For this part of the dissertation, information from the FIP-database is used together with information obtained from published literature.

Developments of pharmacy practice in most countries, especially in the developed world, follow roughly the same line as the one described in Chapter 2. However, it is not always clear yet if the paradigm shift in other countries has now recognised the patients' role in the work of the pharmacist. According to the results of our international questionnaire, the definition used in several countries is the one from Hepler and Strand, in which the main attention is on improving the medical outcomes of pharmacotherapy and quality of life[2]. But looking at literature the interpretation of the definition shows variations. This is not

[*] The research team greatly appreciated the help of Mrs. Bente Frøkjær and Mrs. Helle Scheibel in piloting and processing the questionnaires

unusual since even in the USA, the cradle of the term pharmaceutical care, it is being interpreted in different ways, either as a practice form of clinical pharmacy[3], as a process of improving the drug use process[4] or as a pharmacy practice philosophy[5] (see also Chapter 1). However, the latter interpretation where, apart from outcomes, commitment and words of comfort also play an important role, has only recently received attention.

From the previous chapters it will be clear that there is a Dutch concept of pharmaceutical care (Farmaceutische Patiëntenzorg, FPZ), being: 'The care for the individual patient by the pharmacy team in the field of pharmacotherapy, aimed at improving the patients' quality of life'[†]. The core issues describing the Dutch pharmaceutical care are: avoiding drug related morbidity, continuity of care or 'monitoring', shared responsibility with patient and general practitioner, continuous documenting, the individual patient at the centre of attention and a clear starting point for the patient (intake). Since giving patient information and medication surveillance were already in place, these aspects do not receive much attention in the Dutch definition. This definition was the basis for the project described in Chapter 7, and the analysis in this chapter.

One can question if pharmacists in different countries can provide this form of pharmaceutical care or if there are major structural barriers in pharmacy systems, education or legislation limiting their possibilities.

Based upon the barriers found in the previous chapter, certain requirements for the process and especially the structure for the provision of pharmaceutical care can be formulated for the pharmacist, the pharmacy team and the pharmacy itself. Some major requirements are (in random order): up to date knowledge about diseases and drugs, continuity of involvement in the patients care and commitment to the patients' situation, communicative skills, the trias time-space-money, a structure in planning and/or protocols, a professional attitude and the use of (automated) medication surveillance or medication review.

In Chapter 7 it was found that pharmacists conceived money as the major barrier for delivering pharmaceutical care in practice. Since time, space and money are interrelated, these three primary factors, which are actually common barriers for any new project in an organisation apart from the individual willingness to change, can be translated into following, more practical indicators:

- the workload of pharmacists and staff;
- the available space in the pharmacy;
- the financial situation of pharmacies.

However, there are some other factors that obviously influenced the possibility of delivering pharmaceutical care. Such secondary factors, more specific to pharmaceutical care, are:

- the education of pharmacists (and their staff);
- the proportion of patients visiting the same pharmacy as a factor indicating the possibility of continuity of care;
- the presence of computerised medication surveillance, which makes the necessary continuous drug use review easier;

[†] Definition WINAp, Dutch Scientific Institute for Pharmacy Practice

- the quality of the relationships with physicians to enable exchange of information and change of therapy;
- communication skills being part of the (university) curriculum, since communication is essential for pharmaceutical care.

Less important and not mentioned in Chapter 7, but perhaps significant, are the following tertiary factors:

- the possibility to perform clinical laboratory tests in the pharmacy;
- customised labelling, which is almost a demand for correct use of the drug by the patient[‡];
- the possibility of delivering patient information leaflets to strengthen the counselling;
- the possibility of opening packages and dispensing only the appropriate amount of drug which tailors pharmacotherapy to individual circumstances.

8.2 METHOD

To get an impression of the mentioned practice aspects in different countries, a questionnaire was prepared in co-operation with the community pharmacy section of FIP. (see Appendix 4 to this dissertation). The questionnaire was piloted in December 1996 in 7 countries, adapted and then distributed in September 1997 to the national pharmacist association of 44 member countries of the FIP community pharmacy section. The data obtained were entered into a SPSS, Version 7.5 database.

The major aspects per country were compared as a means of identifying countries where the development of pharmaceutical care has a good chance of succeeding.

To help compare the means of the total available data with data from individual countries, a number of scatterplots were prepared. Bivariate linear regression was performed and 5% limit around the means using SPSS. Points outside the 5% limits were considered to be outliers, i.e. countries that are significantly different from the majority of other countries in that aspect. The Pearsons correlation coefficient (r_p) was calculated. Other data were compared to the mean.

In order to obtain an estimate of the approximate population per pharmacy, the population of the country was divided by the number of pharmacies. This figure was then corrected by the appropriate percentage of the turnover through others (dispensing physicians, hospitals, and nurses). For each relevant item a simple scoring-method was used.

8.3 RESULTS, THE CHANCES FOR PHARMACEUTICAL CARE

The centre received questionnaires back from 30 countries (Table 8-1). The response rate was 68%. Most countries in Asia and Eastern Europe did not reply. The returned questionnaires contained information on the local circumstances of pharmacy practice in the different countries, but the data have not been validated. In some cases remarkably simple but crucial data were not provided, especially in the field of economics. Nevertheless the results of the questionnaire give a reasonable insight into the situation in Western Europe and North America. In South America there are currently no institutional FIP members.

[‡] An inventory on customised labelling in pharmacies around the world is under way, initiated by the International Pharmaceutical Federation

The low number of African countries who are members of FIP limits the view on pharmacy practice on that continent.

Table 8-1 Responding countries to RUG/FIP questionnaire and identified projects

Country	Continent	Country	Continent
Austria	Europe	Poland	
Croatia		Portugal	
Denmark		Spain	
Finland		Sweden	
France		Switzerland	
Germany		Japan	East-Asia
United Kingdom		Korea	
Greece		Canada	North America
Hungary		United States	
Iceland		Eritrea	Africa
Ireland		Ghana	
Italy		Kenya	
Luxembourg		Nigeria	
Netherlands		Zimbabwe	
Norway		Australia	Australia/N. Zealand

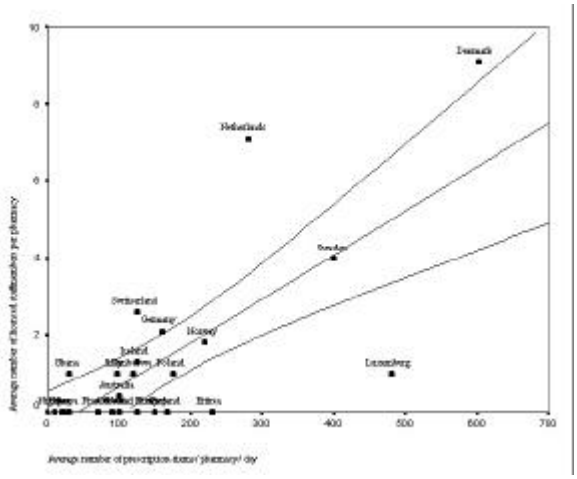
8.3.1 Primary factors

Workload of pharmacists and staff

To obtain some information about the differences in workload in the pharmacy, as a measure for time, we calculated from the available data the average number of prescriptions per day per licensed staff-member and the number of patients served per pharmacy per staff-member per day. For both parameters the regression line was calculated and we identified the outliers outside the 95% confidence interval around the regression line. From our data (r_p = 0,78, see Figure 8-2) it is clear that Luxembourg, Eritrea, and Finland dispense relatively higher number of prescription items per licensed team-member than average. Denmark, Ghana, The Netherlands and Switzerland, and dispense a relatively lower number[§].

The number of patients served per day per pharmacy staff-member (licensed and unlicensed) has also been analysed. The data (r_p=0,62) show that Eritrea, Sweden and Hungary have relatively high number of customers per staff-member than average while Kenya, Nigeria, The Netherlands and Australia have a relatively low number[**].

[§] No data available from Austria, Greece, Ireland and Portugal
[**] No data available from Austria, Canada, Denmark, Greece, Ireland, Norway and Poland



Graph 8-2 Number of prescription items versus licensed team members per country

Available space in the pharmacy

To get an impression on the use of the space in the pharmacy, the average space per pharmacy per country was plotted (in a similar way as the previous paragraph) in relation to the average number of daily customers (r_p =0,68). Pharmacies with less space on average per customer can be found in Eritrea, Ghana, Italy, Korea and Kenya. In Australia, Germany, Iceland, The Netherlands and Switzerland there is more space per customer than average, but the correlation is somewhat weak[††].

Financial situation of pharmacies

In the questionnaire the average annual turnover in US$ per pharmacy per country was asked and from this data a very rough impression can be obtained of the cost level, if the average turnover against the total staff is plotted. This technique has not been applied for African countries because of large differences in standards of living. The remaining countries show a very close relationship between those parameters (r_p=0,89)[‡‡].

Pharmacies in Iceland, Norway and the USA have a much smaller team in relation to their turnover (and probably lower costs) when compared to for instance to Australia, Sweden and Poland, that have a relative large team compared to the turnover.

8.3.2 Secondary factors

Education of pharmacists (and their staff)

The mean duration of university education for pharmacists in the studied countries was 4.6 years, but a university education of less than 4 years can be found in Zimbabwe and Australia

[††] No data available from Austria, Canada, Denmark, Great Britain, Greece, Ireland, Norway, Poland and the United States.
[‡‡] No data available from Austria, Canada and Great Britain.

(both 3 years). A university education of more then 5 years can be found in Finland, the USA (both 5.5 years) and France (6 years).

The average age for graduation is 23.7, but in Great Britain, Japan, Korea, Nigeria, Zimbabwe and Australia pharmacists are relatively young (<23) when they graduate from university (see Table 8-3).

Table 8-3 Countries with the lowest ages of graduation

Country	Age of graduation
Australia	22
Great Britain	22
Japan	22
Korea	22
Nigeria	22
Zimbabwe	21

In Austria, Finland and Iceland, pharmacists are relatively older (26) when they graduate.

In some countries additional training is required before a licence to practice can be obtained. Usually this training lasts 1 year after graduation from university but there are differences (see table 8-4).

Table8-4 Length (years) of post university training required to obtain pharmacist license

Country	Yrs	Country	Yrs
Australia	1	Kenya	1
Austria	1	Netherlands	2
Croatia	1	Nigeria	1
Great Britain	1	Poland	1
Greece	0,5	Spain	0,5
Hungary	4	Switzerland	2
Israel	0,5	Zimbabwe	1

Proportion of patients visiting the same pharmacy

Since continuity is one of the requirements for pharmaceutical care, and medication surveillance will be only effective if all information on drug use is available on one spot, the percentage of patients visiting the same pharmacy is important. From 9 countries out of 32 these data were not available. It seems that providing pharmaceutical care in general is not very logical if 30% or fewer patients repeatedly visit the same pharmacy. This was the case for Croatia (30%), Eritrea (30%), Ghana (5%), Kenya (5%), Nigeria (10%), Zimbabwe (4%) and Australia (10%)[§§].

[§§] No data available from Austria, Canada, Denmark, Finland, Ireland, Italy, Japan, Portugal and Spain

Computerised medication surveillance

If a pharmacy keeps computerised medication records and routinely performs medication surveillance, the possibilities for a justified and standardised intervention in medication are strongly enhanced. Only in 6 of the responding countries all pharmacies, and in 6 other countries most pharmacies, keep computerised medication records. This, however, does not necessarily mean that they also perform medication surveillance routinely (see Table 8-5).

Table 8-5 Medication records in pharmacy

Computerised medication records in all pharmacies	Routine Surveillance	Computerised medication records in most pharmacies	Routine Surveillance
Australia	All pharmacies	Great Britain	Most pharmacies
Canada	All pharmacies	Ireland	Most pharmacies
Denmark	Most pharmacies	Japan	Most pharmacies
Iceland	Some pharmacies	USA	Most pharmacies
Luxembourg	Some pharmacies	Switzerland	Some pharmacies
Netherlands	All pharmacies	Zimbabwe	Some pharmacies

Quality of the Relationships with physicians

In 60% of the responding countries, relationships between physicians and pharmacists are reported to be good or very good. The other countries report relationships as being not so good, loose or very loose.

Communication skills as part of the (university) curriculum

Communication is essential for pharmaceutical care provision. Only 11 countries (34%) reported that communication skills were taught in the university curriculum. In many more countries (20, 63%) communication is a subject in postgraduate education. In Croatia, Eritrea, Greece, Italy, Luxembourg, Poland and Spain communication is no subject addressed in either form of education.

8.3.3 Tertiary factors

Possibility to perform clinical laboratory tests in the pharmacy

If and what tests and analysis may be performed in a pharmacy, differs largely over the responding countries. Only in three countries (Eritrea, Germany, Switzerland) all pharmacies perform blood-pressure tests and in one country (Germany) all pharmacies perform urine-tests, according to the responses to the questionnaire. Invasive tests (e.g. blood tests) are only performed in six countries in some or special pharmacies only (Australia, Great Britain, Kenya, The Netherlands, Switzerland, United States).

Customised labelling

In 72% of the responding countries, all drugs are labelled (customised label) when they are dispensed, mentioning at least the name of the patient and sometimes the daily dosage. Pharmacies in Austria, Denmark, France, Germany[***], Greece, Korea, Nigeria, Poland, Portugal and Switzerland do not label drugs when dispensing.

Delivering patient information leaflets

In many countries the pharmaceutical industry is obliged to include a product information leaflet in the drug-package. In 56% of the responding countries special patient information leaflets are also dispensed with the drug, sometimes even individual patient-tailored. Such leaflets may be prepared either by the pharmaceutical industry or the pharmacists.

Opening packages

Opening original packages is always or sometimes performed in 50% of the responding countries. In the other countries opening a package is exceptional or never done.

8.4 DISCUSSION

Is seems reasonable to assume that pharmaceutical care has a real chance of succeeding in those countries in which the workload in the pharmacy is not excessive, there is enough space to speak with the client and the financial situation of pharmacies is reasonable. In the preceding sections we have evaluated the available data on these issues. A major problem in this procedure, especially around the paramount issues like time, space and money, was the fact that some countries do not have or did not provide the necessary data for this evaluation and therefore the questions could not be assessed properly. This was the case for many developed countries that answered the questionnaire e.g. Austria, Canada, Denmark, Great Britain, Greece, Ireland, Norway, and Poland. In general it could also not be totally excluded that the returned questionnaires contained some socially desirable answers. Using a structured interview instead of a (pre-tested) questionnaire possibly improves the quality of the responses.

In spite of the fact that Portugal did not provide the number of prescriptions per day and the average floor area of the pharmacies in the USA is unknown, we did include those countries in our final evaluation because other essential data were available.

For the African countries we have not taken the economic parameter into account because in developing countries price levels and the costs of labour are very different from the rest of the responding countries. However, in interpreting the results one must also realise in general that pricing systems, costs of personnel and taxes may show large national variations.

Having a computerised medication surveillance system that is used for medication surveillance in (almost) all pharmacies can be considered as a secondary requirement, together with the repeated use by patients of the same pharmacy. In 12 countries there are indeed (almost) always computerised medication records, but a standardised method of

[***] The answer to the questionnaire was that pharmacists in Germany do provide labels. However, from personal communication with several German pharmacists it was learned that this is not the case.

medication assessment on the basis of these records is only customary in 8 of those countries.

Some other elements of pharmacy practice in the field of dispensing can also contribute to the possibility to perform pharmaceutical care but are probably less important and can be called tertiary requirements. Many of these requirements have a cultural and legal background.

There is a large divergence between the different countries for aspects such as university-education and the average age at which a pharmacist graduates as a pharmacist. Educational systems differ around the world. The level of education is very difficult to assess and therefore has not been included in further evaluations. However, it must be said, that a 3-year university education, like in Zimbabwe or Australia, is rather short for learning all the knowledge and attitudes needed to be a pharmaceutical care pharmacist. If the university-education is relatively short, it is reasonable to assume that pharmacists in those countries graduate relatively young. This was not always the case, probably because of the length of the pre-university training.

Since the university training is relatively short in Australia and Zimbabwe and the graduation age of pharmacists is relatively young, a good post-graduate training should be necessary to further educate the pharmacists. According to the results of the questionnaire in both countries an additional 1 year of post-university training is required before a licence to practice can be obtained. A pharmacist in Japan, Nigeria, Korea or Zimbabwe will be only 22 when he or she is allowed to practice independently.

In 13 countries the relationships with physicians are not optimal. In 8 countries no attention is paid to communication skills, while in 9 countries medicines are not labelled before dispensing. Performing tests is not a common activity of pharmacies in most countries.

In 14 countries no patient information leaflets are issued and in 15 countries packages are never or hardly ever opened. Changing these practices could facilitate the introduction of pharmaceutical care in those countries.

A full table of the results of the assessment can be found in section 8.5 (table 8-6).

8.5 Conclusion, What are the chances for the implementation of pharmaceutical care around the world

In order to obtain a good impression of pharmacy practice and the chances for the successful implementation of pharmaceutical care in community pharmacy, the available data from the FIP/RUG questionnaire must be validated and additional data collected for a number of countries. The conclusions drawn here are limited because a number of countries did not have sufficient information available. It must also be realised that most of the available data per country are averages. Within the countries there will always be a variation in pharmacy size, staff size and turnover.

Table 8-6 Concise results regarding optimal opportunities for PhC

Country	Time /space/ money	Patients visit same pharmacy	Medication surveillance	Basic conditions met?	Remarks
Australia	+	no	yes	NO	
Austria					Incomplete
Canada	□				Incomplete
Croatia	+	no	no	NO	
Denmark	□				Incomplete
Eritrea	no	no	no	NO	
Finland	+	?	no	NO	
France	+	+	no	NO	
Germany	+	+	no	NO	
Ghana	+	no	no	NO	
Great Britain					Incomplete
Greece					Incomplete
Hungary	+	+	no	NO	
Iceland	+	+	no	NO	
Ireland					Incomplete
Italy	+	?	no	NO	
Japan	+	?	+	PERHAPS	
Kenya	+	no	no	NO	
Korea	+	+	no	NO	
Luxembourg	+	+	no	NO	
Netherlands	+	+	+	YES	
Nigeria	+	no	no	NO	
Norway					Incomplete
Poland					Incomplete
Portugal	+	?	no	NO	
Spain	+	?	no	NO	
Sweden	+	+	no	NO	
Switzerland	+	+	no	NO	
USA	+	+	+	YES	
Zimbabwe	+	no	no	NO	

+ relatively good conditions
no = relatively bad conditions
□ = data can not be evaluated

On the basis of the first three evaluated items, representing the workload, space and money, one can roughly say that a real chance for the successful implementation of pharmaceutical care exists in most countries. Pharmacies in some countries might have a flaw in one of those items, in Eritrea the low staffing is clear.

Analysing the secondary condition e.g. the possible development of patient relationships, providing pharmaceutical care will be more difficult in Australia, Croatia, Ghana, Kenya, Nigeria, and perhaps in Finland, Italy, Japan and Portugal since 30% or less clients in general visit the same pharmacy. Providing consistent pharmaceutical care then becomes difficult. For the remaining countries no regular medication surveillance or assessment is yet performed in Finland, France, Germany, Hungary, Iceland, Italy, Korea, Portugal and Switzerland, although there are many indications that this is changing.

According to these considerations, providing pharmaceutical care with all basic demands being met, is possible in The Netherlands, the USA and perhaps in Japan and possibly in the 8 countries for which sufficient data for evaluation were not obtained. There are signs that 5 out of those 8 countries are developing pharmaceutical care practices in their community pharmacies (see Chapter 9 and Appendix 5). Pharmaceutical care also seems to develop in countries where, according to our approach, the chances are not optimal but often that development is stimulated by institutions or persons who believe in the concept and stimulate pharmacist to start with the implementation.

In the USA it would be advisable to develop better relations between doctors and pharmacists and that patient information leaflets are provided when dispensing. In Japan and Switzerland the relationships with doctors also need improvement, not only because of pharmaceutical care, but also because of the existence of many dispensing doctors.

The opportunities for providing pharmaceutical care in any country depend very much on local customs, remuneration and legal systems. Small changes in those factors might enable the provision of pharmaceutical care by pharmacies and pharmacists. It is to be hoped that national pharmacist organisations have sufficient power to change the systems if pharmaceutical care is to be the practice philosophy all around the world. The prevailing necessary improvement seems to be the introduction of regular medication surveillance in the pharmacy in all countries.

Another important factor is the strength of clinical pharmacy and computerised medication surveillance. In a number of countries there is a proper clinical pharmacy education, but the national pharmacy system somehow has not yet been targeted at continuous computerised medication surveillance. Those countries are only a small step away from enabling the implementation of pharmaceutical care.

If pharmaceutical care is to be the world-wide practice philosophy of pharmacy in the future, there is still a lot to be done. In this chapter it is shown that only a limited number of countries currently have a very good opportunity to move forward into the standard provision of pharmaceutical care, according to the data obtained from the RUG/FIP questionnaire. In some countries only minor adjustments are necessary to enable community pharmacies to provide pharmaceutical care

If pharmaceutical care is to be implemented world-wide, then pharmacy systems in many countries must be adapted but it is also desirable that more research, with better formulated outcomes and processes, be initiated.

8.6 References to Chapter 8

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9
THE SITUATION OF PHARMACEUTICAL CARE AROUND THE WORLD

In this chapter the status of the practice of pharmaceutical care and pharmaceutical care research in different countries is outlined, based on a literature review and several conference proceedings. More detailed descriptions of projects are added to this dissertation as Appendix 5. As stated before in many countries pharmaceutical care has become the buzz-word in community pharmacy practice. But what is actually happening?

9.1 Introduction

The different interpretations of the term pharmaceutical care lead to major differences in the use of the terminology in research and practice. For instance, in the United States most researchers seem to concentrate on influencing the clinical and economic outcomes when studying pharmaceutical care and not on the content of the care process or humanistic outcomes. In Great Britain the term pharmaceutical care was used for all processes in a pharmacy, only very recently has the focus on the patients and outcomes become clearer (see Chapter 1 and 2). Because the development of pharmaceutical care is relatively new, there is little published and peer reviewed information available. Kennie et al. only could identify 12 articles on research projects, which met their scientific criteria, out of 979 citations found in Medline and the International Pharmaceutical Abstracts between 1988 and 1996[1]. When searching literature, their opinion on the presumed misuse of the term pharmaceutical care was also confirmed. The term pharmaceutical care is often used when actually clinical pharmacy services are described or evaluated.

Plumridge and Wojnar-Horton tried to find articles with sound pharmacoeconomic data on pharmaceutical care, published between 1970 and 1997 by performing searches in Medline and International Pharmaceutical Abstracts. They could not identify one single article[2]. In this chapter the focus lies on pharmaceutical care according to the Dutch definition. If there are doubts about the character of a project, this is mentioned. However, in this chapter it is tried to investigate the major research and implementation projects which are being conducted world-wide under the term 'pharmaceutical care'.

9.2 Method

Data for this of the chapter have been derived from literature (Medline search with keyword pharmaceutical care, from 1985 till 1998) and the Internet. On the Internet a special discussion forum exists in the FIP mailing list on Pharmaceutical care. This moderated list is especially useful for exchange of practical information and philosophical discussions. A call

for projects was placed on this list in December 1997. Eight responses were obtained, 3 about European projects and 5 about non-European projects. Other projects mentioned in this chapter and its appendix were found in national and international (non-peer reviewed) journals, supplements and conference reports.

To complete this overview of pharmaceutical care activities, some personal information from 'frontrunners' in the field therefore is also used in this chapter, of which the printed email messages are available to the interested readers.

Table 9-7 gives an overview of the number of existing projects in different countries at the beginning of 1998. In the mean time the number of projects has increased, but becomes more difficult to assess because there are many publication platforms now, including national conferences.

Table 9-7 identified projects in the field of pharmaceutical care per country (at the end of 1998)

Country	Identified Research projects	Identified Implement. projects	Continent
Austria	1		Europe
Belgium	1		
Denmark	2	1	
Finland	1		
France		1	
Germany	7	1	
United Kingdom	4	1	
Iceland	1		
Ireland	2		
Netherlands	7	4	
Norway	1	1	
Portugal	1		
Spain	4	3	
Sweden	1		
Japan		1	East-Asia
Canada	3	2	North America
United States	11	8	
Australia	3		Australia/N. Zealand

A description of selected projects in individual states or countries can be found in Appendix 5 to this Dissertation.

9.3 THE RESULTS PER COUNTRY

9.3.1 The United States

Pharmacy in the United States is a mixture between forces towards pharmaceutical care and other forces towards managed care. Sometimes these forces merge and certain aspects of pharmaceutical care are implemented through managed care organisations. Although managed care organisations incorporate pharmaceutical care into their services, these forces will probably be economically driven. The economic pressure on individual pharmacists in the United States seems to leave little room for extra services to their clients in practice[3]. Hepler also stated in 1997, when receiving the Remmington award (an award of the American Pharmaceutical Association) that 'pharmaceutical care studies are difficult to set up and impossible to sustain. Because the market has squeezed so much excess capacity out of the community pharmacy, practically nobody has time to play around with pharmaceutical care'[4].

Pharmaceutical care in the US is stimulated by universities, the American Pharmaceutical Association (AphA), individual pharmacists or pharmacists' companies. The latter provide independent assistance to colleagues or patients, as a kind of intermediate between the patient and the patients' own doctor and pharmacist. The Pharmaceutical Care Associates is an example of such a service and can be found on the Internet[*].

However, many research projects are under way. The most integrated study which was found in literature was described by Park and Carter and dealt with a limited number (26) of hypertension patients receiving drug therapy monitoring and educational services in a series of 4 consecutive personal consultations[15]. The study showed a significant increase in the energy/fatigue scale of the Health Status Questionnaire (an extended SF36) in the intervention group but no significant overall difference between intervention and reference group. For unknown reasons this article was not mentioned in Kennies overview[1].

Preliminary reports of research projects can now frequently be found during the short communications or poster sessions of American pharmaceutical conferences. The professional body of pharmacists, the American Pharmaceutical Association, created the American Center for Pharmaceutical Care (ACPC). They constructed a curriculum consisting of a series of learning modules providing comprehensive hands-on instructions in practice reengineering. They also created the AphA foundation, which strongly co-operates with the pharmaceutical industry and helps the profession to re-engineer itself for the future by advancing the proliferation of pharmaceutical care integration and research into the practice setting.

As described in Chapter 1, the first definition of Pharmaceutical Care was invented in the United States, around 1988 and published in 1990. The implementation of pharmaceutical care into practice after this 'invention' however seems to be rather limited for such a large country. In 1993 the American Association of Hospital Pharmacists (ASHP) issued a statement on pharmaceutical care[5]. But at a Health Outcomes and Pharmaceutical Care conference in 1995, Maine and Pathak stated that the vast majority of pharmacists in the

[*] http://www.wnwcorp.com/pharmca

United States are still working in the drug distribution model of pharmacy practice[6]. And in 1996 Carter and Barnette still concluded that there are only few pharmacists providing the full scope of pharmaceutical care[7]. A search on the Internet (Health Infonet) in July 1997 rendered around 80 sites dealing with the subject. But these sites were mainly published by university-pharmacy departments, the American Society for Health System Pharmacists or Pharmweb and did not deal with applying pharmaceutical care in everyday practice.

In the literature one finds descriptions on implementation models for pharmaceutical care programs in hospital and community pharmacy. Since 1992 some results have been published of different projects in different states. Some articles describe the impact on therapy outcomes only[8,9,10], while others also focus on the economic impact[11,12,13]. Only a few researchers describe results directly related to the influence on the patient, like quality of life[14,15] or increase in knowledge[16].

9.3.2 Australia and New Zealand

According to a report distributed through the Internet and written by Alistair IK Lloyd[17], the development of pharmaceutical care in Australia was started by two events. First the launch of the Quality Use of Medicines arm of the National Medicine Drug Policy in August 1992. Second the presentation of the concept of Pharmaceutical Care by Prof. Doug Hepler at the PAANZ conference in Perth. The Victorian Branch of the Pharmaceutical Society discussed the continuing professional development of pharmacists with officials of Glaxo Australia. They concluded that pharmacists could develop a more effective role in achieving quality use of medicines. In 1994 the Victoria Branch prepared an initial outline of a major project to have pharmaceutical care accepted by Australian pharmacists as their normal standard of practice. In June 1994 this outline became a major national project for the profession through the National Council of the Pharmaceutical Society of Australia. A management committee and a National Advisory Group were to develop a project based on the outline. A survey of pharmacists in Australia found that they saw their future role as follows:

- as being involved in the management of patients' condition, in association with other health professionals
- as working in large multi-pharmacists pharmacies and
- as providing counselling and consultations for a fee.

The greatest constraints were seen to be the lack of remuneration incentive and/or time, and the failure of others to recognise pharmacists' ability in providing patient care.

A firm called Health Care Affinity was formed in December 1994 which since has provided limited resources and considerable energy, encouragement and professional help to develop the project. Co-operation with New Zealand is under construction.

Through a strategic plan and discussions with Linda Strand it was found that the Minnesota model of practice (comprehensive pharmaceutical care) could be used as the basis of the Australian version of the practice of pharmacy. The American Pharmaceutical Association then offered to train a number of Australian pharmacists in Iowa in 1996, as a means of giving them experience in the training program of the Iowa Pharmacists Association. Four strategic plan implementation working parties were founded which started meeting in 1996. These working parties are: Practice development and standards,

promotion, data collection and information technology, and training and practice support. The Iowa training program has now been made available for all Australian pharmacists in a slightly adapted version, to make up for the national differences in pharmacy practice and remuneration between the US and Australia.

Several universities in Australia (e.g. Sydney and South Australia) have concluded successful projects on pharmaceutical care in community practice, supported by the government. To date no peer-reviewed publications about those projects have appeared.

According to the messages in AusPharmList, pharmacy in New Zealand closely resembles pharmacy in Australia and there is co-operation in the development and implementation of pharmaceutical care. In New Zealand a research project into the effects of pharmaceutical care in asthma is ongoing and implementation projects are being designed by the Pharmaceutical Society of New Zealand.

9.3.3 Canada

Canadian pharmacy seems to be less driven by managed care than in the US. In 1996 the Canadian Medical Association and the Canadian Pharmaceutical Association published a joint statement on enhancing the quality of drug therapy. The goal of the statement is to promote optimal drug therapy by enhancing communication and working relationships among patients, physicians and pharmacists[18]. From discussions on the Internet it also becomes clear that mail-order pharmacy in Canada is less developed than in its neighbouring country. Different authors attribute this fact to the better-developed individual approach of Canadian pharmacy, where more pharmaceutical care elements are said to be present in daily practice. In general, Canadian pharmacy practice shows more resemblance to Northern European pharmacy then to pharmacy in the United States. A remarkable element is the joint use of data by pharmacies in some states. In Ontario and British Columbia there is a system of medication surveillance by on-line connections to a central database, which includes the surveillance of prescriptions delivered in other pharmacies. In Quebec and British Columbia different aspects of pharmaceutical care are already being remunerated[19,20].

9.3.4 Japan

Physician dispensing is practised extensively in Japan and pharmacists supply medicines to only a limited part of the population. Nevertheless certain developments in the field of pharmaceutical care are also recognisable in this country one of which is that Japanese pharmacists are paid for a variety of services in addition to dispensing drug products.

9.3.5 The current situation in Europe

The situation regarding pharmaceutical care in Europe is almost as variable as it is around the rest of the world. Some countries just have started to think about the concept, but in other countries research centres have been established and the new philosophy of practice is being advertised nation-wide. In the UK, through structural changes in the NHS, pharmaceutical care like activities are now being performed by pharmacists in some GP practices and clinics[21].

National pharmaceutical associations in many countries are implementing pharmaceutical care projects and funding research in the area. Some universities are carrying out or developing research programs. More details on individual projects in Europe can be found in Appendix 5.

The Pharmaceutical Group of the European Community (PGEC) is involved in the development of an OTC supporting telematics system, which will incorporate some pharmaceutical care modules in the field of OTC care[22], in co-operation with 15 national European pharmaceutical associations. In the field of implementation, EuroPharm Forum is active (a co-operation between national pharmacists' organisations and the European WHO office).

The Pharmaceutical Care Network Europe Foundation (PCNE) co-ordinates most of the European research in the field of pharmaceutical care[†].

The active European countries in the field of pharmaceutical care established an informal platform organisation for co-operation in 1993. This platform is called the PCNE, the Pharmaceutical Care Network Europe. The Network generates projects, offers a framework for international co-operation and generates funds. It is also up to the PCNE to keep an open eye for the possible conflicts of interests and the agendas of national professional bodies. Europharm-forum and FIP support the Pharmaceutical Care Network Europe Foundation.

Aim of the co-ordination

The aim of the co-ordination is to enable comparison of the results of the different projects over Europe and to generate new European co-ordinated research and implementation projects. To that purpose the participants are requested to use the same instruments for evaluating the national studies and to use roughly the same implementation protocols. However, methods used have to be adapted to national circumstances and local pharmacy practice. The overall interest of all participants is always to study the outcomes of patient centred pharmaceutical care provision and to compare those results on an international level.

The basic intervention and research method is laid down in a European protocol. A regular consultation between the participating countries ensures exchange of information on the progress of the national studies and the level of adherence to the European protocols.

PCNE is the umbrella that supports the co-ordination of the fund-raising and brainstorming.

International projects

Currently two research projects are being co-ordinated by the PCNE and three more are under development.

The TOM-project, Therapeutic Outcome Monitoring in asthma, is a project based upon the TOM-concept as it has been developed by Hepler in Florida. The project (in different formats) is currently being performed in Belgium, France, Iceland, Malta, Northern Ireland and the Netherlands. Finland has stopped the project because all pharmacies got involved in

[†] A modified form of this section appeared as an article in Int Pharm J 1997;11:10-11

asthma education. Austria is preparing to implement a similar project. Denmark, Germany and The Netherlands have concluded their asthma projects. The results of the Danish project were presented at the FIP conference in Jerusalem in 1996. The Danish research centre is now studying the possibilities of evaluating data on the implementation of the project in different participating countries.

The second project is entitled 'Pharmaceutical Care in the Elderly'. A European protocol has been established based upon the Dutch OMA study, developed by van Mil and Tromp. Participating in this project are currently Denmark, Germany, Ireland, the Netherlands, Northern Ireland, Portugal and Sweden.

A project on self care using OTC-drugs is currently under development, as this field seems to be well suited for pharmaceutical care[23]. Several of the countries mentioned above are participating in this development as well, and Spain is also involved.

Since 1997 there is also some co-ordination between countries involving a study in the field of angina pectoris, i.e. Germany, Northern Ireland and the Netherlands. Spain is in addition looking for partners to become involved in their TOMCOR programme (pharmaceutical care in coronary disease).

Finally a study into implementation barriers for pharmaceutical care in different countries has been carried out under supervision of Dutch researchers (see report in Chapter 7).

Finances

The PCNE also attempts to find funding for the co-ordination of the pharmaceutical care projects. Usually the individual countries must raise the funding for their national implementation. Biomed, a European funding authority, supplies the money for the co-ordination of the Elderly projects, after a successful application co-ordinated by the PCNE and Prof. J. McElnay in Belfast.

Because developing new protocols is essential as well, sources are sought to find seeding money to enable new projects to be started. FIP provided the money for the development of the OTC-project, which is currently being developed. As long as there is no funding for the international co-ordination of a specific project, each participating national organisation pays its own expenses for the international meetings.

Current structure of PCNE

Within PCNE organisations, which perform, research or promote Pharmaceutical Care co-operate. Participants are both representatives of universities and representatives of national pharmacist organisations.

Political considerations of course play a role. If the value of pharmaceutical care can be clearly demonstrated, this will provide an extra argument to the legitimate claims for an increased role of pharmacists in the field of drug provision and selection. The results of the PCNE co-ordinated projects provide data to support and indeed defend the professional content of pharmacists' work. It is for this reason that other pharmaceutical organisations are involved, like Europharm Forum[‡] and FIP.

[‡] Europharm Forum is a co-operation between the European Professional Pharmacist Organisations and the European Office of the World Health Organisation, based in Copenhagen, Denmark

Besides the central organisation, working-groups exist in which the projects are co-ordinated. There are currently working groups on TOM asthma (co-ordinated by Hanne Herborg, Denmark), the Elderly (co-ordinated by James McElnay, Northern Ireland) and OTC (co-ordinated by Peter Noyce, United Kingdom). Every new project will have its own working group in which the (potential) participants discuss the protocol and exchange data. Because the group is growing, the current structure is subject to debate.

9.4 Conclusion, what is the situation of pharmaceutical care around the world

There are activities in many countries in the field of pharmaceutical care. The leading stimulating organisations in research are the University of Florida in Gainesville, the University of Minnesota in Minneapolis and the Pharmaceutical Care Network Europe. Other bodies, especially universities in Australia, Canada, Germany, the Netherlands, Northern Ireland, Spain, the United Kingdom, and the USA are active as well. A number of practice implementation projects are also ongoing, mainly initiated by national pharmacist organisations.

In Africa, Asia, South America and the former Eastern European countries (excluding former East Germany and Czech Republic) very few activities in the field of pharmaceutical care can be identified, either in research or in practice.

Many studies are ongoing, especially in Northern America, Australia, New Zealand and Europe, however, very little published quality data are available. The influence of pharmaceutical care on health-related outcomes and pharmacoeconomics has therefore not yet been established through publications in major peer reviewed biomedical journals.

If pharmaceutical care is to be the worldwide practice philosophy of pharmacy in the future, there is still a lot to be done. In this chapter it has been shown that there are implementation and research projects ongoing, but only on a limited scale. The published results of research projects in general show the need for pharmaceutical care, but the positive effects on outcomes has not yet been satisfactorily demonstrated in a major peer reviewed journal. This will influence the level of acceptance of pharmaceutical care by other health care providers.

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Part IV

Conclusion and summary

10
CONCLUSION OF THIS DISSERTATION

Until the first World War community pharmacy in The Netherlands was primarily a product oriented institution. Then the professionalism of pharmacists declined and they seemed to concentrate especially on the trade aspects because of the increased industrial production of medicines. After the Second World War pharmacy started to change slowly in the direction of service and advising on pharmacotherapy, and reprofessionalisation began. In the 1990s the move towards pharmaceutical care (a patient oriented care model) started in community pharmacy, and most of Dutch community pharmacy is now becoming patient and care oriented. The current change is strongly supported by the Royal Dutch Society for the Advancement of Pharmacy (KNMP) and by the type of pharmacy education provided by the Groningen and Utrecht universities, where pharmacotherapy, clinical pharmacy and social pharmacy are major topics in the curriculum.

One of the bottlenecks for the implementation of pharmaceutical care is the availability of clinical data to the pharmacist. In 1999 the KNMP has reached an agreement with the Dutch government that the Dutch pharmacist will be part of the WGBO. This means that pharmacists will soon be acknowledged care providers by law, and this also enables a free exchange of data between medical and pharmaceutical practitioners.

How valuable is pharmaceutical care to society? In the TOM and OMA studies described in this dissertation and also in many articles and abstracts, it has been proven that the provision of pharmaceutical care has a positive influence on different outcomes of patient care. Although most studies have not yet been published in the major biomedical journals, it has clearly been established that the provision of pharmaceutical care has its value in the case of general ambulatory care[1,2,3,4,5], psychiatry[6], HIV infections[7,8], asthma[9,10,11,12,13 14], diabetes[15,16,17,18,19], hypertension[20,21,22], and hyperlipidaemia[23,24].

It can therefore be stated with confidence that pharmaceutical care definitely improves the outcomes of care. Although there are differences in opinion on the definition of pharmaceutical care world-wide, most western countries now embrace the basic pharmaceutical care concept where the patient is the core of the pharmacist's activities. The opportunities to provide pharmaceutical care, however, depend on several circumstances.

There is quite a difference between pharmacy practice internationally, and a number of country specific barriers have to be overcome. Although small pharmacies, with only one pharmacist and no other staff certainly have low thresholds for their clients, their structure and financial capacities to provide pharmaceutical care most probably are limited. Pharmaceutical care certainly demands extra time, and often also extra staff for it to be properly implemented. There are educational demands to be met as well as demands in the field of knowledge and attitude. Many professional organisations around the world are now addressing these barriers.

The search for definite answers to the question of whether changed pharmacy practice in The Netherlands is possible, a practice in which the community pharmacist has expanded his/her role and influences outcomes in a positive sense, clearly has not ended with the TOM and OMA studies. More research into the outcomes and especially in relation to the processes of pharmaceutical care should be performed.

10.1 The TOM and OMA Studies

In a number of publications, Donabedian presented a model for assessing the quality of health care[25,26,27]. Looking at pharmaceutical care and at both studies presented in this dissertation, his division of the care-process into structure, process and outcomes is helpful for these type of studies.

10.1.1 The structure

In chapter 8 of this dissertation it has been established that pharmacy in The Netherlands is basically well structured for the provision of pharmaceutical care.

The relatively large Dutch pharmacies do offer opportunities to provide pharmaceutical care. The staffs in pharmacies are relatively well trained in counselling and pharmacotherapy, although pharmacists have their doubts about the possible role of assistant pharmacists in the pharmaceutical care process. The layout of Dutch pharmacies is spacious compared with pharmacies in many other countries and counselling has for the last twenty years been part of the activities. There are relatively good relationships with GPs, a well functioning medication surveillance system and most Dutch clients visit the same pharmacy. Almost all pharmacies have a special counselling room. However, during the TOM and OMA studies it became apparent that the Dutch pharmacist is not accustomed yet to document interventions and outcomes in a structured way.

Before and during the TOM and OMA studies attention was paid to the structure by giving additional education to the pharmacists, and helping them to implement the study protocol in their pharmacies. The importance of documentation was stressed as well as the need for a quiet environment for providing care and working in a structured way (see chapter 3).

A major handicap for the interpretation of the results for the TOM and OMA studies was the limited documentation in some of the participating pharmacies, in spite of the extensive training-programme. However, during the studies it became clear that the Dutch computer software has not yet been developed appropriately for proper documentation and that the pharmacy staff needs additional training on this topic.

10.1.2 The process

The initial thoughts expressed in section 3.2.2 about separating two types of reference pharmacies for both studies did not prove to be helpful. The fact that intervention pharmacists provided e.g. care to asthma patients had no or little influence on their care towards the elderly population in their pharmacy. Similarly no influence on asthma patients could be recognised in those pharmacies were care was provided to elderly using 4 or more medicines.

Although the processes for the TOM and OMA study have been thoroughly described (see Chapter 3), they have not been implemented as well as they should have been, in spite of the training sessions before and during the studies. From the pharmacists' reports on the frequency of the consultations, there are indications that the implementation of the process has not been as good as desired. The underlying documentation was not filled out well and more attention should have been paid to the documentation of process-indicators.

The pharmacists participating in the TOM and OMA studies were provided with a structured approach to medication analysis, which in fact is a protocolled way of dealing with potential drug related problems in complex medication regimens, using drug use profiles. If and how this protocol was used, could not be assessed. The latter effect became visible when comparing the number of drug related problems encountered. According to the OMA pharmacists' documentation the number of problems decreased throughout the study, but when the intervention and reference groups were compared at the end of both studies, no difference in the number of drug related problems experienced by the patient could be established. The reasons for this discrepancy can be twofold. Either the pharmacists have not addressed the drug-related problems as experienced by the patients (but mainly the ones they could detect with a potential clinical significance), or the willingness to document decreased during the study. In future studies it is advised that special attention be paid to the way process indicators are established and documented.

10.1.3 The outcomes

The major interesting part of any study into the effect of care processes are the outcomes. In spite of the deficiencies in the TOM and OMA study concerning the structure and process and the relative high drop-out rates, the inclusion of reference groups in the study ensured that changes in outcome could be established between the intervention and reference groups. These changes must have been a result of the process (which perhaps was not exactly the process as planned for the study) and the slightly adapted structure in the participating pharmacies.

As illustrated by chapter 3 of this dissertation, much energy was put into establishing the proper outcomes to be monitored before the study, both final outcomes and intermediate outcomes. But because of the quality of the available data, no highly sophisticated statistical procedures have been applied.

In his major publication in 1993 about outcomes in pharmacoeconomic research, Kozma presented his ECHO-model[28]. This model seems to be very suitable to analyse the outcomes of pharmaceutical care research as well. The model divides outcomes of care into economic, clinical and humanistic. If this model is used to analyse the results of the OMA and TOM studies, then the following picture emerges.

Economic: No comprehensive pharmacoeconomic analysis was performed but some indicators changed in a positive sense in the OMA study, like the number of visits to the GP, the number of visits to a specialist and the number of hospital admissions.

Clinical: There are clear indications that certainly in the case of the TOM study (asthma) some clinical outcomes improved. This finding was supported by the changes in drug use. In the OMA study the intervention has not resulted in changes in the number of dispensed

daily dosages of benzodiazepines, and only in a non-significant change in presumed compliance calculated from the dispensed daily dosages. Other clinical outcomes were not included in the assessments because of the character of the intervention.

Humanistic: The provision of pharmaceutical care improved the satisfaction with care of patients and professionals alike. In the TOM study there are indications that the patients' quality of life improved but not to a clinically or statistically significant degree. In the OMA study a change in quality of life could not be established, probably due to the low sensitivity of the instrument, minor changes in this outcome and the high drop-out rate.

10.2 CONSIDERATIONS FOR PHARMACEUTICAL CARE RESEARCH

Research in the field of pharmaceutical care, which is a form of pharmacy practice research, is relatively new. According to Cotter and Mays, pharmacy practice research can be defined as 'the research into the protection, development and justification of pharmacy roles and services[29]. Systematic major research in this field is rare, although many smaller research projects are being performed, mainly in the United Kingdom[30,31].

The definition of pharmaceutical care research can be formulated as 'the investigation of pharmaceutical needs of individuals and the community and the effectiveness and efficiency of the provision of pharmaceutical services and care to meet those needs'. It is a form of research, which is clearly based upon the patients' viewpoint, a logical result of the definitions of pharmaceutical care. Systematic research in this field is at this time only being performed in a few centres, in Europe mostly by members of the Pharmaceutical Care Network Europe, or in a few universities in Northern America and Australia. Sometimes pharmaceutical care research includes the pharmaco-economic evaluation of the intervention, to estimate the possible beneficial effects to society of the pharmacists' actions, but that clearly remains a difficult topic.

The standard way of academically investigating a problem runs through 4 phases: designing, implementing and collecting data, analysing data, and reporting. During the design-phase two main questions have to be answered, as follows:

- what is to be found out (the research question) exactly and
- what is the best strategy to answer this question.

In the case of pharmaceutical care research in practice, the researchers can hardly influence experimental conditions and there is a large possible variety in outcomes. The outcomes are partially subjective and include a large array of humanistic variables. This also implies that many instruments should be used to measure outcomes, or a limited number should be chosen in the knowledge that not all results of the application of pharmaceutical care, or the fulfilment of all pharmaceutical needs of patients, will be measured. This influences the answers to both questions posed above.

In 1997 the Cochrane Centre published a review (last amended in 1999) in which they stated that only a limited number of studies which could be analysed in the field of pharmacy practice and studying outcomes, supported the expanded roles of pharmacists in patient counselling and physician education[32]. The reviewers had doubt about the generalisability of the studies and the poorly defined nature of the interventions tested. The lack of studies including cost assessment and patient outcome data indicates that more

rigorous research is needed to document the effects on outpatient pharmacist interventions. An article with a similar content by Kennie *et al*. appeared in 1998 in the Annals of Pharmacotherapy[33]. Nevertheless the authors of the Cochrane review conclude that 'Pharmacists should continue their roles in delivering patient counselling regarding drug therapy and educating physicians about drug therapy. A limited literature supports further expansion of pharmacist roles to include therapeutic management of patients independent of physicians and patient counselling on general health issues other than those specifically related to drug therapy.'

The TOM and OMA studies described in this dissertation suffer from some of the flaws mentioned in both reviews above. This is not surprising because they were started in 1994, at a time that outcome research in pharmacy and pharmaceutical care were relatively new. Nevertheless, the chance that the presented findings are a result of the implemented care is high, because of the availability of reference data. However, there are some other reasons why pharmaceutical care research in practice can not always meet the demands of a well-designed clinical study.

10.2.1 Monitoring the process

Pharmacy practice is far from a sterile laboratory. Pharmacists and patients both are human and only the drug is an unchangeable entity. The human influences on any process in care can hardly be standardised. Before and during the TOM and OMA studies, the pharmacists were not only educated on the content of the care to be provided, but also on documenting and using the different documentation forms. Nevertheless there are indications that the documentation was insufficient and that the intervention was not implemented fully as planned. Therefore it would certainly be very useful if the process of the provision of pharmaceutical care and its documentation during studies are closely monitored and documented by an independent supervisor, equal in position to the clinical monitor in clinical studies[34].

An interesting recent development is the publication by Odedina and Segal of an instrument for measuring the pharmacists' activities. This instrument would enable researchers to establish a level of the provision of pharmaceutical care in a pharmacy and monitor how far the implementation process has progressed. Odedina used a multiple-item scale to assess behavioural activities in pharmaceutical care. The scale was proven to be valid, reliable and sensitive[35]. The authors assume pharmaceutical care to be a combination of drug use assessment, counselling and therapeutic outcome monitoring. However, the scale seems sensitive to bias. It will only be valid if the pharmacists abstain from formulating socially desirable answers to the questionnaire. Additionally the questionnaire is quite complex and country (USA) specific. Semantic and cultural translation does not seem an easy task.

10.2.2 Data Quality

Drug data from pharmacies, although very helpful, are not always complete[36]. Drug data used in the TOM and OMA study suffered especially from the fact that the real daily use by the patient was obviously not always in concordance with the daily use as entered into the pharmacy's database. Monitoring e.g. compliance on the basis of such incomplete data then

becomes difficult. The mentioned independent supervisor could also be helpful to detect and repair such discordance at an early stage.

Furthermore the collection of quality humanistic data especially is quite a challenge when an interviewer is involved. In pharmaceutical care research the pharmacist will often take part in the data collection. The chances to receive biased answers under these circumstances are high. The interpretation of a question by the interviewer or even the reader adds to the variability and influences the quality of the data and therefore the results. The validation of data collection instruments and methods is of uttermost importance under practice circumstances.

10.2.3 Availability of validated and practical instruments

Although some outcomes (economic, clinical and some humanistic) can be measured and can provide a firm basis for research, the assessment of other humanistic outcomes is not standardised. Control groups must always be included in pharmaceutical care research because healthcare is changing continuously, and other factors (outside of the pharmaceutical care intervention) may also affect the outcomes.

Currently the emphasis of pharmaceutical care research is heavily placed upon sociological outcomes, and suitable instruments for the assessment of the effects of pharmaceutical care in this field are only now in the process of being developed. Therefore a number of additional challenges can be foreseen when collecting, analysing and interpreting the data.

For one main outcome, the health related quality of life (HRQL), well established research instruments exist, which sometimes have a validated derived linear scale. However, that instruments are designed for assessing the effects of medical care, which often has a more outspoken impact on the life of the patient. Instruments to measure other humanistic outcomes like satisfaction of patients and professionals for the time being cannot be interpreted in such a way, if available, and inclusion of reference groups into studies remains essential.

Bentley *et al*. have researched if the concept of quality of life is clear to pharmacists in community practice[37]. They concluded that there are still a number of questions that must be answered before HRQL questionnaires can become clinical tools in the practice of pharmacy. The issues that pharmacists try to affect when providing pharmaceutical care are the perceived health status of the patient, in combination with limits to functional (dis)abilities. But some find this a debatable viewpoint because essentially there are many different concepts regarding the health related quality of life, originating from different approaches[38,39]. When choosing an instrument, these differences in approaches must also be taken into account.

If the current validated instruments are used, one needs quite a large number of study-subjects in order to demonstrate changes in quality of life over time, significant at a 95% confidence level. In the case of generic instruments the link with clinical significance is difficult to establish. This is especially the case for the provision of pharmaceutical care, because it seems not to influence one single domain, but all (or most) domains simultaneously to a small extend, unless a clear disabling disorder is being addressed.

Apart from isolated attempts to construct pharmaceutical care specific instruments for outcome assessment, a more integrated approach was taken at the Working conference of the Pharmaceutical Care Network in January 1999 in Hillerød, Denmark. Some of the workshops resulted in instruments, which are now being validated*. The proceedings of the Working Conference will be published by the end of 1999. In the mean time a publication has appeared in Germany about the PCNE Attitudes Towards Medicines Questionnaire, which was developed during that conference[40].

10.2.4 Process and outcome documentation

There are no well-designed validated instruments to document the care process. Although one could use the SOAP-notes approach initially developed for medicine, the content of each element (subjective, objective, assessment and plan) still can not be documented in a way that would enable statistical analysis. Medicine also is still struggling to find appropriate Electronical Medical Record (EMR) systems[41].

During our studies the PAS® system was developed (see appendix 2), as an attempt to document elements of the consultation process and to be able to analyse these elements using statistical methods. The results of the evaluation of this instrument indicated that this system was not very valid, although in retrospect the validation method was not optimal either because the cases offered to code were probably too concise and left room for different interpretations[42].

A concise structured documentation system for pharmaceutical care activities has been developed by the Dutch Scientific Institute for Pharmacy Practice (WINAp), and installed on the major Dutch pharmacy computer-systems[43,44]. This system is designed to monitor the performance of the pharmacy. This could be an extremely efficient documentation systen, however, in practice this system is seldom used because the pharmacy-staff in The Netherlands is not accustomed to documenting care-activities.

The International Classification of Primary Care (ICPC) is a classification system and research tool developed in an EC project to classify simultaneously three of the four elements of the problem-oriented construct-SOAP[45]. It is a biaxial classification system developed to order medical concepts into classes, which have been chosen on the basis of their relevance for family practice to code GP-patient encounters and other actions in general practice of medicine. In 1998 a reduced version of the ICPC coding system was published which could be helpful in the documentation process for certain aspects of pharmaceutical care in community pharmacy[46].

Documentation and process implementation could possibly be improved by providing payment to pharmacists for the time invested. However, in studies where this has been done, the documentation quality was reasonable but still not optimal, according to the researchers†. In Quebec (Canada) the available funds for remuneration of pharmaceutical care are hardly being used by the pharmacists[47,48].

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* More information on the validation and a brief report of the meeting can be found at the internet at http://www.pharmakon.dk/Interna/pcne.htm.

† Information obtained at duscussions within the Pharmaceutical Care Network Europe.

10.2.5 Good examples

Potential researchers will not be able to identify many examples of pharmaceutical care research by performing literature searches, due to a certain lack of publication platforms and the erratic use of the term 'pharmaceutical care' in databases like Medline or Embase. Additionally, full descriptions of methodologies have not often been published, possibly because publishers (and therefore authors) seem to concentrate on the clinical or economic outcomes rather than on the process.

As remarked by Kennie, it is true that published studies relating to pharmaceutical care do not always meet the same stringent scientific criteria, which can be applied to studies under laboratory circumstances or in a clinical environment. This is possibly also one of the reasons that it appears to be difficult to find a publication platform for pharmaceutical care research, apart from national pharmaceutical journals. Researchers in different countries are still searching for independent peer reviewed international biomedical journals, which are willing to accept their major publications on the results of their studies, some already concluded in 1996.

Furthermore, a number of projects have been performed with the state or professional pharmacist organisations as the major sponsor. Reports on the effects of those projects have primarily been prepared for the principals or authorities, and have not (yet) appeared in the major biomedical journals (e.g. the projects of the University of South Australia by Gilbert[49] and the University of Sydney by Benrimoj *et al*.[50]). Parts of such projects have, however, sometimes been presented as posters or short communications in national and international pharmaceutical conferences, but not in full in peer reviewed biomedical literature.

For the time being personal communications seem the best way to obtain information about pharmaceutical care research methodology. Apart from the Pharmaceutical Care Network Europe (PCNE), other possible platforms for obtaining such information include the annual International Conference on advances in Pharmaceutical Care and the PharmCare discussion list of the PharmWeb Internet-server in the UK. Increasingly national and international pharmacy conferences also offer opportunities for the exchange of methodologies, especially during the short communications or poster sessions.

10.3 THE FUTURE OF PHARMACEUTICAL CARE AND PHARMACEUTICAL CARE RESEARCH

Although different opinions exist on the definition of pharmaceutical care, the concept has a future in community pharmacy and probably in hospital pharmacy as well. In the latter case the care will be provided through a clinic, as can be seen in many places in the US, and increasingly in the UK.

How easy is it to establish the effect of pharmaceutical care, assuming that the process control is optimal? This largely depends on the outcomes that can be selected for the study. Looking at the literature, and comparing the results of the OMA and the TOM study, it seems that establishing the effect of the provision of pharmaceutical care to a clinically well-defined population is relatively easy. Providing pharmaceutical care to a defined group of patients (e.g. certain age groups, pregnant women, elderly using 4 or more medicines) becomes more difficult. This is due to the fact that the clinical outcomes to be studied are

more difficult to identify. When the effects of interventions to all patients in a pharmacy (for instance the effects of counselling at first and second delivery of a specific medicine) is to be studied, the researchers must rely almost solely upon economic and humanistic outcomes. In the latter case the indications for drug use and thus the clinical outcomes can be manyfold. It is therefore not surprising that articles describing significant changes in final clinical outcomes of care as a result of pharmaceutical care interventions usually deal with clearly identifiable diseases and clinical outcomes. Publications on comprehensive pharmaceutical care concentrate on humanistic outcomes, or on models calculating possible economic benefits.

However, the processes that can lead to the optimal outcomes of pharmacotherapy need to be refined further. Disease specific pharmaceutical care remains a topic requiring more research, during which protocols can be developed and tested for implementation. But protocols can only be developed if standards for optimal care exist. The medical profession is still struggling to describe standards for the optimal treatment of diseases. Many standards of care are country (or health system) specific and are in a constant state of revision. It seems desirable to develop standards for pharmaceutical care, which are more independent of such changes. The Dutch institute WINAp is currently trying to define disease specific pharmaceutical care standards, based upon the Dutch Pharmacy Norms[51] and additional requirements[‡].

The concept of comprehensive pharmaceutical care, as described by Cipolle, Strand an Morley[52], offers the opportunity to provide patients with pharmaceutical care irrespective of medical standards, but based upon drug use and medication related errors. In community pharmacy practice this seems a very useful approach, also because the pharmacist in most countries, including The Netherlands, often lack the indication for drug use. The effects on final outcomes of this form of pharmaceutical care, however, are hard to establish. There have been efforts to link the occurrence of drug related problems (basically a process indicator) to the clinical and/or economic outcome of care, but such studies include many gross assumptions of the impact of drug related morbidity on hospital admissions and other costs [1,53,54]. The studies also usually assume that drug related morbidity is preventable, which is not always the case. Additionally, the frequency of drug related problems would differ between countries due to differences in the implemented systems for prescribing by physicians and medication surveillance in pharmacy. Results of national studies therefore are not representative for other health systems.

The future will be for both types of pharmaceutical care. Where a diagnosis and a good pharmacotherapeutic treatment standard exists, the pharmacist could use that standard to underpin a process of care which will influence a clearly defined outcome; including the same (usually clinical) outcome the standard addresses.

In the case of multimorbidity, or if the goals of the pharmacotherapy are unknown, the comprehensive approach has its value as well, not only to improve patient satisfaction but also to prevent and correct medication related errors and their impact on outcomes. In this latter case it seems especially necessary to establish what drug related problems are

[‡] Several minutes of the WINAp steering group meetings throughout 1998.

preventable, and the consequences of preventable drug related morbidity in terms of economical, clinical and humanistic outcomes.

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hebben gehad op de ontwikkeling van het beroep en die hebben geleid tot farmaceutische patiëntenzorg, als een werktuig om de huidige en toekomstige ontwikken van het apothekersberoep in Nederland te begrijpen. Dezelfde krachten kunnen vermoedelijk ook in andere landen worden herkend, maar de snelheid van de ontwikkelingen kan verschillen.

De recente ontwikkeling van de Nederlandse openbare farmacie naar een praktijkmodel, gebaseerd op farmaceutische patiëntenzorg in de laatste 30 jaar is het gevolg van een aantal invloeden, waaronder:

- De ontwikkeling van de apotheker-arts relatie;
- De ontwikkeling van de patiënt-apotheker relatie;
- Vooruitgang van de apothekersopleiding;
- Toename van de informatie aan patiënten;
- Verbeterde medicatiebewaking en het concept klinische farmacie;
- De ontwikkeling van het vakgebied sociale farmacie.

Veel van deze invloeden hingen niet met elkaar samen, waardoor de ontwikkeling van Farmaceutische patiëntenzorg in Nederland wat sprongsgewijs is verlopen en afhankelijk was van toevalligheid. Voor het samensmelten van de ontwikkelingen in het concept van Farmaceutische patiëntenzorg waren sterke katalysatoren nodig, waaronder de overdenkingen van Hepler en Strand en de toenemende vraag van de maatschappij naar meer informatie rond de therapie met geneesmiddelen.

De gebeurtenissen die vooraf gingen aan de ontwikkeling van farmaceutische patiëntenzorg in Nederland waren op zich niet zo verwonderlijk. Farmacie is een open systeem dat in de markt opereert. In Nederland hebben de apothekers gereageerd op veel invloeden vanuit de regering, de farmaceutische industrie, ziekenfondsen, patiëntengroeperingen en de automatisering. Bijvoorbeeld, de druk van de farmaceutische industrie op voorschrijvers veroorzaakte de ontwikkeling van de adviesfunctie van apothekers aan de artsen en die functie werd later ondersteund door het Ministerie van Volksgezondheid. De ontwikkeling van klinische farmacie begon in de Verenigde Staten door veranderingen op medisch gebied, en wordt in Nederland opgepakt als een toevoeging aan het apothekersberoep, gebaseerd op de kennis inzake farmacotherapie die inmiddels bij de Nederlandse apothekers aanwezig was. De vraag om geneesmiddelinformatie kwam van consumenten organisaties terwijl de ontwikkeling van sociale farmacie bij de universiteiten begon door de druk uit de richting van de maatschappij.

De ontwikkeling van het apothekersberoep is in Nederland dus duidelijk meer van buitenaf geïnitieerd. Maar dat geldt niet alleen voor de apothekers. De meeste andere beroepen hebben een soortgelijk pad gevolgd van reacties op druk vanuit hun 'klant'.

Toch zijn er ook voortrekkers geweest. Enige apotheker met visie hebben de vroege signalen opgepakt en hebben geprobeerd om de beroepsmatige activiteiten te ontwikkelen die door de maatschappij werden verlangd of geëist. Zoiets kost tijd en toewijding vanwege de vele horden die moeten worden genomen. Na enige tijd echter volgde de rest van de professie hun pionierwerk. Als farmaceutische patiëntenzorg daadwerkelijk onderdeel moet gaan uitmaken van het dagelijkse werk in de openbare apotheek en als het beroep van apotheker zich nog verder moet ontwikkelen, dan is het wenselijk dat een dergelijke pro-

actieve houding niet alleen beperkt blijft tot de voortrekkers maar wordt gedeeld door alle apothekers en hun beroepsorganisaties.

Met al deze (internationale) ontwikkelingen op het gebied van farmaceutische patiëntenzorg wordt het ook belangrijk om het effect ervan aan te tonen. In Hoofdstuk 3 wordt de methode beschreven van twee onderzoeksprojecten. De projecten (TOM bij astma patiënten en OMA bij ouderen die 4 of meer geneesmiddelen gebruiken) werden in 1994 gestart bij de Afdeling Sociale Farmacie en Farmacoepidemiologie van de Rijksuniversiteit Groningen. Het ontwerp van beide studies is vergelijkbaar en omvatte een referentie groep die geen speciale zorg kreeg. Toch zijn er enkele essentiële verschillen in de processen van de studies en op het terrein van de bekeken resultaten. Het TOM project was meer klinisch georiënteerd. Er werd speciaal aandacht besteed aan het onderwijzen van een goede inhalatietechniek en astma zelfmanagement, en aan het bevorderen van therapietrouw met preventieve medicatie. Bepaalde gedefinieerde klinische resultaten konden worden gemeten zoals de astma status. De OMA studie was meer diffuus, er werd speciale aandacht besteed aan het verbeteren van therapietrouw en het begrip van de werking van de medicijnen en aan het verminderen van het gebruik van benzodiazepines. Door de heterogene samenstelling van de populatie was het moeilijker om klinische resultaten te meten en werd speciaal gekeken naar verbeteringen in kwaliteit van leven en kennis over geneesmiddelen en ziekten.

Het OMA project, naar het effect van farmaceutische patiëntenzorg bij ouderen, werd uitgevoerd tussen 1995 en 1997. In Hoofdstuk 4 staan enige resultaten van deze studie op patiëntenniveau beschreven gevolgd door een discussie. Het verlenen van farmaceutische patiëntenzorg aan ouderen die 4 of meer medicijnen gebruiken veroorzaakte een hoge graad van tevredenheid onder de patiënten, maar er kon geen belangrijke invloed worden vastgesteld op de kennis of de kwaliteit van leven (volgens de SF-36). Er kon ook geen duidelijke invloed worden vastgesteld op de therapietrouw met diuretica, vermoedelijk door het relatief kleine aantal patiënten aan het eind van de studie, en de beperkte periode waarover de geneesmiddelgegevens beschikbaar waren vóór de start van de studie. Ook het gebruik van benzodiazepines werd niet duidelijk gereduceerd in de studiegroep. Enkele andere resultaten vertoonden wel een tendens in de goede richting, maar niet statistisch significant. Het plaatje met betrekking tot geneesmiddel gebonden problemen is tweeledig. Hoewel de apothekers een duidelijke afname van dergelijke problemen rapporteerden (vooral met betrekking tot bijwerkingen), gaven de patiënten aan het eind van het project aan dat er geen verschil was tussen de interventie en de referentiegroep wat betreft de problemen die zij ondervonden.

Ook de TOM studie werd uitgevoerd tussen 1995 en 1997. Enkele resultaten van dat project staan beschreven in Hoofdstuk 5. Het algemene beeld van de resultaten van dat project is positief. In de interventie groep zijn meer patiënten begonnen een piekstroom meter te gebruiken en deden aan zelf management dan in de referentiegroep. Daarbij gebruikten meer patiënten de luchtwegverwijders vóór de preventieve medicatie, als die beide werden gebruikt. Er was ook een betere astma status in de interventiegroep. Dat gegeven werd nog eens extra ondersteund door de analyse van het geneesmiddelgebruik waarbij bleek dat de gebruikte hoeveelheid luchtwegverwijders verminderde evenals het aantal benodigde

kuurtjes (van antibiotica of corticosteroïden). Er zijn ook aanwijzingen dat de kwaliteit van leven (gemeten met de the Asthma Quality of Life Questionnaire van Junniper) veranderde ten positieve als gevolg van de verleende zorg. De kennis over gebieden die verwant zijn met astma, namelijk chronische bronchitis en emfyseem verbeterde ook. De patiënten waren tevreden over de verleende zorg en vond de regelmatige consulten nuttig, zeker in het begin van de studie. Het imago van de apotheker in de ogen van de patiënten verbeterde en na de studie hadden ze een positievere mening over de mogelijkheden van de apothekers om hen te helpen met hun geneesmiddelgebruik en het omgaan met hun aandoening. Maar de relatief hoge uitval in de interventiegroep gaf wel aan dat de patiënten een project van 2 jaar erg lang vonden.

Patiënten zijn niet de enigen die betrokken zijn bij farmaceutische patiëntenzorg. De zorgverleners (in dit geval de apothekers) en de huisartsen van de patiënten zijn er ook bij betrokken. In Hoofdstuk 6 worden de invloeden op deze hulpverleners beschreven, gebaseerd op de ervaringen in het TOM en OMA project. Die resultaten worden in perspectief gezet door twee kleinere projecten waarbij naar de relaties tussen apothekers en huisartsen wordt gekeken, en waarbij de gewenste taakverdeling tussen de apothekers en hun assistenten in de Nederlandse apotheken nader wordt geanalyseerd.

Het is zeker niet verwonderlijk dat de intensiteit van de samenwerking tussen de apothekers en de huisartsen op het gebied van zorg grotendeels afhankelijk is van de kwaliteit van hun relatie. Naast de beroepsmatige aspecten hebben ook persoonlijke aspecten een invloed op die samenwerking. Als apothekers farmaceutische patiëntenzorg verlenen maken de huisartsen zich het meeste zorgen over een verondersteld gebrek aan kennis over ziekten bij de apothekers. Maar hoe meer apothekers zijn betrokken bij farmaceutische patiëntenzorg, des te minder ze twijfelen over hun eigen kennis op ziektegebied.

Voor zowel het TOM als het OMA project, waarbij het zo nu en dan nodig was om medicatie te veranderen, was het duidelijk dat er samengewerkt moest worden met de huisartsen. Maar in het algemeen kan men zeggen dat de Nederlandse apothekers, met hun uitnemende kennis over farmacotherapie, zich correctief opstellen ten aanzien van de voorschrijver en dat kan weerstanden veroorzaken. Deze weerstand komt bij beide projecten, maar ook wel in andere studies, duidelijk aan het licht. Men kan zich echter ook vormen van farmaceutische patiëntenzorg voorstellen waarbij de samenwerking huisarts-apotheker niet absoluut noodzakelijk is, zo lang er geen noodzaak bestaat tot het veranderen van de farmacotherapie en de apotheker taken uitvoert op het gebied van de farmacoepidemiologie en het geven van gebruiksinstructies. Dus als de relatie apotheker-huisarts niet optimaal is, behoeft dat nog geen excuus te zijn voor de apothekers om dan maar helemaal geen farmaceutische patiëntenzorg te verlenen.

Wanneer we kijken naar de mogelijke verdeling van de taken behorende bij farmaceutische patiëntenzorg dan blijkt dat, volgens apothekers, het eigenlijke werk door de apothekers gedaan zou moeten worden hoewel sommige nevenactiviteiten en een gedeelte van het patiëntencontact ook door de assistenten gedaan zou kunnen worden.

In de TOM en OMA studies is bewezen dat het verlenen van farmaceutische patiëntenzorg een positieve invloed heeft op de resultaten van de patiëntenzorg. Het staat nu ook wel vast

dat farmaceutische patiëntenzorg zinvol is bij niet geïnstitutionaliseerde zorg, bij de psychiatrie, HIV infecties, astma, diabetes, hoge bloeddruk en hyperlipeadiemie. Ondanks dit bewijs staat het nog te bezien of alle apothekers wel bereid zijn om farmaceutische patiëntenzorg een onderdeel te maken van hun dagelijkse praktijk want dat zou een houdingsverandering en een verandering in het dagelijkse werk inhouden. In Hoofdstuk 8 wordt het resultaat beschreven van een Europees onderzoek naar hindernissen voor de implementatie van farmaceutische patiëntenzorg.

De apothekers in Europa vinden tijd en geld de belangrijkste barrières om te beginnen met het verlenen van farmaceutische patiëntenzorg. Uit het onderzoek is gebleken de apothekersorganisaties in Europa aandacht moeten besteden aan de vergoedingssystemen, als ze willen dat farmaceutische patiëntenzorg zich in hun land verder ontwikkelt. Maar het is ook duidelijk dat ze blijvend moeten werken aan een houdingsverandering bij de apothekers en de mening van andere werkers in de gezondheidszorg zullen moeten beïnvloeden. Dat laatste wordt niet uitsluitend bereikt door initiatieven op het terrein van de 'public relations' maar ook door het ondersteunen van de onderzoekers bij hun publicaties. Belangrijke hindernissen zijn ook gevonden op het terrein van de opleidingen. Meer en een betere opleiding van de Europese apothekers op het terrein van klinische farmacie, communicatie, documentatie en management lijkt noodzakelijk.

In de openbare farmacie lijkt er momenteel wereldwijd een rol voor farmaceutische patiëntenzorg weggelegd te zijn. In het bijzonder de sectie 'community pharmacy' van de Internationale Farmaceutische Federatie (FIP) heeft farmaceutische patiëntenzorg gestimuleerd als een nieuwe rol voor de apotheker. In 1996 heeft de FIP die rol vastgelegd in hun gezamenlijke declaratie inzake goede apotheekpraktijk (Good Pharmacy Practice, GPP) in de openbare en ziekenhuisfarmacie, samen met de Wereld Gezondheidsorganisatie (WHO). Momenteel is die nieuwe rol in sommige landen duidelijker dan in andere.

Hoe kunnen verschillende facetten van de openbare farmacie de introductie van farmaceutische patiëntenzorg vergemakkelijken in een land, en hoe veel gebeurt er nu eigenlijk. In Hoofdstuk 8 wordt een analyse gegeven van de huidige apotheekpraktijk en de kansen voor de ontwikkeling van farmaceutische patiëntenzorg in verschillende landen, gebaseerd op de resultaten van een internationale vragenlijst die is ontwikkeld, samen met de sectie openbare farmacie van de FIP. De analyse toont aan dat de omstandigheden in Nederland, de Verenigde Staten en Japan optimaal zijn voor het verlenen van farmaceutische patiëntenzorg door openbare apothekers. Dat is mogelijk ook het geval in acht andere landen, maar de afwezigheid van bepaalde sleutelgegevens verhinderde een volledige evaluatie. Er zijn echter signalen farmaceutische patiëntenzorg zich ook positief ontwikkelt in Canada, Denemarken, Oostenrijk, Ierland, Noorwegen en het Verenigd Koninkrijk.

Ondanks de minder gunstige omstandigheden in bepaalde landen, kunnen onderzoeks- en implementatie activiteiten ook worden waargenomen in Australië, Duitsland, Finland, IJsland, Portugal, Spanje en Zwitserland. Details van dergelijke activiteiten in de hele wereld kunnen worden gevonden in de Hoofdstuk 9 en de bijbehorende appendix.

In het laatste hoofdstuk van het proefschrift worden de resultaten van de TOM en OMA studies gezet in het perspectief van de gezondheidszorg, met gebruik van het Donabedian

SAMENVATTING

FARMACEUTISCHE PATIËNTENZORG, DE ZORG VAN DE APOTHEKER (PHARMACEUTICAL CARE)

Wat is farmaceutische patiëntenzorg? Het eerste hoofdstuk van het proefschrift gaat over systemen van gezondheidszorg en de plaats en de definitie van farmaceutische patiëntenzorg.

Farmaceutische patiëntenzorg is een manier van omgaan met patiënten en hun medicatie. Het is een concept dat gaat over de manier waarop mensen medicijnen zouden moeten krijgen en de bijbehorende gebruiksaanwijzingen. Het gaat ook over de verantwoordelijkheden van patiënten en professionele hulpverleners, medicatiebewaking, advisering en de resultaten van zorg. In uitzonderlijke gevallen is zelfs het inkopen van geneesmiddelen door een apotheek onderdeel van het concept.

In het proefschrift wordt de volgende werkdefinitie gebruikt, tenzij anders aangegeven. Farmaceutische patiëntenzorg is de zorg van het apotheekteam voor de individuele patiënt op het gebied van farmacotherapie, gericht op het verbeteren van de kwaliteit van leven'(de Nederlandse WINAp definitie 1998). Bij deze definitie wordt er van uitgegaan dat farmaceutische patiëntenzorg wordt verleend door het team in de apotheek (de apotheker en de apothekersassistenten), en dat een systeem voor medicatiebewaking aanwezig is.

Het concept van farmaceutische patiëntenzorg is zonder twijfel een onderdeel van de gezondheidszorg. Er zijn essentiële verschillen tussen de concepten van farmaceutische patiëntenzorg, *disease management* en *managed care*, hoewel er ook overeenkomsten zijn. De belangrijkste verschillen liggen in de mate van invloed die de patiënt kan uitoefenen op het zorgproces of zorgconcept en in de drijvende kracht achter het zorgconcept. Maar toch kan farmaceutische patiëntenzorg deel uitmaken van *disease management*, terwijl *managed care* de strategieën van *disease management* gebruikt om de kosten te beheersen.

Er zijn belangrijke conceptuele verschillen tussen de beschrijvingen of definities van farmaceutische patiëntenzorg in verschillende landen. In enkele landen worden zulke verschillen over het hoofd gezien en dat leidt tot verwarring. Als farmaceutische patiëntenzorg in een land gedefinieerd wordt, dan moet de cultuur, de taal en de apotheekpraktijk van dat land betrokken worden in de interpretatie van de definitie. Sociale en cultureel gebonden activiteiten zoals farmaceutische patiëntenzorg moeten opnieuw gedefinieerd worden, afhankelijk van nationale factoren en de plaatselijke ontwikkelingen van de gezondheidszorg. Als een definitie letterlijk vertaald wordt, moet ook rekening gehouden worden met conceptuele linguïstische verschillen.

De lange geschiedenis van het beroep van apotheker in Nederland kent vele belangrijke ontwikkelingen. Evenals in veel andere landen heeft het beroep zich ontwikkeld van het maken van magistrale receptuur en de verkoop van geneesmiddelen tot het verstrekken van geneesmiddelen en hulpmiddelen gekoppeld aan advisering. In Hoofdstuk 2 van het proefschrift wordt geprobeerd om de belangrijkste krachten te identificeren die een invloed

model voor de kwaliteit van de gezondheidszorg. Dat model splitst zorg op in structuur, proces en resultaat ('outcome'). De resultaten van de studies worden vervolgens bekeken met behulp van het ECHO model van Kozma.

De TOM en OMA studies zijn praktijkstudies. Dat houdt in dat rekening moet worden gehouden met een aantal kenmerkende barrières tijdens het onderzoek. Onder de hindernissen die in het laatste hoofdstuk worden besproken zijn het volgen van het proces, de kwaliteit van gegevens uit de praktijk, de beschikbaarheid van gevalideerde instrumenten, de documentatie en de afwezigheid van goede voorbeelden in de literatuur.

Als dergelijke hindernissen kunnen worden genomen, hoe makkelijk is het dan om het effect van farmaceutische patiëntenzorg vast te stellen als het proces van die zorg is geoptimaliseerd? Dat hangt voornamelijk af van de beschikbaarheid van de *outcomes* die voor een dergelijke studie kunnen worden gemeten.

Statistisch significante veranderingen in klinische resultaten ten gevolge van farmaceutische patiëntenzorg kunnen gewoonlijk worden aangetroffen bij studies met een goed definieerbare ziekte en goed definieerbare meetpunten. Toch moeten de processen die zulke verschillen kunnen geven nog verder worden verfijnd. Ziekte specifieke farmaceutische patiëntenzorg blijft een dankbaar onderwerp voor onderzoek en de praktijk. Protocollen kunnen worden ontwikkeld en getest voor toepassing in de dagelijkse praktijk. Toch biedt ook een algemeen model van farmaceutische patiëntenzorg een mogelijkheid om alle patiënten van zorg te voorzien, ongeacht de vraag of er wel een standaard is voor de aandoening waaraan ze lijden maar gebaseerd op algemeen geneesmiddelgebruik en geneesmiddel gebonden problemen. In de openbare farmacie lijkt dit een nuttige benadering omdat in vele landen, waaronder Nederland, de indicatie waarvoor een geneesmiddel wordt gegeven meestal niet bekend is in de apotheek. De effecten van deze algemene benadering op de resultaten van de zorg zijn echter moeilijk vast te stellen. Om de effecten van farmaceutische patiëntenzorg in de praktijk te kunnen meten zou de indicatie voor het geneesmiddelgebruik eigenlijk bekend moeten zijn en daartoe is een betere samenwerking tussen de behandelend arts over individuele patiënten nodig.

Farmaceutische patiëntenzorg is eigenlijk niet meer weg te denken. Hoewel er nog vele verbeteringen denkbaar zijn is duidelijk dat de klinische en humanistische uitkomsten van de zorg erdoor verbeteren en dat de patiënten er erg tevreden over zijn. Men kan zich afvragen hoe belangrijk de economische aspecten dan nog zijn. Het verbeteren van de patiëntenzorg betekent nu eenmaal niet altijd dat de kosten direct omlaag gaan. De winst zit hem meestal op de langere termijn. Politici lijken dit vaak te vergeten. Het verbeteren van alleen klinische resultaten, zoals zorgverleners vaak doen, lijkt ook geen goede doestelling voor de gezondheidszorg.

De patiënten (of de maatschappij) zullen uiteindelijk zorg altijd beoordelen op grond van de humanistische resultaten. Farmaceutische patiëntenzorg, als onderdeel van de gezondheidszorg, is zeker ook in staat om bij patiënten de kennis te vergroten, de kwaliteit van leven en de tevredenheid met de verleende zorg te verhogen.

The more recent movement of Dutch community pharmacy during the last 30 years towards a pharmaceutical care model of practice is the result of many discrete influences, including:

- Development of the pharmacist-physician relationship,
- Development of the pharmacist-patient relationship,
- Advances in the education of pharmacists,
- Increased provision of information to patients,
- Improved medication surveillance and conceptualisation of clinical pharmacy,
- Development of social pharmacy;

Many of these influences were unrelated, making the development of pharmaceutical care in The Netherlands somewhat episodic and dependent on chance. The convergence of various influences into the pharmaceutical care pharmacy practice model required strong catalysts including the intellectual philosophy advocated by Hepler and Strand and the emerging demands of society for more information about medication therapy.

The events preceding the development of pharmaceutical care in the Netherlands, however, are not so surprising. Pharmacy is an open system that operates in the marketplace. As such is also sensitive to many outside influences. In the Netherlands, the pharmacy profession appears to have been reactive to the influences of government, industry, sick funds, patient-groups and automation. For instance, the pressure of the pharmaceutical industry on prescribers initiated the development of the pharmacists' advisory activities to physicians and was later supported by the health authorities. The development of clinical pharmacy was initiated in the United States as a reaction to changes in the field of medicine, and followed up in the Netherlands as an addition to pharmacy practice based upon the pharmacotherapeutic knowledge of the Dutch pharmacists. The demand for drug information came from consumer organisations, while the university community as a result of societal pressure has initiated the development of social pharmacy.

The development of the pharmacy profession in The Netherlands obviously has depended much more on outside forces than on pressures from within the profession. It should be stressed, however, that pharmacy as a profession is not alone in this 'forced' evolution. Most other professions have followed a similar path of reacting to pressures from their 'clientele'.

The existence of a front-runner role of some pharmacists must be acknowledged. Some professionals with vision, picked up early signals and tried to develop the professional activities that were required and desired by society. This takes time and especially dedication due to the many barriers that have to be overcome. The rest of the profession eventually follows their pioneering work. A proactive attitude, not only from the front-runners, but from the entire profession and professional organisations, is desirable if pharmaceutical care is to be incorporated into routine community pharmacy practice and for a further development of the profession.

With all the (international) developments involving pharmaceutical care in community pharmacy it becomes important to establish its effects. In Chapter 3 the methodology for two research projects is described. The projects (TOM in asthma patients and OMA in the elderly using 4 or more different medicines) were started in 1994 at the Department of Social Pharmacy and Pharmacoepidemiology of the University of Groningen. The design of both

projects is similar and included a reference group, which did not receive special care. Nevertheless there are some essential differences in the processes of the studies as well as in the field of the outcomes studied. The TOM project had a more clinical orientation. It concentrated on teaching good inhaler technique and asthma self-management, and on improving compliance with preventive medication. Certain definite outcomes could be monitored such as the asthma status. The OMA study was more diffuse, the process concentrated on improving compliance and understanding of medicines, and trying to decrease the use of benzodiazepines. As a result of the heterogeneous population, this study dealt with less well defined outcomes, and therefore concentrated on the quality of life and improvements in patient knowledge of medicines and diseases.

The OMA study into the effects of pharmaceutical care in the elderly was carried out between 1995 and 1997. In Chapter 4 some results of this study at the patient level are described and discussed. The provision of pharmaceutical care to elderly using four or more different medicines led to a high satisfaction amongst patients. However, no major influence was seen on knowledge or quality of life (according to the SF-36). There was no clear picture with regards to the influence on compliance with the use of diuretics, probably due to low numbers of patients at the end of the study and the short pre-study period of available drug data. No influence on the use of benzodiazepines in the intervention group could be seen. Some other outcomes, however, changed in the expected way, but not to a statistically significant degree. The picture with regard to drug-related problems was mixed. Although the pharmacists recorded a decreasing number of problems while providing care (mainly problems dealing with side effects), according to the patients at the end of the project there was no difference between the intervention and reference groups with regards to the problems with medicines they really experienced.

The TOM study was also conducted between 1995 and 1997. Some results of this project at the patient level are described in Chapter 5. In general terms the results of the TOM project are positive. In the intervention group more patients started to use peak-flow meters and became involved in self-management than in the reference group. In addition more patients were now using their reliever medication before their preventive medication if they used both. There was better asthma control in the intervention group. This finding is clearly supported by the analysis of the drug use, which shows a decrease in the amount of reliever and rescue medication (short courses of antibiotics and/or oral corticosteroids). There is also an indication that the quality of life (according to the Asthma Quality of Life Questionnaire (Junniper) improved as a result of the care provided. The knowledge about illnesses related to asthma, e.g. chronic bronchitis and emphysema, improved. Patients were satisfied with the care provided and found the regular consultations useful, certainly in the beginning of the study. The patients' image of a pharmacist changed and after the study they had a more positive opinion of the capability of pharmacists to help them with their drug use and in coping with their disease. However, the relative high drop-out rate in the intervention group was probably an indication that asthma patients might not appreciate a 2 year long study.

Patients are not the only people involved in pharmaceutical care. The providers (in this case the pharmacists) and the patients' GPs are also involved. In Chapter 6 the influences on

those professionals are described, based upon the opinions and experiences in the TOM and OMA study. These results are put in perspective by two additional smaller projects into the relationship between pharmacists and physicians, and into the role-division of pharmaceutical care tasks between pharmacists and assistant pharmacists in Dutch community pharmacy.

It is not surprising that the intensity of co-operation between pharmacists and GPs in the field of care depends largely on the quality of their relationship. Apart from professional aspects, personal aspects of the relationship also seem to influence the co-operation. When pharmacists provide pharmaceutical care, currently the major worry of GPs seems to be the assumed lack of knowledge of the pharmacist about diseases. However, the more pharmacists are involved in pharmaceutical care, the less they doubt their own knowledge in this field.

For both the TOM and the OMA project, in those cases where medication had to be changed, the necessity to co-operate with GPs is apparent. In general one can say that Dutch community pharmacist, with their excellent pharmacotherapeutic knowledge, perform their advisory roles towards prescribers in a corrective manner and this may provoke resistance amongst the physicians. This resistance can be recognised in the results of both studies and in other projects. One can, however, imagine forms of pharmaceutical care where this co-operation is not absolutely necessary, as long as there is no necessity to change pharmacotherapy and the pharmacist sticks to tasks in the field of pharmacoepidemiology and giving instructions for drug use. Therefore, if the relationship between pharmacists and physicians is not optimal, that should not be an excuse for pharmacists to abstain from providing any form of pharmaceutical care to their patients.

When it comes to incorporating the tasks of providing pharmaceutical care into the Dutch pharmacy organisation, according to the pharmacists, the real core of the work still should be done by the pharmacists themselves, although some side-issues and part of the patient-contact can also be delegated to the assistant pharmacist.

In the TOM and OMA studies it has been proven that the provision of pharmaceutical care has a positive influence on the outcomes of patient care. At this point of time others have also clearly established that the provision of pharmaceutical care has its value in the case of general ambulatory care, psychiatry, HIV infections, asthma, diabetes, hypertension, and hyperlipaedemia. In spite of this evidence, it remains to be seen whether all pharmacists are willing to implement pharmaceutical care into their routine practice because this would imply a change in professional attitude and daily work. In Chapter 8 the result of a European survey of implementation barriers for pharmaceutical care are described.

Pharmacists in the European countries studied perceive time and money as the major barriers for the implementation of pharmaceutical care. Both issues are interrelated. From the survey it is clear that the European Pharmaceutical Associations must pay attention to remuneration issues if they would like pharmaceutical care to advance in their countries. It is also clear that they need to work continuously on a change of attitude amongst pharmacists and try to influence the opinions of other health care providers. The latter could not only be reached by public relations initiatives, but also by supporting researchers in publishing the results of their projects. Important barriers have also been identified in the

educational domain. More and/or better education of European pharmacists in the field of clinical pharmacy, communication skills, documenting skills and management skills therefore seems necessary.

In community pharmacy around the world there currently is a role for the pharmaceutical care. Especially the community pharmacy section of the International Pharmaceutical Federation (FIP) has advocated pharmaceutical care as a new role for pharmacist. In 1996 FIP itself advocated that role in its joint statement on Good Pharmacy Practice (GPP) in community and hospital practice settings, together with the World Health Organisation (WHO). Currently that new role is more obvious in some countries than in others.

How do different aspects of pharmacy practice enable or hinder the introduction of pharmaceutical care in a country and how much is actually happening? In Chapter 8 an analysis is given of the current status of pharmacy practice and the chances for the development of pharmaceutical care in different countries, based upon the results of an international questionnaire which was developed together with the community pharmacy section of FIP. From this analysis it became clear that the circumstances in the Netherlands, the USA and Japan are optimal for the provision of pharmaceutical care by community pharmacies. There is some evidence that this is also the case in eight other countries but the lack of certain key-data made a full evaluation impossible. From latter eight countries it is obvious that pharmaceutical care develops in Austria, Canada, Denmark, Great Britain, Ireland, and Norway.

In spite of less favourable circumstances in certain countries, research and implementation activities can also be found in Australia, Finland, France, Germany, Iceland, Portugal, Spain, Sweden and Switzerland. Details of those activities can also be found in chapter 9 and appendix A5.

In the last chapter of this dissertation the TOM and OMA studies are put in a health care perspective, using the Donabedian trias for the quality of healthcare, which divides health care into structure, process and outcomes. The outcomes of the study then are briefly evaluated using Kozma's ECHO model.

The TOM and OMA research projects were 'real life' studies. This implies that many research barriers had to be overcome which are inherent to pharmacy practice research. A number of such barriers are given and discussed, including process monitoring, the data quality in practice, the availability of validated instruments, the documentation, and the absence of good research models.

If such barriers are overcome, how easy is it then to establish the effect of pharmaceutical care, assuming that the process control is optimal? This largely depends on the availability of outcomes and outcome measures that can be selected for the study.

Significant changes in final clinical outcomes of care as a result of pharmaceutical care interventions usually have come from projects with clearly identifiable diseases and clinical outcomes. However, the processes that can lead up to optimising outcomes of pharmacotherapy need to be refined further. Disease specific pharmaceutical care remains a topic for requiring much further research. Protocols can be developed and tested for implementation. However, the concept of comprehensive pharmaceutical care offers the

SUMMARY

The first chapter of this dissertation deals with issues surrounding health systems and the position and definitions of pharmaceutical care. Pharmaceutical care is a way of dealing with patients and their medication. It is a concept that deals with the way people should receive and use medication and should receive instructions for the use of medicines. It also deals with responsibilities of patients and professionals, medication surveillance, counselling and outcomes of care. In some countries the concept also deals with the way people should obtain information about disease states and lifestyle issues. In exceptional cases even purchasing medicines by a pharmacy is considered to be part of the concept.

Throughout this dissertation, the following working definition has been used, unless stated otherwise. 'Pharmaceutical care is the care of the pharmacy team for the individual patient in the field of pharmacotherapy, aimed at improving the quality of life' (the Dutch WINAp definition 1998). This definition assumes that the pharmaceutical care is provided by the pharmacy team (in the Netherlands the pharmacist and the assistant-pharmacists), and that a medication surveillance system is in place.

The concept of pharmaceutical care is, beyond any doubt, part of health care. There are essential differences between the concepts of pharmaceutical care, disease management and managed care, although there are also some relationships. The main difference can be found in the extent of influence of the patient on the process or concept of care, and the driving force behind the care concept. However, pharmaceutical care can be, and often is, part of disease management while managed care uses disease management strategies to contain costs.

There are important conceptual differences between the descriptions or definitions of pharmaceutical care in different countries. In some countries such differences are overlooked and this leads to a confusing use of the terminology. When defining pharmaceutical care, at least the culture, the language and pharmacy practice in the country of origin have to be taken into account. Social and culturally bound activities like pharmaceutical care need rephrasing, depending on factors in the country of origin and the health care system developments over time. When literally translating definitions, one must take conceptual language differences into account.

The long history of the profession of pharmacy in the Netherlands has been filled with many important developmental issues. As is the case in many other countries, the profession developed from the extemporaneous preparation and selling of medicines to the dispensing of medicinal products coupled with patient counselling. In the Chapter 2 of this dissertation an attempt is made to identify the forces influencing the development of the profession and convergence into pharmaceutical care, as a tool to help improve understanding of the current and future professional developments of pharmacy in The Netherlands. The same issues can probably be identified in other countries, although the pace of change may differ.

opportunity to provide all patients with pharmaceutical care irrespective of medical standards, but based upon drug use and medication related errors. In community pharmacy practice this seems a very useful approach, because the pharmacist in most countries, including the Netherlands, often lack information on the indication for drug use. The effects on final outcomes of the comprehensive form of pharmaceutical care, without knowing the indication for drug use, are hard to establish. To be able to measure the effects of pharmaceutical care in practice, the indications for drug use should preferably be known and more and better co-operation with the treating physicians about individual patients therefore should be established.

Pharmaceutical care is here to stay. Its format may be refined further, but from many of the studies performed to date it is clear that clinical and humanistic outcomes improve and that the patients are very satisfied as well. Worthy of consideration is how important the economic outcomes should be under such circumstances. Improving care should and cannot always mean decreasing direct costs. The gain would be long-term. Policy makers often seem to forget this. Only improving clinical outcomes should not be the goal for care either, a fact often overlooked by the professionals.

Patients (or the society) will in the end always look for improved humanistic outcomes. Pharmaceutical care can, as a part of the total network of care, certainly help to improve the knowledge, quality of life and satisfaction of patients.

participating pharmacies and my assistants in the university. Apart from the input of my promotors Dick Tromp, Lolkje de Jong-van den Berg and James McElnay, I especially valued the philosophical and scientific support of Almut Winterstein, Bente Frøkjær, Birthe Søndergaard, Hanne Herborg, Doug Hepler, and Rein Vos.

Of course I am also very grateful to the external examining committee of this dissertation, which consisted of Marion Schaefer, Albert Bakker, Ton Steerneman . Last but not least a special thanks for the project-assistants, Barbro Melgert and Geeske IJben, who managed to be systematic where I was not, and to Frank Venema who was helpful as ever with the layout of this dissertation.

In the beginning of the research, a special foundation was formed to support the research, the Stichting Pharmaceutical Care. The members of the board of this foundation, Dinie van Hagen-van Hoorn, Loek Arts and Jan van Tienen, are thanked for putting me on the track.

The list of people to be thanked further is very, very large and because I can be systematic at times I appended the list at the end of epilogue in alphabetical order. In spite of the size of that list, my gratitude to those whom I mentioned is really heartfelt.

Zuidlaren, December 1999

Those people I want to thank for their patience and attributing to my thinking and working on this research and dissertation.

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And all those other people who gave me the opportunity to discuss about pharmaceutical care and the pharmacy profession.

EPILOGUE

Dear Reader,

Why is a 43-year-old pharmacist inclined to write a dissertation and to finish before he turns 50? To be honest, I think only a few are eager, some will consider and all the others couldn't care less. I belonged, and still belong to the last group. For me this dissertation was not a goal in itself. It is a reflection of my interest in my profession and pharmacy practice research.

In 1977 at the time when social pharmacy emerged and community health centres were still new in the Netherlands, I graduated as a pharmacist. Pharmacy was an interesting subject. The view on the role of the patient in healthcare made community pharmacy definitely interesting to me and I started working in the pharmacy of a community health centre in Lewenborg, Groningen. Co-operation with physicians was exciting and the world was pretty OK. Pharmacotherapy and clinical pharmacy became gradually more important to me, also because of the aforementioned co-operation. I changed to another pharmacy in a small village in 1981 and most of my energy went into getting the place running and establishing good contacts with the local GPs.

Because an objective Dutch journal on pharmacotherapy was lacking, and because I am sometimes (too?) adventurous, I started a biweekly independent Dutch drug bulletin called Pharma Selecta in 1982. After about 5 years, the financial situation of the drug bulletin asked for a new initiative. Pharma Selecta started PS on-line, a literature retrieval database for Dutch community pharmacists on pharmacotherapy. Again almost 5 years later, everything being well in place and life becoming regular again, I was asked to complete some work for Prof. Flora Haayer at the University of Groningen on the character of exported drugs to third world countries. This project being terminated after a couple of month, I was looking for some new pharmaceutical excitement when in 1993 Prof. Dick Tromp approached me. He asked if had ever heard of pharmaceutical care (on which the answer was no) and if I would like to work out a research project in that field (on which I answered yes), the latter being another sample of my too adventurous character. Because it was only when I already had said yes, that Dick told me he expected me to get a PhD degree on the project. This was certainly not my initial objective. But when Dick made the choice clear, no PhD, no research project, I gave in.

And let me now be honest, I am grateful for his offer. Through this project I met with so many new, interesting, caring and very nice people, with so many new and exciting (sorry for the Americanism) ideas, that it was well worth it. And having the steady home-base of a trustful and understanding partner Roelof Bijleveld, dedicated personnel in my pharmacy and inspiring and supportive staff members at the department of Social Pharmacy and Pharmacoepidemiology, I could complete the research and this dissertation.

This piece of research could never have been completed without my strong links with pharmacy practice, the (sometimes also financial) support of many professional organisations in the field of pharmacy and its practice, practical support from the

Part V

Appendices

Appendix

A1 THE DRUG USE EVALUATION IN THE TOM AND OMA STUDY

To assist the pharmacists in performing a drug use evaluation for the patients, a protocol was provided, based upon the drug use profile (DUP). The protocol was published in the Dutch independent drug bulletin Pharma Selecta[1].

INSERT DUP

Fig. A1.1 Example of a drug use profile

A1.1 THE DRUG USE PROFILE (DUP)

The Drug Use Profile is a chronological reproduction of the drug use of a specific patient over a limited amount of time (usually 12 months). In the Netherlands Prof. Dr. A. Porsius of the Pharmacy Department of the University of Utrecht in his series of 'farmacocasus' first used this kind of outline. Usually a DUP is made

retrospectively, but a certain amount of prospective perspective can be obtained by incorporating the drugs that are still going to be in use, according to the medication history.
A Drug Use Profile can of course be made manually, but some Dutch pharmacy computer systems like Pharmacom® and Euroned® can automatically produce these profiles in print. The following picture shows an example of a DUP.

A1.2 USE OF THE STRUCTURED APPROACH TO MEDICATION ANALYSIS

The pharmacists had not used Drug Use Profiles for drug use evaluation previously to the projects. The participating pharmacists accepted the technique very well. Especially in the OMA-(Elderly) project after 6 months the method was very useful as can be seen in table A1-2.

Table A1-2 Usefulness of DUP in pharmaceutical care

	6 months(%)			12 months (%)		
	Useful	Not useful	Neutral	Useful	Not useful	Neutral
OMA-pharmacies	63	0	37	66	0	33
TOM-pharmacies	39	0	61	75	0	25

A1.3 PROTOCOL FOR DRUG USE ANALYSIS

A drug use analysis should preferably be protocolled, as to guarantee the quality of the work. An example of a possible protocol which has been used in both the OMA as the TOM study, using the DUP, is following:
1. Select the group of patients you want to perform the medication analysis on.
2. Contact the local GPs in case you want to suggest medication-changes, and inform them of your activities
3. Make a drug-use profile (DUP) per patient, in which you group the drugs in ATC or indication-order
4. Interpret the DUP.
   - Check dosage-appropriateness of drugs
   - Check compliance/adherence (lines crossing or gaps)
   - Check for non-active or hardly active drugs
   - Check for (pseudo) double-medication
   - Check for relevant interactions.
   - Check for contra-indicated drugs, if the disease-states are known
   - Check for drugs possibly being used to suppress the side-effects of other drugs
- Check for drugs contra-indicated in pregnancy or breast-feeding, if appropriate
5. Discuss the results with the patient and the GP, if necessary. Propose necessary changes in the medication or laboratory tests.

In the Dutch system, medication surveillance on dosage, incompatibilities etc. is usually performed when the prescription is being filled. Nevertheless, in the retrospective medication analysis often some new critical items can be found which the pharmacist neglected at the first time of evaluating. Making DUPs and performing DUEs should therefore be a continuous process.

A1-2 REFERENCE TO APPENDIX A1

[1] van Mil JWF, Melgert B, Moolenaar F. Medicatie analyse, tijd om te starten. Pharm Selecta 1995:120-123

Appendix

A2 THE PAS® SYSTEM*

A coding system for use in Pharmaceutical Care consultations

TO THE POTENTIAL USERS OF THE PAS®-SYSTEM

The PAS system has been developed to code the problems, analyses and solutions with medicines, which become clear during a pharmaceutical care consultation, between patent and pharmacist
The system has been partially validated, *but proved to be not very reliable in s test-retest validation procedure*. However, this could be due to the procedure used. We welcome any remarks about the PAS®-system.

You cannot use the PAS®-system without prior consent of the head of the Department Social Pharmacy and pharmacoepidemiology of the Rijksuniversiteit Groningen. If you plan to use the PAS®-system then we will ask you to contribute to its validation.

Acknowledgements:
Our special thanks to Prof. Dr. J. McElnay, Belfast and Mr. J. Max, Liverpool for their help in translating the PAS® system into English.

The system can be referred to as follows:

The PAS® System, a Coding System for Pharmaceutical Care Consultations
J.W.F. van Mil, B. Melgert, Th.F.J. Tromp, L.T.W. de Jong van den Berg
Working Group Social Pharmacy and Pharma co-Epidemiology
Rijksuniversiteit Groningen, February 1995

All correspondence about the PAS®-system maye be sent to:
J.W.F. van Mil, Pharm D., Dept. Social Pharmacy en Pharmacoepidemiology, Ant. Deusinglaan 2, 9713 AW Groningen, The Netherlands
Telephone: +31 50 633291 Email: foppe@farm.rug.nl Fax: +31 50 633311 Version 1.2

PAS®-Coding system

The PAS®-system has been developed for use during pharmaceutical care consultations, to code drug related questions or complaints of patients, their analysis and the solutions offered by the pharmacist. Please code and **AFTER** the consultation.

Problems

During the consultation between pharmacist and patient certain problems will be mentioned. They can be coded with a P-code. Usually only one P-code is needed for the problem.

Analysis

During the analysis phase, the problem will be translated into the pharmacists' terminology and coded with the A-codes. Several A codes are possible because there may be more reasons for a problem.

Solutions

The solutions offered can be coded with a S-code. Several solutions are possible, even at the same time. Solutions also depend on individual pharmacists, and are therefore not very reproducible between different pharmacists.

The category 'Otherwise' is an escape code In all three code. Please use it as little as possible.

---

* An extensive evaluation and validation of this system has been descibed in: IJben G, van Mil JWF, Tromp ThFJ, van den Berg LTW. Het Pas systeem, een codeersysteem voor farmaceutische patiëntenzorg gesprekken. Evaluatierapport. Rijksuniversiteit Groningen, juni 1997

PROBLEMS/COMPLAINS AS MENTIONED BY THE PATIENT AND THEIR CODES

Difficulties with .....

P1 Difficulties handling the packaging of the drug
P2 Difficulties applying the drug properly
P3 Difficulties with stopping the drug
P4 Difficulties with the change of the appearance of the drug
P5 Difficulties taking or using the drug
P6 Difficulties understanding the package insert
P7 Difficulties in adherence with the precautions (e.g.avoiding sunlight)
P8 Difficulties performing the instructions for use
P9 Difficulties with changes in the instructions for use

Real trouble with ....

P11 Trouble with the action of a drug
P12 Trouble with the side-effects of a drug
P13 Trouble with the combination food/alcohol and a drug
P14 Trouble with the effect of combining drugs
P15 Trouble when stopping a drug (addiction?)

Fear of ....

P21 Fear of the action of a drug
P22 Fear of the combination food/liquor and a drug
P23 Fear of the effect of combining drugs
P24 Fear of side-effects
P25 Fear of stopping a drug
P26 Fear of other people's reactions on taking a drug

Dissatisfied with ...

P31 Dissatisfied with the information of the doctor
P32 Dissatisfied with the information of the pharmacy
P33 Dissatisfied with the treatment of the condition
P34 Dissatisfied with the action of a drug

Otherwise

P91 Forgets sometimes to take the drug by accident
P92 Problems with the pricing of the drugs
P93 Confused by different advises of different professionals

P100 Others e.g. .....

N.B. Problem according to patient! No interpretation yet. Clarification with patient allowed. Analysing is next step.

ANALYSIS OF THE PATIENTS PROBLEMS/COMPLAINTS AND THEIR CODES

Choice of treatment

A1 Drug prescribed but seems not to be indicated
A2 No prescribed drug, but indication seems to exist
A3 Poor or wrong combination of drugs
A4 Other drug is drug of choice for indication

Patient

A11 (Diffuse) fear of drugs
A12 Limited knowledge of drugs effects and/or side effects
A13 Limited knowledge of his/her drug-use
A14 Limited knowledge of prices/costs
A15 Not satisfied with current treatment
A16 Patient uses more of the drug then prescribed or meant/recommended
A17 Patient uses less of the drug then prescribed or meant/recommended
A18 Patient deliberately does not use or take the prescribed drug

Use

A21 Wrong technique in using/applying the drug
A22 Wrong time of taking the drug
A23 Correct drug but wrong form of administration or generic equivalent
A24 Other forms of poor drug-use

Pharmacotherapeutic

A31 Occurrence of interactions
A32 Occurrence of side-effects/ADRs
A33 Insufficient effect of the drug

Communication

A41 Change in appearance of the drug not mentioned
A42 Text of the package-insert too difficult
A43 Too much information on package-insert
A44 Apparent contradictory information on package-insert
A45 Patient insufficient/wrongly informed by the doctor
A46 Patient insufficient/wrongly informed by the pharmacy
A47 Good information misunderstood
A48 Fear of troubling doctor with questions

Miscellaneous

A91 Error on the label (dosage, drug-name)
A92 Error in doctors prescription
A93 Wrong drug dispensed

A100 Others, e.g.: .....

Perform analysis when the problem/complaint is clear.
Analysis = professional interpretation of the problem.

SOLUTIONS TO THE PROBLEMS/COMPLAINTS OF PATIENTS AND THEIR CODES

Directly with patient

S1 Information provided
S2 Motivated patient
S3 Patient shown how to use the drug
S4 Offered apologies to patient for pharmacy's error
S5 Reassured or offered support to patient
S6 Made patient stop medication involved
S7 Changed form of administration

Referral

S11 Referred patient to GP
S12 Referred patient to specialist
S13 Referred patient to self-help group/consumer-organisation
S14 Referred patient to district nurse

Contacted other professional

S21 Got in touch with GP
S22 Got in touch with specialist
S23 Got in touch with district nurse
S24 Got in touch with colleague (another pharmacist)
S25 Got in touch with university

Information

S31 Information on action of drug
S32 Information on side-effects of drugs
S33 Information on drug-drug interaction
S34 Information on drug-disease interaction
S35 Information on use of medical aids
S36 Information on drug-pricing
S37 Other information given

Otherwise

S91 Presented conflict with GP/specialist to the patient
S92 Got in touch with family

S100 Otherwise e.g.: .....

N.B. Do not forget to discuss the solution with the patient first!

Appendix

A4 DEFINING THE ROLES OF GPs AND PHARMACISTS FOR PHARMACEUTICAL CARE

This is an overview of the results of an exercise to define the roles of GPs and pharmacists during a GP-Pharmacist discussion in the context of the CARA Check program in 1998 at the 'Anjer Apotheek'. 11 GPs and 3 pharmacists participated.

Subject		GP*	C**	Ph***
Diagnosing asthma or COPD		11		
Choice of medication		11		
Choice of inhaler type		9	2	
Giving extensive inhaler instruction		6	2	3
Inhaler check	After 2 weeks	4	1	3
	After 3 months	4	1	5
	After 1 year	2	1	4
Providing instruction material for inhaler systems			2	9
Searching indicators for possible wrong use of medicines	Suitable inhaler type	1	3	6
	Different inhalator types		3	8
	Use of oral antimycotic agents	3	2	6
	Overuse beta-mimetics in asthma	2	3	6
	Under-use cromoglicate/corticosteroids in asthma	2	2	6
	Overuse beta-mimetics/ipratropium in COPD	2	3	6
	No inhaler therapy with oral beta-mimetic	3	2	6
	No corticosteroid with beta-mimetic in asthma cases	3	2	6
	Use of deptropine for children >1.5	3	1	5
	Use of cromones by children <5	3	2	6
	Use of theophylline in asthma	4	2	4
Improving compliance		9	2	
Use peak-flow meter		11		
Correcting treatment plan		9	2	

* Role of the GP
** Role of GP and pharmacist in co-operation
*** Role of pharmacist

A4 THE RUG/FIP QUESTIONNAIRE

QUESTIONNAIRE INTERNATIONAL PHARMACY PRACTICE
Version 16 September 1997

Questionnaire number: ……

N.B. For pharmaceuticals, medicaments or medicines we use the American term 'Drugs', meaning substances to heal or prevent disease, or to linger symptoms.
If we mention pharmacist or pharmacy, we always mean community pharmacist or community pharmacy, unless otherwise specified.

General Questions

1. What is the actual population of your country (number of inhabitants) ……..

2. How many community pharmacies are there in your country (number) …….

3. Are there other shops or traders selling OTC or prescription drugs to the public in your country? Yes / No

3.1 If yes, what is their financial share in the selling of drugs on national scale?
(Outside a pharmacy) …….%

4. Are there other professionals selling drugs in your country? Yes / No

4.1 If yes, what is their financial share in the selling of drugs on national scale

Doctors	…… %
Nurses	…… %
Veterinarians	…… %
Others	…… %

The Pharmacies

1. What is the average size of a community pharmacy (in square meters)?
(or, in case of large stores, of the dispensing area including waiting facilities) ..... (m^2)

1.1 If there is a large variety, please indicate the percentage of the indicated size:

10-20 m^2	..... %
20-50 m^2	..... %
50-100 m^2	..... %
100-200 m^2	..... %
200-300 m^2	..... %
over 300 m^2	..... %

2. How many pharmacists work on average in one community pharmacy? (number) ……..

3. How many other staff work on average in one community pharmacy under the responsibility of the pharmacist?

Licensed staff (not pharmacists but licensed to prepare and dispense)	……..
Non licensed staff (e.g. shop assistants)	……..

Business matters

1. What is the average annual turnover per community pharmacy in US $ …….

2. What is the proportion of turnover on average per community pharmacy in the following product-groups:

Drugs on prescription	..... %
Drugs without prescription	..... %
Medical aids	..... %
Cosmetics and other beauty related products	..... %
Food	..... %
Dietary supplements (non registered vitamins or minerals)	..... %
Non-food (except for the mentioned items)	..... %
Others:	..... %

Pharmacy Practice

1. Are pharmacists in your country allowed to open a package and only dispense part of the contents?
   - O Always
   - O Sometimes
   - O In exceptional cases
   - O No

2. Do pharmacies/pharmacists prepare (compound) oral drugs in your country? (please tick a box)
   - O All pharmacies
   - O Most pharmacies
   - O Some pharmacies
   - O A few, special pharmacies
   - O No

3. Do pharmacies/pharmacists prepare (compound) sterile drugs in your country? (please tick a box)
   - O All pharmacies
   - O Most pharmacies
   - O Some pharmacies
   - O A few, special pharmacies
   - O No

4. Do pharmacies/pharmacists in your country perform urine tests (pregnancy, glucose)? (please tick a box)
   - O All pharmacies
   - O Most pharmacies
   - O Some Pharmacies
   - O A few, special pharmacies
   - O No

5. Do pharmacies/pharmacists in your country perform blood pressure tests? (please tick a box)
   - O All pharmacies
   - O Most pharmacies
   - O Some pharmacies
   - O A few, special pharmacies
   - O No

6. Do pharmacies/pharmacists in your country perform cholesterol tests? (please tick a box)
   - O All pharmacies
   - O Most pharmacies
   - O Some pharmacies
   - O A few, special pharmacies
   - O No

7. Do pharmacies/pharmacists in your country perform blood glucose tests? (please tick a box)
O All pharmacies
O Most pharmacies
O Some pharmacies
O A few, special pharmacies
O No

8. Do pharmacies/pharmacists in your country perform general invasive tests (like blood tests)? (please tick a box)
O All pharmacies
O Most pharmacies
O Some pharmacies
O A few, special pharmacies
O No

9. Is the presence of a pharmacist on the premises obligatory in your country, to be able to dispense drugs? Yes / No

10. What approximate proportion of the population in general visits usually the same pharmacy (provided they do not move)? …….. %

Dispensing in the community pharmacy

1. Are all drugs dispensed on prescription labelled with at least the name of the patient and the dosage? Yes / No

2. Are all drugs dispensed on prescription dispensed with a drug information leaflet? Yes / No

3. Do pharmacies keep computerised, patient medication records? (please tick one box)
O All pharmacies
O Most pharmacies
O Some pharmacies
O A few, special pharmacies
O No

3.1 If yes, do these records also contain information on non-prescription drugs? (please tick one box)
O Always
O Most cases
O Some cases
O No

4. Do pharmacies routinely perform computerised interaction checks on Adverse Drug Reactions (drug-drug interactions, drug-disease interactions, contra-indications)?
O All pharmacies
O Most pharmacies
O Some pharmacies
O A few, special pharmacies
O No

5. How many prescription items per day are dispensed per average pharmacy (number) ……

6. How many people a day are being helped (prescription, advice and/or OTC) on average by one community pharmacy? (number) ……..

Over The Counter (OTC) in community pharmacies

1. Is it possible in your country to buy OTC (Over The Counter drugs, without prescription) in other places than community pharmacies? Yes / No

1.1. If yes, tick a box of the kind of places, indicate roughly what financial proportion in money and if they need a special licence.

Place	Proportion	Special Licence
O Hospital pharmacies	.....%	yes / no
O Drug store	.....%	yes / no
O Gas station	.....%	yes / no
O Supermarkets	.....%	yes / no
O Bars/Restaurants	.....%	yes / no
O Other places	.....%	yes / no

2. Is it possible in your country to obtain a prescription only-drug without prescription *in* a pharmacy (please answer this question in practical sense)? Yes / No

2.1 If yes, please indicate how easy that would be
O Very easy
O Easy
O Not easy
O Exceptional

3. Is it possible in your country to obtain a prescription only-drug without prescription *outside* a pharmacy? Yes / No

3.1 If yes, please indicate how easy that would be
O Very easy
O Easy
O Not easy
O Exceptional

Pharmacists in community pharmacies

1. How long is the university-educational program for pharmacists in your country *after* the secondary level (highschool, college) in years ..... Years

2. By what age does a pharmacist on average completes his/her university study ..... year

3. Is there a compulsory post-university (post masters) training for a pharmacist to licence as community pharmacist, after the completion of the university study? Yes / No

3.1 1 If yes, how long is this extra education to obtain the licence? ..... years

4. Is there a compulsory post-graduate education for community pharmacists in your country, to be able to keep their licence to practice? Yes / No

5. Is there an optional post-graduate education for community pharmacists in your country? Yes / No

5.1 If yes, please indicate the rough proportion of participating pharmacists following such training
O All pharmacists
O Most pharmacists
O Some pharmacists
O Very few pharmacists
O None

6. Who pays this post graduate education (please tick the appropriate box(es))
O The individual pharmacists
O The pharmacist organisation
O Third parties (industry?)

7. Do community pharmacists in your country in general have regular consultation meetings with local general practitioners?

O All pharmacists
O Most pharmacists
O Some pharmacists
O A few, special pharmacists
O No

8. How are the relations between community pharmacists and medical doctors in your country? (please tick one box)

O Very good
O Good
O So so
O Tense
O Very tense

9. Do community pharmacists in your country in general have the right to prescribe medication?

Yes / No

Are there any other items, specific and relevant for pharmacy in your country, which we did not mention in this questionnaire? If yes, Please note below.

If possible could you give us your national definition or description of what you consider Pharmaceutical Care to be (in English of course).

Appendix

A5 SELECTION OF ONGOING PHARMACEUTICAL CARE RESEARCH AND IMPLEMENTATION PROJECTS

A5.1 UNITED STATES

The nation-wide American Pharmaceutical Association has created the AphA foundation, which strongly co-operates with the pharmaceutical industry and helps the profession to re-engineer itself for the future by advancing the proliferation of pharmaceutical care integration and research into the practice setting. Advanced skills training is provided by the Advance Practice Instiute, which is hosted by different univerities each year. The foundation projects are called ImPACT (Improve Persistence and Compliance with Therapy). The hyperlipedimia project includes 32 pharmacy practice sites and is conducted in co-operation with Merck & Co. Results recently have been described in an series of posters at the 1998 AphA conference.
Also in co-operation with Merck & Co, the AphA instituted practice research chapters at different Schools of Pharmacy throughout the USA. These chapters sometimes address pharmaceutical care issues, but especially in the field of student education.
In general comprehensive pharmaceutical care is rarely provided through community pharmacies, nevertheless pharmaceutical care is often provided through specialised clinics.

10.4.1 A5.1.1 California

The AphA-Merck chapters at the Pacific School of Pharmacy in Stockton is currently carrying out an implementation and value analysis of pharmaceutical care in a high volume prescription practice setting. Initially designed for a more comprehensive approach, the project now concentrates on program development for diabetes, hypertension, asthma, smoking cessation and general drug use review[1].

10.4.2 A5.1.2 Florida

In the birthplace of Pharmaceutical Care it is not surprising that the University of Florida is very active. Therapeutic outcome monitoring (TOM) programs have been developed for asthma, diabetes, angina, hypertension and hyperlipidaemia[2]. These programs, however, seem to be being exported to other countries rather than being used in the state itself. A TOM-asthma study has been completed and the mixed results have been published. Currently the key pharmaceutical care researcher, Prof. Hepler, is involved in the assessment of preventable drug related morbidity, and the (economic) impact of DRPs through focus groups[*]. At the same institute, Segal is concentrating on behavioural aspects of the implementation of pharmaceutical care.
One older published study by Kimberlin et al. described a project in the elderly dealing with the effects of an education program for community pharmacists on detecting drug-related problems in elderly patients. During the project patients were also telephoned for an interview, but no differences in patients' knowledge of medication, medication use or the odds of having various potential problems with drugs could be found [3]. The documentation system used in this study is described in another article[4].
Through the Internet, details of a practice project were obtained. In 1997 an office based, non dispensing pharmaceutical care practice was set up in Seminole Fl. with a grant from the American Pharmaceutical Association. Customers are billed for the services. No results from this project are available yet. The project (or firm) is called 'Pharmaceutical Care of Florida Inc.'[5].
According to some messages on the Internet, there now exists a possibility for pharmacists in Florida to prescribe a limited number of drugs from a formulary, but only in a pharmacy where the drug is dispensed[6]. A prescribing pharmacist certainly could provide comprehensive pharmaceutical care if additional follow up is provided.

10.4.3 A5.1.3 Iowa

The Iowa Centre for Pharmaceutical Care has instructed 100 Iowa pharmacies to date and over 200 pharmacists and 100 technicians on the principles of pharmaceutical care practice and the required skills[7]. The program is based upon the Minnesota model and therapeutic outcome monitoring and has been described[8]. There is a

[*] Personal information Dr. C.D. Hepler, Dubow Centre for Pharmaceutical Care, Gainesvill, Florida, USA

supportive process of visiting and peer counselling for pharmacists in the implementation phase. To date results from the pharmaceutical care practice in those pharmacies are not known.

10.4.4 A5.1.4 Maryland

The University of Maryland is preparing a community based research study into the effects of an intervention in diabetes patients, to prevent the development of nephropathy by screening patients for microalbuminurea and stimulating the use of ACE-inhibitors[9]. Another research project at the same university aims at enhancing and studying patient compliance with hormone replacement therapy[10].

10.4.5 A5.1.5 Michigan

The Department of Pharmacy of the Wayne State University has carried out research into the effects of pharmaceutical care in diabetes and hypertension, on the basis of a model, which seems slightly like Therapeutic Outcome Monitoring. Although the diabetes study had a very high rate of patients drop-out (because of lack of interest), the method and the results are interesting[11]. The final glycated hemoglobin and fasting plasma glucose concentrations in the intervention group were significantly changed, indicating a better degree of glycemic control. No change in Quality of Life was demonstrated, using a derived SF-36 measure, the Health Status Questionnaire.

In the hypertension study over a period of 5 months, a significant decrease in mean blood pressure were noted from baseline to final assessment[12]. In the reference group no significant change could be found. No change in Quality of Life could be demonstrated.

At the University of Michigan a Pharmaceutical Care Research & Education project is active, but apart from an intake form, no other information could be found.

10.4.6 A5.1.6 Minnesota

A major project that has just been concluded by Strand, Cipolle and Morley, involved the implementation of the comprehensive pharmaceutical care philosophy into practice. The results have not yet been published in a peer reviewed journal , but are currently occasionally being distributed in presentations and can be found in Chapter 6 of the book Pharmaceutical Care Practice[13]. Some results of the project can also be found in an interview conducted by the editor of the Pharmaceutical Journal. The practicalities of the project were described in American Pharmacy[14,15].

Many drug therapy problems have been identified and solved during the two-year research period. There was an average of 0.8 drug problems per patient and 43% of the patients had problems, according to the pharmacists. Remarkable is the fact that the most frequent indications for patients receiving pharmaceutical care were sinusitis, bronchitis, otitis media, hypertension and pain. None of the diseases for which disease oriented models are being developed elsewhere, appear in this list, apart from hypertension. Amazingly the most frequent problem was that patients needed additional medicines (23%) and adverse drug reactions accounted for 21% of the problems. Most of the problems were solved because of the care provided.

10.4.7 A5.1.7 Ohio

The Ohio State University College of Pharmacy has implemented a cholesterol management program in two community pharmacies[16] and has recently started a pharmaceutical care pharmacy attached to a medical clinic in a homeless shelter[17]. The college also supports a certified pharmaceutical care network of 10 independent pharmacies[18].

Another group within the same university has studied the perceptions of patients and pharmacists during pharmaceutical care in hypertension[19].

10.4.8 A5.1.8 Texas

In a study by the University of Texas College of Pharmacy into the effects of pharmaceutical care for asthma patients it was found that in a small group of patients (22 intervention and 22 reference patients) the mean health care payments and utilisation were lower after the provision of pharmaceutical care. However those results did not reach statistical significance. The quality of life improved significantly in the study group. A larger study is planned[20].

Texas is also the state where Stasny developed PharmCare, a commercial organisation, which focussed on structural design. This programme was used in the AphA training program, which is currently undergoing revision.

10.4.9 A5.1.9 Virginia

The Department of Pharmacy and Pharmaceutics of the Virginia Commonwealth University has published the results of a study into the effects of pharmaceutical care in hyperlipidaemia[21]. It was a very small study involving only 2 pharmacies and 25 patients. However, they used some validated instruments and could conclude that the care provided improved the lipid values, the quality of life (2 domains of the SF-36) and the satisfaction of the patients with the services.

Another larger non-academic study in Virginia has been published by Munroe et al[22]. They evaluated the economic effects of the pharmacists' contribution to disease management programs in the field of asthma, diabetes, hypertension and hypercholesterolaemia. The pharmacy based interventions were in fact pharmaceutical care-like, although they were dictated by disease management protocols. The interventions were proven to be cost effective in spite of the fact that the prescription costs in the intervention group were higher than those in the reference group.

10.4.10 A5.1.10 Washington

In Washington the emphasis of the work in pharmaceutical care seems to be on the epidemiological aspects. An asthma study by Sterchasis is ongoing, but publications that study could not be identified.
Recently a number of articles appeared in the Journal of the American Pharmaceutical Association, which indicated that a project in Medicaid patients (CARE) was conducted in the state of Washington. Christensen et al. (the researchers come mainly from North Carolina) researched the implementation of pharmaceutical care, which they call cognitive services. They implemented successfully a system for documentation and payment[23]. The performance of the pharmacists was strongly influenced by payment and e.g. practice setting and volume of prescriptions dispensed[24]. The study showed a potential saving effect of the cognitive services unless the intervention resulted in addition of drug therapy[25].

A5.2 AUSTRALIA AND NEW ZEALAND

10.4.11 A5.2.1 Australia

At the Victoria College of Pharmacy in Parkville a new project, based upon asthma management is still in its infancy. The content of the project reflects the European TOM-asthma studies and a number of quantitative measures are being studied. A cost-benefit analysis is going to be part of this project as well. A pilot was started in the first half of 1998. The project is called 'The use of asthma as a model to evaluate the implementation of pharmaceutical care in the community pharmacy'[26].
In 1997 Gilbert concluded a study into the effects of comprehensive pharmaceutical care at the University of South Australia, where a beneficial effect of the care was proven[27]. Benrimoj at the University of Sydney also is continuously involved in projects to prove the value of pharmaceutical care to society, from a clinical pharmacy perspective[28]. The new commercialised practice model of 'Forward Pharmacy', which has a number of pharmaceutical care aspects like medication review and counselling, also has been initiated by this group[29,30].
A continuous debate on practice models in Australian pharmacy can be found in AusPharmList on the Internet, a mailing list moderated by Mark Dunn †.

10.4.12 A5.2.2 New Zealand

An asthma intervention study is being performed in the Southland Region, to demonstrate the impact of providing comprehensive pharmaceutical care on the health outcomes of asthmatic patients (clinical outcomes and quality of life). There will be 5 pharmacists providing care[31]. Preliminary results were presented in 1999[32].

A5.3 CANADA

10.4.13 A5.3.1 Quebec

In this province certain elements of pharmaceutical care have been implemented in community pharmacy practice for some time now. Because managed care might interfere with the locally provided pharmaceutical care, the Ordre de Pharmaciesns du Québec has issued a position paper. In this position paper the Ordre states that all managed care programs in the province should be endorsed by the Ordre and a number of conditions for approval are formulated[33].
Canada, especially the Quebec region, has been one of the first to pay for the extra pharmaceutical care activities by pharmacists in the field of concurrent drug use evaluation. These payments are result based. A fee of $ 15.45 CND rewards the documented delivery of a 'opinion pharmaceutique'. The possible components of this 'opinion' are stated in the table A5-1.
Even if, through any documented pharmacist intervention (see tableA5- 2 for a list of combined codes for recommendation and reason) a certain drug is not delivered, the pharmacist gets a financial compensation for the invested time i.e.$ 7,00 CND.
The Quebec system ensures the documentation of some medication-surveillance activities, which since 1997 also are being demanded by law. Additional payments are being made when the pharmacist reports his findings to the prescribers. All special fees are paid from a fund, which has been created, with 1% of the total of normal pharmacist fees in 1992. This fund has not yet been exhausted. In spite of the payment only 70% of the Quebec

† More information and back-issues on the World Wide Web: http://www.tassie.net.au/~mdunn

pharmacy teams have charged the fund for these special fees, which means that apparently 30% of the pharmacies do not yet perform medication surveillance or at least do not bother to document their interventions and seek payment. The number of claims per pharmacy is still very low[34].

Table A5-1 Codes list of reasons for refusalto dispense in Quebec

999383	Prior intolerance
999407	Falsified prescription
999415	Prior allergy
999423	Prior failure or non response to treatment
999431	Significant interaction
999458	Irrational choice of product
999466	Dangerously high dosage
999474	Sub-therapeutic dosage
999482	Irrational duration of treatment
999490	Product not working for indication
999504	Irrational quantity
999512	Overuse
999520	Therapeutic duplication

Table A5-2 Code list 'Opinion pharmaceutique' Quebec

999539	Interruption of a drug. Re: allergy
999547	Interruption of a drug. Re: Side effect
999555	Interruption of a drug. Re: Interaction
999563	Interruption of a drug. Re: Pregnancy or breast feeding
999571	Modifying dosage. Re: Side effect
999385	Modifying dosage. Re: Efficacy
999598	Therapeutic substitution. Re: Side effect or intolerance
999601	Therapeutic substitution. Re: Interaction
999695	Therapeutic substitution. Re: Efficacy
999628	Therapeutic substitution. Re: Pregnancy or breast feeding
999636	Adding required complimentary medication
999644	Reporting non-compliance. Overuse > 20%
999652	Reporting non-compliance. Underuse >20%

The system, which now also has been introduced in British Columbia, appears to be the only structured approach to remuneration of pharmaceutical care activities on an individual pharmacy-level, apart from the payment provided in Australia and New Zealand for performing drug use evaluations.

10.4.14 A5.3.2 Ontario

The Faculty of Pharmacy of the University of Toronto also is active in the field of pharmaceutical care. They started with analysing the practice functions necessary for the delivery of pharmaceutical care[35]. They then developed an education and practice model based upon the philosophy of pharmaceutical care. Six hospital pharmacists and one community pharmacist developed a tool for teaching and providing pharmaceutical care, called the 'Pharmacist's Management of Drug-Related Problems', which has been published[36].

10.4.15 A5.3.3 Alberta

The University of Alberta runs a practice research project based upon a systematic approach in identifying drug related problems. Retaining actual patient information and documentation is part of the project[37]. The principal researchers, Karen Farris and Rosemin Kassam are leading a research project on the effects of Pharmaceutical Care, which is somewhat similar to the Dutch OMA-project (See chapter 4), but on a more general level with a lesser defined patient group. The objectives are:

- to implement a model of pharmaceutical care to elderly patients in community based pharmacy
- to monitor the behaviour of all participants
- to compare health related quality of life and satisfaction with pharmacy services in an intervention and reference group
- to compare health utilisation and costs including prescription medications, physician office visits and hospitalisation
- monitor the behaviour of all participants including patients, pharmacists and prescribers

The actual project, called the Pharmaceutical Care Research and Education Project (PREP) took shape around August 1996 and is funded by professional organisations as well as the pharmaceutical industry. The participating intervention pharmacists in 5 participating pharmacies have adapted their sites to the requirements and have received training[38]. Five other pharmacies have been assigned to be control pharmacies. Patients were recruited in the fall of 1997[39].
Some results of the pilot study are now available. The number of medicines utilised by the treatment group was significantly lowered from 6.9±2.6 to 5.3±2.0 (p=0.02). Changes in most other parameters had a trend in favour of pharmaceutical care, but were neither statistically nor clinically significant in the pilot[40]. The same study group have also developed and validated an instrument to assess patient satisfaction with pharmacists providing pharmaceutical care[41] and is soon to publish information and results on the training program for the pharmacist.

10.4.16 A5.3.4 Nova Scotia

In May 1997 a project to address seven of the most common barriers for pharmaceutical care was completed in Halifax, Nova Scotia[42]. The project was carried out in one pharmacy only and included the role of technicians, the development of outcomes management tools and an appointment-based care program was implemented in 50 patients. Results from this project have been described[43,44]. The title of the project was 'Dalhousie's pharmaceutical care project'. Some work has also been done on assessing and documenting pharmacotherapeutic outcomes[45] and on describing patient-specific drug related problems[46].

A5.4 SOUTH AMERICA

To get information about pharmacy in general on this continent is difficult. It is even harder to discover the possible developments in pharmaceutical care research or implementation. During the FIP congress 1999 in Barcelona a short presentation was given on a pilot implementation project by the University of Buenos Aires, in the province of Buenos Aires, Argentina[47]. The need for an external consultant during the implementation process in community pharmacy was expressed.
In Chile there seems to be some interest in the concept of pharmaceutical care according to the Spanish Fundación Pharmaceutical Care España.

A5.5 ASIA

10.4.17 A5.5.1 Japan

The Japanese Ministry of Health and Welfare has established a payment structure for all Japanese health care providers, including pharmacists, that is based upon a point system. Table A6-3 sums up the possible services that are paid for, and the points earned. Each point yields approximately US $ 0.10 (= 0.10 Yen).

Table A6-3 Points for PhC services in Japan

Service	Points
Obtaining drug histories and counselling	21 per prescription
Suppl. Medication counselling + written info	5 or 20 per prescription [1)]
Detection of drug interactions resulting in changed prescription	25
Detection of drug duplications resulting in changed prescription	25
PhC services at home, prescribed by physician	550/month/patient (2 visits/months)
Preparing sterile home care IV-products	30
Clinical pharmacy fee	600/months/patient
Hospital pharmacokinetic fee	650-3350/month/drug [2)]

1) Fee depends on prescription duration
2) Fee depends on drug type and clinical setting

Apart from these fees, which certainly will stimulate Japanese pharmacists to enter into the field of pharmaceutical care, a project is underway to evaluate an integrated circuit card ('smart card') containing disease and medication histories. Because physicians dispense most medications in Japan, the involvement of pharmacists with IC cards has so far been limited, but pharmacy specific software is now under development[48].

A5.6 EUROPE

10.4.18 A5.6.1 Denmark

Although the structure of Danish pharmacy (large, well equipped pharmacies, highly developed social pharmacy) is ideal for the provision of pharmaceutical care, the strict privacy laws of that country prevent pharmacists from keeping medication data in their pharmacies without individual informed consent from each patient. Computerised drug use evaluation has not yet been implemented and this strongly hinders the national development of pharmaceutical care as well as the fact that the pharmacy owners await the development of a payment structure for additional services. Additionally the attention of the Danish pharmacists for the time being is focussed on Good Pharmacy Practice and quality-management. In hospital there is a low level of the development of the clinical role of pharmacy but that is improving.

However, in co-operation between the Danish College of Pharmacy Practice, the Danish Pharmaceutical Association and the University of Florida, a Therapeutic Outcome Monitoring project for asthma patients was initiated in 1993. The results have not yet been fully published, but can partially be studied in the proceedings of the section for community pharmacists of the 1996 FIP conference[49]. All participants in the study, patients, doctors and pharmacists, perceived the Danish TOM program as being effective in changing medication use and in improving clinical and psychosocial outcomes.

Apart from the Biomed elderly study, other Danish projects are currently a TOM diabetes project, a project in the field of angina pectoris, and a model development for pharmaceutical care at the counter.

The driving force behind pharmaceutical care (research and continuing education) in Denmark seems to be the Research and Development Division at the Pharmakon, The Danish College of Pharmacy Practice in Hillerød. This department also provides the co-ordinator for the PCNE Asthma collaboration, and furthermore has programs on outcome assessment and counselling.

10.4.19 A5.6.2 Finland

When the European TOM-asthma project was propelled in 1995, Finland was an enthusiastic partner in the PCNE co-operation. However, a large-scale study was stopped when asthma counselling became obligatory for all Finnish pharmacies in 1997. Nevertheless, the first results of the small asthma-TOM project in Finland (only 28 patients) have recently been published as a poster. The clearest change was in the severity of the asthma symptoms[50]. Other results are pending.

10.4.20 A5.6.3 France

In France the concept of pharmaceutical care is not yet fully known to the community pharmacists[51]. In spite of this barrier the 'Ordre National des Pharmaciens' is trying to establish implementation projects for pharmaceutical care in the French community pharmacies. Currently (1998-1999) some standards exist and are being piloted for the 'suivi pharmaceutique' in asthma. This implementation project is partially based upon the different TOM-asthma projects in Europe[52,53]. Implementation of projects in French pharmacy is difficult, because there is an unwritten understanding that a pharmacy should not distinguish itself from its colleagues. The basis for the implementation of future pharmaceutical care is currently being laid through the development of a system of 'opinion pharmaceutique', which basically is the implementation of a system to document potential drug related problems and their solutions in community and hospital pharmacy.

10.4.21 A5.6.4 Germany

The German pharmacists until recently have concentrated their attention on the logistics of their pharmacies and over the counter sales. The education of pharmacists is still rather traditional and usually does not include pharmacotherapy or social pharmacy (except for Berlin, Greifswald and Halle). Only in 1989 pharmacology became part of the curriculum and recently clinical pharmacy. However, in the former East Germany these topics were well developed within the educational system. In Berlin and soon in Marburg pharmaceutical care is introduced for students into the last semester at the universities.

In 1994 the German Pharmacist Association (ABDA) introduced the concept of pharmaceutical care (or 'Pharmazeutische Betreuung) in Germany at a symposium in Frankfurt, where Hepler was also present[54]. At the same time Schaefer described the new paradigm in the pharmacist journal[55]. Schaefer also described the German status of pharmaceutical care in 1996 and indicated that in Germany there was, and still is, some scepticism with the concept in practice[56]. The relationships with medical practitioners have only just been receiving some attention, but overall it seems that in Germany is quite fast developing in the direction of pharmaceutical care practice. Currently there are two major co-operating research centres for pharmaceutical care in Germany and some activity has also started on a local scale.

One centre is the Department of Pharmacoepidemiology and Social Pharmacy of the Humbolt University in Berlin. They are performing one study into pharmaceutical care in the elderly in close co-operation with the PCNE. A similar study in Berlin has been concluded[57], and results will be available in November 1999 in the dissertation of Winterstein. The co-operation with the Netherlands has resulted in the publication of an article on the comparison of the role of education and pharmacy practice in pharmaceutical care between the two

countries[58]. In 1999 in Berlin the centre also started recruiting pharmacists and physicians for a joint effort to decrease elevated blood pressure. The other centre is the information and documentation centre of the ABDA. They have been is co-ordinating one study, a TOM asthma study[59]. This study has been concluded in 1999 and publications are under way.
Both centres offer workshops on pharmaceutical care for pharmacists and now also co-operate in further studies like a study into the effects of pharmaceutical care in congestive heart failure (Lipopharm) [60]. This start of this project is delayed while awaiting the approval of the regional association of physicians.
There also have been some developments in the field of pharmacy software. A description of a basis-module by Prof. Schaefer (Berlin) is supported by the (ABDA) and seven software houses have now implemented such modules[61].
Apart from these major studies there is an active group of community pharmacists in Augsburg, which has been applying pharmaceutical care in asthma and COPD, and evaluated its effects. Furthermore there are active groups in Hessen focussing on OTC counselling in dyspepsia[62], one in Brandenburg focussing on pharmaceutical care in hypertension and one in Baden Würtemberg which is focussing on type II diabetes. These last three studies are being carried out under the supervision of the social pharmacy workgroup from the Humboldt University in Berlin[63].
Finally there is some activity at the University of Halle. One project on patient counselling concluded in 1995 and dealt with the practical problems of patients taking drugs. Currently the university is trying to start a working group on Pharmaceutical care and Pharmacoeconomics.
New projects are ongoing in the field of metabolic syndrome (Saarland), detecting drug related problems and pharmaceutical care in rural areas (Bavaria)[64,65], pain (Dresden) and neurodermitis.

10.4.22 A5.6.5 Great Britain

The development of pharmaceutical care in Great Britain suffers from three major characteristics of their health system. The British pharmacies operate under the National Health System (NHS) and this implies that remuneration for dispensing, including the costs of the drugs, has to be in line with the available limited budget. Secondly computerised medication surveillance is not customary, although most community pharmacies hold computerised medication records. Thirdly British pharmacies are relatively small and therefore their pharmacists do not have a large staff and the available time for providing care is limited. On the other hand, because most pharmacies are small, there are good relations between the pharmacists and clients.
The British pharmacists, headed by the Royal Pharmaceutical Society of Great Britain, also have pharmaceutical care as a central theme for future development. In 1992, when the report of the joint working party on the future role of the community pharmaceutical services appeared[66], the concept of pharmaceutical care was limited and more oriented towards providing services than towards providing care. In October 1995 the council of the society published a discussion paper for their members on 'Pharmacy in the new age' with 3 different scenarios for the future of pharmacy in Great Britain[67]. The nation-wide discussion (over 5000 participants) resulted in the consultation paper 'The New Horizon' from which a strategy for the future was derived[68]. This strategy was published as 'Building the Future' in 1997 and contains many elements of pharmaceutical care, including the focus on the patient and counselling[69]. However, there still is little emphasis on the continuity and documentation of care.
The role of the client is being studied separately from the provision of care, as is best illustrated by Morrow et al.[70] (in N. Ireland) or more recently by Tully et al.[71].
To date no literature on pharmaceutical care projects in Great Britain has been found but the country is one of the leaders in pharmacy practice research.

10.4.23 A5.6.6 Ireland

Since 1997 Irish community pharmacies have been obliged to perform a medication review and some form of individual patient care for all patients. This is provided for in a Contract between the Pharmacy and the Health Board, the agent of the Department of Health. The number of contracts is limited on the basis of 'public health need' and entitles pharmacies to supply medicines to all patients whose medicines costs are partly or wholly reimbursed by the State, which is nowadays most patients. This legislation recognises explicitly the role and expertise of the pharmacist in primary care. The contract also initiated a patient-care fee instead of a dispensing fee for the pharmacy for certain medicines that were previously dispensed from a hospital e.g. interferons. Also a provision has been installed for the pharmacist who refuses to dispense a prescribed medicine based upon the professional judgement, and the fee will still being paid.
Apart from the PCNE elderly project, Dr. Henman of Trinity College in Dublin is involved in the Unicare project. This is an implementation project of pharmaceutical care in 32 pharmacies. Attached to the implementation is also a research programme to study the effectiveness of the provided care and the procedures that need to be adopted to implement pharmaceutical care in the Irish healthcare system. The same Unicare project is the driving force behind three smaller programs, one to re-engineer the pharmacy environment, one to implement suitable information systems, and one to promote pharmaceutical care to the patients and others

such as GPs. Especially the last program is interesting because the promotion of pharmaceutical care seems to be a forgotten topic in many countries. The long term aim of the project is to change the basis of community pharmacy practice in Ireland[‡].

10.4.24 A5.6.7 The Netherlands

Research projects

From 1992 onwards a number of studies has started into pharmaceutical care in community pharmacy practice. Smaller projects, both at the University of Groningen and the University of Utrecht deal with elements of pharmaceutical care in community pharmacy practice.

- Barriers for Pharmaceutical Care

Co-operation of the Department of Social Pharmacy and Pharmacoepidemiology of the Groningen University with the Pharmaceutical Care Network Europe (PCNE Foundation) has led to a study into the barriers for the provision of pharmaceutical care in a European context of which the report can be found in this dissertation (Chapter 8).

- Effects of the pharmaceutical care in asthma and the elderly (TOM and OMA)

From 1995 to 1997 two studies into the effects of intensive pharmaceutical care have been performed in the elderly and asthma patients, named OMA and TOM respectively. Both projects are conducted with international co-operation under the auspices of PCNE and the co-operation for the elderly project is funded by Biomed. The studies are both co-ordinated at the Department of Social Pharmacy and Pharmacoepidemiology of the Groningen University and the results of are presented in this dissertation.

- Protocols and diabetes care

At the same department a research project into the structure and effect of pharmaceutical care in diabetes is being performed. This study concentrates on drawing up and implementing protocols for providing care, to help the pharmacist and to stimulate the co-operation between pharmacists, GPs and specialists.

- Effects of pharmacists on inhaler medication in asthma

A group of pharmacists started a project in 1998 under the supervision of the University of Maastricht. During the project a number of asthma patients will receive pharmaceutical care, whereas the reference patients will not receive special care. The project should result in a cost-benefit analysis of the provided care[72].

- Master-classes of the Stevenshof Institute for Research (SIR)

The Stevenshof Institute in Leiden, which is related to the University of Utrecht, organises yearly master-classes in pharmacy practice research for community pharmacists. Many of the research projects in this institute deal with the development and implementation of pharmaceutical care. Examples from 1996-1997 are cardiovascular diseases, asthma/COPD, rheumatic diseases and postmenopausal hormone substitution[73,74].

Protocol development on a national scale

Apart from the development of protocols within research projects and courses, national organisations also became active, especially since 1995.

The Health Base Foundation, a subsidiary of the software company Pharmapartners, was one of the first organisations to start developing care protocols which could also be implemented in community pharmacies. However, their FPZ protocols are incorporated in a care-concept ('Zorgconcept') that leans strongly on good co-operation with the GP, because Pharmapartners also develops software for the medical profession.

The WINAp (a division of the KNMP) and the Health Base Foundation now co-operate to develop protocols and care standards for community pharmacists, based upon the Dutch quality standards for pharmacy (NAN = Dutch Good Pharmacy Practice Standards). The protocols and care standards, which have already been developed by the KNMP/WINAp, served as a cornerstone for pharmaceutical care weeks in all Dutch pharmacies. During three consecutive years these weeks have been organised with different topics; in spring 1996 about the elderly, in 1997 about childhood diseases and in 1998 about hypertension. During the hypertension week, the newest WINAp FPZ standard was used[75]. The standard on cancer will be used in 1999. WINAp also contributes to two implementation projects called Cara-check (in asthma) and Diabetes-Check.

10.4.25 A5.6.8 Northern Ireland

The strategy for community pharmacy of the Pharmaceutical Society of Northern Ireland does acknowledge pharmaceutical care as a primary objective of pharmacy in the future[76]. Bell at al. studied the extend to which pharmacists in N. Ireland provided pharmaceutical care. From this study it appeared that community pharmacists scored well on patient record screening (an activity for which they are paid) but less well on direct patient related activities[77]. In another publication the qualitative investigations of the attitudes and opinion of community pharmacists to pharmaceutical care has been described[78].

[‡] Personal information from Dr. M. Henman, Trinity College, Dublin, Ireland

Although not much has been published apart from an asthma project conducted in the early nineties[79],[80], the School of Pharmacy of Queens University in Belfast is also carrying out a number of projects. They are the co-ordinating centre for the European PCNE project in the elderly, have carried out a TOM-asthma study in Malta and have piloted studies in angina pectoris, the eradication of Helicobacter Pylori, and smoking secession. Work is ongoing on OTC drug misuse and on the provision of domiciliary pharmaceutical care to elderly patients. The results of most studies appear in PhD thesises or are presented at the British Pharmaceutical Conferences. Especially the thesises are difficult to access for outsiders.
Additionally the Queens School of Pharmacy is involved in some pharmaceutical care research on Malta.

10.4.26 A5.6.9 Norway

Like in other Scandinavian countries, Norwegian pharmacy practice resembles the Dutch structure. However, since automation of pharmacies has not yet come to the point where medication surveillance is an automatic part of drug-delivery, the opportunity for the implementation of comprehensive pharmaceutical care fully is still somewhat limited.
Currently there are only two pharmaceutical care projects. The Norwegian Association of Proprietor Pharmacists has conducted a pilot TOM-asthma study that was concluded in August 1998 and reported in the spring of 1999. The collection of data from the main study will finish during the autumn 1999.
The Nordstjernen pharmacy in Bergen started an individual drug-counselling service also in 1997. This service concentrates on detecting and correcting drug-related problems and on providing information to the patient, especially in the elderly. An interesting aspect of this project is that the local patient organisations have accepted that the pharmacy will charge the patients for this service (about the same amount as for a doctor' consultation)[§].

10.4.27 A5.6.10 Spain

Although the interest for pharmaceutical care in Spain, which is called 'Atencion Farmacéutica', is increasing, there is also increasing pressure on pharmacy of managed care plans, diminishing reimbursement, pressure on deregulation of pharmacy law and pressure of consumer organisations[81]. Efforts to implement pharmaceutical care have met with a number of barriers from pharmacists, doctors, patients and the healthcare system[82].
In co-operation with Hepler the TOMCOR program started in 105 pharmacies in different cities in Spain by the end of 1997. The project comprises pharmaceutical care for patients with coronary heart disease. The project is organised by REAP, a Spanish primary care network. Because of a lack of social pharmacy education sites, academic support is obtained from the Department of Preventive Medicine at the Medical School of Oviedo[83,81]. Results are not available yet, but the researchers had to deal with a 25% drop-out initially due to co-operation problems with pharmacists and physicians[82].
Another 'Atencion Farmacéutica' project is being co-ordinated by the Pharmaceutical College in Valencia. The aim of that project is to give information to the patients and help them control the interaction with their pharmaceutical treatment, if necessary in co-operation with their doctor. From the data available it is unclear whether the activities in this project could be called pharmaceutical care. The core fields seem to be atherosclerosis and the distribution of medicaments in minor diseases[84].
During the FIP conference in 1999 the results of a pharmaceutical care project in hypertension was presented, conducted by 7 pharmacists in Sevilla, under supervision of the Univerity of Granada and the local college of pharmacy[85]. The methodology of another hypertension project in the Barcelona region was presented as a poster[86]. Another project dealt with inflammatory bowel diseases[87]. These Spanish projects seem to concentrate on identifying and solving drug related problems according to the methodology of Strand[13], but for the time being not on final outcomes.
A pharmaceutical care project on migraine is soon to be started in several provinces. But because projects have not been published in accessible literature, it is difficult to get better descriptions of the research and implementation projects in Spain.

10.4.28 A5.6.11 Sweden

Sweden is the country where the concept of Good Pharmacy Practice (GPP) has originated, and taken up much time and energy of the professional organisation. Currently the only identifiable project in the field of pharmaceutical care is the Swedish OMA project, part of the PCNE Biomed study.

[§] Personal information from participating pharmacists, Norstjernen Pharmacy, Bergen, Norway

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A6 QUESTIONNAIRES USED IN THE TOM (AND OMA) PROJECT

This appendix gives an overview or the questionnaires used in the TOM. The sets or questionnaires for the OMA project was similar. Minor differences can be found for questions about asthma, which were replaced by questions about e.g. benzodiazepine use in the OMA project or omitted. If appropriate, reference patients did not receive all questions. For them, questions specifically about pharmaceutical care were omitted.
These translations into English have **not** been validated, and cannot be used as such. The lay out has also been changed to fit the format of the thesis.

A6.1 Final patient questionnaire TOM project

This questionnaire has been used for the final evaluation of the TOM project, and was sent directly to the intervention patients. Reference patients also received a similar questionnaire. Questions not posed to the reference patients are marked with an asterix (*).

Patient no: .....

SATISFACTION-QUESTIONNAIRE PATIENTS TOM PROJECT (INTERVENTION)

0. What date are you completing this questionnaire? …..-……-……..

1. How often do you get the pharmacy to collect your medicines or do you receive your medicines from the pharmacy? ..... times per months or ..... times per year

2. Do you always get information leaflets with your medicines? (Please tick one answer)
O No, never
O Usually not
O Occasionally
O Usually
O Always

3. If yes, do you understand these leaflets (Please tick one answer)
O No, never
O Usually not
O Occasionally
O Usually
O Always

4. Do you sometimes have one of the following problems with your medicines? (Please tick one answer per topic)

- Swallowing medicines	**O Yes O No**
- Opening containers etc..	**O Yes O No**
- Using strips	**O Yes O No**
- Dirty taste of medicines	**O Yes O No**
- Forgetting to use medicines	**O Yes O No**
- Reading labels on containers	**O Yes O No**
- Reading information leaflets	**O Yes O No**
- Occurrence of side-effects	**O Yes O No**

5. Have you been admitted to hospital since1 January 1995 (Please tick one answer)
O Yes
O No (go to Question 6)

5.1 If yes, how often? ..... times

5.2 How often have you been admitted because of your asthma? ..... times

6. Did you have a personal contact with your GP during the last 6 months? (Please tick one answer)
O Yes
O No

6.1 If yes, how often? ..... times

7. Has the GP or specialist diagnosed any new diseases in your case during the passed year
O Yes
O No

7.1 If yes, what disease(s)? .....
.....
.....

The next questions deal with the pharmacist of the pharmacy where you normally get your medicines.

8. Do you personally know the pharmacist of your pharmacy? (Please tick one answer)
O Yes
O No
O Don't know

9. According to your experience, does your pharmacist have contact with your GP? (Please tick one answer)
O Yes
O No
O Don't know

10. Do you think the pharmacist is an expert in the field of medicines? (Please tick one answer)
O Not at all
O Somewhat
O Reasonably expert
O Expert
O Very expert
O Don't know

11. Did you talk with the pharmacist personally during the last year (Please tick one answer)
O Yes
O No (go to question 19)

11.1 If yes, how often? ..... times

11.2 How long did those talk last on average? ..... minutes

12. Where did you speak with the pharmacist? (Please tick one answer)
O In the pharmacy
O At home
O Both at home and in the pharmacy
O By phone
O Other: .....

13. How often during the last year have you initiated the contact with the pharmacists, to discuss problems with your medicines? (by phone or in the pharmacy) ..... times

14. What did you talk about with your pharmacist? (please tick one box per topic)

	Always	Usually	Some times	No
- The action of your medicines	O	O	O	O
- The side effects of your medicines	O	O	O	O
- The correct use of your medicines	O	O	O	O
- The use of over the counter medication	O	O	O	O
- The pharmacy	O	O	O	O
- Home delivery of medicines	O	O	O	O
- Your diseases and complaints	O	O	O	O

- You lifestyle habits (smoking, drinking, exercise)	O	O	O	O
- Your hobby's	O	O	O	O
- Your home situation	O	O	O	O
- Your relationships with physicians	O	O	O	O
- Health and disease in general	O	O	O	O
- Other topics, e.g.	O	O	O	O

15.* What did you think about those consultations in general (please tick one box per topic)

	Yes	Sometimes	No
- Clarifying	O	O	O
- Pleasant	O	O	O
- Useful	O	O	O
- Professional	O	O	O
- Too short	O	O	O
- Personal	O	O	O
- Friendly	O	O	O
- Too long	O	O	O
- Annoying	O	O	O
- Meaningful	O	O	O
- Unstructured	O	O	O
- Informative	O	O	O

16. Did your medicine use change as a result of your **contact with the pharmacist** during the last year?
(Please tick one box)

O Yes
O No (go to question 17)
O I don't know
(go to question 17)

16.1 If yes, what has changed? (Please tick one box per item)

- The number of medicines to be used (more or less)	O Yes	O No
- The time of use	O Yes	O No
- The frequency of use per day	O Yes	O No
- The way of use	O Yes	O No
- The use of OTC medication	O Yes	O No
- Something else, e.g.		

17. Did your pharmacist during **the last 12 months** de discuss the directions for use, effect and/or side effects of your medicines with you?
(Please tick one answer)

O Yes
O No
O Don't know

You may skip question 18, if you have not spoken with the pharmacist during the last 12 months

18. How incorrect or correct do you find following statements? Please indicate per statement by ticking the appropriate box.

	Absolutely correct	Mainly correct	I don't know	Mainly incorrect	absolutely not correct
a. My pharmacist is interested in my wellbeing					
b. When I speak with the pharmacist, there is enough privacy					
c. When I speak with the pharmacist, there is sufficient time					
d. I am satisfied about the way the pharmacist talked with me about my medicines					

The following questions deal with the assistant-pharmacists in the pharmacy

19. Do you know the pharmacy assistants of your pharmacy? (Please tick one answer)
- O Yes
- O No
- O Some

20. Did an assistant-pharmacist during **the last 12 months** discuss the directions for use, effect and/or side effects of your medicines? (Please tick one answer)
- O Yes
- O No
- O Don't know

21. Do you find the assistant pharmacist an expert in the field of medicines? (Please tick one answer)
- O Not at all
- O Somewhat
- O Reasonably expert
- O Expert
- O Very expert
- O Don't know

You may skip question 22, if you have not spoken with the assistant-pharmacist during the last 12 months

22. How incorrect or correct do you find following statements? Please indicate per statement by ticking the appropriate box.

	Absolutely correct	Mainly correct	I don't know	Mainly incorrect	Absolutely not correct
a. The assistant- pharmacist is interested in my wellbeing					
b. When I speak with the assistant-pharmacist, there is enough privacy					
c. When I speak with the assistant-pharmacist, there is sufficient time					
d. I am satisfied about the way the assistant-pharmacist talked with me about my medicines					

The following questions deal with the GP

23. Did your GP during **the last 12 months** discuss the directions for use, effect and/or side effects of your medicines?
- O Yes
- O No
- O Don't know

(Please tick one answer)

24. Do you find your GP an expert in the field of medicines? (Please tick one answer)
- O Not at all
- O Somewhat
- O Reasonably expert
- O Expert
- O Very expert
- O Don't know

You may skip question 25, if you have not spoken with your GP during the last 12 months

25. How incorrect or correct do you find following statements? Please indicate per statement by ticking the appropriate box.

	Absolutely correct	Mainly correct	I don't know	Mainly incorrect	Absolutely not correct
a. My GP is interested in my wellbeing					
b. When I speak with my GP, there is enough privacy					
c. When I speak with the GP, there is sufficient time					
d. I am satisfied about the way my GP talked with me about my medicines					

The next questions deal with your NEW medicines

26. Have you been prescribed new medicines **during the last 12 months** (Please tick one answer)
O Yes
O **No** (to question 29)

27. Did the physician provide you with information about that new medicine? (Please tick one answer)
O Yes
O No (to question 28)

27.1 What did the physician inform you about? (Please tick one answer per topic)
- How the medicine works O Yes O No
- The side effects of the medicine O Yes O No
- The way the medicine should be used O Yes O No

27.2 Do you appreciate the information given by the physician (Please tick one answer)
O Yes
O No

28. Did your pharmacist provide you with information about that new medicine? (Please tick one answer)
O Yes
O No (to question 29)

28.1 What did the pharmacist inform you about? (Please tick one answer per topic)
- How the medicine works O Yes O No
- The side effects of the medicine O Yes O No
- The way the medicine should be used O Yes O No

28.2 Do you appreciate the information given by the pharmacist? (Please tick one answer)
O Yes
O No

On the label of a medicine it is written when and how often you should take your medicine. Some people sometimes take more or less of the medicine than marked on the label.

29. Do you sometimes use less of a medicine than indicated on the label?
O Yes
O No (go to question 30)

29.1 If yes, please indicate: (Please, one answer per drug)
- What medicine?
- How often it happens?
- Why it happens?

Medicine	**How often?**	**And why?**
1	... times per months	O Forgot to take it O The disease for which I should take it, did not bother me O I dislike the side effects O Other, e.g.:.....
2	... times per months	O Forgot to take it O The disease for which I should take it, did not bother me O I dislike the side effects O Other, e.g.:.....
3	... times per months	O Forgot to take it O The disease for which I should take it, did not bother me O I dislike the side effects O Other, e.g.:.....

30. Do you sometimes use more of a medicine than marked on the label?
O Yes
O No (go to question 31)

30.1 If yes, please indicate:
(Please, one answer per drug)

- What medicine?
- How often it happens?
- Why it happens?

Medicine	How often?	And why?
1	... times per months	O The disease for which I should take it, bothered me much O I thought I had forgotten to take the medicine O Other, e.g.:.....
2	... times per months	O The disease for which I should take it, bothered me much O I thought I had forgotten to take the medicine O Other, e.g.:.....
3	... times per months	O The disease for which I should take it, bothered me much O I thought I had forgotten to take the medicine O Other, e.g.:.....

31. Please indicate to what degree you agree with the following statements.
(Please tick one box per statement)

	Totally agree	Agree	Disagree	Totally disagree
a. I find I can communicate well with my GP.	O	O	O	O
b. As for me, repeating prescriptions can be done directly by the pharmacy	O	O	O	O
c. If I want to know things about my medicines, I first think of the pharmacist	O	O	O	O
d. It is hard to contact the pharmacist if I want to speak to him/her	O	O	O	O
e. It is easier now to contact the pharmacist with questions about my medication	O	O	O	O
f. I think that they have all the information about my medicines in the pharmacy	O	O	O	O
g. The GP keeps close watch on my medicine use	O	O	O	O
h. The pharmacist does not know a thing about my diseases	O	O	O	O
i. The pharmacist knows more about medicines than I used to think	O	O	O	O
j. I think I can communicate well with my pharmacist.	O	O	O	O
k. It is hard to contact the GP if I want to speak to him/her	O	O	O	O
l. It is easier now to contact the pharmacist with questions about my diseases	O	O	O	O
m. I don't care if I speak to the pharmacist or a assistant-pharmacist	O	O	O	O

Now we would like to ask some questions about asthma and self-management.

32.1 Does wheezing or tightness of the chest bother you at least once a week? O Yes O No

32.2 Did you fail to attend school or work during the last year because of your asthma O Yes O No

32.3 Do you wake up at least once a week because of wheezing or tightness of the chest? O Yes O No

33. Do you use a peak-flow meter? (please check one box)

- O Yes, almost daily
- O Yes, only when I am tight on my chest
- O Yes, when the pharmacist asks me
- O Yes, when the GP asks me
- O No
- O Other e.g.……

34. Do you adapt your medicine use on the guidance of your peak-flow? (please check one box)

- O Yes, by myself
- O Yes, after consultation with pharmacist
- O Yes, after consultation with GP
- O Has not (yet) been necessary
- O No

35. Do you know what self-management is in asthma? (please check one box)

- O Yes exactly
- O Yes, approximately
- O No (go to question 39)

35.1 Do you apply self-management in your own case? (please check one box)

- O Yes
- O Sometimes
- O No

36. What is your opinion on asthma-self management? (please check one box)

- O Useful
- O Only useful when my asthma bothers me
- O Not useful

37. What is your opinion on the pharmacists' support of your self management? (please check one box)

- O Fine
- O I prefer support by the GP
- O I do not need support

The following questions deal with the TOM project

38. What do you think now about the personal counselling you received in the TOM project, if you consider the whole project period (please check one box)

- O Positive
- O Negative
- O Neutral

39.1 When was the coaching the most useful to you? (please check one box)

- O The first 6 months
- O After the first 6 months
- O Especially the last 6 months
- O The whole period

40 Was there a part of the TOM project you especially liked? (please check one box)

- O Yes
- O No (go to question 41)

40.1 If yes, what part ……..

41 Was there a part of the TOM project you especially **dis**liked? (please check one box)

- O Yes
- O No (go to question 42)

41.1 If yes, what part …….

42. How could the pharmacy/pharmacist improve the provided care? …….

43. Do you have the impression that you are better now than if you had not received the special care? (please check one box)

- O Much better
- O Better
- O No difference
- O Worse
- O Much worse

The following questionnaires are the SF-36 and the AQLQ. You have both completed them before. If you have any questions, please phone the research team at 050 3633291

A6.2 FINAL PATIENT EVALUATION QUESTIONNAIRE, TOM PROJECT

This questionnaire was sent to the pharmacists, and completed by the pharmacist during the last consultation with the intervention patients in the TOM project. Pharmacists were instructed how to deal with those questionnaires. Text in bold is meant to be said almost literally by the pharmacist.

PATIENT-NUMBER : TI.....
EVALUATION DATE :
PHARMACIST NAME :

Good morning/Good afternoon

'This consultation is meant to once again review your medicine use, and collect data for the TOM project. The consultation will last approximately 30 minutes. After we have answered the questions of the questionnaire, you can ask me other questions if you like. OK?

By the end of the consultation I would like to check the data we have about you in our computer, but first I have a number of questions. '

Health and disease

1-1 **How would you say your health has been during the last 6 months? Above average, average or below average for someone of your age?**

- O Above average
- O Average
- O Below average

1-2 **How often did your phone your GP last year with questions about your health?**

..... times

1-3 **How often did you visit a physician during the last year?**

the GP ..... a months
or ..... a week

specialist..... a months
or ..... a week

1-3a **How often because of your asthma?**

the GP ..... per months
or ..... a week
specialist..... per months
or ..... a week

1-3b **How often for other complaints?**
The GP

Complaint: .... per months or ..... a week
Complaint: .... per months or ..... a week
Complaint: .... per months or ..... a week

The specialist

Complaint: .... per months or ..... a week
Complaint: .... per months or ..... a week
Complaint: .... per months or ..... a week

1-4 **Have you been admitted to hospital during the last year?**
- **O** Yes
- **O** No (go to 1-5)

1-4a **How often with complaints relating to your asthma?** ..... times

How often 4 days or less? ..... times
How often more than 4 days? ..... times

1-4b **How often for other complaints?** (if more than 2, just name the most important)

Complaint: .... times

How often 4 days or less? ..... times
How often more than 4 days? ..... times

Complaint: .... times

How often 4 days or less? ..... times
How often more than 4 days? ..... times

1-5 **Did the GP or specialist discover a new disease during the last 6 months**
- **O** Yes
- **O** No (go to 1-6)

1-5a **If yes, what ailment or disease?**
1.....
2.....
3.....

1-6 **Do you take care of your own medicines**
- **O** Yes
- **O** No

1-7 **Did you receive an influenza vaccination in 1996?**
- **O** Yes
- **O** No

1-7a **Would you like to have an influenza vaccination next year?**
- **O** Yes
- **O** No

<u>Asthma and behaviour</u>

1-8 Do you smoke?
- O Yes
- O No (go to 1-9)

1-8a If yes, how many a day?
..... cigarettes
..... cigars
..... times a pipe

<u>Asthma and asthma status</u>

1-9 Are you bothered by wheezing or tightness of the chest once a week?
- O Yes
- O No

1-9a Did you fail to attend school or work during the last year because of your asthma
- O Yes
- O No

1-9b Do you wake up at least once a week because of? wheezing or tightness of the chest?
- O Yes
- O No

(In case of the following questions, it may happen that the patient does not recognise the terminology, in spite of the fact that you have previously discussed it. Then the answer should be NO, and you can explain after completing this whole form.)

1-10 **Do you know what a peak-flow meter is?**
- O Yes
- O No (go to 1-12)

1-10a **Do you use the peak flow meter?**
- O Yes
- O No (go to 1-12)

1-10b **If yes, how often per months do you use the peak flow meter**
..... per months

1-10c **When do you use the peak flow meter?**
- O Without a clear reason
- O When my asthma bothers me
- O The doctor told me
- O The pharmacist told me
- O Other reason

1-11 **Have you been instructed in self-management of asthma**
- O Yes
- O No (go to 1-12)

1-11a **When do you perform self-management?**
- O Never
- O When my asthma bothers me
- O When the doctor tells me
- O When the pharmacist tells me
- O (Almost) daily

1-12 **In what sequence do you use the blue and brown inhaler, if you use them both?**
- O First blue, brown next
- O First brown, blue next
- O I don't pay attention
- O (N.A)

1-13 **Has your house been sanitised from dust etc.**
- O Yes
- O No (go to 1-14)

1-13a **If yes, who advised you to do that**
- O The pulmonologist
- O The GP
- O The district nurse
- O Other

1-14 **If you know that you are going to visit a place where your asthma might bother you, do you take special precautions?**
- O Yes
- O No (go to 2-1)

1-14a **If yes, What precautions?**
- O Extra inhalation blue
- O Extra inhalation brown
- O A tablet (antihistaminic)
- O Other, e.g.
.....

1-15 **Do you read the information leaflets with you medicines**
- O Yes
- O Almost always
- O Never

1-16 **Do you find reading information leaflets difficult?**
- O Yes
- O No

2. KNOWLEDGE QUESTIONNAIRE

(In this section you check the knowledge of the patient. First put an open question and check the box if appropriate. If you do not get a satisfactory answer, then pose the question in a closed manner, using the mentioned knowledge items.)

'Now I would like to pose some questions about asthma and related diseases. Most people know very little about this, so you should not be ashamed if you don't know the correct answer'

2-1 **What is asthma?**

Item	Spontaneous	After reminding
Shortness of breath		
Wheezing		
Coughing		
Irritation/inflammation of the lung		
Reversible		
Constriction of airways		
Hypertension		
Headache		
Allergy		

2-2 **Do you know what provokes an asthma attack in general?**

Item	Spontaneous	After reminding
Allergic reaction		
Hairs/dust-mites and other allergens		
Sharp sunlight		
Smoke/smoking		
Exercise		
Driving a car		
Cold air		
Stress		

2-3 **Do you know what chronic bronchitis is?**

Item	Spontaneous	After reminding
Shortness of breath/tightness of the chest		
Inflammation		
Tearing eyes		
High mucus-production		
Fever		
Repeating disease, several times a year		

2-4 **Do you know what emphysema is?**

Item	Spontaneous	After reminding
Shortness of breath/tightness of the chest		
Hardly/not reversible		
'Lung cannot stretch anymore'		
Relation with smoking		
Ear ache		
You may get it when you are older		

2-6 **Do you know the purpose of the differently coloured of asthma medication?**
(wait for spontaneous answers)

Colour	Purpose	Yes	No
Blue	Against shortness of breath/tightness of the chest		
Brown	Preventive		
Green	Longer term reliever		

2-7 What is self-management in asthma?

Item	Yes	No
Self management in asthma		
Principle: Feedback between PEV value and medication		
Using peak flow		
60-80-100% intervals in peakflow		
Adapting medication		

2.8 **Can you tell me the drugs you are currently using, and what their purpose is?**
(Only mark spontaneous answers.)

2-9 **Are there specific medicines you cannot tolerate well, and what the are the complaints**

Medicine	

2-10 **Now I like to check your actual drug use.**
(Check the medication details in the computer as follows: 'Do you still use [name drug] and if yes, how often per day?' for all active drugs in the medication history. Complete 0-1 or 0-2)

2-11 **Do you use other medicines, not mentioned on this list, chronic or occasionally, for example medicines you can obtain without a prescription, and the reason for taking them?** *(Complete 0-3)*

SECTION 0, TO BE COMPLETED BY THE PHARMACIST BEFORE AND DURING THE CONSULTATION

0-1 What medication is used daily, and what dosage? (active medication only)

	According to pharmacy computer			
	Medicine	Use	Medicine	Use
1				
2				
3				
4				
5				
6				
7				
8				
9				

0-2 What medicines are being used occasionally and what dosage? (active medication only)

	According to pharmacy computer		According to patient	
	Medicine	Use	Medicine	Use
1				
2				
3				
4				
5				

0-3 What medication is being used without prescription, and what dosage? (also non-regular use)

	According to pharmacy computer		According to patient	
	Medicine	Use	Medicine	Use
1				
2				
3				
4				

3. DRUG RELATED PROBLEMS

3-1 **Are you having problems with any of the medicines you are currently using**

O Yes
O No (go to 4-2)

3-1a **If yes, what problems and with what medicines?**

Medicine	ATC	DDD	P code	A code	S code	Clarification

(N.B. Please code the problems after the consultation, using the PAS® codes and ATC code. Document also for your own use)

3-2 **Any other questions about the research project, your diseases or medicines?**

.....

.....

Thank you for your patience. I will now (if applicable) **have a further look ate the problems you have mentioned.**

(Try and suggest solutions. Make a new appointment if solving the problem is difficult. Keep the Hepler/Strand scheme in mind.)

CONCLUSION:

This is the end of the questionnaire and the research project. Thank you for your co-operation. Last but not least I would like to check upon your inhaler technique.

4. QUESTIONS FOR THE PHARMACIST

4-1 **Could the patient hear, understand and answer your questions, easily?**

O yes (go to 4-1b)
O No

4-1a **If not, what was the reason?**

- Difficulties hearing — O Yes O No
- Difficulties understanding — O Yes O No
- Difficulties to speak — O Yes O No

4-1b **Please indicate the hearing of the patient**

- O Normal
- O Uses effective hearing aid
- O Hard of hearing
- O Deaf

4-2 **Please indicate the vision of the patient**

- O Normal
- O Uses reading glasses
- O Always uses glasses
- O Visually handicapped
- O Blind

A6.3 Intervention Pharmacist final questionnaire

This questionnaire was sent to the pharmacists, at the end of the project.

Pharmacy number: Date:

Current number of patients in project:

The first questions deal with the amount of time you spent for this project. We like to know how you spent that time exactly.

How often (on average) did you speak to a project patient during the last year of the project?
(Please select one answer)

- O not at all (go to question 7)
- O 1 time
- O 2 times
- O 3 times
- O 4 times
- O 5 times
- O more than 5 times

2. How much time did you invest during the last year in counselling all intervention patients, apart from the evaluation session? (Please select one answer)

- O Less than 30 minutes per week
- O per week ½ to 1 hour
- O per week 1-2 hours
- O per week 2-4 hours
- O per week 4-8 hours
- O more than 8 hours per week

3. What was the average duration of the evaluation sessions?

- O 10-20 minutes
- O 20-30 minutes
- O 30-45 minutes
- O 45-60 minutes
- O more than 60 minutes

4. How long did the average other consultations with project patients last during the last year?

- O 5 minutes
- O 10 minutes
- O 15 minutes
- O more than 15 minutes

4a. How much time did you spend during the last year on other activities concerning pharmaceutical care for the project patients (preparations, drug use review, travel etc.) ..... minutes

The following questions are about the communication during the last year of the project

5. What did you think about the communication with the project patients? (Please tick one box per item)

		Yes	Sometimes	No
a	Clarifying	O	O	O
b	Pleasant	O	O	O
c	Useful	O	O	O
d	Too long	O	O	O
e	Too short	O	O	O
f	Personal	O	O	O
g	Friendly	O	O	O
h	Professional	O	O	O
i	Annoying	O	O	O
j	Useless	O	O	O

6. What were the topics of conversation? (Please tick one box per item)

		Always	Usually	Sometimes	No
a	The effects of medicines	O	O	O	O
b	The side effects of medicines	O	O	O	O
c	The correct use of medicines	O	O	O	O
d	The use of OTC medication	O	O	O	O
e	The importance of compliance	O	O	O	O
f	The diseases of the patient	O	O	O	O
g	The lifestyle (eating, drinking smoking etc.),	O	O	O	O
h	De hobbies of the patient	O	O	O	O
i	The family of the patient	O	O	O	O
j	The relationships between the patient and physicians	O	O	O	O
k	Health and disease in general	O	O	O	O
l	The pharmacy	O	O	O	O
m	Home-delivery of medicines	O	O	O	O
n	Something else e.g.	O	O	O	O

7. Do you think that the use of medicines by the patient has changed because of your consultations during the last year of the project? (Please tick one box)

- O Yes
- O No, go to question 8
- O Don't know, go to question 8

7a. If yes, what has changed? (Please tick one box per item).

a	The number of medicines in use	O Yes	O No
b	The way of use	O Yes	O No
c	The time of use	O Yes	O No
d	The frequency of use	O Yes	O No
e	The use of OTC medication	O Yes	O No
f	Compliance/adherence	O Yes	O No

g Inhaler technique O Yes O No
h Other e.g.: .....

8. Did you contact the GPs about the project during the last year?
(More boxes can be ticked)

O Yes, personally, face to face
O Yes, personally by phone
O Yes, during the pharmacotherapeutic consultation
O No (go to question 9)

8a. If yes, what was usually the reason for the contact? (More boxes can be ticked)

O Issues concerning a prescription for a project patient
O Issues concerning the total medication of a project patient
O A question initiated by the physician
O Other e.g.:.....

8b. How often have you spoken with GPs about project patients during the last year?
..... times

The next question deal with possible other structured and documented care activities in your pharmacy

9. Do you provide structured and documented pharmaceutical care as a project or routine, other than the TOM project?

O Yes
O No, go to question 10

9a. What group of patients do you provide with this care? (More boxes can be ticked)

O All patients with lung disorders
O Diabetes patients
O Patients with gastro-intestinal disorders
O Patients with incontinence
O Other patient-groups, e.g. .....

9b. Please describe this pharmaceutical care
.....
.....

9c. In what phase is the provision of pharmaceutical care (excl. TOM project)? (Please tick one box)

O Starting projects
O Initial phase of a project
O Evaluation phase of a project
O Routinely providing care to the target groups

9d. How much time do you and/or your staff invest in providing structured and documented pharmaceutical care (excl. TOM project)? (Please tick one box)

O less than 1/2 hour per week
O per week ½-1 hour
O per week 1-2 hours
O per week 2-4 hours
O per week 4-8 hours
O more than 8 hours per week

The following question is about the amount of time you have spent on talking to patients, unrelated to pharmaceutical care or the TOM project, during the last year. We only mean conversation in the consulting area, your office or at the home of the patient.

10. How much time have you invested in general during the last year in conversations with patients (excl. TOM project) in a consultation room, your office or at the patients' home (Please tick one box.)

- O less than 1/2 hour per week
- O per week ½-1 hour
- O per week 1-2 hours
- O per week 2-4 hours
- O per week 4-8 hours
- O more than 8 hours per week

Back to the TOM project

11. What have you, as a pharmacist, noticed of the provision of pharmaceutical care in the TOM project, apart from the invested time? (please tick one box per item)

	noticed nothing	noticed sometimes	noticed often
a. More referrals of patients to physicians	O	O	O
b. Better contact between you and the GPs	O	O	O
c. More contact between you and the GP	O	O	O
d. Better control of the patients over their disease	O	O	O
e. Better contact between you and the patients	O	O	O
f. Disseminating effect of pharmaceutical care to other patients in your pharmacy	O	O	O
g. Increased awareness/ assertiveness of the patients	O	O	O
h. Your increased understanding of diseases in general	O	O	O
i. Your increased understanding of the drug use of patients	O	O	O
j. Thwarting of prescribing policies of doctors	O	O	O
k. Thwarting of your policies in the pharmacy	O	O	O
l. Other e.g.:			

12 Which of the following aspects of pharmaceutical care are currently being performed by an assistant pharmacist in your pharmacy (please tick one box per item)

	Yes, by all assistant pharmacists	By experienced assistant-pharmacists only	No
a. The intake	O	O	O
b. Dispensing	O	O	O
c. Giving instructions for use	O	O	O
d. Drug use review	O	O	O
e. Discussing compliance	O	O	O
f. Discussing possible changes in therapy	O	O	O
g. Answering questions about drugs, side-effects and interactions	O	O	O
h. Responsible advising on OTC drugs	O	O	O
i. Answering questions about diseases	O	O	O
j. Conducting consultations	O	O	O
k. Coaching diabetes patients	O	O	O
l. Giving inhaler instructions	O	O	O
m. Coaching asthma self-management	O	O	O

13. Below we ask your opinion on a number of statements (please tick one box per item)

	Totally agree	Agree	Disagree	Totally disagree
a. The intake is an essential part of pharmaceutical care	O	O	O	O
b. I can communicate well with my patients	O	O	O	O
c. The patients liked the better coaching of their medicine use	O	O	O	O
d. I really don't know enough of the diseases of the patients to be able to counsel them properly	O	O	O	O

	Totally agree	Agree	Disagree	Totally disagree
e. I don't think it is necessary to inform the GP about my activities in the field of pharmaceutical care	O	O	O	O
f. Because I am part of the TOM project, I now also offer pharmaceutical care to other patients	O	O	O	O
g. When I provide pharmaceutical care, I damage the key-role of the GP in health care	O	O	O	O
h. The intensive counselling of patients is useful	O	O	O	O
i. I find that I should personally inform the GP when I provide pharmaceutical care	O	O	O	O
j. Project patients now ask more questions	O	O	O	O
k. I find it difficult to find time for providing pharmaceutical care	O	O	O	O
l. I noticed that the GPs find that I come on their territory when I provide pharmaceutical care	O	O	O	O
m. It is difficult to get access to specialists about medication	O	O	O	O
n. Because I provide pharmaceutical care I am also more active in my pharmacy	O	O	O	O
o. Because I provide pharmaceutical care I feel more committed to all my patients	O	O	O	O

Did you help any of your project-patients to start self-management *during the last year*?

O Yes
O No

14a. Did you help any project-patient to solve problems concerning self-management *during the last year?*

O Yes
O No

14b. Did you check the inhaler technique and peak-flow during the last evaluation?

O Yes
O No

15. What is your opinion on your activities in the field of pharmaceutical care during the last year of the TOM project? (Please tick one box)

O Positive
O Negative
O Neutral

15a. What do you feel about the duration of the TOM project, regarding the necessity to counsel the patients? (Please tick one box)

O Too short
O Good
O Too long

15b. What do you feel about the duration of the TOM project, with regard to the pressure from the university? (Please tick one box)

O Too short
O Good
O Too long

15c. What part of the project did you like most? .....

15d. What part of the project you did not like at all? .....

15e. Do you have suggestions for improvement, when the project framework is to be used in other pharmacies?

a. .....
b. .....
c. .....

15f. Do you think you contributed in a positive sense to the quality of life of the project-patients?

- O Yes
- O No

16. Now the TOM project stops, we would like to know if you continue to offer pharmaceutical care to asthma patients.

- O Yes
- O Yes, but I'll change the format
- O No

17. Providing structured and documented pharmaceutical care proves to be difficult in everyday practice. Could you give 3 reasons why? .....
.....
.....

We also would like to know some details about your documentation on pharmaceutical care activities

18. Do you have a documenting system for keeping track of the pharmaceutical care data, apart from a system to keep medication records and address details? (Please tick one box)

- O Yes, a written card system
- O Yes, an electronic patient dossier from my software provider
- O Yes, an electronic patient dossier from another provider
- O No (go to question 19)

18a. Do you use this system in normal practice? (Please tick one box)

- O No
- O Yes, daily
- O Yes, weekly
- O Yes, monthly

18b. Who are authorised to update the dossiers? (Please tick one box)

- O All workers in the pharmacy
- O All pharmacists and assistant-pharmacists
- O Experience assistant pharmacists and the pharmacists only
- O Pharmacists only

18c. Who are authorised to consult the dossiers? (Please tick one box)

- O All workers in the pharmacy
- O All pharmacists and assistant-pharmacists
- O Experience assistant pharmacists and the pharmacists only
- O Pharmacists only

19.What pharmacy computer-system do you have?

- O Pharmacom
- O Pharmacom (/CB81)
- O Euronet
- O Microbias
- O Cendata

At the end of the project we would (again) like to have information on your pharmacy. These details will of course not be published

20. How many clients do you serve from your pharmacy .....

21. How many pharmacists work in your pharmacy?
(Please calculate in full equivalents) ..... Equivalents

22. How many assistant-pharmacists work in your pharmacy?

(Please calculate in full equivalents) ..... Equivalents

23. How many non pharmaceutical staff are employed?
(Please calculate in full equivalents) ..... Equivalents

Thank you again for your co-operation

A6.4 Final Questionnaire GPs, TOM project

This questionnaire was sent to all GP's of patients in the TOM project.

GP number: **Date:**

Name pharmacist (if known):

---

1. Have you been informed about the activities of the pharmacist in the field of pharmaceutical care?
(Please tick one box)
- O Yes, I was informed during the last 6 months (go to question 1.1)
- O Yes, But I was already informed more than a year ago (go to question 2)
- O No, please return this questionnaire

1.1 If Yes, how have you been informed
(Please tick one box)
- O The Pharmacist informed me
- O A patient informed me
- O Both the pharmacist and a patient informed me
- O A colleague informed me

2. Do you know which one of your patients participate in the TOM project?
- O Yes, one/some
- O No (go to question 3)

2.1 If yes, how many of your patients are participating, according to your information?
..... Patients

3. Did you notice anything of the activities of the pharmacist in the field of pharmaceutical care, during the last year?
- O Yes
- O No (go to question 7)

3.1 Did you help any of the project patients to install asthma self-management, during the last year?
(Please tick one box)
- O Yes
- O Yes, but not all project patients
- O No

4. What did you notice of the provision of pharmaceutical care in your patients during the last half year
(Please tick one box per item).

	noticed nothing	noticed sometimes	noticed often
4.1 More contact between me and the pharmacist	O	O	O
4.2 Better contact between me and the pharmacist	O	O	O
4.3 Increased awareness/assertiveness of the patients	O	O	O
4.4 Participating patients have a better control over their diseases	O	O	O
4.5 Increased compliance/adherence	O	O	O
4.6 More contact between me and my patients	O	O	O
4.7 More referrals from the pharmacy	O	O	O
4.8 Less bothersome patient during my consultations	O	O	O
4.9 Thwarting of formulary agreements	O	O	O
4.10 Thwarting of my treatment policies	O	O	O

5.Has the use of medicines by your TOM patients changed, as a result of the contact with the pharmacist, during the last year? (Please tick one box)

- O Yes
- O No, go to question 6
- O Don't know, go to question 6

5.1 If yes, what has changed? (Please tick one box per item)

- The number of medicines in use	O Yes	O No
- The way of use of te medicines	O Yes	O No
- The time of use of medicines	O Yes	O No
- The frequency of use of medicines	O Yes	O No
- The use of OTC medication	O Yes	O No

- Others e.g:.....

6. Does the patient understand his disease better now than a year ago, because of the counselling by the pharmacist?

- O Yes
- O No

7. Do you find the pharmacist a competent professional for medication counselling?

- O Yes
- O No

7.1 Do you find the pharmacist a competent professional for counselling about asthma self-management?

- O Yes
- O No

8. Here we ask your opinion on a number of statements. Please tick one box per item

	Totally agree	Agree	Disagree	Totally disagree
8.1 The pharmacist (partially) takes my chair when providing pharmaceutical care	O	O	O	O
8.2 I find the intensive counselling on the medication by the pharmacist useful	O	O	O	O
8.3 I think that the patient likes the counselling about medicine use by the pharmacist	O	O	O	O
8.4 As for me the pharmacist may expand his/her activities in the field of pharmaceutical care	O	O	O	O
8.5 I don't think it is necessary that the pharmacist informs me about his/her activities in the field of pharmaceutical care	O	O	O	O
8.6 When the pharmacist provides pharmaceutical care, he/she damages my key-role in health care	O	O	O	O
8.7 The pharmacist does not know enough about diseases to be able to counsel the patients	O	O	O	O
8.8 I think I am in a better position to counsel patients on their drug use than pharmacists	O	O	O	O
8.9 I see project patients less in my office	O	O	O	O
8.10 I cannot always change medication according to the propositions of the pharmacist, because it has been initiated by a specialist	O	O	O	O
8.11 When the pharmacist counsels patients on drug use, I get more time for my core activities	O	O	O	O

9. What is your opinion now on the activities of the pharmacist in the field of pharmaceutical care? (Please tick one box)

- O Positive
- O Negative
- O Neutral

CURRICULUM VITAE

J.W.F. (FOPPE) VAN MIL

EDUCATION

Jan Willem Foppe van Mil, was born on July 16th 1950 and raised in Waalwijk, The Netherlands. After the Dutch highschool/college (HBS-B), he studied Pharmacy in Utrecht finishing in December 1977. While in the university, he was treasurer for several student organisations. He participated in a student exchange program, living in Canada and Israel for a six and three-month period respectively.

As a student he travelled to other European countries like Denmark, France, Germany and the United Kingdom. While on the board of the Dutch Association of Pharmacy-students (ANPSV) he helped to develop a European curriculum. During his last four years at the university, he taught drug-identification to undergraduates.

Foppe van Mil speaks and writes Dutch, English, German and French.

PROFESSIONAL CAREER

After Foppe van Mil completed his studies, he became community-pharmacist in a community health-centre in Lewenborg, Groningen in January 1978.

In 1981 he took over the pharmacy in the village of Zuidlaren, where he has been practising since. The pharmacy has 15 employees including two other pharmacists.

ACADEMIC CAREER

After the completion of his university studies, Foppe van Mil returned to the alma mater in 1993 and worked several months for The Noordelijk Centrum voor Gezondheidswetenschappen (NCG) of the University of Groningen. He investigated the export of Dutch drugs to developing countries, which resulted in the report 'Dutch Drugs in developing countries'. From June 1993 till to date he worked (part-time) for the working group Social Pharmacy of the University Centre of Pharmacy in Groningen on the concept of Pharmaceutical Care. During this phase of his university career, Foppe van Mil still worked in his pharmacy.

In 1995 and 1996 he organised two national Symposia on Pharmaceutical Care in the Netherlands. He teaches in several continuing education programs for FIP, KNMP, Astra and Postgrade/Glaxo Wellcome. Over the last couple of years Foppe van Mil has been invited to many national and international conferences as a speaker or workshop-leader on subjects related to pharmaceutical care, pharmacy practice research, social pharmacy, and the role of pharmacists in the combat against AIDS.

KNMP (ROYAL DUTCH SOCIETY FOR THE ADVANCEMENT OF PHARMACY)

- From 1979 till 1984 he was member of the Commissie voor Collectieve Voorlichting (CCV) of the KNMP. This committee created the public relation initiative of KNMP and Dutch pharmacists.

- In 1987 he was member of the Congrescommissie, a committee which organised the yearly three-day convention for all Dutch pharmacists.
- From 1987-1989 he also was mentor for the interprofessional assessment of colleagues.
- In 1988, with F.J. Venema he co-authored a book on Drug-usage for laymen titled *Slikwijzer*. The book was published in co-operation with KNMP.
- From 1990-1995 he was member of the pharmacotherapeutic committee of the KNMP. In this committee several aspects of the rational use of pharmaceuticals were discussed. The committee also gave some guidance to the KNMP-Drug Information Centre and assessed the contents of the Informatorium.
- Since October 1994 he is the chairman of the Pharmaceutical Care on AIDS working group, supported by KNMP and Dutch AIDS-foundation. The project partially finished in July 1997 with the publication of the book 'Pharmacists and Aids, an unknown territory.
- From 1998 he is a member of the steering committee on pharmaceutical care for WINAp, a division of KNMP. The steering committee advises the WINAp on pharmaceutical care activities and co-ordinates the activities of the Special Interest Group on pharmaceutical care.

PHARMA SELECTA

- Foppe van Mil founded *Pharma Selecta* in 1985, an independent and critical journal for Dutch retail and hospital pharmacists in The Netherlands, currently read by 3100. *Pharma Selecta* is an associate member of the International Society of Drug Bulletins (ISDB). He was chief-editor of the bulletin till 1994. In 1999 the bulletin received the Innovation Award of KNMP.
- In 1990, he started a database under *Pharma Selecta*, called PS-On Line. It contains 3500 excerpts from pharmacotherapeutic articles that the Dutch pharmacist can easily access and now is marketed as PS-on disk, to support the journal.
- In 1990 and 1995 he co-developed and co-organised also under *Pharma Selecta* postgraduate pharmacotherapeutic training seminars for Dutch retail-pharmacists, the 'Doedagen', attended by over 200 participants.

AWARDS

- In October 1993 Foppe van Mil received the 'Innovation Award' of the K.N.M.P., for his innovative work in Dutch pharmacy.
- In March 1995 he received the 'Opwierda prijs' as co-author of an article on Pharmaceutical Care and asthma from the Pharmaceutisch Weekblad.
- In October 1999 he received the Official Pharmaceutical Association of Gipuzkoa Award in recognition of the research work in the field of pharmaceutical care.

OTHER (PROFESSIONAL) ACTIVITIES

- Served from 1978 till 1992 on the board of several regional organisations of community pharmacists such as *GAV* and 'Departement Groningen van de KNMP'.
- Participated the founding of the 'Geneesmiddelenwinkel' (1981) of the University of Groningen and a community health-centre in Beijum, Groningen (1981).

- Organised and guided excursions in 1979 and 1982 for Dutch community pharmacists to Sweden and the United Kingdom.
- Teaching applied pharmacotherapy to GP's at the University of Groningen between 1986 and 1995.
- Reviewed post-graduate community pharmacy students from 1985 to 1995.
- Since September 1994: Member of the Committee for continuing education of the section Community Pharmacy of the International Pharmaceutical Federation (FIP).
- From October 1994 till October 1996: Member of the board of the Special Interest Group for Drug Information of the European Society for Clinical Pharmacy and since October 1996 the Chairman of this SIG.
- Since 1995 member of the FIP working group on AIDS and Drug Addiction
- From May 1995- September 1998: Chairman of the Organisation Committee of the ESCP-Drug Information Conference in Amsterdam, held in May 1997.
- From July 1996 till February 1999 member of the Editorial Board of Pharmacy World and Science
- From August1996 till September 1999: Chairman of the Pharmaceutical Care Network Europe (PCNE). Now a normal member of this network.
- Chairman of the organising committee of the International Working Conference on Outcome Measurements in Pharmaceutical Care, held January 26-29, 1999 in Hillerød, Denmark
- Chairman of the Mini Symposium of the ESCP SIG Drug information in Orlando, Florida, USA held at 11th april 1999 during the International Congress on Clinical Pharmacy 'Documenting the value of Clinical Pharmacy Services'.

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