ULLA NÄRHI

Implementing the Philosophy of Pharmaceutical Care into Community Pharmacy Services - Experiences with Asthma Patients in Finland

Doctoral dissertation

To be presented by permission of the Faculty of Pharmacy of the University of Kuopio for public examination in Auditorium L2, Canthia building, University of Kuopio, Friday 3rd August 2001, at 12 noon

Department of Social Pharmacy
Faculty of Pharmacy
University of Kuopio
ABSTRACT

The concept of quality in health services can be defined as meeting the set requirements at the lowest possible cost. Health care services need to be of good quality for achieving the desired outcomes. These principles were extended to the community pharmacy services via the philosophy of pharmaceutical care in the beginning of 1990's. In pharmaceutical care, pharmacists take more responsibility for the outcomes of patient’s drug therapy, i.e. they become active participants of a health care team. The quality of care can be improved by identifying, resolving and preventing possible problems in patient’s drug therapy according to the principles of pharmaceutical care. Therapeutic Outcomes Monitoring (TOM) is a protocol designed to help implementation of pharmaceutical care based services.

The aim of this dissertation was to examine how the principles of pharmaceutical care could be implemented into Finnish community pharmacy practice by experimenting with asthma patients. Firstly, the possibilities of community pharmacists to detect potential drug-related problems during routine dispensing were assessed in an ordinary community pharmacy. The study population consisted of the customers (n=119) who presented a prescription for an inhaled asthma medicine in the pharmacy during the study period. Community pharmacists were able to detect problems by using simple tools like prescription information and discussions with the patient. Deficiencies were found in the medications. Also instructions in the prescriptions were found to be incomplete and lacking crucial information about the type and the purpose of the medication.

Therapeutic Outcomes Monitoring (TOM) protocol was applied in the implementation of the pharmaceutical care based services and to evaluate their impact on the outcomes of asthma patients. This was studied in four community pharmacies, with 28 asthmatics taking part in a one-year intervention. Significant improvements were measured in the patient clinical and process outcomes. Some of the improvements were still significant one year after the intervention. Compared to the baseline, half of the patients did not consider that they had any problems at the end of the intervention. Due to the limitations (a convenience sample and the lack of controls) of the study, the results have to be interpreted with caution.

The third part of the study assessed to what extent asthma patients were trained to monitor their disease and to adjust asthma medications as recommended by the national asthma guidelines established in 1994. This was surveyed by a questionnaire targeted to all asthma patients (n=2,860) obtaining their asthma medicines from Finnish community pharmacies during a two-day period in 1998. The majority of the respondents (86%) had been instructed in one of the methods recommended by the national guidelines. The patients over 65 years and those who had been taking asthma medication more than 5 years encountered the most deficiencies in their asthma follow up.

Community pharmacists can detect and solve patients’ problems in asthma medication and help them with self-management. Enhanced education, counselling and outcomes monitoring by community pharmacists can improve outcomes in the treatment. Therapeutic Outcomes Monitoring is a useful protocol for pharmacists in implementing the philosophy of pharmaceutical care. More models need to be developed and evaluated in order to find the best one for use in pharmacy practice.
To Hannu,
Anne and Johanna
ACKNOWLEDGEMENTS

This study was carried out at the Department of Social Pharmacy, University of Kuopio, during the years 1996-2001.

I wish to express my deepest gratitude to Professor Hannes Enlund, Ph.D. (Pharm.) who introduced me to this subject and provided an insightful view of social pharmacy. I am also most grateful to Professor Riitta Ahonen, Ph.D. (Pharm.) for her guidance, support and practical help in many aspects. My sincere thanks go to Marja Airaksinen, Ph.D. (Pharm.) for her support and encourage; and also for the excellent ideas and valuable comments during this study. The present work would not have succeeded without their supervision and vast experience in the area of social pharmacy.

I am grateful to Professor Timo Keistinen from the University of Oulu and Professor D.K. Raynor from the Division of Academic Pharmacy Practice, University of Leeds, who were the official reviewers of this thesis. They made useful comments and suggestions on how to improve the text.

My sincere thanks go to the entire personnel of the Department of Social Pharmacy, University of Kuopio, for the friendly atmosphere, which has made this work so enjoyable. I would especially like to thank Kirsti Vainio, Lic. (Pharm.), one of the co-authors, who taught me how to do research. Special thanks also to Leena Lahnajarvi M.Sc. (Pharm.) who shared with me “the room with no exit without a thesis” and also shared the periods of desperation during this study. I am very grateful to Pia Snellman M.Sc. (Pharm.) and Heidi Pääkkilä M.Sc. (Pharm.) for fruitful discussions during my studies. I especially want to thank Ms. Raija Holopainen and Ms. Paula Räsänen for their kind help in practical aspects and in many other kinds of problems encountered during these years.

With pleasure, I express my gratitude to Ewen MacDonald, Ph.D. (Pharm.) for revising my text to proper English and for his constructive criticism as well as caring and warm attitude during these years. I am grateful to M.Sc. Veikko Jokela for revising the statistics and also giving new ideas about the work.

My special thanks go to Paavo Tanskanen M.Sc. (Pharm.), one of the co-authors; with whom I designed the protocol of the ASTHMA-TOM study. I also want to thank Sirpa Peura M.Sc. (Pharm.), Maija Holopainen M.Sc. (Pharm.), Merja Kahela M.Sc. (Pharm.) and Leena Nummela M.Sc. (Pharm.) who were involved in the planning and implementation of the ASTHMA-TOM study. I want to thank all the patients, pharmacists, nurses and physicians who were involved in the study. Especially I want to thank the pharmacy owners Rintala M.Sc. (Pharm.) and Vesa Riimikäki M.Sc. (Pharm.) and all the staff from the Nivala pharmacy who participated in the study with me.

I want to thank my many colleagues for sharing ideas about pharmacy practise with me. I also want to thank Eeva Savela, M.Sc. (Pharm.), who set me a good example of studying along with daytime work.

I want to thank Director General Hannes Wahlroos, Professor Erkki Palva, my colleagues in the Drug Information Centre and in the National Agency for Medicines for providing such an inspiring working atmosphere.

I extend my warmest thanks to my parents Kirsti and Pentti Ukkonen for taking care for my family and me. I send my special thanks to my aunt Aili, to my sister and my
brothers and their families for nurturing and supporting me during my whole life. I warmly thank my parents-in-law Elsa and Reino Närhi for helping me in so many ways during these years. I also want to thank my husband's brother and his family for their support.

Finally, from the bottom of my heart, I wish to thank my dear husband Hannu who has encouraged me with great understanding and love. To know you is to love you. Anne and Johanna, I am very proud and grateful for having such wonderful daughters. Thank you for understanding your mother who spends a lot of time in front of a computer.

Financial support from the Elli Turunen Fund of the Finnish Cultural Foundation, the Association of Finnish Pharmacies, the Association of the Pulmonary Disabled and The Environment, Health and Society - programme of the University of Kuopio is gratefully acknowledged.

Nivala, June 2001

Ulla Närhi
OPERATIONAL DEFINITIONS OF THE KEY TERMS

Community pharmacy
A pharmacy that dispenses medicines to outpatients and is not a part of a hospital or a health centre. Physically they are located apart from other health care units. In Finland all the community pharmacies - except the Helsinki University Pharmacy and the Kuopio University Pharmacy - are owned privately.

Pharmacist
A person who is allowed to dispense medicines independently in a community pharmacy. In Finland, a pharmacist is a person with a master’s degree (5-year education at the university, “proviisori”) or a person with a bachelor’s degree (3-year education at the university, “farmaseutti”).

Traditional dispensing
A pharmacist takes responsibility for dispensing the correct medicines with correct doses to the patient. The focus is in the dispensing process. The pharmacist will provide advice on how to use the medicines. Co-operation with patients and other health professionals is restricted mainly to technical problems e.g. problems with prescriptions.

Pharmaceutical care
In pharmaceutical care, the pharmacist is taking more responsibility for the patient’s management with the drug treatment. The pharmacist is identifying potential problems in drug therapy, solving them in co-operation with the patient and other health professionals, educating and counselling the patient and monitoring the management. The purpose is to achieve definite outcomes that improve a patient’s quality of life (Hepler and Strand 1990). Documenting about the care and feedback to the patient and other health professionals are also included.
**Self management**

The patient is aware of the basic information about the disease, treatment and medication and is able to establish the correct treatment in his/her daily life. A more advanced approach to self-management is guided self-care.

**Guided self-care**

A new approach to the treatment where the patient is encouraged to take more responsibility about the management with help, support and training by health professionals. In asthma, the patient monitors his or her condition on the basis of symptoms and preferably with Peak Expiratory Flow (PEF) measurements and adjusts medication in accordance with specific instructions.

**Therapeutic Outcomes Monitoring (TOM)**

A disease-specific monitoring protocol for implementing the philosophy of pharmaceutical care. The TOM protocol gives instructions for a pharmacist to identify therapeutic objectives, monitor patient progress, identify potential problems and resolve them (Hepler 1997).

**Outcome**

A direct measure of a decline or an improvement or some other change resulting from an intervention. Outcomes can be measured by clinical measures (e.g. changes in laboratory tests), by monetary measures (changes in costs) and by quality measures (changes in patient’s attitudes or satisfaction with the treatment).

**Quality assessment**

An umbrella term for coordinated activities to evaluate, measure and develop the quality of services by finding and correcting possible departures from the defined standards.
**Quality assurance**
Activities that assure the acceptable levels of quality. In health care, this level should be reached with a minimum of total expenditure. Continuous monitoring and measuring of the quality belongs to the assurance.

**Surrogate endpoint**
A measure that reflects final outcomes. Laboratory tests or PEF measurements can be considered as surrogate endpoints.

**Patient counselling**
Health professionals (e.g. physicians, nurses and pharmacists) are supporting and teaching the management of the disease including drug therapy and measurements for follow up (e.g. Peak Expiratory Flow). The guidelines of the treatment will be tailored to the patient’s daily life.
LIST OF ORIGINAL PUBLICATIONS

This thesis is mainly based on the data presented in the following original papers, referred to in the text by Roman numerals I-V. The thesis also contains some previously unpublished data.


IV Närhi U, Airaksinen M, Enlund H. Pharmacists solving problems in asthma management - experiences from a one-year intervention programme in Finland. J Appl Therap Research, in press

V Närhi U, Airaksinen M, Enlund H. Are asthma patients trained to follow up their disease - a nationwide survey in Finland. Pharm World Sci, accepted
# CONTENTS

1 INTRODUCTION ........................................................................................................... 17

2 QUALITY ASSURANCE IN HEALTH CARE .......................................................... 20

  2.1 Structure of the quality .................................................................................. 20

  2.2 Improving the quality ................................................................................. 22

3 QUALITY ASSURANCE IN DRUG THERAPY ...................................................... 25

  3.1 Origins of assessment ............................................................................... 25

  3.1.1 Clinical pharmacy ................................................................................ 25

  3.1.2 Drug Utilization Review .................................................................... 26

  3.2 Pharmaceutical care as an ongoing process to improve pharmacy services... 26

  3.2.1 Pharmaceutical care versus traditional drug dispensing ..................... 30

  3.2.2 Therapeutic Outcomes Monitoring and its applications ..................... 32

4 DIMENSIONS OF OUTCOMES ........................................................................... 35

  4.1 Economic outcomes ............................................................................... 35

  4.2 Clinical outcomes ................................................................................... 36

  4.3 Humanistic outcomes ............................................................................. 36

  4.4 The ECHO model .................................................................................... 37

  4.5 Process outcomes .................................................................................... 38

5 OUTCOMES RESEARCH IN COMMUNITY PHARMACIES .................................. 40

  5.1 Context of the intervention studies with patients ..................................... 41

  5.1.1 Content of pharmaceutical work in the interventions ....................... 42

  5.1.2 Evaluation designs ............................................................................ 44

  5.1.3 Results .............................................................................................. 49

  5.2 Interventions measuring process outcomes ............................................. 55

  5.2.1 Subjects in the interventions ............................................................. 55

  5.2.2 Data collection and documenting ...................................................... 57

  5.2.3 Results .............................................................................................. 58

  5.3 Evaluation of the studies ......................................................................... 63

  5.3.1 Validity of outcomes measures in community pharmacy studies ...... 63

  5.3.2 Interventions with patients ............................................................... 63

  5.3.3 Interventions measuring process outcomes ...................................... 66

  5.4 Summary of the outcome research ......................................................... 66

6 AIMS OF THE STUDY ............................................................................................ 69
APPENDICES

ORIGINAL PUBLICATIONS
1 INTRODUCTION

Optimal drug therapy would be viewed by the patient as consisting of the appropriate medication used at the correct doses taken at the right time. This optimum drug therapy has not always been reached and many kinds of problems in drug treatment have been noted. Drug-related problems such as errors in the process of prescribing, dispensing, or administering a drug are relatively common even in hospitalised patients and can result in increased morbidity and mortality (van den Bemt et al. 2000). An increasing trend in medication-error deaths has also been reported (Philips et al. 1998). Suboptimal drug therapy may even cause adverse drug events (Bates et al. 1995). These will cause problems not only for patients but also for the whole society, for example by increasing the total health care costs.

In addition to the appropriate medication, the patient has to know how to use the medicines. The patient should be able to use his/her medicines correctly until the outcomes of drug therapy can be achieved. Patient education and counselling have been shown to improve outcomes of drug treatment (Kelso et al. 1996, Gallefoss et al. 1999). It is possible to reduce the harm caused by drug-related problems and adverse drug events by monitoring more closely the drug therapy (van den Bemt et al. 2000, Dormann et al. 2000). Supporting the management and monitoring of outcomes by health professionals have reduced the suffering and costs associated with disease (Partridge et al. 2000).

The concept of pharmaceutical care was launched as part of the new attitude of considering health professionals more as supporters in a patient’s self management. This switched the focus of pharmaceutical work from dispensing to an active partnership of the disease management and emphasised the pharmacists’ responsibility for the drug treatment (Hepler and Strand 1990). In pharmaceutical care, the pharmacist takes more responsibility for achieving the desired outcomes of the drug therapy. The pharmacist identifies possible problems in drug therapy, solves them in co-operation with the patient and other health professionals and constructs a monitoring programme for following up the patient’s management with the drug treatment. Pharmaceutical care can be considered as a new concept for improving the quality of pharmacy
services. The goal of these services is the patient’s wellbeing and good quality of life. Pharmacists cannot – and they need not – provide all aspects of patient management, but as experts in drug therapy they can improve outcomes of drug treatment.

In Finland, the annual number of dispensed prescriptions increased by more than five millions from 1990 to 1999 (Finnish Statistics on Medicines 1999). More patients are treated in outpatient care which also increases the number of prescriptions dispensed. In addition to dispensing medicines, community pharmacists each day have a multitude of contacts with other customers including patients who do not want to use or do not need other health care services. Pharmacists have great challenges to improve outcomes of drug treatment by educating and supporting; identifying; and solving drug-related problems.

Implementing the philosophy of pharmaceutical care into pharmacy practice is a long process. Pharmacists will need to experiment with these new service concepts so they can be seamlessly integrated with traditional dispensing. This includes a systematic development and evaluation of pharmacy services. Evaluating should be structured and produce information about the current situation and the needs for changes. The aim of this study was to experiment with the implementation of pharmaceutical care in Finnish community pharmacies. It begins with an evaluation of outcome studies that have been conducted in community pharmacies. Then, the possibilities for community pharmacists to detect potential problems with medication among asthma patients during routine pharmacy visits were measured by using simple tools such as prescription information and discussing. A pharmaceutical care intervention was arranged using asthma patients as study subjects. The effect of community pharmacists’ extended role in patients management and the influence of enhanced educating, counselling and outcomes monitoring by community pharmacists to the outcomes of asthma treatment were evaluated. The Therapeutic Outcomes Monitoring - model which was modified from Danish studies - was used as a tool for implementing pharmaceutical care in practice. The outcomes measured were clinical outcomes (severity of asthma symptoms, changes in the number of patients having peak expiratory flow values below 85% or 70% of the optimal; changes in daily asthma medication; and changes in the number of patients needing courses of oral steroids); humanistic outcomes (problems in self-management
perceived by asthma patients or detected by pharmacists; usefulness of the topics taught by pharmacists, opinions about the enhanced education, counselling and outcomes monitoring by community pharmacists, physicians and nurses); and process outcomes (changes and correlations in knowledge about and attitudes towards asthma as a disease and its medication). Finally, the implementation of national asthma guidelines among asthma patients was studied by determining their ability to follow-up the disease and adjust their medication according to specific instructions.
2 QUALITY ASSURANCE IN HEALTH CARE

Quality assurance can be defined as all the activities that have been taken to predict and prevent poor quality (Øvretveit 1992). In the health services, the quality has been defined as requirements that are fully met at the lowest possible costs. According to Øvretveit (1992), quality management consists of three dimensions: Client Quality (what clients and carers want from the service), Professional Quality (the good quality of health professionals and techniques provided) and Management Quality (the most effective and productive use of resources) (Øvretveit 1992). Recently, the health care services have been forced to be produced with limited resources. They need to be of good quality if they are to be effective for achieving desired outcomes. In quality assessment, the services need to be evaluated against some standard. Departures from standards should be detected and corrected as early as possible (Donabedian 1978).

2.1 Structure of the quality

Donabedian was the first to place the health care quality measures into three categories: structure, process and outcome (Donabedian 1978). He postulated that the quality of health care can be regarded as a function of the structure of the health care, the process that is carried out in the health care to produce the services and the outcomes of the health care (Donabedian et al. 1982). These three categories can also be recognised in pharmacy services.

Structure denotes the attributes of the settings in which the care is provided. It consists of material resources such as facilities, equipment and money (Donabedian 1988). When one wishes to measure the structure, then the presence or absence of systems and facilities essential for quality of care will be evaluated (Holdford and Smith 1997). Structure in community pharmacies refers to the material and personnel available. It covers all the materials: the pharmacy room, manufacturing and analysing property, equipment and furniture (Mullins et al. 1996). The computer system and number of computers per pharmacy is a part of the structure as is the personnel, number of pharmacists and technicians per pharmacy. When implementing pharmaceutical care,
the structure should include elements that help patient counselling and monitoring e.g. patient medication records.

Process can be regarded as series of actions that make up the patient’s health care. Process describes all the patient’s and practitioner’s activities in health care including seeking care, making a diagnosis and recommending or implementing treatment (Donabedian 1988). The health care providers have to know their service process step by step, if they want to recognise the defects and improve the services. An optimal health care process could be a continuous seamless care where the patient is getting all the needed services with good quality from physicians to pharmacists.

For community pharmacies, process activities can be viewed as dispensing prescriptions as the minimum. Dispensing prescriptions can also include patient education and counselling, and outcomes monitoring. Analysis of raw materials, manufacturing and all the activities related to drug dispensing are part of the pharmacy process. Process characteristics in dispensing include checking each prescription for drug interactions and allergies, ensuring that drug concentrations are within the appropriate range, conducting drug-use evaluations, and filling prescriptions (Gouveia and Chapman 1995).

Donabedian (1978) suggested that process criteria of quality assessment could be categorised as technical or interpersonal. Technical quality represents all the activities from gathering prescription information, entering it into a computer to delivering medicines to the patient (Farris and Kirking 1993). Contacting the prescriber about possible problems or errors with the prescription also is a part of the quality assessment of the technical process. The interpersonal component of the process denotes the interaction between patients and pharmacists (Farris and Kirking 1993) including the pharmacist’s willingness to listen, his/her empathy and respect for the patient. All these processes should be evaluated when improving the quality of pharmaceutical services.

Outcome is usually considered as a result of one or more consequences. Lohr (1988) characterized outcomes of medical care with five D’s: death, disability, disease, discomfort and dissatisfaction. He regarded outcomes as end results of medical care: what happened to the patient in terms of palliation, control of illness, cure, or
rehabilitation. The weakness of the definition is that it includes many terms that do not have concrete meanings and are difficult to measure.

Donabedian (1978) made another definition of outcomes. He placed outcomes in the context of quality measurement (Donabedian 1978, Donabedian et al. 1982). Outcomes are defined as changes in the patient’s health status resulting from health care services. In addition to changes in health status, outcomes take into account the psychological, economic and social factors that affect the patient’s health and quality of life (Farris and Kirking 1993). Outcomes can be considered as ultimate validators, determining the extent of benefit or harm to the patient (Donabedian 1978). Outcomes also measure the end-points or the results of the process. Traditionally, an outcome measuring has focused on changes in patient’s clinical status. Mortality (death) and morbidity (increased or additional illness) have been considered as available outcomes measures in health care (Mullins et al. 1996). Other physical and health related outcomes are curing or slowing the disease process or preventing or reducing symptoms (Hepler 1990). In recent years, more attention has been placed on humanistic outcomes e.g. quality of life.

In a summary, good structure increases the likelihood of good process and good process increases the likelihood of a good outcome (Donabedian 1988). Neither one should be perceived as being more important than the other (Brook 1979). However, the relationships between structure, process and outcomes have not been clearly demonstrated. Do better structures really improve patient health status or quality of life? Does a renovation of the structure lead to a better process? Also other factors that were not directly involved in the structure or in the process could have improved the outcomes.

2.2 Improving the quality

Quality assessment with evaluation of the outcomes is a continuous process. Its aim is a continuous quality improvement. This has been described as a Quality Management Cycle by Øvretveit (1992, Figure 1):
Inputs cover requirements (service brief) and service design (from service strategy). All of the relevant background data and results of the earlier measurements should be available for selecting the quality features. At the start only a few features should be selected so that the full cycle can be established.

After selecting the quality features, the standards for Client Quality (clients needs), Professional Quality (health professionals and techniques) and Management Quality (the use of resources) should be formulated. The departures should be noticed and then those features are selected where changes may improve all dimensions of quality at the same time. After formulating the standards, all the performance against them should be collected and recorded by using scientific methodology, when appropriate.

All the documentation of actions should preferably be done in terms of graphs and charts that show the variations specifically. These have to be easy to understand and made available to all staff. Decisions have to be made about what to measure and report.
frequently and what is assessed on a longer-term basis. After setting standards and measuring performance, the planned actions have to be established. Corrective action may be simple or it may need more work. When the quality performance is stable and standards have been met, the cycle then returns to the quality features part. It should be reassessed to find out whether there are needs which could elevate the standards or to add new quality features.

The ideas and goals of the Quality Management Cycle can be adapted to pharmacy practice and community pharmacy settings. Key quality features can be selected for each of the Client Quality, Professional Quality and Management Quality dimensions. Such features in Client Quality could be improvements in patient counselling and client satisfaction to pharmacy services. Professional Quality could include improvements in pharmacists’ knowledge and readiness to educate the patients. The goal of the Management Quality could be to produce the services with good quality, e.g. good quality of pharmaceutical services with low waiting times for patients.
3 QUALITY ASSURANCE IN DRUG THERAPY

The idea of quality assurance in drug therapy was first introduced in the USA in 1960’s mainly in hospital pharmacy settings. The aim of this chapter is to give a short overview of the development that led to attempts to improve pharmacy services by introducing and implementing the philosophy of pharmaceutical care.

3.1 Origins of assessment

3.1.1 Clinical pharmacy

Clinical pharmacy was a new concept that was introduced around the 1950s’ in the USA (Nilsson 1981). It did not become widely used among pharmacists until the late 1960’s (Nilsson 1981). In the 1960’s, the health care system in the USA had encountered numerous problems for example in financing, shortcomings in the organization, and in the ability of health professionals to modify their methods according to new demands (Whitney 1972). The occurrence of medication errors in hospitals received considerable attention both among health professionals, politicians and in the popular press (Nilsson 1981). During these decades, loss of the function of preparing medicines also forced pharmacists to replace this task with new roles.

The new role of the pharmacists evolved and was introduced under the principles of clinical pharmacy. This emphasised more patient-oriented aspects of pharmacy practice and included more responsibility of drug information; medication errors; and monitoring adverse effects of medicines (Francke 1972). It focused on the increased control of drug use and on the role of pharmacists as therapeutic advisors in drug information, drug distribution, teaching and research programs (Hepler 1987).

Clinical pharmacy was initially developed in hospital settings where the pharmacists relocated to medical units to work in closer proximity to the patients (Summers 1996). This was often also a start of closer co-operation with nurses and physicians who had many questions regarding the patient’s medication. A clinical pharmacy program in the hospital was often implemented as a unit dose drug distribution system in which the
drugs were available in single unit packages and medication charts (Tester 1972) documented the drug therapy. The closer co-operation between health professionals was seen as a means to solve medication errors and drug-related problems.

### 3.1.2 Drug Utilization Review

The next step for improving the quality of pharmacy services was to concentrate on the patient’s medication. Drug Utilization Review (DUR) included a systematic, structured and on-going program to review and analyse patient’s drug therapy and drug use (Summers 1996). The aim of the DUR process was to improve patient care through optimal drug therapy and it was regarded as an ongoing process with continuous reiteration and feedback (The United States Pharmacopeial Convention Inc. 1997).

Later, the term Drug Utilization Review has been broadened to cover the activities that increase the appropriateness of drug therapy (The U.S. Pharmacopeia Drug Utilization Review Advisory Panels 2000). It can be differentiated according to timing of the process: prospective DUR which involves a review of each prescription before it is dispensed; concurrent DUR which happens while the patient is undergoing therapy; and retrospective DUR while the patient is receiving the drug or after the patient has completed therapy (The United States Pharmacopeial Convention Inc. 1997).

The value of DUR services has been documented for example in studies where pharmacists have identified prescribing-related problems (Rupp 1992, Rupp et al. 1992). In the USA, the DUR services by pharmacists have to be available for example in Health Maintenance Organisations for Medicaid patients and it has been beneficial there in identifying drug-related problems (Christensen et al. 1981). Cost savings have also been reported as a result of the drug utilization review (Dobie and Rascati 1994).

### 3.2 Pharmaceutical care as an ongoing process to improve pharmacy services

The philosophy of clinical pharmacy moved the pharmacist closer to the patient. The concept of patient-oriented practice, however, was subjected to many different interpretations, some of them emphasised pharmacy practice functions such as control
of drug use or research into biological systems rather than concentrating on individual patients (Hepler and Strand 1990). The introduction of clinical pharmacy had not been able to reduce drug-related morbidity or mortality (Hepler and Strand 1990). The next step in the process was concentrating more on the interaction with the patient. This was introduced as pharmaceutical care mainly in hospital settings. Hepler and Strand (1990) were the first to introduce the concept of pharmaceutical care, in which they emphasised also the responsibility of community pharmacists towards the patient. The balance of pharmacy practice should be shifted away from product and biological factors more to the patient (Summers 1996). It was agreed that a clear emphasis on the patient’s welfare should be seen in pharmacy practice (Hepler and Strand 1990). Hepler and Strand (1990) postulated that pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient’s quality of life. Such outcomes are cure of a disease, elimination or reduction of a patient’s symptomatology, arresting or slowing of a disease process, or preventing a disease or symptomatology (Hepler and Strand 1990).

Pharmaceutical care can be regarded as a systematic approach that gathered together the relevant aspects in quality assurance such as Drug Utilization Review (Angaran 1991, Gitlow and Melby 1991). Pharmaceutical care was considered as a new concept for improving pharmacy services and achieving the desired outcomes in patient management. The provision of pharmaceutical care was not limited to pharmacists in inpatient, outpatient or community settings (American Society of Hospital Pharmacists 1993) or any particular types of medicines. Pharmaceutical care oriented services were also seen to help patients using non-prescription drugs as self-medication (Srnička 1993).

In pharmaceutical care, the pharmacist co-operates with the patient and health care professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient (Hepler and Strand 1990, Hepler and Grainger-Rousseau 1995, American Society of Hospital Pharmacists 1996 and 1999). Hepler and Strand (1990) defined the pharmacist’s major functions when implementing pharmaceutical care as follows (Figure 2):
Figure 2. The major functions of pharmacists when implementing pharmaceutical care (Hepler and Strand 1990).

These were implemented to pharmacy practice as a six-step process (Strand et al. 1991). The steps are:

1. The pharmacist collects and documents relevant information in a systematic, structured manner. The purpose is to determine if the patient is experiencing potential or actual drug-related problems. During this process, the pharmacist is gathering all the information needed in the evaluation of the therapy. Firstly, the pharmacist has to get to know the patient. Pharmacist’s empathy and communication skills are prerequisites for the rapport between a patient and a pharmacist and optimally, the patient ceases to be viewed simply as a case.

2. The pharmacist identifies and lists the drug-related problems. The pharmacist decides how much the problems require attention and identifies and lists the drug-related problems the patient is experiencing or is at risk of experiencing.

3. The pharmacist establishes and lists the therapeutic outcomes. This should be done for each drug-related problem that has been identified. The pharmacist should also identify the successful outcomes. The patient should be respected as a major participant in treatment decisions and the pharmacists should balance the adequate information about the disease with patient management.
4. The pharmacist considers and ranks all the therapeutic interventions that might be expected to produce the desired outcomes. The pharmacist should decide which are the most appropriate alternatives available for resolving the problems. The pharmacist should be able to assess the relative importance of problems and make evidence based decisions.

5. The pharmacist decides which therapeutic alternatives to select. Recording of patient’s dosage regimen for each medication also belongs to this decision. The regimen should meet the pharmacotherapeutic goals established with the patient.

6. The pharmacist formulates and documents a pharmacotherapeutic-monitoring plan to verify that the drug-related decisions implemented have resulted in the desired outcomes. All the solutions agreed by both the pharmacist and the patient must be implemented and monitored. The pharmacist must be willing to re-evaluate the therapeutic plan, when needed.

The philosophy of pharmaceutical care launched by Hepler and Strand (1990) provoked a worldwide discussion. Pharmacists and their advocates mostly agreed the statements of the pharmacist’s responsibility of patient’s drug therapy. Debates of the meaning of the concept of pharmaceutical care, instructions for getting started and marketing of pharmaceutical care based services were published (Penna 1990). Theoretical models about the levels and needs of pharmaceutical care were established (Smith and Benderev 1991, Strand et al. 1991). The influence of pharmaceutical care to the educational needs of pharmacists was discussed (Galinsky and Nickman 1991, Speedie 1992, Becker and Schafermeyer 1993).

Pharmaceutical organizations soon accepted the idea of pharmaceutical care as a part of their recommendations of the contents of pharmacy practice. The American Society of Hospital Pharmacists (ASHP) made their own statements of the principal elements of pharmaceutical care in practice (American Society of Hospital Pharmacists 1996 and...
International Pharmaceutical Federation (FIP) acknowledged pharmaceutical care as a part of good pharmacy practice in 1993 (International Pharmaceutical Federation 1993). These guidelines have also been updated frequently.

However, pharmaceutical care is not a procedure that could be established only in one structured way. There is no one way to practice it. All the activities of pharmacists to take a responsibility for helping patients manage their disease and drug therapy can be regarded as pharmaceutical care. Establishing guidelines step by step and documenting them help in verifying the pharmaceutical care process.

### 3.2.1 Pharmaceutical care versus traditional drug dispensing

Pharmaceutical care differs from the traditional dispensing because it focuses more on achieving the desired outcomes in drug treatment. In traditional dispensing, the pharmacists focus more on dispensing instead of the patient’s needs. The differences between these two approaches are illustrated in Table 1.

Table 1. Differences between traditional dispensing and pharmaceutical care (Hepler and Strand 1990, Strand et al. 1991).

<table>
<thead>
<tr>
<th>Traditional drug dispensing</th>
<th>Pharmaceutical care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus on dispensing the medicine</td>
<td>Focus on patient’s management and outcomes with the drug treatment</td>
</tr>
<tr>
<td>Patient’s education and counselling concentrate on technical advice</td>
<td>In addition with technical advice, the pharmacist is training the patient to practice the drug treatment in every day life</td>
</tr>
<tr>
<td>No monitoring of the outcomes of the drug treatment</td>
<td>The pharmacist is finding methods to monitor the outcomes of the drug treatment</td>
</tr>
<tr>
<td>Drug-related problems will emerge if the patient tells about them</td>
<td>The pharmacist is actively and systematically identifying possible problems in drug treatment</td>
</tr>
<tr>
<td>No responsibility for the drug treatment</td>
<td>The pharmacist takes responsibility that the desired outcomes of the drug treatment will be achieved</td>
</tr>
</tbody>
</table>
In traditional dispensing, the pharmacist will consult with the physician mainly on technical problems: e.g., prescription errors. In pharmaceutical care, the service has become extended: there are more connections, consultations and feedback between pharmacists, physicians, nurses and patients. The pharmacist intentionally and systematically tries to identify, solve and prevent all possible drug-related problems. The outcomes are monitored in cooperation with the patient and the physician. Providing feedback both to the patient and the physician also is a major part of pharmaceutical care.

When possible, pharmacists can make conclusions on the basis of medication-, disease-, patient- and also laboratory test-specific information (American Society of Hospital Pharmacists 1996). They can also use checklists, work sheets, computer programs or other methods when determining and documenting the presence of medication-therapy problems (Rogers et al. 1994, McCallian et al. 1996, McDonough 1996, Rahimtoola et al. 1997, Wood et al. 1998). It is easier to practice pharmaceutical care when the pharmacists are able to use all of the available patient’s medical information. For example, in the USA, the federal legislation, in particular the Omnibus Budget Reconciliation Act of 1990 (OBRA’90) established new patient-based standards for pharmacists including making prospective drug use reviews, maintaining patient drug profiles and documenting pertinent information (Christensen and Penna 1995). In Europe, for example in the United Kingdom, the pharmacists create patient medication records (PMRs) to assure appropriate medication (Rogers et al. 1994). Since 1990, almost all Dutch pharmacies have had computer systems that maintain patient medication data and perform medication analysis (van Mil 1999).

In Finland, community pharmacists are not able to use patients’ medication records or health records when assessing drug therapy. This does not hinder implementing the practice according to pharmaceutical care. Instead of medication records, community pharmacists can use prescriptions as a tool in identifying the drug-related problems. Conclusions will be drawn on the patient’s therapeutic needs and possible problems on the basis of prescriptions and discussions with the patient. Pharmacists can estimate the adequacy and the appropriateness of the medications and screen prescriptions for interactions. Pharmacists can also make conclusions according to the refilling days of
prescriptions and see if there is over- or underuse, or if the patient has taken medicines according to physician’s instructions. Discussions with the patient will give pharmacists more information about drug use and pinpoint any possible problems.

### 3.2.2 Therapeutic Outcomes Monitoring and its applications

The Therapeutic Outcomes Monitoring (TOM) protocol was developed in the USA, in the University of Florida (Hepler 1997) and it can be considered as a tool of pharmaceutical care. According to the principles, the TOM protocol gives instructions for a pharmacist to identify therapeutic objectives, monitor patient progress, identify potential problems and resolve them (Hepler 1997). The TOM idea has four main strategic concepts (Hepler 1997). Firstly, it provides clear standards of practice through practice guidelines and documentation. The TOM concept consists of modules that contain background information on diseases and drug therapy for pharmacists. Secondly the focus of TOM-modules is the treatment protocol with training programs for pharmacists. Thirdly, the goal of the TOM is to create pharmaceutical care systems in community practice and fourthly, the TOM protocol focuses on co-operation between health professionals in patient drug therapy and management.

Hepler (1997) described that the steps of Therapeutic Outcomes Monitoring are identical with the ones in pharmaceutical care including collecting and recording of patient information, assessing and designing therapeutic and monitoring plans and implementing the monitoring plan (Figure 3). Therapeutic Outcomes Monitoring activities may include diagnostic or prescriptive process that are performed by a physician. These processes also begin with recognising and evaluating the possible problems in patient management. Assessing the problems leads to creation of a therapeutic plan that should be made in co-operation with the patient. Implementation of the therapeutic plan may lead to a prescription by a physician, which means that the patient will once again co-operate with the pharmacists.
Figure 3. Therapeutic Outcomes Monitoring in a pharmaceutical care system (Hepler 1997). The three steps of a prescribing process are illustrated in the loop at the top-right. The steps labelled “S”, “O”, “A” and “P” represent the diagnostic and prescriptive process e.g. the portion which may be performed by a physician. The loop at the bottom is describing the steps of pharmaceutical care process using TOM as a tool.

Therapeutic Outcomes Monitoring (TOM) is a disease-based system and there are already modules available for asthma and diabetes mellitus (Segal 1997). This idea of a disease specific Therapeutic Outcomes Monitoring was adopted to Europe for improving pharmacy services. EURO-TOM is an European collaboration to implement a model for Therapeutic Outcomes Monitoring in asthma treatment. The collaboration was established with EuroPharm Forum (EURO-TOM 1994). The participating
countries signed an agreement with the University of Florida for securing the TOM-concept and all the national manuals were based on this same manual. The project started in 1994 in Denmark, Iceland, the Netherlands and the Great Britain. Subsequently Malta, Northern Ireland, Iceland, Germany, Norway and Belgium have also participated.

Van Mil (1999) has reported the implementation of TOM protocol to asthma patient’s management in the Netherlands. At the beginning of the study, there were 191 patients recruited, but due to a large drop out, only 70 patients continued until the end of the study. Control patients were divided to internal reference (n=129) and external reference (n=81) groups and they did not receive any enhanced pharmaceutical services during the study. The patients in the intervention group received education about asthma, drug and non-drug management and the self-management of asthma over a period of 24 months. The analysis of the results showed that in the intervention group there were no statistically significant changes in patient management, e.g. quality of life. However, more patients started to use a peak-flow meter and became involved in self-management. The number of short courses of antibiotics and oral corticosteroids, and the use of reliever medication in the intervention group decreased. Although the general picture of the results was positive, the changes were not statistically significant.

In a Danish TOM study, there were 264 intervention and 236 control patients (Herborg et al. 1996). The patients were educated about asthma and medication by the pharmacists. They also evaluated and monitored patients drug using and drug therapy and gave instructions in self-monitoring and self-regulation of medicines (Appendix 1). As clinical outcomes, patients asthma status improved 12% and asthma morbidity decreased by 3.2 days. There was a 34% improvement in patient quality of life and a 27% improvement in patient knowledge about asthma. Also the inhalation technique that was used improved.

Finland implemented the Therapeutic Outcomes Monitoring idea with an ASTHMA-TOM programme that begun in 1996. This programme was based on the Danish protocol and their experiences have been used when developing the Finnish version of the Therapeutic Outcomes Monitoring. The programme and the results are reported in this presentation.
4 DIMENSIONS OF OUTCOMES

The goal of pharmaceutical services is to improve the patient’s quality of life. This produced a need to evaluate the outcomes that should be measured. Measures for evaluating changes in patient health or quality of life can be divided to economic, clinical and humanistic outcomes and these have also been used in community pharmacy interventions (Smith and Wertheimer 1996).

4.1 Economic outcomes

Economic outcomes establish the “value for money” and include assessment of both inputs and outcomes. The inputs or resources consumed include the direct costs of providing care (the direct medical costs e.g. costs of drugs and the direct non-medical costs e.g. transportation costs), the indirect costs (e.g. production losses due to patients being off work due to illness) and the intangible costs (e.g. pain or suffering associated with therapy) (Kobelt 1996). When counting the total costs, the assessment of the economic outcomes should include identifying the relevant resources, quantifying these resources in physical units, valuing the different resources used and dealing with uncertainty in time (discounting) (Kobelt 1996). An often used measure is an opportunity cost which express as the value of the alternative endeavours that might have been undertaken with the same resources (Luce and Elixhauser 1990). In community pharmacy interventions, the economic impact is often based simply on the costs that are saved by the pharmaceutical work or intervention. Other measured economic outcomes include number of hospital admissions and medical contacts or freed physician time, decreased costs in health care or in medication, improved quality of care and decreased needs of physicians to refer their patients to specialists (Chriscilles et al. 1984a, Chriscilles et al. 1984b, Reeder et al. 1995).
4.2 Clinical outcomes

Clinical outcomes can be considered as all of the medical events that occur as a result of a disease or a treatment (Smith and Wertheimer 1996). They have traditionally been considered as changes in a patient’s health that can be measured clinically. However, there is not a single definition for clinical outcomes, and many kinds of measures can be used when evaluating them (Smith and Wertheimer 1996). Clinical outcomes include for example measuring serum drug levels, blood pressure, blood glucose and cholesterol levels used in evaluating the health status. Clinical outcomes are usually expressed as numbers. It is simple to use laboratory test and obtain a clear idea of improvements or decrements in patient’s health. It is also crucial to evaluate which are the useable and appropriate outcomes for the intervention, because results may vary according to chosen outcomes. For example in a quit smoking campaign it depends on one’s perspective what should be considered as the more relevant outcome: number of participants who try to quit smoking or decreased incidence of lung cancer. When evaluating the pharmacy services, patients suffering from asthma, diabetes or hypertension have mostly been used as study subjects, because changes in clinical outcomes can be easily measured.

4.3 Humanistic outcomes

Humanistic outcomes measure the effects of medical care on the physical, social, and emotional well being of the patient. Quality of life is one of the most important humanistic outcomes. There have been several attempts to develop and validate measures for quality of life (Kong and Gandhi 1997). It has been measured for example by disease-specific or general instruments (Bungay et al. 1996).

General instruments include large health profiles and utility-based instruments. They are used to give information about the impact of the condition on patient’s general function and well being (Bungay et al. 1996). Health profiles are quality-of-life scales that are based on the theory that there is a true quality-of-life value that cannot be measured directly. It can be assessed indirectly by asking a series of questions as
“items”, each of which measures one construct of the whole quality of life (Testa and Simson 1996). These assessments usually include physical functioning, social and role functioning, mental health, and perception of general health components (Bungay and Wagner 1995). One of the most used health profile scales is the Nottingham Health Profile, which consists of scales that measure the distress of the patient (Hunt et al. 1981, Koivukangas et al. 1995). In some community pharmacy studies, general health profiles have been used, though these are not used widely (Grainger-Rousseau and McElnay 1996, Jaber et al. 1996, Carter et al. 1997). Also self-made ad hoc scales have been used when measuring patient satisfaction with pharmacy services (Herborg et al. 1996). These instruments have not usually been validated.

Disease-specific instruments are intended to provide information about particular outcomes and they are used specifically. One example is an Asthma Quality of Life Questionnaire (Juniper et al. 1993) which defines asthma patients’ satisfaction with the treatment.

Later, patient satisfaction was admitted as an integral component of the measurement of medical care quality and it has been added as an outcome itself. It is not just a consequence of outcomes, but it can be categorised as a humanistic outcome (Smith and Wertheimer 1996). Patient satisfaction with community pharmacy services can also be used as a relevant measure for evaluating the pharmacy practice (Smith and Wertheimer 1996).

4.4 The ECHO model

The ECHO model was one of the very first attempts to measure economic, clinical and humanistic outcomes into a single entity (Kozma et al. 1993). It is a theoretical model that explains a causal relationship between diseases, patient outcomes, and medical care interventions. The “value” of treatment alternatives is multidimensional. The ECHO model widens the traditional model of decision making away from the restricted viewpoint which considered that the value of treatment could be measured only via clinical outcomes.
Clinical indicators, which are used for selecting the treatment alternatives, are surrogates for clinical outcomes. Clinical outcomes and indicators may also be affected by “treatment modifiers”, which include factors for example related to patient compliance or provider/patient relationship (Kozma et al. 1993). Thus, ECHO-model adds a systematic evaluation of humanistic and economic outcomes to the traditional medical decision-making model (Kozma et al. 1993).

The model also strives to solve the traditional problem of perspective in outcome research. No analysis should focus on only one or two of the dimensions. The value of the ECHO-model is that it attempts to assess all of these dimensions at the same time – they all should be taken into account in the decision making process.

When evaluating the results, it depends on one’s perspective what consequences can be considered as measured outcomes (Kozma 1995). The effectiveness of a drug used by a patient can be considered as an outcome. From a wider perspective, outcomes could be the number of individuals who suffer strokes or changes in functional status (Kozma 1995). The clinician is looking for changes in physiological parameters, while the patient usually concentrates on relief of symptoms (Lipowski 1996). Economic evaluations provide their own perspective on outcomes measuring.

### 4.5 Process outcomes

An advantage of the ECHO model is that it puts all three important dimensions of outcomes together to facilitate decision making. One disadvantage is that it does not consider any other outcomes. For example, it does not consider the process or process outcomes of the care. However, pharmaceutical work includes different kinds of processes: steps taken when dispensing prescription medicines or selling non-prescription medicines, correcting prescription errors and monitoring patient medication for potential drug interaction. These processes help patients to achieve the best possible outcome from the medication. It is not, however, possible to categorise the impact of any single process directly on the clinical, economic or humanistic outcomes. They can be considered as process outcomes that contribute to improvements in the final definite outcomes assessment.
Holdford and Smith (1997) suggested that process and structure measures may be appropriate for use in outcome studies in pharmacies when
1. the outcome that has been chosen lacks a valid or reliable measurement method
2. measurement of the outcome is not economically or logistically possible
3. the outcome of interest is far removed from the process
4. the process or structure measures are closely associated with outcomes
All these principles can be recognised in the community pharmacy practice.

Changes in patients’ knowledge levels as well as improvements in patients’ attitudes with respect to their disease or management and improvements in adherence to guidelines can be considered as process outcomes (Holdford and Smith 1997). Improvements in patient compliance can also be categorised as process outcomes. These changes are not real endpoints, but they can lead to improvements in clinical, economic or humanistic outcomes.
5 OUTCOMES RESEARCH IN COMMUNITY PHARMACIES

The goal of the outcome research is to determine the value of services on the basis of their relative impact on health outcomes (Holdford and Smith 1997). The purpose of outcome research is to support outcome management that strives to improve health or quality of life (Reeder et al. 1995). In community pharmacy practice, the purpose of outcome research is to improve or find new pharmaceutical service process that can improve patient outcomes. Outcome research will also serve as a tool in decision making by giving information of the value of different interventions. In drug therapy, the outcomes are related to successful drug treatment and patient satisfaction.

The pharmaceutical care interventions describe changes in patients’ health or quality of life or changes in economic outcomes as a result of the pharmacist’s extended services. Interventions of process outcomes have mostly measured the effect of pharmacist’s counselling, correcting prescribing errors and making prescription interventions (Rupp et al. 1988, Rupp et al. 1992). In this presentation, the outcomes related to counselling on equipment use such as inhalation devices were excluded.

The aim of this section is to introduce some of the outcomes that have been measured in community pharmacy interventions. Studies were selected through MEDLINE and IPA (International Pharmacy Abstracts) databases during 1985-2000 with key words outcome* and community pharm* (Table 2). References from the articles that were found were also searched to find more reports on interventions.

Specific criteria for selecting the interventions were:
1. the services were provided by pharmacists in community pharmacies or in other ambulatory settings
2. the intervention was done by community pharmacists or by outpatient pharmacists

The criteria for exclusion were:
- the interventions were conducted in hospital or institutional settings
- the intervention was not published in scientific journals (i.e. symposium publications)
- the article was not published in English
- the outcomes were not measured in the intervention
- the study was conducted as a descriptive study with no measurements at the baseline
- intervention was not pharmacist directed

Table 2. Articles included in the review.

<table>
<thead>
<tr>
<th>A database</th>
<th>Number of articles with search term “outcome* and community pharm*”</th>
<th>Number of articles after exclusions</th>
<th>Articles included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medline</td>
<td>96</td>
<td>10</td>
<td>Ibrahim et al. 1990</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rupp et al. 1992</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Grainger-Rousseau and McElnay 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sclar et al. 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Shibley and Pugh 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carter et al. 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Berringer et al. 1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hawksworth et al. 1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bluml et al. 2000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nola et al. 2000</td>
</tr>
<tr>
<td>IPA</td>
<td>223</td>
<td>2</td>
<td>Donaldson et al. 1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Caleo et al. 1996</td>
</tr>
<tr>
<td>Articles found by following pharmaceutical journals</td>
<td>16</td>
<td></td>
<td>Watman and Harris 1986</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rupp et al. 1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dobie and Rascati 1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Berardo et al. 1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Poston et al. 1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Van Veldhuizen-Scott et al. 1995</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Loh et al. 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Herborg et al. 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Park et al. 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Jaber et al. 1996</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Fincham and Gottlob 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Munroe et al. 1997</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Knapp et al. 1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Knoell et al. 1998</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Westerlund et al. 1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rodgers et al. 1999</td>
</tr>
</tbody>
</table>

5.1 Context of the intervention studies with patients

One of the studies was done in a chain pharmacy (Park et al. 1996) and two of the studies were done in outpatient clinics (van Veldhuizen-Scott et al. 1995, Jaber et al. 1996). The setting was not clearly reported in one of the studies (Knoell et al. 1998). All
the other studies were done in privately owned community pharmacies. Most of the study pharmacies were not reimbursed for the time or resources used during the study or there was no mention about any reimbursements. In a Danish study Herborg et al. (1996) explained that pharmacies received reimbursements for the time spent on the project.

5.1.1 Content of pharmaceutical work in the interventions

In community pharmacy based interventions, the pharmacist were educating (e.g. taught how to use equipment, how to take the medicine and to adjust the medication according to symptoms) the patient and monitoring the outcomes of the therapy (e.g. checking patient's current satisfaction and symptoms). The pharmacists also solved drug-related problems. In addition to subjective monitoring, the pharmacists carried out laboratory tests (e.g. cholesterol, blood sugar) and measured blood pressure, peak flow rate, weight, pulse, and respiratory rate during the intervention. Usually the pharmacists developed the education or monitoring guidelines in conjunction with general practitioners. They also made recommendations on drug therapy.

The training of pharmacists prior to the intervention was reported in five of the studies (Shibley and Pugh 1997, Carter et al. 1997, Munroe et al. 1997, Berringer et al. 1999, Bluml et al. 2000, Table 3). Usually, the training started with the fundamental facts and information about the disease, medication and management. This was supplemented by training on pharmaceutical care in practice, a review of the skills needed in interviewing the patient and in counselling. Only one of the studies reported training on clinical monitoring. As a whole, not much time was spent on training of the pharmacists and there was no estimation of the adequacy of the training.

Time devoted to consultations with the patients varied in the studies (Table 3). The first consultation was usually the longest: from 15 to 40 minutes and the others lasted about 15 minutes. In a Danish study Herborg and her colleagues (1996) calculated that the time spent for other work than patient consultations which were for telephone consultations 9.5 minutes/consultation, for reports 34 minutes and for additional paperwork six hours/month.
Table 3. Preparation of the pharmacists to the interventions (time spent on training and contents of the training) and pharmacist’s time spent on sessions with patients during the intervention.

<table>
<thead>
<tr>
<th>Study (the country)</th>
<th>Training before the study (days/hours)</th>
<th>Contents of training</th>
<th>Pharmacist’s time (minutes) spent on sessions with a patient (the first/other consultations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herborg et al. 1996 (Denmark)</td>
<td></td>
<td></td>
<td>40.5</td>
</tr>
<tr>
<td>Park et al. 1996 (USA)</td>
<td></td>
<td></td>
<td>30.7/14.6-19.9</td>
</tr>
<tr>
<td>Shibley and Pugh 1997 (USA)</td>
<td>Part time basis for 3 months before the study</td>
<td>Review on the basics of the disease; discussions about medication selection and monitoring; staged patient interviews and patient education sessions to practice the technique; teaching and developing the study protocol</td>
<td></td>
</tr>
<tr>
<td>Carter et al. 1997 (USA)</td>
<td></td>
<td>Problem solving; practising the experiment</td>
<td></td>
</tr>
<tr>
<td>Munroe et al. 1997 (USA)</td>
<td></td>
<td>Review of the basics of the diseases; physical assessment and communication skills; basics of clinical monitoring and laboratory procedures</td>
<td>15-20</td>
</tr>
<tr>
<td>Knoell et al. 1998 (USA)</td>
<td></td>
<td></td>
<td>30-60</td>
</tr>
<tr>
<td>Berringer et al. 1999 (USA)</td>
<td></td>
<td>Training in disease therapy</td>
<td></td>
</tr>
<tr>
<td>Bluml et al. 2000 (USA)</td>
<td>2.5 days</td>
<td>According to the program of the national pharmacy association</td>
<td>30-60 (mean 45)/ 10-30(mean 22)</td>
</tr>
</tbody>
</table>
5.1.2 Evaluation designs

The interventions were done with patients suffering from asthma (Watman and Harris 1986, Herborg et al. 1996, Grainger-Rousseau and McElnay 1996, Knoell 1998), diabetes (Jaber et al. 1996, Berringer et al. 1999), hypertension (van Veldhuizen-Scott et al. 1995, Park et al. 1996, Carter et al. 1997), or hypercholesterolemia (Ibrahim et al. 1990, Shibley and Pugh 1997, Bluml et al. 2000, Nola et al. 2000). One of the studies had patients suffering from hypertension; diabetes, asthma or hypercholesterolemia in the same study (Munroe et al. 1997). The evaluation designs, study periods and measuring points, study populations and interventions by community pharmacists in patient intervention studies are presented in Table 4. Classification of the evaluation designs has been done according to Øvretveit (1998).
Table 4. Evaluation designs, study populations, and interventions of the studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Study population (study period – measurement points)</th>
<th>Intervention</th>
<th>Main outcome measures used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised controlled</td>
<td>Park et al. 1996 (USA) 27 patients, 26 controls</td>
<td>Patient education and monitoring of drug therapy and compliance, recording heart rate and blood pressure, screening for drug interactions and adverse drug reactions</td>
<td>Mean systolic and diastolic blood pressures, number of normotensive patients and stages of hypertension, quality of life, compliance with prescribed therapy, recommendations to physicians and patients</td>
</tr>
<tr>
<td>experimental</td>
<td>(7 months; no scheduled visits)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaber et al. 1996 (USA)</td>
<td>17 patients, 22 controls (4 months; before-after)</td>
<td>Patient education and counselling, evaluation of medication, instructions about diet, exercise plan, training for self-monitoring</td>
<td>Fasting plasma glucose, glycated hemoglobin, blood pressure, serum creatinine, creatinine clearance, microalbumin to creatine ratio, cholesterol values, quality of life</td>
</tr>
<tr>
<td>Carter et al. 1997 (USA)</td>
<td>25 patients, 26 controls (6 months; blood pressure monthly, others before-after)</td>
<td>Patient education and outcomes monitoring with hypertension, identifying drug-related problems</td>
<td>Blood pressure measured by physicians and pharmacists, quality of prescribing, quality of life, patient satisfaction, cost analysis</td>
</tr>
<tr>
<td>Nola et al. 2000 (USA)</td>
<td>25 patients, 26 controls (6 months; pretest, midpoint, posttest)</td>
<td>Patient education and counselling of the disease, medication and lifestyle, monitoring of cholesterol levels, evaluation of the medication</td>
<td>Total cholesterol, low-density- and high-density lipoprotein cholesterol, triglyceride levels, risk factor prediction scores, patient satisfaction with pharmaceutical care, patients’ knowledge of hyperlipidemia.</td>
</tr>
<tr>
<td>Study</td>
<td>Authors</td>
<td>Country</td>
<td>Participants</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
<td>---------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Before-After</strong></td>
<td>Watman and Harris 1986</td>
<td>Great Britain</td>
<td>106 patients</td>
</tr>
<tr>
<td></td>
<td>Ibrahim et al. 1990</td>
<td>USA</td>
<td>51 patients</td>
</tr>
<tr>
<td></td>
<td>Van Veldhuizen-Scott et al. 1995</td>
<td>USA</td>
<td>10 patients (group I), 11 control patients with group intervention (group II) and 11 control patients with personal intervention (group III) (2 months; weekly measure points)</td>
</tr>
<tr>
<td></td>
<td>Herborg et al. 1996</td>
<td>Denmark</td>
<td>264 patients, 236 controls (1 year; before-after)</td>
</tr>
<tr>
<td></td>
<td>Munroe et al. 1997</td>
<td>USA</td>
<td>188 patients suffering from hypertension, diabetes, hypercholesterolemia or asthma, 401 controls (17 months; before-after)</td>
</tr>
<tr>
<td></td>
<td>Knoell et al. 1998</td>
<td>USA</td>
<td>45 patients and 55 controls suffering from asthma (45 days; before-after)</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Outcomes</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td><strong>Before-After, patients serving as their own controls</strong></td>
<td>152 patients (6 months; 2 months baseline phase with 3 assessments and 6 months treatment phase with 3 assessments)</td>
<td>Group I: no intervention; Group II: education only (use of inhaler devices, advice on asthma medication and on asthma pathology); Group III: monitoring only (advice on the use of PEF and on interpretation of PEF charts); Group IV: monitoring and education</td>
<td>Pulmonary function tests, quality of well-being, symptom control, inhaler technique, medication profiles</td>
</tr>
<tr>
<td>Grainger-Rousseau and McElnay 1996 (Northern-Ireland)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shibley and Pugh 1997 (USA)</td>
<td>25 adults with confirmed dyslipidemia (1 year; baseline 6, 12 months)</td>
<td>Patient education and counselling, drug therapy recommendations to physicians, feedback to physicians</td>
<td>Fasting lipoprotein profiles at 6 and 12 months, quality of life, patients satisfaction and opinions on the role of a pharmacist</td>
</tr>
<tr>
<td>Berringer et al. 1999 (USA)</td>
<td>52 diabetics (1 year; baseline, 6, 12 months)</td>
<td>Evaluation of current drug therapy, identifying drug-related problems, recommendations to patients and physicians</td>
<td>Self-monitored blood glucose, medication adherence, recommendations to patients and physicians</td>
</tr>
<tr>
<td>Bluml et al. 2000 (USA)</td>
<td>397 patients (an average 24.6 months; beginning, midpoint, ending)</td>
<td>Patient education and counselling, assessing for the therapy, feedback to physicians</td>
<td>Rates of patient persistence and compliance, total cholesterol, triglycerides, high-density lipoproteins, low-density lipoproteins</td>
</tr>
</tbody>
</table>
Most of the studies can be called experimental, because the design is a “classic” evaluation design with measurements in study and in control groups (Øvretveit 1998). More than half of these studies had a control group, and in the rest of the studies, the study patients served as their own controls. Instead of a control group, Ibrahim et al. (1990) used a group of patients who did not fulfil the inclusion criteria but suffered from the same disease. In the study of Watman and Harris (1986), the groups were crossed over after one year.

The before-after evaluation design can be used when measuring the differences that the intervention makes to the target (Øvretveit 1997). Most of the reviewed studies had a before-after design with measurements also during the study. Four of the studies had a before-after evaluation design with no control group i.e. patients were serving as their own controls. Twelve of the studies used measurements only before and after the study (Ibrahim et al. 1990, Grainger-Rousseau and McElney 1996, Herborg et al. 1996, Jaber et al. 1996, Park et al. 1996, Munroe et al. 1997, Carter et al. 1997, Shibley and Pugh 1997, Knoell et al. 1998, Berringer et al. 1999, Bluml et al. 2000, Nola et al. 2000) and eight of them included measurements also during the intervention (Ibrahim et al. 1990, Grainger-Rousseau and McElney 1996, Herborg et al. 1996, Park et al. 1996, Shibley and Pugh 1997, Berringer et al. 1999, Bluml et al. 2000, Nola et al. 2000).

Interventions were mostly done according to pharmaceutical care procedure, consisting enhanced education and counselling, and outcomes monitoring by community pharmacists. Pharmacists identified drug-related problems and resolved them usually in co-operation with other health professionals. The outcome measures were mostly quantified by laboratory screenings.

The study patients were mostly recruited as a convenience sample from pharmacy customers (Ibrahim et al. 1990, Herborg et al. 1996, Park et al. 1996, Shibley and Pugh 1997, Bluml et al. 2000). In three of the studies, a prescription database in the pharmacy was used at least partly as the basis of enrolment (Grainger-Rousseau and McElney 1996, Berringer et al. 1999, Nola et al. 2000). The study patients had also been recruited from an outpatient clinic (van Veldhuizen-Scott et al. 1995, Jaber et al. 1996, Carter et al. 1997, Knoell et al. 1998), on the basis of data from health insurance company (Munroe et al. 1997) and from a health facility (Watman and Harris 1986).
Participants were selected by pharmacists, by physicians or both. One of the studies used insurance claim data; thus the patients had to be insured by a certain company (Munroe et al. 1997). Inclusion criteria for patients were the disease, age, the medication, a patient not institutionalised, patient’s ability to return to the pharmacy for follow-ups, the possibility of clinical improvements, patients not receiving counselling from any other sources or patients willingness to participate. These criteria depended on the study design or the disease. The inclusion criteria were not mentioned in one of the studies.

Most of the studies had rather few study patients, varying from 17 to 264. There were 397 patients in the observational based before-after designed study of Bluml et al. (2000). The medication histories of patients were collected via interview of the patients by pharmacists or by pharmacists and physicians.

The shortest study lasted for 45 days and the longest for 24.6 months. Three of the studies lasted for a one year period (Herborg et al. 1996, Shibley and Pugh 1997, Berringer et al. 1999) and five of the studies (Ibrahim et al. 1990, Grainger-Rousseau and McElnay 1996, Park et al. 1996, Carter et al. 1997, Nola et al. 2000) lasted for six to seven months. There was only one study lasting more than a one-year study period (Bluml et al. 2000) and there was no information about the time in one of the studies (Watman and Harris 1986).

5.1.3 Results

Clinical outcomes of the community pharmacy studies had been mainly positive, but there were exceptions (Table 5). There were studies reporting no improvements during the intervention. Most of the changes in clinical outcomes had been measured and verified by laboratory tests or measurements (Ibrahim et al. 1990, van Veldhuizen-Scott et al. 1995, Park et al. 1996, Shibley and Pugh 1997, Carter et al. 1997, Berringer et al. 1999, Nola et al. 2000, Bluml et al. 2000).

In studies with asthma patients, there were improvements in patients’ asthma status and a decrease in asthma morbidity (Herborg et al. 1996). No statistically significant differences were found in PEF levels, pulmonary functions or asthma symptoms during
the intervention compared to the baseline (Watman and Harris 1986, Herborg et al. 1996). The improvements with diabetes patients also were not so clear. Some improvements had been reached with clinical outcomes among hypertensive patients. With patients suffering from elevated cholesterol levels, there was a statistically significant reduction of cholesterol values in two of the studies but no statistically significant difference in one study.

Economic outcome studies have rarely been successful in demonstrating clear cost savings through community pharmacists’ interventions (Table 5). The average costs per prescription were statistically significantly higher in the intervention group among patients with hypertension, diabetes, asthma and/or hypercholesterolemia (Munroe et al. 1997), and differences in total monthly prescription costs were significantly higher for patients with asthma (Munroe et al. 1996). However, pharmacists’ interventions have been reported to decrease the need for hospitalisation.

It seems that extended work by pharmacists increases the short-term costs but decreases long-term costs. In these estimations for savings of the intervention, one should take into account the possible influence of age, comorbid conditions, and disease severity.

Patients were satisfied with the pharmacy services and the care. They were especially satisfied with the education, counselling and outcomes monitoring by community pharmacists. They requested that pharmacists should continue providing these kinds of services. A positive change on the patients’ opinions of the role of the pharmacists as an educator was reported in two of the studies (van Veldhuizen-Scott et al. 1995, Shibley and Pugh 1997). Also Herborg and her colleagues (1996) reported that the majority of the study patients experienced improved co-operation with the pharmacist.

Outcomes that can be categorised as process outcomes were also documented in some of the interventions. Three studies reported positive outcomes in patients’ knowledge levels (van Veldhuizen-Scott et al. 1995, Herborg et al.1996, Nola et al. 2000). Also some improvements in patient compliance were documented during the interventions (Park et al. 1996). As a positive process outcome, a statistically significant increase in assessment of adverse reactions was found in the study group compared to the controls.
(Carter et al. 1997). Significantly more asthma patients made PEF measurements in the study group compared to the controls (Knoell et al. 1998).

The physicians usually approved pharmacists’ recommendations about the medication. The rates of acceptance varied from 53% to 90% (Grainger-Rousseau and McElray 1996, Park et al. 1996, Berringer et al. 1999).
Table 5. The most important economic, clinical and humanistic outcomes of the community pharmacy interventions reviewed.

<table>
<thead>
<tr>
<th>Study</th>
<th>Main outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct economic outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grainger-Rousseau 1996 (Northern Ireland)</td>
<td>Hospitalisation</td>
<td>No statistically significant differences</td>
<td></td>
</tr>
<tr>
<td>Munroe et al. 1997 (USA)</td>
<td>Monthly medical costs</td>
<td>Average costs per prescription were statistically significantly higher in the intervention group. Estimated savings ranged $143.95-$293.39 per patient per month in long term.</td>
<td>Savings were estimates accounting for the possible influence of age, comorbid conditions and disease severity</td>
</tr>
<tr>
<td>Carter et al. 1997 (USA)</td>
<td>Mean charges for hypertension-related services</td>
<td>Statistically significantly higher in the study group</td>
<td></td>
</tr>
<tr>
<td>Knoell et al. 1998 (USA)</td>
<td>Physician visits, hospitalisations, emergency department visits, drugs</td>
<td>No statistically significant differences</td>
<td></td>
</tr>
<tr>
<td><strong>Indirect economic outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watman and Harris 1986 (Great Britain)</td>
<td>Days out of school or work, GP consultations</td>
<td>Decrease depending on age</td>
<td>No information about statistical significances</td>
</tr>
<tr>
<td>Knoell et al. 1998 (USA)</td>
<td>Days out of school or work</td>
<td>No statistically significant differences</td>
<td></td>
</tr>
<tr>
<td><strong>Clinical outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jaber et al. 1996 (USA)</td>
<td>Glycated hemoglobin, fasting plasma glucose Blood glucose values</td>
<td>Statistically significant improvements</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Van Veldhuizen-Scott 1995 (USA)</td>
<td></td>
<td>Statistically significant lower average weekly blood glucose values with control patients. Increased percentage of normoglycemic episodes and a decreased percentage of hyperglycaemic episodes. No statistically significantly difference in net percentage change in blood glucose. No statistically significant reduction in self-monitored blood glucose values or frequency</td>
<td></td>
</tr>
<tr>
<td>Berringer et al. 1999 (USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Methodology</td>
<td>Findings</td>
<td>Condition</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Watman and Harris 1986 (Great Britain)</td>
<td>PEF measurements, Pulmonary function testing, symptom score evaluation</td>
<td>No differences, No statistically significant differences</td>
<td>Asthma</td>
</tr>
<tr>
<td>Grainger-Rousseau and McElnay 1996 (Ireland)</td>
<td>Asthma status, Peak-flow of the day, Asthma morbidity, Asthma symptoms</td>
<td>+12%, No change, 3.2 days less, No statistically significant differences between patients and controls</td>
<td>Asthma status not mentioned</td>
</tr>
<tr>
<td>Herborg et al. 1996 (Denmark)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knoell et al. 1998 (USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Park et al. 1996 (USA)</td>
<td>Blood pressure</td>
<td>Statistically significant decrease, Statistically significant decrease (systolic at 6 months, diastolic at 2.4 and 5 months)</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Carter et al. 1997 (USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibrahim et al. 1990 (USA)</td>
<td>Total cholesterol and low-density lipoprotein cholesterol values</td>
<td>Statistically significant decrease in mean total blood cholesterol concentrations between visits 1 and 2 and between visits 1 and 3</td>
<td>Patients with confirmed dyslipidemia</td>
</tr>
<tr>
<td>Nola et al. 2000 (USA)</td>
<td>Total cholesterol, low-density lipoprotein cholesterol, triglyceride levels</td>
<td>No statistically significant differences, Statistically significant decrease in total cholesterol, triglycerides and low-density lipoproteins, Statistically significant increase in high-density lipoproteins</td>
<td></td>
</tr>
<tr>
<td>Bluml et al. 2000 (USA)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Humanistic outcomes</td>
<td>Quality of life, Asthma related quality of life</td>
<td>+34%, +12%</td>
<td>Quality of life</td>
</tr>
<tr>
<td>Herborg et al. 1996</td>
<td></td>
<td>The scales used were not mentioned</td>
<td></td>
</tr>
<tr>
<td>Park et al. 1996</td>
<td>Quality of life</td>
<td>Statistically significant increase in the energy/fatigue scale</td>
<td>The scales used: The Health Status Questionnaire 2.0 and The Hypertension/Lipid Form 5.1 Quality of well-being scale</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Study Title</td>
<td>Findings</td>
<td>Measuring Instrument</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------</td>
<td>----------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Grainger-Rousseau and McElnay 1996</td>
<td>Jaber et al. 1996</td>
<td>No statistically significant changes</td>
<td>Health Status Questionnaire 2.0</td>
</tr>
<tr>
<td>Carter et al. 1997</td>
<td></td>
<td>No statistically significant changes</td>
<td>SF-36 as a scale</td>
</tr>
<tr>
<td>Carter et al. 1997</td>
<td>Nola et al. 2000</td>
<td>Statistically significant improvements within study patients in physical functioning, physical role limitations, and bodily pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Study patients were more satisfied (significance in some items)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No differences between treatment and control groups, except the study patients considered pharmacists more approachable and requested the health care system to enable the pharmacists to continue with these pharmacy services</td>
<td></td>
</tr>
<tr>
<td>Knoell et al. 1998</td>
<td>Patient satisfaction with care</td>
<td>Study patients were significantly more satisfied</td>
<td></td>
</tr>
</tbody>
</table>
5.2 Interventions measuring process outcomes

5.2.1 Subjects in the interventions

Process outcomes studies in community pharmacies have usually been descriptive. This means that they report interventions in the pharmacists’ routine work in dispensing or in patients’ self-medication. The aim of such process outcome studies is to determine the value and the usefulness of the intervention. This kind of outcomes measuring is easy to establish in a community pharmacy setting and the researchers can also use observers to report on the interventions.

The aspects that were documented in the reviewed studies can be divided as in Table 6:
Table 6. Documented processes in reviewed studies.

<table>
<thead>
<tr>
<th>The study</th>
<th>Identifying prescribing errors</th>
<th>Drug therapy problems (e.g. overuse, underuse, interactions)</th>
<th>Results of pharmacists interventions</th>
<th>Intervention to self-medication</th>
<th>Cost Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incomplete, illegible or inadequately written prescriptions</td>
<td>Incorrect drug, dose, dosage form or strength</td>
<td>The prescription clarified/changed and dispensed or not dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rupp et al. 1988</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rupp et al. 1992</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dobie and Rascati 1994</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Berardo et al. 1994</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poston et al. 1995</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Donaldson et al. 1995</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Loh et al. 1996</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sclar et al. 1996</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Caleo et al. 1996</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fincham and Gottlob 1997</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Knapp et al. 1998</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Westerlund et al. 1999</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hawksworth et al. 1999</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Rodgers et al. 1999</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

\(^1\text{X = estimated cost savings}\)
Drug related cost savings included for example generic substitution and therapeutic substitution savings, drug discontinuance savings, savings accrued due to a drug not being dispensed. Estimated savings were the avoidance of hospitalisation, emergency room visits, physician visits, long-term care admissions and additional prescriptions.

5.2.2 Data collection and documenting

Most of the studies documenting process outcomes were done in the USA and only four in Europe. The observation periods were quite short varying from 2 weeks to 1 year. In one of the studies there was no defined study period but the pharmacists intervened in the first 1,500 consecutive prescriptions being handled by the pharmacy (Dobie and Rascati 1994).

Three of the studies described the training arranged for pharmacists before the study (Caleo et al. 1996, Knapp et al. 1998, Hawksworth et al. 1999). In addition, some pharmacies reported using videotaped vignettes for training the externs or pharmacists to identify and document the prescribing problems (Rupp et al. 1992, Dobie and Rascati 1994). In one study, the pharmacists also assessed hypothetical situations in order to practise using the documentation (Dobie and Rascati 1994).

In the majority of the studies, documenting and data collection were done by pharmacists (Poston et al. 1995, Caleo et al. 1996, Loh et al. 1996, Knapp et al. 1998, Westerlund et al. 1999, Hawksworth et al. 1999). Externs, i.e. pharmacy students, were used to observe and document the prescription interventions in three of the studies (Rupp et al. 1988, Rupp et al. 1992, Sclar et al. 1996). A standard documentation form was used to help in this process in most of the studies (Rupp et al. 1988, Rupp et al. 1992, Dobie and Rascati 1994, Donaldson et al. 1995, Poston et al. 1995, Caleo et al. 1996, Fincham and Gottlob 1997, Knapp et al. 1998). In one study, the pharmacists recorded their actions in diaries (Rodgers et al. 1999).
5.2.3 Results

Results of these process outcome interventions were similar: checking and intervening prescriptions are an important part of the pharmacists’ work. The estimated number of pharmacists interventions in these studies ranged from 0.7% to 6.9% of all new or old prescriptions (Table 7). Most of the prescription errors reported were a result of illegible or inadequately written prescription orders (errors of omission). The other common errors were errors with comission, i.e. errors caused by prescribers specifying an incorrect drug, dose or strength of a medication.

The most typical problems with prescription medications were drug interactions, side effects and patient non-compliance (Table 7). Also problems connected to drug distribution and supply were documented.

The most frequent action taken by pharmacists was contacting the prescriber for checking the medication and changing the drug, strength or directions, when needed. Medication was changed in 32%-56.3% of the problematic prescriptions before dispensing. The evaluation of the pharmacists’ interventions highlighted that many of the problems would have been harmful to the patients if they had not been rectified, for example toxic or side-effects of the drug or an inadequate control of the patient’s condition. Other negative outcomes avoided as an outcome of the pharmacists’ interventions were emergency room and physician visits and hospitalisations.

In some of the studies, outside expert panels were used to evaluate the interventions by the pharmacists. According to these studies, in 53%-66.5% of the interventions no adverse consequences would have resulted if the pharmacist had not intervened. But in 20.6%-47% of the interventions, there would have been a potential harm (Rupp et al. 1992, Dobie and Rascati 1994). The respective values were much lower in the study of Hawksworth et al. 1999. Caleo and her colleagues (1996) used a clinical expert panel to evaluate a random sample of 50 interventions that resulted in a change in therapy. The mean level of discomfort avoided was 0.36 (varying +/- 0.20) where 0 is no discomfort and 1 extreme discomfort. Only 0.37% of the interventions could have saved a physician’s visit.
In a controlled trial, the effect of pharmacist’s interventions in prescribing costs was evaluated (Rodgers et al. 1999). The costs in intervention group were significantly lower compared to the control group. Remarkable differences were found in gastrointestinal system and infection medications. The estimated costs related to pharmacists interventions were 5.7 cents-$3.50 per dispensed prescription (Dobie and Rascati 1994). Loh and his colleagues (1996) estimated that prescription interventions per pharmacists resulted in $79.6 to $103.1 million savings to the Canadian health care system each year. Fincham and Gottlob (1997) estimated the saving due to pharmacists’ interventions as $427,193 per year per a study pharmacy.
Table 7. The main process outcomes in community pharmacy studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Main outcome measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rupp et al. 1988 (USA)</td>
<td>Number of pharmacists’ interventions</td>
<td>2.6% of new prescription orders 51% errors of omission, 29% errors of omission 53.6% the prescription order was clarified and dispensed, 32% of the problematic prescription orders were changed</td>
<td>Nine community pharmacies, 5,874 new prescriptions</td>
</tr>
<tr>
<td></td>
<td>Type of prescription errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results of pharmacists’ interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rupp et al. 1992 (USA)</td>
<td>Number of pharmacists’ interventions</td>
<td>1.9% of the new prescription orders 45.6% errors of omission, 36.4% errors of omission 28.3% could have caused patient harm</td>
<td>Eighty-nine community pharmacies, total of 53,941 prescriptions</td>
</tr>
<tr>
<td></td>
<td>Reasons for pharmacist intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluation of the interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dobie and Rascati 1994 (USA)</td>
<td>Number of pharmacists’ interventions</td>
<td>0.78% of the new prescription orders 51.1% of the prescriptions were clarified and dispensed, 31.9% changed and dispensed, 6.4% dispensed as written, 10.6% not dispensed</td>
<td>Four community pharmacies, 1,500 prescriptions per pharmacy</td>
</tr>
<tr>
<td></td>
<td>Results of pharmacists’ interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Berardo et al. 1994 (USA)</td>
<td>Identifying of drug-related problems</td>
<td>In 65% of all prescriptions 22% non-compliance, 17% drug side-effects, 13% drug-drug interactions, 8% misunderstanding regimens Job satisfaction, determine extent of patient counselling, confident in communication with patients, enough time to consult with physician</td>
<td>57 community pharmacists trained to identify elderly patients' medication problems</td>
</tr>
<tr>
<td></td>
<td>Type of problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Factors related to identifying</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poston et al. 1995 (Canada)</td>
<td>Number of pharmacists’ interventions</td>
<td>2% of the new prescriptions  In 63.4% of cases the prescription was stopped (7.1%) or changed (56.3%) before dispensing Drug distribution and supply (38.8%), therapeutic problems (36.9%) Pharmacist recommended an OTC-product in 84.1% of the cases, 8.3% direct and 25.1% conditional referral to physicians, 22.7% recommendation of non-drug treatment</td>
<td>527 community pharmacies, considerable variation in intervention rates between pharmacies</td>
</tr>
<tr>
<td></td>
<td>Outcomes of interventions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Category of problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interventions in minor ailments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Number of pharmacists’ interventions</td>
<td>Nature of intervention</td>
<td>Total prescribing costs</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------</td>
<td>------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Donaldson et al. 1995</td>
<td></td>
<td></td>
<td>6.9% of items (in a follow-up study 3.3%)</td>
</tr>
<tr>
<td>(United Kingdom)</td>
<td></td>
<td></td>
<td>9% below the local average in the intervention practice (not analysed statistically)</td>
</tr>
<tr>
<td>Loh et al. 1996</td>
<td></td>
<td></td>
<td>1.4% of prescriptions filled</td>
</tr>
<tr>
<td>(Canada)</td>
<td></td>
<td></td>
<td>42.6% changed the intended purchase resulting $1.53 reduction in costs, potential adverse outcomes of OTC medication were prevented in 7.1% of the study population</td>
</tr>
<tr>
<td>Sclar et al. 1996</td>
<td></td>
<td></td>
<td>1.5% of the prescriptions, of which in 1.2% the dispensing could not have occurred without consultation</td>
</tr>
<tr>
<td>(USA)</td>
<td></td>
<td></td>
<td>53.1 interventions per pharmacy during four weeks</td>
</tr>
<tr>
<td>Caleo et al. 1996</td>
<td></td>
<td></td>
<td>1.5% of the prescriptions, of which in 1.2% the dispensing could not have occurred without consultation</td>
</tr>
<tr>
<td>(Australia)</td>
<td></td>
<td></td>
<td>53.1 interventions per pharmacy during four weeks</td>
</tr>
<tr>
<td>Fincham and Gottlob 1997</td>
<td></td>
<td></td>
<td>53.1 interventions per pharmacy during four weeks</td>
</tr>
<tr>
<td>(USA)</td>
<td></td>
<td></td>
<td>53.1 interventions per pharmacy during four weeks</td>
</tr>
<tr>
<td>Knapp et al. 1998</td>
<td></td>
<td></td>
<td>0.7% of the prescriptions (range, 0.4-4.1%)</td>
</tr>
<tr>
<td>(USA)</td>
<td></td>
<td></td>
<td>56.1% resulted to contacting the prescriber</td>
</tr>
<tr>
<td>Study</td>
<td>Number of prescription problems identified</td>
<td>Type of problems</td>
<td>Type of intervention</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>--------------------------------------------</td>
<td>------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Westerlund et al. 1999 (Sweden)</td>
<td>6.1 for pharmacists, 2.6 for prescriptionists and 1.1 for pharmacy technicians per 100 patients</td>
<td>One in four problems was related to dosage, one in two to uncertainty about the aim or function of the medication</td>
<td>The most common was patient medication counselling</td>
</tr>
<tr>
<td>Hawksworth et al. 1999 (United Kingdom)</td>
<td>0.75% of the prescriptions</td>
<td>Evaluation of the interventions</td>
<td>0.12% of the interventions may have prevented a drug-related hospital admission, 0.24% could have prevented harm, 0.18% had the potential to improve the efficacy of the therapeutic plan, 0.37% of the interventions improved clinical outcomes and could have saved a visit to a physician</td>
</tr>
<tr>
<td>Rodgers et al. 1999 (United Kingdom)</td>
<td>Net ingredient costs for overall prescribing</td>
<td>Statistically significantly lower in intervention group compared to the control group</td>
<td>Statistically significantly lower costs in prescribing involving gastrointestinal system and infections</td>
</tr>
</tbody>
</table>
5.3 Evaluation of the studies

5.3.1 Validity of outcomes measures in community pharmacy studies

The measure should be specific to the clinical condition so that the effects can be appropriately detected (Mullins et al. 1996). Measuring the clinical endpoints, for example morbidity, is not always possible. Instead, one can use surrogate endpoints such as laboratory tests that are commonly measured both in health outcomes studies and community pharmacy studies (Daniels 1996). The laboratory measures used in these community pharmacy studies were relevant: PEF-measurements, blood pressure, glucose and cholesterol measurements all of which reveal changes in the patient’s physical condition.

Using laboratory tests as a measure is simple and it is possible to get numeric values that can be compared to the baseline. The weakness is that improvements in laboratory test do not necessarily indicate improvements in patient’s health, a point that should be kept in mind when evaluating the results. For example, reduced blood pressure does not necessarily automatically mean any improvements in the patient’s health status. Measuring of true endpoints is almost impossible, because there are not many such outcomes and patients very seldom are cured from chronic diseases. Intermediate outcomes, for example clinical signs and symptoms and use of medical care can be used as outcome measures (Lipowski 1996).

5.3.2 Interventions with patients

Most of the studies had a very short study period which makes it difficult to discern changes in outcomes. This could also be seen in the source of conflicts in results between studies. However, there were also positive outcomes, in spite of the short study periods. This may indicate that the outcomes could have been more positive if the study periods had been longer.

An appropriate study design is the basis for the evaluation of the intervention. In randomised controlled experimental studies, patients are allocated randomly to controls and cases (Concato et al. 2000). Control groups are used to measure the change and
random assignment is also the major strength of this study design (Strom 1994). There were only four studies using randomised-controlled design (Park et al. 1996, Jaber et al. 1996, Carter et al. 1997, Nola et al. 2000).

In community pharmacy studies, the main problem is that randomised controlling may be too “clinical”. It is difficult to observe differences in conditions between controls and cases. There are also some ethical problems for it may be unacceptable not to give information or advice to control clients (Glantz 1989). The pharmacists usually tailor their education and counselling to the needs of patients. It may be difficult to adapt the demands of the clinical trial to the pharmacy environment and tailor the work to the needs of the study. Pharmacists may also be aware that they are participating in a trial.

Most of the pharmaceutical care interventions reviewed here used a before-after design with measurements also during the intervention. Adding a control group to the research makes the results more comparable. However, the control selection may be problematic. Watman and Harris (1986) reported that study patients and controls were matched taking into account age, sex, and physician. In other studies it is possible that the selection has been biased by the health status or age or that those patients who already had a positive attitude to pharmacists’ intervention at the baseline were selected to the study.

One of the disadvantages in these study designs is the possible bias of exposure data. Did the patients get the same kind of education, counselling and monitoring during the intervention? There may have been variations in pharmacies, for example in record-keeping capabilities (e.g. access to computers or computer programmes) or in the presence of appropriate drug information references (Mullins et al. 1996). There may have been limitations in the private patient counselling areas which could have influenced the counselling provided by pharmacists. Individual practice variations between pharmacists and the intervention could also have affected the results.

Confounding variables are other variables that may relate independently to both the risk factor and the outcome variable (Strom 1994). Such possible confounders could be more intensive care by physicians or nurses that were not reported in most of these studies. Health campaigns or health information from the media could also have
improved patient compliance and attitudes to self-management.

Reporting of the research should also contain a clear description of patient demographics (Kennie et al. 1998) or other data information. There was a lack of such detailed description in many of these studies. On the other hand, data from prescriptions were reported more detailed which may reflect the fact that the pharmacists really are more used to work with prescriptions than patient data.

In most of these studies the pharmacists were trained for the intervention or at least they reviewed background literature on the disease and treatment. There was no description about the adequacy or pharmacists’ attitude towards the training. Details on how to conduct research have very seldom been part of the university training of community pharmacists. In the same way, documenting and providing feedback may be strange for pharmacists. This surely introduces variation into the studies. When planning a study in community pharmacies, one has to create very careful and detailed education and directions for pharmacists. This does not mean that the pharmacists are not able to conduct research. They just do not usually need those skills in their daily work. Maybe they should, because we need more research and documentation about the advantages of pharmaceutical work (Cotter and Mays 1996).

Pharmacists should become more aware of the patients’ outcomes and offer value-added professional services with outcomes monitoring (Hatoum and Vlasses 1991). The outcomes measuring should be more structured and the pharmacists should identify appropriate indicators to ensure that drug therapy leads to favourable patient outcomes. Formal recording of the outcomes measures means that the decision making becomes more structured (Mullins et al. 1996). Ideally, patient reports and provider assessments would be linked to information from patients’ medical records making for a more structured monitoring of outcomes (Mullins et al. 1996). Results from laboratory tests, patient’s satisfaction with the care should be added to the records and the pharmacists should be able to access the information.
5.3.3 Interventions measuring process outcomes

Measuring of process outcomes needs careful directions to pharmacies. The pharmacists should be educated and they should get detailed instructions for categorising the interventions. In practice, there may be variability regarding how a particular problem or intervention should be categorised. A means of documentation is a prerequisite for the success of the intervention and the documentation should not be complicated or take too much time.

The method of assessing affects to the results (Ortiz et al. 1989). Self-reporting in community pharmacy interventions may lead to under-reporting – for example because of lack of time due to other work. In addition to self-reporting, Poston et al. (1995) used observers to document the interventions. For prescription drugs, the under-reporting was 49.4% (median 50%) and for OTC (over-the-counter) drugs 51.2% (median 50%). Loh et al. (1996) reported that pharmacists reported only 50.6% of all eligible interventions.

The study periods were short also in process outcome studies. When measuring the outcomes of pharmaceutical work, the length of the study period should not be considered as the most important factor that can influence the results. Clearly, the numbers of prescriptions or prescription errors do not vary very much from day to day.

5.4 Summary of the outcome research

The results of pharmaceutical care interventions were generally positive. The value of the pharmaceutical work being done in pharmacies could be demonstrated with this kind of research. However, all of the results were not positive and this could be seen especially among clinical outcomes.

Cost savings as a result of pharmacist interventions have not been clearly demonstrated. There was an increase in the average daily drug costs that may even be regarded as a positive outcome. It points to improved compliance in the intervention group. The measured decreases in patients medication costs reflect rationalising of the drug regimen and removal of unnecessary medicines which also is a positive outcome of the pharmacist’s work. There is a dilemma in demonstrating cost savings as a result
of pharmacists’ interventions. Do the increased costs lead to cost savings in the long run? This has been documented with high-risk groups and patients with severe asthma (Liljas and Lahdensuo 1997). The economic consequences have been shown to depend on the specific set up of the local healthcare system (Soendergaard et al. 1992).

Pharmacist interventions on Health-Related-Quality of Life have not revealed significant improvements. In these studies, there have been insufficiently large sample sizes that may explain why they failed to demonstrate any impact of the pharmaceutical services on patients’ quality of life (Pickard et al. 1999).

Most of the improvements attributable to the pharmacists’ interventions were in process outcomes. In these studies, prescription errors were corrected, drug-related problems were identified and resolved and patients’ drug regimen were rationalised and corrected. Health care researchers usually desire clinical outcomes and this may explain why these factors are often preferred in pharmacy interventions (Smith and Wertheimer 1996). In the future, the pharmacists will be expected to prove that improved process outcomes can actually lead to positive clinical outcomes. One example of such a valuable research is the SCRIP trial (Study of Cardiovascular Risk Intervention by Pharmacists) that is planned to evaluate the effect of community pharmacists intervention to optimise cholesterol risk management in patients at high risk for a cardiovascular event (Tsuyuki et al. 1999). This study, including 1000 study patients in the USA, may give extra information about the benefits of the work done in community pharmacies in monitoring patient outcomes.

Pharmacists perform many activities that save time and money and benefit patients and physicians (Fincham 1993). What is needed is formal recording of outcomes that could also make decision making more structured. An attempt must also be made to measure all outcomes of the intervention to obtain a comprehensive and accurate picture of the impact of pharmaceutical services (Singhal et al. 1999). Patient medical records which contain information on demographics, allergies, medical history, comorbidities and concurrent treatment as well as results from laboratory tests and assessments would represent an ideal tool for measuring outcomes (Mullins et al. 1996).

In conclusion, pharmaceutical care and prescription interventions by community pharmacists do seem lead to positive results. They appear to save costs, improve patient
health and quality of life. When improving pharmacy services, novel concepts of pharmacy service should be implemented and tested. Both controlled studies with scientific methodologies and practical experiments are needed to evaluate the value of the extended services in community pharmacy work. Studies with appropriate experimental designs are needed to demonstrate their true value in health care. Also practical experiments should be organised to give information about the implementation and feasibility of the extended services.
6 AIMS OF THE STUDY

The aim of the present study was to experiment the implementation of the philosophy of pharmaceutical care into Finnish community pharmacy services. The specific aims of the study were:

1. To determine whether it is possible for community pharmacists to detect potential problems with medication among asthma patients during routine community pharmacy visits
2. To evaluate whether the implementation of the philosophy of pharmaceutical care as Therapeutic Outcomes Monitoring (TOM) by community pharmacists could improve clinical outcomes of asthma patients
3. To assess the impact of Therapeutic Outcomes Monitoring (TOM) on asthma patients’ knowledge about and attitudes towards asthma as a disease and its medication
4. To assess what problems asthma patients encounter in self management, and how they perceive the community pharmacy-based intervention
5. To assess to what extent Finnish asthma patients are trained to follow-up their disease and adjust their medication according to specific instructions
7 CONTEXT OF THE STUDY

7.1 Selection of the target group

The main reasons for selecting asthma patients as a target group of this study were as follows.

Firstly, asthma can be regarded as one of the greatest health problems in Finland. Its prevalence has remarkably increased since the 1960s, especially among adolescents (Haahtela et al. 1990, Rimpelä et al. 1995). In 1999, asthma was the second most common chronic disorder requiring medication with approximately 185,000 asthma patients receiving special drug reimbursements from the national Social Insurance Institution (Finnish Statistics on Medicines 1999). In addition to increased morbidity, also the costs attributable to asthma have increased.

Secondly, during the past decade, there have been major changes in the treatment of asthma. These include changes in drug therapy and management (US Department of Health and Human Services 1997). The new guidelines of asthma treatment emphasise the patient’s own responsibility for the treatment, but also the role of health professionals in training the patient to management. Asthma has often been used as a model when studying the effects of enhanced patient training and counselling to patients’ outcomes (Clark and Nothwehr 1997). In asthma, the changes in clinical outcomes are easy to measure and the measurements provide reliable data that can be applied in all asthmatic patients (Meszaros and Vincze 2000). Although the measuring of factors other than clinical outcomes may be more difficult, asthma patients have often been used as target groups when studying the impacts of extended pharmacy services to the outcomes of disease management (Watman and Harris 1986, Grainger-Rousseau and McElnay 1996, Herborg et al. 1996, Knoell et al. 1998).

Thirdly, there had been co-operation between European countries for investigating the effects of improved pharmacy services to asthma patient management (EURO-TOM 1994). There have already been studies reporting of the implementation of a TOM model to outcomes of asthma patients (Herborg et al. 1996, van Mil 1999).
7.2 Treatment of asthma in Finland

In 1994, the Ministry of Social Affairs and Health set up a working group to design a national action programme to prevent problems and to reduce the costs related to asthma. The goals for prevention and treatment were to cure as many patients as possible with early asthma, so that they would no longer suffer the symptoms of asthma. Thus their ability for work and functional capacity would correspond to their age. Furthermore it was hoped to decrease the percentage of patients with severe and moderate asthma from the current level of 40% to 20% (Ministry of Social Affairs and Health 1996). Other goals were to decrease the number of bed-days suffered by asthma patients and to decrease by 50% the annual costs per patient as a result of more effective prevention and treatment.

The principles of the treatment of asthma according to the Asthma programme were (Ministry of Social Affairs and Health 1996):

1. The primary drug therapy should be anti-inflammatory medication to treat inflammation of the mucus and it should be started at an early stage. Inhaled corticosteroids are the most effective, but chromoglycate and nedocromil also can potentially be used. Any remaining symptoms should be treated with bronchodilators as necessary.

2. Asthma treatment should focus on guided self-care. The patient should be responsible for his/her treatment. Guided self-care means that the patient will monitor his/her condition on the basis of asthma symptoms, and preferably with Peak Expiratory Flow measurements. The patients should also be able to adjust their asthma medication in accordance with specific instructions.

3. The patient should be given adequate information about asthma and its treatment and instructions on how to undertake self-management. The primary health care system is responsible for the treatment of adult patients. They should be transferred to specialised care as necessary and returned back to primary care when specialised care is no longer needed. Paediatricians in specialised care are primarily responsible for the treatment of children.
Implementation of the guidelines of Asthma Programme requires training and dissemination of information both to patients and to key groups in health care. According to the Asthma Programme, these responsibilities have to be shared between many organisations. The Ministry of Social Affairs and Health, in co-operation with The Association of Finnish Pharmacies and The Association of the Pulmonary Disabled, published a separate programme for pharmacists to help them to implement the asthma guidelines in pharmaceutical practice (Ministry of Social Affairs and Health et al. 1997). These guidelines emphasise the role of the pharmacist as an integral member of the health care team involved in education and counselling of the asthma patients. According to the Pharmacy Programme, the pharmacist should:

1. Give basic information about the pharmacology of asthma medications. Special emphasis should be focused on differences between symptomatic and preventive asthma medicines
2. Motivate the patient to use asthma medicines correctly
3. Check the use of asthma devices and Peak Expiratory Flow meters
4. Provide written material about asthma, asthma management and patient organisations
5. Monitor asthma treatment, for example by supervising prescriptions and by discussions with the patient
6. Direct the patient to the physician, when needed

One of the goals of the Asthma Pharmacy programme was to establish one pharmacist in every Finnish pharmacy to be trained to take care of asthma patients and to arrange co-operation between health professionals in asthma treatment. Also training of asthma education and counselling have been arranged in co-operation with other health professionals.

7.3 The Finnish pharmacy system

In Finland, medicines are sold to the public only in community pharmacies (National Agency for Medicines 1995) that are privately owned (exceptions: the Helsinki
University Pharmacy, owned by the University of Helsinki and the Kuopio University Pharmacy, owned by the University of Kuopio). At the end of 1999, there were 794 community pharmacy outlets in Finland with average six pharmacists working in each pharmacy (Finnish Statistics on Medicines 1999).

Almost all of the Finnish community pharmacies now process prescriptions via some computerised system (Hirvonen et al. 1999) but the software has been developed to keep an account of reimbursements, to type the physician’s orders and to keep a record of the prescriptions dispensed. The current systems do not support outcomes monitoring. The possibilities for keeping patient or medication records are limited. Additionally, according to Finnish law, it is not possible to keep any medical or patient record without authorisation from the patient.

According to the current Medicines Act, it is the responsibility of pharmacists to ensure that consumers are familiarised with the correct and safe use of the medications they have been prescribed (National Agency for Medicines 1995). Novel recommendations from the National Agency of Health emphasise the need for cooperation between physicians and pharmacists in health care. The prescriber and the pharmacist have to ensure that the patient receives uniform and sufficient information about using the medicine that he/she has been prescribed (Ministry of Social Affairs and Health 1999, National Agency for Medicines 1999). Local groups of pharmacists and physicians should evaluate the principles about safety and try to find savings in medicine costs. The pharmacist should also recommend that the patient contact the physician, when necessary. In practice, co-operation between physicians and pharmacists in Finland has mainly concentrated on technical aspects and has not been very active (Tanskanen et al. 1997).

The Association of Finnish Pharmacists published the Finnish national standards in quality assessment in community pharmacies in 1995 (Association of Finnish Pharmacies 1995). These guidelines are based on the international guidelines that were established by the International Pharmaceutical Federation (FIP) in 1993 (International Pharmaceutical Federation 1993). The national standards were intended to provide a manual to help community pharmacists to create pharmaceutical services in a step by step manner. “Quality pays – a manual for pharmacies” gives very practical instructions
and examples of ways to improve the quality of all pharmaceutical services. It does not
give special advice for practising pharmaceutical care. The basic element is that the
quality should be improved in all pharmaceutical services. Quality improvement is a
continuing process when the best results will be achieved with structured evaluation of
the work.
8 MATERIALS AND METHODS

8.1 Study design (I-V)

This study consists of three parts that were conducted during 1993-1998. While working in an ordinary community pharmacy, I noticed that many asthma patients were not coping with the treatment and their medication was not in accordance with the latest recommendations. In the first study, I wanted to know what are the possibilities of community pharmacists to detect problems in asthma patients’ medications in routine dispensing. This was studied in 1993 by collecting information from asthma patients who were receiving their asthma medicines from Nivala pharmacy. The information was collected during one month (study I, Table 8). The next part of my study consisted of the implementing of the philosophy of pharmaceutical care into community pharmacists’ work. Therapeutic Outcomes Monitoring was used as a tool for investigating the effect of the better training, counselling and outcomes monitoring by community pharmacists in the management of asthma patients. This was studied in four ordinary community pharmacies (studies II, III and IV, Table 8). This project – called ASTHMA-TOM - was organised during 1996-1998. In the third part of my study, the implementation of principles of appropriate follow-up by asthma patients was investigated in 1998 (study V, Table 8). In this study, information was collected from all the asthma patients who obtained their medicines from Finnish pharmacies during the study period. A summary of the methods, outcome measures, indicators and statistical methods used in original publications is presented in Table 8.
Table 8. Methods used in original publications (I-V).

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Outcome measures</th>
<th>Indicators</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Descriptive survey in 1993 - questionnaire to all asthma patients who obtained their inhaled asthma medicines from the Nivala pharmacy (n=119) during one month study period - telephone calls to patients who had problems in asthma medication (n=21)</td>
<td>Refill compliance. Information content of prescriptions. Problem detecting by community pharmacists.</td>
<td>Refilling too late, too early or at scheduled times. Type and purpose of the medication. Establishing the treatment of asthma patients.</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Intervention in four community pharmacies with 28 asthma patients. - a pre/post-test design, with study patients as their own controls</td>
<td>Clinical outcomes.</td>
<td>Severity of asthma symptoms. Changes in the number of patients having peak expiratory flow (PEF) values below 85% or 70% of the optimal. Changes in daily asthma medication and number of patients needing courses of oral steroids.</td>
<td>Statistical significances: - differences between symptom severity scorings at 4, 8, 12 and 24 months compared to baseline: nonparametric Friedman 2-way analysis of variance for repeated measures - the scored symptoms at 12 months and 24 months compared to baseline: Wilcoxon rank sum test - differences in the number of patients having PEF values below 85% and 70%: Cochran Q test.</td>
</tr>
<tr>
<td>III</td>
<td>Intervention in four community pharmacies with 28 asthma patients. - questionnaires measuring knowledge about and attitudes towards asthma and its medication</td>
<td>Knowledge and attitude scores about asthma and its medication. Relationship between knowledge and attitudes.</td>
<td>Changes and correlations in knowledge about and attitudes towards asthma as a disease and its medication.</td>
<td>Statistical significances: - pre- and post-intervention status at 12 months and 24 months: Friedman 2-way analysis of variance for repeated measures - groups compared with each other: Wilcoxon rank sum test. Correlations between knowledge and attitudes of asthma patients: Spearman’s Rank correlation.</td>
</tr>
</tbody>
</table>
| IV | Intervention in four community pharmacies with 28 asthma patients.  
- measuring the impact of pharmacists as problem solvers in asthma patients self-management.  
Questionnaire measuring asthma patients’ opinions about the Therapeutic Outcomes Monitoring by community pharmacists. |
|-----------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
|                | Problems in self-management.  
Usefulness of the education  
Satisfaction to the intervention |
|                | Problems in self-management perceived by asthma patients or detected by pharmacists.  
Usefulness of the topics educated by pharmacists  
Opinions about the enhanced education, counselling and outcomes monitoring by community pharmacists |

| V | Population survey in 1998  
- questionnaire to all patients who obtained their asthma medicine from Finnish pharmacies during two days (n= 2,860) |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Asthma patients follow up.  
Agreements with a physician on adjusting asthma medication according to specific instructions. |
|   | Following asthma status on the basis of a) PEF measurements b) asthma symptoms c) both d) other methods e) not at all.  
The number of patients who received specific instructions from their physician on how to adjust their asthma medication |
|   | Differences among subgroups: chi square independence test. |
8.2 Descriptive survey in the Nivala pharmacy (I)

The aim of this study was to determine whether it is possible for community pharmacists to detect potential problems with medication among asthma patients during routine pharmacy visits in a traditional pharmacy setting by using simple tools such as prescription information and discussions with the patient. This was an attempt to develop pharmacy services according to the philosophy of pharmaceutical care.

The study was carried out in a community pharmacy in Nivala which is a rural community with about 11,500 inhabitants. The study population consisted of all customers (n=124) who presented a prescription for an inhaled asthma medicine in the pharmacy during a four-week period in September 1993. There were 119 patients eligible for the study (60 males and 59 females), mean age $49.8 \pm 23.3$ (SD) years, the youngest being three years old, and the oldest 88 years. The following information was gathered from the patients:

- drug regimen and reimbursement status
- physicians’ written instructions about dosage of the inhaled asthma medication
- previous refill dates and amounts dispensed
- prescribing physician

Twenty-one patients (11 males and 10 females) were selected from the 119 for a more detailed interview by phone two weeks after their visit to the pharmacy. The selection criteria were: patients who had reported problems with taking their medication or who did not use preventive medicines according to instructions. We excluded patients with no telephone and those in home-care with nurses responsible for the medication. No attempt was made to assure the representativeness of this interview group.

The patients were interviewed by telephone. An open-theme interview was used to survey their medicine using, the possible problems in self-management and attitudes towards asthma medication. Counselling was offered according to the needs of the patient. The methods are described in more detailed in study I.
8.3 Therapeutic Outcomes Monitoring (TOM) in four community pharmacies (II-IV)

8.3.1 The study protocol

The effects of TOM based protocol on asthma patients outcomes was studied in four community pharmacies. The TOM protocol used was based on the Danish version (Herborg et al. 1996, Appendix 1). We used the same protocol with a nominated pharmacist to train the patient and monitor the outcomes. We also used partly same outcome measures: patients’ satisfaction to services, knowledge about asthma, Peak Expiratory Flow measurements and symptoms scoring. The idea of using a questionnaire for measuring changes in patients knowledge was also adopted from the Danish model. Modification to the Finnish pharmacy system was done by a group of experts consisting of two researchers from the Department of Social Pharmacy (University of Kuopio), and members from the Association of Finnish Pharmacies, the Association of the Pulmonary Disabled and each of the pharmacies that participated in this study.

A one-day training course was arranged for the pharmacists participating in the study. The training dealt with:
- the aims and the protocol of the project
- the basics of asthma as a disease and its treatment
- identifying possible problems in medication by patient interviewing
- the use of the inhalation devices and peak expiratory flow meters

In addition to the training, the participating pharmacists also self studied asthma treatment, and self management according to the national asthma guidelines (Ministry of Social Affairs of Health 1996).

The pharmacists recruited local physicians and nurses taking care of asthma patients, to join in the study. Before the intervention, the pharmacists, the physicians, the nurses and the representatives of the local asthma patient organisations decided about the details of the patient education and outcomes monitoring. The same manual and
documents were available in each place, but the health professionals were asked to adopt them to fit the practice in their local conditions.

A total of 31 patients were enrolled into the intervention, varying from 6 to 10 in the different communities (Table 8). Three patients withdrew and the remaining 28 participants, 7 men and 21 women, were aged 23-56 years (mean age $41.3 \pm 12.2$, SD). Twenty-one of the patients were recruited by physicians and seven by pharmacists. The inclusion criteria for patients were: age between 20-64 years, asthma diagnosis, problems with asthma management (i.e., the patients were not compliant or were compliant but still had asthma symptoms or had perceived problems with asthma management) and volunteering to participate.

To minimise the seasonal effects, the patients started the intervention between May and October in 1996. During the one-year intervention period, the patients visited the pharmacists between 4 and 8 times (median 4, mean 5.2 visits per patient), the number of visits depending on the needs of the patient. Each session lasted from 15 to 120 minutes (Table 8), the first session always being the longest. The study patients were invited to the last follow up one year after the intervention.

In the pharmacies, every participant had their own pharmacist who educated and monitored the patient according to the principles of self-management of asthma. The pharmacists were asked to move the emphasis from dispensing to counselling and to focus on individual care and support of self-management.

Patient training consisted of:

- information about asthma pathology
- instructions on the use of a PEF meter in monitoring airway function
- use of medications and inhaler devices
- recognising and managing asthma symptoms

The pharmacists consulted the physician or the nurse when necessary. During the intervention, the pharmacists also gave recommendations about changing the asthma medicines or dose or whether the patients should consult a physician. If no optimal peak expiratory flow values had previously been determined; these were evaluated by physicians before the intervention.

The pharmacies did not get any reimbursements for participating in the study. All of
the participating pharmacists were asked to document the training they had for the intervention and how much time they spent on the training (Table 9).

Table 9. Training of pharmacists before the intervention, number of study patients and time spent in consultations with study patients according to the pharmacists.

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Total time spent preparing for the intervention hours/pharmacist</th>
<th>Self studied topics before the intervention (in addition studying of study protocol; basics of asthma; treatment; medication; and inhalation device)</th>
<th>Number of study patients (withdrawals)</th>
<th>Time spent for an appointment/patient (minutes first visit/other visits)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>27</td>
<td>Training which was arranged in co-operation with the nurse and the physician responsible for asthma care (arranged by a pharmaceutical company)</td>
<td>7 (1)</td>
<td>75-100/25-90</td>
</tr>
<tr>
<td>II</td>
<td>.1</td>
<td></td>
<td>6 (1)</td>
<td>30-90/35-100</td>
</tr>
<tr>
<td>III</td>
<td>13</td>
<td>Practising of interviewing with patients.</td>
<td>9</td>
<td>55-85/25-50</td>
</tr>
<tr>
<td>IV</td>
<td>27</td>
<td></td>
<td>9 (1)</td>
<td>80-120/30-100</td>
</tr>
</tbody>
</table>

1 No information

8.3.2 Outcome measures

The measuring points for the statistical analysis were selected at four month intervals. Thus, the results are based on measurements at baseline, at 4 and 8 months after starting the intervention, at 12 months (the end of the intervention) and at 24 months (one year after the end of the intervention) (Figure 4).

The patients’ knowledge and attitudes towards asthma and its medication were assessed at baseline, immediately after the intervention (12 months) and one year after the intervention (24 months) (Figure 4). The opinions of the study patients about the community pharmacy-based intervention were assessed at the end of the intervention (12 months) by a separate questionnaire (Appendix 2).
At every visit the pharmacist recorded the severity of asthma symptoms, the current medication, patient’s perceived or pharmacist’s detected problems in self-management. Basic information about smoking, work and other personal details related to asthma were asked at the first visit. The information was documented in a special form.
(Appendix 3). In subsegment session, the pharmacists tried to detect possible problems associated with the treatment and the patients were encouraged to report if they had encountered any problems in their asthma management. The pharmacists devised a management plan in co-operation with the patient for solving the problems. All the information was recorded and the pharmacists used this information in his/her evaluation of the patient’s asthma status and situation before every visit.

The clinical, process and humanistic outcomes during the intervention were measured as reported in Table 10.

Table 10. The outcomes measured in ASTHMA-TOM study.

<table>
<thead>
<tr>
<th>The outcomes</th>
<th>Outcome measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Severity of asthma symptoms</td>
<td>Scored subjectively by study patients on a ten point scale (0-10)</td>
</tr>
<tr>
<td>Peak expiratory flow (PEF)</td>
<td>Changes in the number of patients with suboptimal scores</td>
</tr>
<tr>
<td>values below 85% or 70% of</td>
<td></td>
</tr>
<tr>
<td>the optimal</td>
<td></td>
</tr>
<tr>
<td>Changes in daily asthma</td>
<td>Number of changes</td>
</tr>
<tr>
<td>medication</td>
<td>Number of patients</td>
</tr>
<tr>
<td>Need of courses of</td>
<td></td>
</tr>
<tr>
<td>antibiotics and oral steroids</td>
<td></td>
</tr>
<tr>
<td><strong>Humanistic outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Problems in self management</td>
<td>Number of problems perceived by patients or detected by pharmacists</td>
</tr>
<tr>
<td>Usefulness of the intervention</td>
<td>Perceived usefulness scored by patients on a five point scale (1-5)</td>
</tr>
<tr>
<td>Satisfaction with counselling</td>
<td>Patients perceived satisfaction with counselling by physicians, nurses and</td>
</tr>
<tr>
<td></td>
<td>pharmacists</td>
</tr>
<tr>
<td><strong>Process outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Knowledge about asthma and</td>
<td>Measured by a questionnaire</td>
</tr>
<tr>
<td>its medication</td>
<td></td>
</tr>
<tr>
<td>Attitudes towards asthma</td>
<td>Measured by a questionnaire</td>
</tr>
<tr>
<td>and its medication</td>
<td></td>
</tr>
</tbody>
</table>

According to the ECHO-model, intermediaries that for example can be effects of disease or treatment (Kozma et al. 1993) affect outcomes. In this study, the concept of clinical outcomes was assessed via changes in asthma patients’ medication and needs for courses of antibiotics and oral steroids, because they have a clear impact on the final clinical outcomes (Table 10). Kozma and his colleagues (1993) also reported that humanistic intermediaries could be regarded as effects of disease or treatment on humanistic outcomes. That is why we included self-management problems perceived by asthma patients or detected by pharmacists to humanistic outcomes. Patients’ perceived
usefulness and satisfaction with counselling were also measured as humanistic outcomes. As process outcomes, we measured asthma patients’ knowledge about and attitudes towards asthma and its medication.

For measuring the severity of asthma symptoms, the patients scored all the asthma symptoms they had had at least once a week during the last month before the visit to the pharmacy. The symptoms included night or daytime wheeze, nighttime cough, increased mucus excretion and allergic symptoms. These were scored subjectively on a scale that was modified from a symptom scale that was used in the Kuopio University Hospital for assessing the severity of asthma patients’ symptoms. The symptoms were scored on a ten point scale (0 to 10) where 0-1 = no symptoms, 2-5 = minor symptoms, 6-8 = moderate symptoms and 9-10 = severe symptoms.

The patients were asked to measure PEF values at home twice a day for two weeks before the appointment with the pharmacist. PEF measurements were made every morning and evening before taking asthma medicines and they were recorded in a diary. The patients were instructed to blow three times into a peak flow meter. The best reading out of the three was recorded and the pharmacists checked the measurements.

The pharmacist recorded the current asthma medication at every visit and any changes since the last session. All changes in type of medicines, strength or inhalation device were documented. The need for courses of oral steroids for asthma were recorded from six months before the baseline, from six months before the session at 24 months and from four months before sessions at 4, 8 and 12 months.

Patient knowledge about asthma and its medication and attitudes towards asthma and its medication were assessed by a separate structured questionnaire (III, Tables 1 and 3). The pharmacists posted or gave the questionnaires to the participants in the pharmacy, asked them to complete them at home, and return them to the pharmacy (at baseline) or to the university (at 12 months and 24 months). The pharmacists went over the correct answers to the factual questions during the last appointment at 24 months.
8.4 Population survey with asthma patients (V)

The implementation of the national asthma programme was evaluated for the first time in 1998, four years after the guidelines were established. In this study, we wanted to assess asthma patients’ management by asking which methods they used to follow-up their disease. We also wanted to know whether they had received and understood specific instructions from their physician on how to adjust their asthma medication.

The management was evaluated by a questionnaire sent to all asthma patients who were obtaining their asthma medicines from Finnish pharmacies during two days in June 1998. Seventy-seven per cent (n=605) of Finnish pharmacies participated in the study and information was gathered from 2,860 asthma patients. Characteristics (gender and age) of study patients were compared to the whole Finnish chronic asthma population according to the reimbursement status of the asthma medication and the groups were rather similar.
9 RESULTS

9.1 Detecting problems of asthma patients in routine dispensing (I)

Only slightly more than a half (59%) of the study patients had been prescribed their asthma medication according to current guidelines, i.e. they had a combination of an inhaled beta-agonist together with an inhaled corticosteroid as asthma medication. One in every four study patients was using an inhaled short acting beta-agonist as their only medicine for asthma, and this is not in accordance with the current guidelines (Ministry of Social Affairs and Health 1996).

On the basis of prescription analysis, 26% of the medicines were refilled according to instructions (within +/- 14 days from the exact refill day). Half of the prescriptions were refilled too late (Table 1, I). The instructions in prescriptions were incomplete and lacking crucial information. No information was given about the type of medication in 62% of the symptomatic and 80% of the preventive medicine prescriptions. The purpose of medication was lacking in 53% of the symptomatic and in 61% of the prophylactic prescriptions.

Only seventeen percent of the study patients (n=119) reported having problems with their asthma medication when visiting the pharmacy (Table 3, I). Half of the problems were related to taking or handling asthma medication. In telephone discussions, two patients out of 21 reported not having any preventive medicine and almost half of the rest (8 out of 19) reported taking less preventive medicine than the physician had instructed. Almost half of the patients (9 out of 21) were not receiving any regular follow up by their physician.

9.2 Therapeutic Outcomes Monitoring (TOM) with asthma patients

9.2.1 Clinical outcomes

Positive clinical outcomes were achieved during the one-year intervention (Table 11). Three out of five symptom measures reflecting the severity of asthma symptoms
improved statistically significantly during the intervention (II, Table 1). The improvements were still statistically significant in two of these three indicators one year after the intervention. A result that did not achieve statistical significance was a decrease in number of patients having PEF values below 85% and 70% of the optimal during the intervention (II, Table 4).

More than every second patient (57%) had changes in their asthma medication during the intervention. About one third (32%) had experienced more than one change. The pharmacist had consulted the physician about changes in medication for four patients. Recommendations for change of medication had been given to six patients in the pharmacy.

9.2.2 Humanistic outcomes

The number of reported problems in asthma patients’ management decreased during the intervention (IV, Table 1). Compared to the baseline, half of the patients did not consider that they had any problems at the end of the intervention as reported by pharmacists or by themselves. The patients ranked as the most useful the instructions that they received about changing asthma medication according to asthma symptoms and the management of asthma symptoms (IV, Table 2). Almost as useful were ranked the correct use of asthma medicines and knowledge about asthma in general.

Patients’ satisfaction with the pharmacy services was good. Twenty-five of 28 study patients were satisfied with the education and counselling given by community pharmacists; and 20 of 28 patients with the education and counselling given by physicians; and 17 of 28 with the education and counselling provided by nurses during the intervention (IV, Table 3).

9.2.3 Process outcomes

Statistically significant improvements were achieved in asthma patients knowledge about asthma as a disease and about its medication when measured with a questionnaire one year after the beginning of the intervention (Table 11). Those improvements were
still statistically significant one year after the intervention (III, Table 2). The improvement was greatest in items referring to the use of Peak Expiratory Flow meter to measure asthma status (III, Table 1).

There was also a statistically significant improvement in the attitudes of the asthma patients towards asthma as a disease, while attitudes towards medication remained static during and after the intervention compared to baseline (III, Table 4). At baseline, the patients reported the most negative attitude towards the effect of asthma symptoms on their mood and they wished to receive more information about asthma and its management. The most significant improvements during the intervention were found in attitudes reflected as worrying about asthma (III, Table 3). At the end of the intervention, significantly fewer patients reported that they had problems with asthma management and fewer considered their asthma symptoms as being serious and that they needed more information compared to the baseline.

There was a negative correlation between knowledge and attitudes towards asthma as a disease at baseline (III, Figure 1). This meant that when the patients had more knowledge they also had more negative attitudes. The correlation between attitudes towards asthma as a disease and attitudes towards medication was also negative at baseline. Statistically significant correlations between knowledge and attitudes towards medication were found at 12 (p=0.041) and 24 (p=0.041) months. The correlation between knowledge about asthma as a disease and medication was also statistically significant at 12 months (p=0.044).

Table 11. Outcomes of the community-pharmacy based, ASTHMA-TOM intervention one year after the start of the intervention (12 months). Only statistically significant results are included.

<table>
<thead>
<tr>
<th>Type of outcomes</th>
<th>Outcomes measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity of asthma symptoms</td>
<td>Symptom scores</td>
<td>Statistically significant improvement in three out of five symptom measures</td>
</tr>
<tr>
<td><strong>Process outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study patients knowledge about asthma and its medication</td>
<td>Scored by a questionnaire</td>
<td>Statistically significant increase in knowledge about asthma and its medication</td>
</tr>
</tbody>
</table>
Study patients attitudes towards asthma and its medication |
Scored by a questionnaire |
Statistically significant improvement in attitudes towards asthma but not in attitudes towards medication

9.3 Asthma patients’ follow up (V)

The follow up survey in 1998 showed that about two thirds of the study patients had a named physician responsible for the asthma treatment (Figure 5). The majority of those patients had also been given specific instructions by their physician on how and when to adjust their asthma medication. However, less than a half (47%) of the patients had an optimal follow up with a named physician and specific instructions for adjusting asthma medication four year after the new national asthma guidelines had been established.

Figure 5. Named physicians for asthma care of asthma patients and number of patients having received specific instructions from their physician on how and when to adjust their asthma medication.

The survey revealed that a majority of the respondents (86%) were instructed on a method recommended by the national guidelines in follow up of their symptoms. They used Peak Expiratory Flow (PEF) based technique (39% of the respondents), a
symptom-based technique (34%) or both (13%) (V, Table 2). There were no differences between the type of a physician (a general practitioner vs. a specialist) in the number of patients following their asthma according to the guidelines. Ten per cent of all the study patients reported not following their asthma status at all, this being more commonly the case in the elderly subjects (17%). Following asthma by PEF measurements was most common among patients who had been on asthma medication for less than a year. Those who had been on asthma medication for more than five years reported following their asthma status statistically significantly less than others.

A smaller proportion of the respondents (58%) was instructed on adjusting their medication according to symptoms (V, Table 3). The lowest rates for adjusting asthma medication according to symptoms was found among the elderly (64% not instructed on adjusting the medication), among those on asthma medication less than one year (56%), and among males (46%).
10 DISCUSSION

10.1 Study populations and methods

10.1.1 Experiment with detecting problems of asthma patients

The first part of this study which was intended to assess the possibilities of community pharmacists to detect problems in asthma patients' management was conducted in 1993. In Finland, the current Finnish guidelines of asthma treatment, the Asthma Programme (Ministry of Social Affairs of Health 1996), was published in 1994. The Therapeutic Outcomes Monitoring (ASTHMA-TOM) intervention in four community pharmacies was arranged during 1996-1997 and the last aspect of the study, assessment of asthma patients’ self-management was established in 1998. This means that there may be variations in the backgrounds of these three studies. However, it is obviously that the management of asthma patients has not changed extensively during five years, from 1993 to 1998. If any changes had occurred, they may be viewed as improvements, bringing patients in line with the accepted consensus guidelines in asthma treatment.

The first study is reporting results from only one community pharmacy. The purpose of the study was to investigate routine practice in a community pharmacy and it gives valuable information about the pharmacy practice in ordinary dispensing. The data was collected during one month that also gives a good picture of the profile of asthma patients' medication and management with the disease. This study was descriptive and depending of pharmacists' pressure of work, there may be variations in documenting.

10.1.2 ASTHMA-TOM intervention

The intervention in four pharmacies had to take into account practicalities and thus a rather small convenience sample was selected. This limits the extent to which the results can be generalised. We had 28 patients with a before-after study design and no control group. Therefore, the results have to be interpreted with caution. If there had been a
control group, a better statistical evaluation of the results would have been possible. However, this was the first time that Finnish pharmacists had been involved in such a long lasting patient intervention and at the onset of the study we had no experience on how it should be managed. It seemed advisable to start with a small group, so we could obtain more experience about pharmacists’ and patients’ attitudes towards this kind of service.

We used a convenience sample including the patients who attended to pharmacies and they were between 20 and 64 by their age. This means that those patients who may be most in need of counselling (e.g. the elderly patients and housebound) were excluded. It could have been possible to get more realistic results by extending the study groups.

The study patients evaluated their recent asthma symptoms and scored them from mild to severe. We did not verify the symptoms with pulmonary function measurements. The focus was on the patients’ own experiences and his/her own opinions about the severity of the symptoms. We did not check the patients’ health status or medication from medical records. In Finland, the pharmacists are not able to assess these records in daily practice and we wanted the study to be implemented as realistically as possible.

In this study, we wanted to test the applicability of the TOM model in Finnish community pharmacies. When selecting the measured outcomes we wanted to take into consideration the circumstances. We preferred patients own experiences and the clinical outcomes were measured subjectively. Patients’ knowledge about and attitudes towards asthma and its medication, the usefulness and satisfaction to services were also measured subjectively. When measuring humanistic outcomes, we did not use any general or disease specific scales. The main purpose was to survey patients’ own experiences in a way that could be adopted into community pharmacy practice and instead of measuring with numbers, we wanted to emphasise patients’ own assessments of how their disease interfered with their daily life (Stockwell et al. 1992).

The physicians and nurses were asked not to change the care of asthma patients, except that they should increase their co-operation with pharmacists. We cannot be sure if any improvements in patients’ outcomes were solely attributable to the pharmacists’
input of the intervention. A health campaign and enhanced counselling by nurses or physicians may have had a positive outcome. However, during the intervention the pharmacists provided feedback to the patients and other health professionals on asthma management and the patients if necessary paid extra visits to their physicians, which can also be considered as a positive outcome.

10.1.3 Assessing follow up of asthma patients

A large study population with 2,860 patients gives possibilities to generalise the results to the whole asthma population in Finland. The age and gender of the study population matched quite well with those of the entire Finnish chronic asthma population if this is measured by the reimbursement status for asthma medication (V, Table 1). However, only those patients that were obtaining their asthma medicines during the study period were included. It is possible that only the most active patients in asthma self-management were selected to the study.

One deficiency in the questionnaire was that the measures were not implemented in a sufficiently detailed manner from the current national guidelines. More specific questions about the medication and asthma management would have given more information about asthma patients’ self-management. We did not ask whether the asthma follow-up was done at home or at the physician’s or nurse’s office. Thus, there might be patients who have included in their response measurements carried out by a physician or a nurse.

One of the basic principles of guided self-care is that the patient should receive specific instructions from their physician about the principles for adjusting his/her preventive asthma medication (Ministry of Social Affairs and Health 1996). In this study, we did not distinguish between instructions for sympathomimetic and preventive medications. This was because we wanted to evaluate the patients’ own perceptions about whether they had been given understandable instructions. Some patients may still have responded positively on the basis of having understood when to adjust only their sympathomimetic medication.
10.2 Key findings

10.2.1 Implementation of the guidelines to asthma patients’ follow-up

This study showed that there were variations in the implementation of follow-up of asthma patients. Asthma patients’ gender, age and duration of asthma medication affected the follow-up. There were also patients who reported not following their asthma at all. However, the principles of following up the symptoms were implemented better than patients simply being instructed to adjust their medication according to the guidelines. The worst deficiencies of implementation of the guidelines of follow up were found with the elderly patients (65 years or more) and those who had been on medication for more than five years. Those who had been on asthma medication for less than a year had not often received specific instructions but obviously their asthma status has not yet stabilised. The elderly and the asthma patients who have been on medication for more than five years seem to be the subgroups who need extra counselling and support in their asthma management. It has also been reported that the number of asthma related hospital treatment periods is higher among the elderly (65 years and over) compared to the other subgroups (Keistinen et al. 1993).

The same trend about poor compliance of current outpatient management with consensus guidelines has been reported from other countries (Legorreta et al. 1998, Taylor et al. 1999). Recently, it has also reported that the current level of asthma control in Europe does not reach the goals for long-term asthma management (Rabe et al. 2000).

In Finland, it has been reported that since the current guidelines for asthma treatment were published, both the numbers of days in hospital and mortality due to asthma decreased (Haahtela and Klaukka 1998). According to national drug consumption statistics, at the same time the use of asthma medicines in Finland has moved towards the recommendations in the guidelines (Finnish Statistics on Medicines 1999). The consumption of inhaled corticosteroids is increasing while the use of inhaled beta₂ sympathomimetics is decreasing. These can be regarded as positive signs of improved treatment of asthma patients. However, these results do not give any information about
asthma patients’ quality of life and about their managing with the treatment. In our
study, we showed that although the treatment has improved in general, there are still
many patients who need extra counselling and support in their self-management. More
studies about the implementation of the treatment guidelines in asthma patients’ every
day life should be established. This is important, because it has been reported that there
are variations in survival of asthma patients which is characteristic of areas with
extensive medication and easy access to treatment (Tuuponen et al. 1997).

In this study, the asthma patients with a named physician for asthma care had more
commonly made agreements for adjusting the medication. However, less than a half of
the patients had an optimal situation i.e. they followed their asthma according to the
guidelines and had received specific instructions for adjusting their asthma medication.
A personal supporter in asthma care seems to improve outcomes in self-management
and more focus should be paid on patient training for self-management according the
principles of guided self-care (Lahdensuo et al. 1996). Guided self-care has even proved
to produce financial net savings in a long term (Kauppinen et al. 1998).

Patients attitudes and their complying with instructions given by health professionals
have been described by a term “compliance” (Stimson 1974). In the United Kingdom,
this term has recently been replaced by the definition of concordance which is a new
approach to the prescribing and taking of medicines. It is an agreement reached after
negotiation between a patient and a health care professional that respects the beliefs and
wishes of the patient in determining whether, when and how medicines are to be taken
(The Concordance Coordinating Group 1997). It implies a better understanding of the
ways in which the patient perceives the illness and the treatment and then tests the
appropriateness and the usefulness of the physician’s picture of the illness (The
Concordance Coordinating Group 1997). The focus is in the equality between the
prescriber and the patient. The same trend can also be recognised in the philosophy of
guided self-care which also emphasis patient’s own responsibility of the treatment.

In Finland, the primary health care system is responsible for the asthma care of most
of the adult asthma patients. According to the national guidelines, there should be a
named physician and a named nurse in every health centre responsible for asthma care
(Ministry of Social Affairs and Health 1996). As a result of the Asthma Programme for
Pharmacists, there is already a named pharmacist responsible for asthma services in almost every Finnish community pharmacy (Association of Finnish Pharmacies 2000, unpublished data) which should be regarded as an improvement in pharmacists’ possibilities to counsel asthma patients.

10.2.2 Possibilities of community pharmacists to improve patients outcomes

This study showed that it is possible to improve asthma patient outcomes by enhanced education, counselling and outcomes monitoring by community pharmacists. The structured training and counselling by community pharmacists increased asthma patients’ awareness about asthma as a disease. It also improved patient attitudes and reduced anxieties about asthma.

This study was conducted in outpatient care, but positive outcomes as a result of the pharmacists’ intervention have been reported also in previous studies in hospital and inpatient setting studies. Participation of pharmacists can significantly reduce the length of stay in a hospital (Haig and Kiser 1991, Bjornson et al. 1993). In addition, reductions in medication costs have been reported (Haig and Kiser 1991, Lobas et al. 1992, Bjornson et al. 1993). The inclusion of a pharmacist into the health care team in hospital settings has been reported to reduce inappropriate prescribing and possible adverse drug effects (Hanlon et al. 1996, Smythe et al. 1998), to have a positive impact to glycemic control in patients with type 2 diabetes (Coast-Senior et al. 1998) and to decrease drug costs (Smythe et al. 1998). This has been shown also in a long-term care facility (Grymonpre et al. 1994). Structured education and counselling by pharmacists have been reported to improve both clinical and humanistic outcomes and compliance in congestive heart failure patients (Varma et al. 1999) and drug information services by pharmacists have also been shown to lead to cost savings (Kinky et al. 1999).

In community pharmacy settings, significant improvements have also been achieved but there have been shortcomings in the methods used in many studies. Lack of control groups, an adequate study design or appropriate outcome measures can be recognised (Kennie et al. 1998, Singhal et al. 1999). This can also be seen in studies that were reviewed in this presentation. Pharmacy practice research has not yet attained the same
standard as other areas of health service research (Cotter and Mays 1996). To understand better the consumer’s perspective, the pharmacists should focus less on the process of care and more on the objectives, i.e. the outcomes of the services (Rupp 1992). More valid studies with acceptable study design, sufficiently large numbers of study patients and relevant outcomes measures will be needed in order to verify the role of pharmacists in health care.

### 10.2.3 Community pharmacists’ role in training and supporting of asthma patients

Community pharmacists can detect problems in asthma patients medication and self-management in their routine work. This study showed that by using simple tools, such as prescription review and short patient interviews, it is possible to detect many potential problems in the pharmacy without the need for extensive documentation and any extra workload. Prescription information is useful also for evaluating the counselling needs of the patient. When combined with patient interviewing it provides a means to monitor patient outcomes and evaluate the difficulties and problems encountered by asthma patients in coping with their illness.

The asthma patients seem to have more problems with their medication compared to their ability and willingness to follow up their disease. The experiment in Nivala showed that the information content of prescription instructions was poor and information about type and purpose of the medication was often missing. This emphasises the pharmacists’ role in patient education and counselling. Pharmacists should ensure that the patients are made aware of the basic information of their medication. When training the patients to use their asthma medicines according to the guidelines, the pharmacists should focus on a few items (Table 12).
Table 12. The crucial items the pharmacists should focus on when counselling asthma patients to use their medicines.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The purpose of the medication (symptomatic or preventive)</td>
</tr>
<tr>
<td>2</td>
<td>The type of the medication (regularly, when needed)</td>
</tr>
<tr>
<td>3</td>
<td>Follow up of the symptoms (PEF measurements, symptoms)</td>
</tr>
<tr>
<td>4</td>
<td>The use of inhalation devices</td>
</tr>
<tr>
<td>5</td>
<td>Adjusting the medication according to specific instructions by a physician</td>
</tr>
<tr>
<td>6</td>
<td>Support of self management</td>
</tr>
</tbody>
</table>

Patient counselling should be tailored according to his/her needs. The issues reported in Table 12 should be monitored by pharmacists with every asthma patient but the focus depends on the individual patient’s needs. Those patients who have become asthmatic recently need basic knowledge about asthma and its medication and self-management. Although they have been trained by a physician or/and by a nurse, the pharmacists should ensure that they know how to manage with their medication including the use of inhalation devices (issues 1-4, Table 12). Patients who have been suffering from asthma longer and who have been on asthma medication for years may be tired of self-management and have poor compliance. Nonadherence to asthma treatment has been reported to be one of the biggest problems in asthma patients’ management (Bender et al. 1997). Then, patient counselling also by pharmacists should focus more on supporting the asthma self-management (issues 4-6, Table 12). It has been reported that community pharmacists tend to give extra counselling especially to new patients i.e. those who are receiving their medicine for the first time (Blom et al. 1993). More attention should be given to long-term users with refills. Identifying problems also in medication of chronic patients and their management is crucial, because they may use many kinds of medicines at the same time (Ahonen 1993).

In Finland, community pharmacies do not get any reimbursements for patient counselling or outcomes monitoring. The pharmacists should ensure that the patient knows how to use his/her medicines and a sufficient information about the medicines belong to their price (Association of Finnish Pharmacies 1997a). More valid than discuss about money, the pharmacists should discuss about improving the quality of
services by implementing the patient-oriented attitude to their work. After that, it should be evaluated, what actually belongs to sufficient information and what are the services that should be reimbursed. The resources of community pharmacies to produce extended services should also be estimated.

Pharmacists should put more focus on monitoring patient outcomes. Monitoring of outcomes means a systematic evaluation of patient’s management with the disease. The pharmacists should use prescriptions and discussions with the patient as tools for evaluating the management. In every visit, the pharmacists should identify and solve the possible problems in patient’s self-management and the issues reported in Table 12 can be used when monitoring asthma patients outcomes. The pharmacist should also be able to direct the patient to the physician, when appropriate. In asthma, this should happen for example when the patient has not received specific instructions from the physician for adjusting the medication according to asthma symptoms.

It has been reported, that asthma patients are satisfied with the services provided by their pharmacists (Liu 1999) but the frequency of counselling by pharmacists is not high (Liu 1999, Osman et al. 1999) and has not to any statistically significant extent increased during recent years (Morris et al. 1997). This may reflect that in addition with training in communication skills, pharmacists also need more education in basic pharmacotherapeutic skills. There have been changes in asthma treatment and pharmacists may be uncertain in counselling the patients in treatment and self-management. However, pharmacists are interested in becoming more involved in asthma care (Butler and Ayres 1987, Comino et al. 1992, Heslop et al. 1994), but they need reorientation to focus the counselling to patients’ needs (Airaksinen et al. 1994, Itkonen 2000). In guided self-care, asthma patients are encouraged to take the responsibility for the self-management (Ministry of Social Affairs and Health 1996). In addition with basic knowledge about the disease and the treatment, the pharmacists should also adopt a more patient oriented attitude in their pharmaceutical practice for supporting patients in their self-care.
10.2.4 Using Therapeutic Outcomes Monitoring (TOM) to improve the quality of pharmaceutical services

The Therapeutic Outcomes Monitoring (TOM) protocol was one of the very first structured models for implementing pharmaceutical care in the pharmacy practice. Results from the TOM studies have already been reported from Denmark and the Netherlands (Herborg et al. 1996, van Mil 1999) and they have been in the same direction with our study. In the Danish TOM study, the asthma patients clinical outcomes improved and they were satisfied with pharmacy services (Herborg et al. 1996). In the Dutch TOM study, patients were very satisfied with the education, counselling and outcomes monitoring provided by community pharmacists (van Mil 1999). The asthmatics learnt to use the PEF meter to evaluate their asthma symptoms and to adjust their medication accordingly. The numbers of courses of antibiotics and oral steroids decreased, though not statistically significantly.

When establishing extended services according to the Therapeutic Outcomes Monitoring (TOM) procedure, Grainger-Rousseau and his colleagues (1997) reported that the two most problematic areas for pharmacists were documenting and feedback to physicians. In our study, the pharmacists also complained of the paperwork and the inflexible study protocol. According to pharmacists’ reports, the investment of time and resources in the pharmacies to the intervention did not seem to be very high. The largest problem was to arrange enough time for appointments with patients because of the shortage of the pharmacy personnel. Although we did not systematically study pharmacists’ opinions, it could be seen that the pharmacists needed detailed training into the protocol and how to conduct documentation.

It is not possible to spend as much time as in this study on every chronic patient who visits the pharmacy. Enhanced education and counselling - as documented in the TOM model – could be regarded as a more patient oriented attitude in the pharmacy practice. The pharmacist should tailor the training and monitoring according to patient’s needs and identify those patients who would need more extra counselling and who would benefit from enhanced education and counselling. Indicators for finding such patients have been proposed to be large number of medicines or doses per a day, more than three
concurrent disease states present, history of non-compliance and presence of drugs that require therapeutic drug monitoring (Koecheler et al. 1989). Although the resources of community pharmacies are limited, good outcomes in patient care can be achieved by investments in the content of the pharmaceutical work in the day to day contacts between pharmacists and patients.

Asthma patients were satisfied with the counselling provided by community pharmacists. This represents a signal that outcomes monitoring and enhanced education and counselling should be the direction that pharmacists should move their work in the future. Therapeutic Outcomes Monitoring is one valuable example of potential ways to implement pharmaceutical care into pharmacy practice. More new models should be developed and evaluated in order to find the best that could be implemented into pharmaceutical practice.

10.2.5 Improving Finnish community pharmacy services through the philosophy of pharmaceutical care

Finnish reimbursement rules ensure that the patients are able to obtain a three month supply of their medicines. Thus chronic patients must visit community pharmacies at least four times a year which gives good possibilities for pharmacists to monitor the patient’s treatment and provide support to patients in their disease management. In addition, according to prescribing rules in Finland, the prescription can be repeated up to three times without the prescriber actually physically seeing the patient. In rare situations this could mean that the patient would receive medication for four years without ever being in contact with his/her physician. For those patients, pharmacists may be of particular importance in detecting and monitoring therapeutic outcomes and providing information about the disease management and if necessary, the pharmacist should urge referral to the physician. For some patients, the pharmacist may be the only source of information about the disease and its management (Smith and Baumann 1988).

Even though the Finnish pharmacists are responsible for ensuring that the patients know how to use their medicines, outcomes of patient education have not been good.
Pharmacy services mostly consist of traditional dispensing, although the customers would prefer more counselling and outcomes monitoring (Airaksinen 1996). This means that pharmacists have underestimated the demand for crucial pharmacotherapeutic information (Airaksinen et al. 1993). Also Vainio et al. (1998) reported that counselling of patients is restricted mainly to technical aspects (e.g. how to use equipment), but not to monitoring patients’ problems or communication with the patient in general.

The pharmacists have to improve their attitudes to counselling as one of the most important parts of pharmaceutical work. There is a wide consensus that the next step for improving the quality of pharmacy services is to adopt the outcomes-oriented role when dispensing medicines and counselling patients (Airaksinen et al. 1994, The United States Pharmacopeial Convention Inc 2001). In addition with a new attitude to the pharmaceutical work, pharmacists need good communication skills and pharmacotherapeutic skills (Airaksinen et al. 1998). The concept of improving the pharmacy services through this outcomes-oriented attitude needs also to be implemented in practice by all the pharmacists: from pharmacy owners to those who work with customers (Association of Finnish Pharmacies 1997b).

The need for a more patient oriented attitude in pharmacy practice lead to a more active co-operation between authorities and pharmacy organisations to find ways to improve the quality and quantity of education and counselling being delivered by pharmacists. A new national joint programme, TIPPA (Appropriate information from pharmacists for patient’s good) was established to improve patient counselling. This project has been supported by the national pharmacy authorities and organisations; the Social Insurance Institution and the universities.

The main aims of the programme are to promote rational use of medicines; to decrease negative effects of inappropriate use of medicines, including self-medication; and to decrease health care costs by enhanced counselling (Peura et al. 2000). The focus is to teach pharmacists a new outcome-oriented approach to patient counselling, provide tools for updating pharmacotherapeutic knowledge and for learning communication skills. Other purposes of the programme are to promote the rational use of medicines; to decrease the negative effects of inappropriate use of medicines, including self-
medication; and to decrease health care costs by enhanced counselling (Peura et al. 2000).

The implementation of the programme has been divided to four parts. In the first part that started in 2000, the main objective was to survey the present situation in patient counselling by community pharmacists. In the second part (during 2001-2002) the purposes are to educate the pharmacists to improve the patient counselling and to tailor counselling concepts for community pharmacies. During 2002-2003, the quality assurance of the counselling models will be established. The evaluation of the programme will be done in 2004.

A computerised database on prescription medicines for counselling, Tietotippa, was created to help the pharmacist to give customised information to the patient (Hirvonen et al. 1999, Hirvonen et al. 2000). This system provides basic information about prescription drugs and it can be accessed while the patient is waiting in the pharmacy for his/her medication to be dispensed. The programme is aimed at assisting pharmacists to provide oral information; it is not possible to use the programme to print written information to the patient.

10.2.6 Co-operation between patients and health care professionals

Multidisciplinary teams of health professionals deliver most of the health care services provided to patients. Each team and even each member of the team brings different knowledge and skills to the service of patient health care. Working together requires good co-operation between these health professionals. This approach where different health care teams are working successfully together is called seamless care (Heath 1998). Pharmacy services can be regarded as one of the services that are included in patients’ seamless care.

In this study, we investigated how to establish seamless care between health professionals, patients and representatives from patient organisations in local circumstances. We did not systematically study health professionals’ opinions or experiences about the co-operation. The patients involved in the Nivala pharmacy study (I) and in the ASTHMA-TOM study (II, III and IV) were satisfied with these services.
In the beginning of the intervention, the patients reported problems that prevented them from achieving the defined outcomes in self-management. The number of perceived problems in asthma patients self-management decreased due to the enhanced education, counselling and outcomes monitoring by community pharmacists. A successful cooperation between health professionals was established to solve these problems.

In practice, there may be problems in establishing active co-operation with other health professionals. They all are busy with their own routine work and may find it difficult to find the time to contact each other, which limits the communication between physicians, nurses and pharmacists. There may also be lack of knowledge about what the other groups actually do. It has been reported that pharmacists tend to assume that the patients are already well educated by physicians and nurses (Ellis and Friend 1985, Vainio et al. 1998). Good results have been achieved in establishing co-operation for example in developing practice formularies and holding regular prescribing meetings between pharmacists and physicians (Ekedahl et al. 1994, Tordoff and Wright 1999). There is a need to create a new culture of co-operation in practice that pays attention to deeper and more regular communication between health professionals (Tanskanen et al. 1997). Education about co-operation should also include learning how to work as a team and how to establish patient-centred care (Coles 1995). The goal of the health services should be seamless care of the patient in which the health professionals - e.g. physicians, nurses and pharmacists - are all working successfully together with goal of improving the patient’s outcomes.
11 CONCLUSIONS

Based on the results of this study, the following conclusions can be drawn:

1. It is possible for community pharmacists to detect and solve problems in asthma patients’ medication and to help them with self-management. Prescription review and short patient interviews are tools that can be routinely used in detecting problems and evaluating patients’ counselling needs. Access to patient medical records would enhance the possibilities for pharmacist intervention.

2. Therapeutic Outcomes Monitoring is a useful tool for pharmacists to implement the philosophy of pharmaceutical care. More new models should be developed and evaluated in order to find the best way to implement this concept.

3. Enhanced education, counselling and outcomes monitoring by community pharmacists can improve outcomes in the treatment of asthma patients. It also improves asthma patients’ knowledge about and attitudes towards asthma. Because of the limitations (a convenience sample and the lack of controls) of the study, the results have to be interpreted with caution. As well as dispensing medicines to patients, pharmacists should also educate the patient about the disease and the medication; support the patient in practising self-management and monitor the outcomes of the management.

4. Asthma patients are satisfied with the enhanced services provided by community pharmacists. The quality of pharmacy services can be improved by patient-oriented attitude by community pharmacists according to the principles of pharmaceutical care.

5. The principles of asthma follow-up according to the asthma guidelines were generally successfully implemented four years after the guidelines were established. Those patients over 65 years and those who have been on asthma medication for more than 5 years seem to be the subgroups who need extra counselling and outcomes monitoring in their management.
12 REFERENCES


Airaksinen M. Customer feedback as a tool for improving pharmacy services in Finland. Doctoral dissertation, Department of Social Pharmacy, University of Kuopio, Kuopio, 1996


Association of Finnish Pharmacies. Community pharmacies in Finland. For your health. Publications of the Association of Finnish Pharmacies, 1997a

Association of Finnish Pharmacies. Guidelines for a professional community pharmacy in Finland. Publications of the Association of Finnish Pharmacies, 1997b


Brook RH. Studies of process-outcome correlations in medical care evaluations. Med Care 17:868-873, 1979


Coles C. Educating the health care team. Patient Educ Couns 26:239-244, 1995


Donabedian A. The quality of care - how can it be assessed? JAMA 260:1743-1748, 1988


Ellis ME, Friend JA. How well do asthma clinic patients understand their asthma? Br J Dis Chest 79:43-48, 1985

EURO-TOM. The impact of pharmaceutical care on the management of asthma patients. A mission statement of a European collaboration on implementation of a model for Therapeutic Outcomes Monitoring, 1994


Fincham JE. The importance of outcome research for pharmacy. Am Pharm NS33(12 Suppl): S1-S2, 1993

Fincham JE, Gottlob A. The Kansas report. Am Pharm 5:30-33, 1997


International Pharmaceutical Federation. The Tokyo Declaration: Standards for quality of pharmacy services, 1993
Itkonen J. Autonomy and paternalism in the information given by community pharmacists. Doctoral dissertation, Department of Social Pharmacy, University of Kuopio, Kuopio, 2000 (in Finnish)


Reeder CE, Kozma CM, McCollan AR. Overview of pharmaceutical outcomes, pharmacoeconomics and quality of life. In the book: A pharmacist’s guide to principles and practices of managed care pharmacy. A publication of the foundation of managed care pharmacy, Alexandra, Virginia, USA, pp. 159-170, 1995


Rupp MT, DeYoung M, Schondelmeyer SW. Prescribing problems and pharmacist interventions in community practice. Med Care 30:926-940, 1992


Smith NA, Bauman AE. The potential for pharmacists as patient educators in asthma. Aust J Hosp Pharm 18:244-248, 1988


Speedie MK. Curriculum change: pharmaceutical care or missed opportunity? Am J Pharm Educ 56:94-95, 1992


Tordoff JM, Wright D. Analysis of the impact of community pharmacists providing formulary development advice to GPs. Pharm J 262:166-168, 1999


Watman GP, Harris ND. Influence of pharmacist counselling on the management of asthma patients in the community. Pharm J 1:560-561, 1986


