Towards Improved Medication Use

Increasing Understanding of Professional Efforts

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**Abstract**


Professionals and researchers have developed a number of strategies aimed at improving the quality and safety of medication use. However, studies continue to demonstrate persistent problems. For instance, the first paper in this thesis reveals the prevalence of potentially harmful drug combinations among elderly people in Europe. The following four papers focus on two professional groups and how they have approached safety and quality issues related to medication use: 1) the Swedish drug and therapeutics committees (DTCs) and 2) pharmacist involved in pharmaceutical care, an international movement. Qualitative research approaches were applied.

Papers II and III focus on the DTCs: analyses indicate a development of the perception of the DTC role over time. The focus of the activities was broadened – from targeting prescribing physicians to incorporating decision-makers and patients. However, a clear patient-centered perspective was generally lacking. Moreover, the findings indicate a shift in focus from cost aspects of medication use to an increased focus on quality and safety aspects.

In the studies addressing pharmaceutical care (Papers IV and V), the findings propose that different classification systems for drug-related problems had different characteristics which reflected differences in goals in the pharmaceutical care process. It was also found that the concept of pharmaceutical care was understood in different ways and that the perceptions were based on at least two different understandings of health and illness. First, a patient-centered perspective characterized by a *holistic* understanding of health and illness, and, second, an “EBM perspective” primarily based on a *biomedical* understanding of health and illness.

This thesis has disclosed new aspects of how two groups of professionals perceive their work towards improved quality and safety of medication use. A patient-centered perspective among healthcare collectives is not obvious; therefore, efforts and comprehensive strategies supporting change are necessary. Strategies should focus on challenging the traditional thought patterns and care approaches among professionals and students.

**keywords**: drug quality problems, drug and therapeutics committees, pharmaceutical care, perceptions, patient centeredness

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List of Papers

This thesis is based on the following five articles, which will be referred to in the text by their respective Roman numerals:

I. **Drug-drug interactions in the elderly.**
   Björkman I, Fastbom I, Schmidt I, Bernsten C

II. **The role of drug and therapeutics committees - perceptions of chairs and information officers.**
    Björkman I, Bernsten C, Schmidt I, Holmström I

III. **Developing the role of the drug and therapeutics committees – perceptions of chairs.**
     Björkman I, Schmidt I, Holmström I, Bernsten C
     *International Journal of Health Care Quality Assurance* Accepted

IV. **Comparing four classification systems for drug-related problems: processes and functions.**
    Björkman I, Sanner M, Bernsten C
    *Submitted*

V. **Care ideologies reflected in four classification systems for drug-related problems.**
   Björkman I, Bernsten C, Sanner M
   *Submitted*

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# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
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<tr>
<td>ANOVA</td>
<td>Analysis of variance</td>
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<td>DDI</td>
<td>Drug-drug interaction</td>
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<td>DRP</td>
<td>Drug-related problem</td>
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<td>DTC</td>
<td>Drug and therapeutics committee</td>
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<td>DTP</td>
<td>Drug-therapy problem</td>
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<tr>
<td>EBM</td>
<td>Evidence-based medicine</td>
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<td>GP</td>
<td>General practitioner</td>
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<td>GT</td>
<td>Grounded Theory</td>
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<tr>
<td>HRQoL</td>
<td>Health-related quality of life</td>
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<tr>
<td>NHS</td>
<td>The National Health System (UK)</td>
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<tr>
<td>OMA</td>
<td>Not really an abbreviation! Means “Grandmother” in Dutch and German</td>
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<tr>
<td>PC</td>
<td>Pharmaceutical Care</td>
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<td>RTC</td>
<td>Randomized Clinical Trial</td>
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<td>UK</td>
<td>The United Kingdom</td>
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1. Preamble

What is good and how can this be reached?

This question is central in philosophy and applicable to a variety of aspects in our lives, both personally and collectively. It also connects with the notion of the world being experienced as content and form – form and content as inseparable qualities of all phenomena. In this thesis I have used this question to explore medications and how they are used in society. Actually this was not explicitly formulated when I started. However, as I summarize my work, I can see that this question has been a lodestar during my studies.

Early in 2002, when I had to write a research title on the application form to register as a PhD student, I chose the simple formulation “Good drug use”, a very broad title that was left open for later interpretations. At that time my research question was more a feeling of something important to focus on. Looking back I can see that even though this interest of mine was vague and not explicit expressed, it has given direction to my research.

My background as a pharmacist has had a decisive impact on this thesis. It has given me a broad insight into various aspects of the medication field, not from a scientific academic perspective but from the ground up. My experience as a pharmacist at several community pharmacies in Stockholm allowed me to meet thousands of patients coming to get their prescribed medicines, asking about minor illnesses, and participating in health promotion activities. I have also met healthcare professionals in various situations; for several years I presented independent drug information and met GPs at healthcare centers, and for some years I worked on multidisciplinary teams, which reviewed patients’ drug use in nursing homes. Before being an Apoteket AB employee I met with several specialist physicians for a couple of years promoting drugs at a drug company.

However, there was one experience that started to change my understanding of the patient’s role in healthcare. For some years I was the project leader of the Swedish part of a European study on pharmaceutical care, called the OMA project. The aim of the study was to explore whether elderly patients who used medications could benefit from consultations with a pharmacist. Through the stories of the 11 OMA pharmacists about their struggles with the elderly and their drug use I started to realize how different people think about their therapy and how little attention we as professional
pharmacists paid to these ways of thinking. In pharmacy school I had not learned anything about this social side of using drugs. We studied how pharmacological substances made the body function better. However, there is something very crucial missing there, and that is that drugs are used by individuals and they (or read “we”) have their (our) own preferences and ways of treating themselves (ourselves).

My intention in this thesis was to study how professionals work for improved quality in drug use, but not to focus explicitly on the role of the patients. However, in all analyses (except in the first paper) the question of the patient’s role has been on my mind. I noticed, and was astonished to see, that when professionals discuss drug use improvements, the patient is often left out. Drug use is often viewed in abstract terms, as an object that can be ruled like other objects. Consequently, it was impossible for me not to include the question of the patients’ position in my thesis.

Most doctoral studies contain a mental journey, and so do mine. What I have learned is literally that the world appears different depending on which “glasses” you put on. This is obvious when you think about it, but very easy to forget. For me the encounter with the qualitative research method phenomenography and its underlying theories has been important. I found this approach fascinating and useful not only in a classroom situation but also as a means of contributing to professional development. Moreover, the phenomenographic analysis inspired me to use other qualitative methods. Clearly, this learning gave me new tools to explore phenomena in a field that was familiar to me.
2. Introduction and aims

The focus of this thesis is on medications and how they are used in society. Medications are thought of as agents that bring good to humanity. However, a body of studies shows that this is not entirely true. We use more medications than we ever have before, and with the increased usage new problems are created. People actually get ill and even die from using medications. This is a problem that affects us all, directly or indirectly, and thus it has become a public health issue that demands our attention.

Efforts towards safer drug use are desired – from the individual patient’s perspective, from a professional healthcare perspective, and from a public health perspective. The question is how to work out specifically what should be achieved and how can this be reached. There are many possible approaches, but the problem persists and therefore it is important to scrutinize these approaches further. In this context, and in order to create new understanding, I have chosen to explore two approaches that aim at improved drug use.

The explorations in this thesis are based on two basic assumptions.

a) The world we live in – including science, healthcare, and the delivery of healthcare services – is socially constructed. By living and acting in the world, we constitute our society. Therefore I think it is worthwhile to take a second-order perspective and study how professionals describe their work themselves, because how they think about their work simultaneously shapes their work.

b) The way in which professionals regard patients, when they describe their professional work, is essential. This can give a hint of how patients are involved or not involved in healthcare. Patient participation in healthcare is desired and requested – both from policy level and from patients – and, at least in theory, it is a common notion that the patients, being the end-users of medications, need to be involved in order to improve the quality of medication use.

The two approaches I have selected for exploration are 1) a healthcare policy approach – the work performed at drug and therapeutics committees (DTCs) and 2) a professional approach – pharmacists and pharmaceutical care (PC). These two approaches have many differences but a similar aspect is that both are under development. Due to the complexity of the issue of improved drug use, which is a challenge for the professionals, knowledge from various perspectives is necessary.
The first approach that was studied is an example of a national healthcare policy. DTCs have existed in Sweden for over 40 years but a new law passed in January 1997 changed their assignments. From then on their goals were to contribute to reliable and rational drug use within their own counties. However, the law does not specify the details of how this shall be done, and consequently interpretation of goals and development of strategies is performed locally by the county councils and DTCs.

The second approach is an international professional movement: pharmaceutical care. Pharmacists who before were the producers of drugs now find that the task of working for improved drug use in society is within their domain. To meet this new challenge, pharmacists are changing their profession to include their new role in a way they believe is appropriate, and are developing methods for patient care.

The perspective I want to use is that in each of these approaches there is an idea that is brought into play by practicing professionals. These are, respectively, the goals of the law and the idea of pharmaceutical care. An idea is a timeless entity in the minds of people but when the idea is practiced in reality it must be translated into time-space, the actual now which constitutes our common existence. This thesis focuses on describing how this translation comes out, as expressed by the professionals themselves.

Aims

The overall aim of this thesis is to increase our understanding of how two professional collectives – the Swedish drug and therapeutic committees and the international pharmacy profession – have approached the safety and quality problems related to medication use in healthcare.

Specific aims:
I. Study the prevalence and type of potential drug-drug interactions among elderly Europeans, as well as to describe differences between countries.
II. Explore how DTC chairs perceive the DTC role and how information officers perceive their own roles, and determine whether DTC professionals considered patients in their answers.
III. Explore the variations in how committee chairs perceive the DTC role, and make comparisons with the previous study.
IV. Compare four classification systems for documenting DRPs and describe their characteristics in order to understand their similarities and differences.
V. Explore the care ideologies that are reflected in four established classification systems.
Outline of this thesis

In the Background section I will present various research areas that are related to this thesis. The areas include problems related to drug use, different methods for quality improvements, drug policy in Sweden, implementation of political decisions, patient involvement in healthcare, drug and therapeutics committees, and pharmaceutical care.

The penultimate paragraph in the Background presents ideas about how a scientific fact is generated. This paragraph may be regarded as being odd in the context but is included because it demonstrates how human beings are co-creators of our world. It can provide insights and open up for new understanding, which I consider valuable. The last paragraph in the Background addresses methodologies used in the papers.

The following chapters present the five papers included in this thesis. At the end the methods and findings are discussed.

Overview of the data and the analysis methods that are used in the studies.

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<th>Analysis method(s)</th>
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3. Background

Quality and safety problems with medication use

Prescribing medicines is a common treatment strategy today, probably the most common. Drug prescribing continues to increase; in Sweden as well as in many other countries (National Board of Health and Welfare 2005). New medicines make the treatment of new diseases possible, and large randomized controlled trials propose beneficial outcomes from the use of already existing therapies on new indications. Furthermore, risk factors increasingly are being diagnosed and treated and the proportion of elderly patients in Sweden, as in other countries, is increasing. All these factors inevitably lead to increased prescribing of medications.

Parallel to the increased usage of medications, numerous studies show that inappropriate or excessive use of medication can cause distress, ill health, hospitalization, and even death (Pouyanne, Haramburu et al. 2000; Ebbesen, Buajordet et al. 2001; Juntti-Patinen and Neuvonen 2002; Gandhi, Weingart et al. 2003; Yee, Hasson et al. 2005). In American studies it has been suggested that drug-related morbidity is probably the major cause of iatrogenic illness, i.e. illness caused by the healthcare system itself (Lazarou, Pomeranz et al. 1998). About 5-12% of all admissions to hospitals are caused by adverse drug reactions (Beard 1992; Mannesse, Derkx et al. 2000; Mjörndal, Boman et al. 2002; Pirmohamed, James et al. 2004). An early study in Sweden found that insufficient drug effect was also a common reason for hospital admission (Bergman and Wiholm 1981).

Sometimes adverse effects (and occasionally therapy failures) are caused by drug-drug interactions. They are not a major cause of hospital admissions; a review of nine studies found that 0-2.8% of admissions were caused by DDIs (Jankel and Fitterman 1993). Nevertheless, researchers find DDIs important to address because many reactions are predictable and thus can be avoided or managed (Seymour and Routledge 1998). Accordingly, to study the occurrence of potential DDIs is one way to acknowledge the magnitude of drug-related problems, and this was the focus in Paper I in this thesis.

Lately, patient safety within healthcare has gained increasing attention, and inappropriate and risky drug use is one of the major safety issues. This issue was put on the political agenda after a report from the Institute of Medicine in USA in 1999 (Institute of Medicine (IOM) 1999; Quality of
Health Care in America Committee 2000; Elwyn and Corrigan 2005; Leape and Berwick 2005). The message was that to change the trend of increased harm, a cultural shift was urgent. Healthcare should be viewed as a system, and errors in healthcare were the results of weaknesses in this system. To build a safer system all procedures should be quality-assured and errors should be voluntarily reported and learnt from. The aviation industry was highlighted as a good example (Reason 2000). In the United Kingdom the government launched several measures, e.g. the establishment of the National Patient Safety Agency (Elwyn and Corrigan 2005). Patient safety was taken into the agenda of WHO and this led to a resolution in 2002 (WHO 2002). In Sweden the National Board of Health and Welfare published a report on patient safety (National Board of Health and Welfare 2004b). Hence, strategies to improve drug use were on the agenda.

Strategies to improve drug use

The quality and safety problems within healthcare demands attention and a variety of improvement strategies have been developed. The specific activities that have addressed drug use problems include:

- A number of continuing education strategies, directed towards prescribers, often with the purpose of reinforcing guidelines (Thomson O'Brien, Oxman et al. 2001).
- Policy changes, e.g. the Omnibus Budget Reconciliation Act of 1987 (OBRA-87) and new guidelines specifically concerning the prescription of antipsychotic medications in nursing homes (Snowden and Roy-Byrne 1998), and the activities performed by DTCs.
- Organizational changes, such as the formation of multidisciplinary teams with the aim of improving quality of drug use in nursing homes and other settings (Schmidt 1999), and changes in professional approaches, e.g. pharmaceutical care.
- Computerized decision-aid support for prescribers (Sjöqvist, Bergman et al. 2002; Bastholm Rahmner, Andersen-Karlsson et al. 2004)
These activities have been carried out on both local and national levels, have developed out of professional ambitions or research, and have sometimes been related to policy changes.

The following section will pay specific attention to recent drug policy changes in Sweden, and a professional approach within pharmacy, and how these strategies and efforts are related to concerns of quality and safety in patients’ drug use.

A healthcare policy approach – drug and therapeutics committees
The Swedish healthcare system is publicly funded and organized on three levels – the national, regional, and local. The 21 county councils make up the basis of the healthcare system, including the responsibility for the largest part of the costs for medications. Eighty percent of the drug costs are covered by public funding. During the past decade the Swedish drug policy has been the target of several major changes.

In 1997 a reform introduced a new reimbursement system and began the transfer of medication costs from the state to the county councils. The rationale for this reform was to create incitement for county councils to work for cost control and cost-effectiveness (Social Ministry 1996). The government proposition stated that drug costs had increased heavily during the previous ten years. This increase was partly a result of the drug industry’s promotion of new expensive drugs. The increased drug costs were also related to benefits – economically for the society (e.g. drug treatment instead of surgery, shorter treatment time) and medically for the patients (increased quality of life). However, a radical reform was considered necessary in order to use the collective resources as effectively as possible. Problems related to drug use were also addressed, e.g. the over- and under-prescribing of medications, hospitalization related to drug use, and noncompliance among patients. A second important aim of the reform was to increase the quality of drug prescribing (Social Ministry 1996).

As a part of the 1997 reform, a new law was passed requiring all county councils in Sweden to have a drug and therapeutics committee (DTC). DTCs had existed in Sweden for several years. They were viewed as the counties’ expert boards on drug issues and many of them had been shown to have a good impact on the healthcare. An intention of the law was to increase the DTCs’ influences on drug prescribing (Social Ministry 1996). Financial resources were allocated for DTCs to develop their activities.

Generic substitution was introduced in October 2002, leading to a large reduction in drug expenditures. The same year a new state authority, the Pharmaceutical Benefits Board, was founded. The task of this authority is to decide whether a medicine shall be included in the pharmaceuticals benefit scheme and under what conditions it will be reimbursed. The new board was
supposed to contribute to a more strict reimbursement policy. However, so far almost all medications in Sweden are reimbursed.

**Drug and therapeutics committees and their role**

The first committees were established in hospitals in the USA in 1959/60 (Wade, Spruill et al. 1996) and the first committee in Sweden was formed in 1961 (Sjöqvist, Bergman et al. 2002). Committees also exist in Canada, Australia, and several European countries. The committee tasks have varied and expanded throughout the years. In Sweden, for instance, the first committees focused primarily on issues related to the local hospital. Common DTC tasks have included promotion of rational drug use, making up formulary lists, and controlling drug costs. Common activities are establishing recommendations and drug prescription follow-up, running drug information centers, sending out newsletters, and, since the 1990s, educating medical staff (Henriksen 1982; Wade, Spruill et al. 1996; Sjöqvist, Bergman et al. 2002). The members of the committees have traditionally been physicians and pharmacists, with physicians as the dominating profession (Cross 2001; National Board of Health and Welfare 2004a).

In Sweden the conditions for DTC work were changed by the legislation in 1997. Prior to the law their activities were voluntary, but from then on it was stated that each county council was required to have at least one DTC. The DTCs were also given a common goal, that of contributing to reliable and rational drug use.

Five years after the passing of the law, the National Board of Health and Welfare was commissioned by the Swedish Government to evaluate the DTCs’ accomplishments. The inquiry demonstrated that the DTC activities had an effect on the drug prescribing, and that DTCs had focused mainly on reducing drug costs and producing lists of recommended medications (National Board of Health and Welfare 2004a). Increasingly, however, new strategies to educate prescribers had been used, such as local prescription audit and feedback. The inquiry resulted in a number of proposals to the DTCs, including 1) more focus on safety and quality issues, 2) less focus on developing recommendations similar to those already existing on a national level, 3) focus on cooperation across county councils, and 4) the strengthening of the committees’ competence in education and communication.

**Implementation of political decisions**

The conditions for the DTCs in Sweden as well as their tasks were changed by the new law. One way to describe and understand the implications of this new direction is to view the DTCs’ work as an example of how political decisions are implemented. The theories that are presented below were used
Implementation research has developed in the field of political science during the past 30-40 years. This research concentrates on the operational performance and the conditions for realization of decisions in a democratic system (Spångberg Winblad 2003). The implementation as such can be understood as the meeting between the formal content of the politics and the reality (Spångberg Winblad 2003). Here, this means that the formal content is the new legislation of the DTCs; the reality is the output “out there”; and the point of the meeting concerns how the DTCs actually work to fulfill the goals stated in the law. This meeting includes a transformation of formal content to DTC activities and this transformation reflects how members of the committees understand their task.

The two most common implementation models are the top-down (Pressman and Wildawsky 1973; Mazmanian and Sabatier 1983) and the bottom-up perspectives (Lipsky 1980). The top-down model focuses mostly on structural explanations and the bottom-up model on the actors of the system. Newer models often combine these two but I will use the models separately to simplify the reasoning.

In short, the ideal top-down model means that a decision comes from the leaders at the top and starts a reaction within the ideal hierarchical bureaucratic system. On each level of this system there are ideal bureaucratic workers who operationalize the decisions by following the politicians’ instructions without reflection. “Ideal” means here an ideal type as outlined by Weber (Weber 1993). An ideal type is a simplified model of a real social phenomenon and is used to analyze social interactions. There are no values linked to an ideal type, and it has nothing to do with the “idealized” type which is “the best”.

In contrast, the bottom-up model teaches that the actual policy are shaped in the meeting with the public and the ‘street level’ bureaucrats (Lipsky 1980). The people who work at the lower levels in the political system do not act according to detailed directions. These people have high expertise and are given the freedom to shape the activities without central control. However, in Lipsky’s bottom-up model the actors also make choices and act without reflection, i.e. they use their knowledge in a non-reflected way. Another aspect from Lipsky concerning the actions of the bureaucrats is that the actors according to this idea develop “survival strategies” to make their work possible. One strategy is to prioritize the easier tasks and to avoid the complicated and time-consuming tasks where no standard methods are available.

The use of these theories gave new perspectives on the DTC work and these findings will be presented in the discussion at the end of this thesis.
A professional approach – pharmacists and pharmaceutical care
The pharmaceutical profession has worked with drugs and with selling drugs to people for hundreds of years. Traditionally the pharmacy was the place where medications were produced, controlled, and distributed. However, during the second half of the twentieth century the production of medications was taken over by the growing pharmaceutical industry and the pharmacy’s role was reduced to that of a distribution channel. During this period there was a de-professionalization of the pharmaceutical profession. Contributing factors to this development were found to be issues like internal splits among pharmacists, the strong professional connection to the drugs as such, and the notion that pharmacists were viewed traditionally as a sub-profession to physicians (Claesson 1989).

One new role that pharmacists are developing, and which Papers IV and V focus on in this thesis, is working with pharmaceutical care. The background is, besides the professional change among pharmacists described above, the increased availability of potent drugs, leading to more complex and advanced drug treatment programs, and to new demands on patients and healthcare. This has opened up new opportunities for pharmacists to broaden their competence and market their profession as the drug experts of the society.

Beginning during the 1960s in the USA, pharmacists have developed a new clinical role at hospitals in cooperation with other health professionals (McLeod 1976; Parker 1985; McLean, Lalonde et al. 1989; Lipton and Bird 1994; Cording, Engelbrecht-Zadvorny et al. 2002; Schumock, Butler et al. 2003). Here the Swedish situation is different compared to, for example, the situation in North America and the UK. In Sweden pharmacists rarely work in hospital wards. This may be to some extent related to the lack of educational programs for clinical pharmacists in Sweden, something that has changed recently; the first clinical pharmacy program started at Uppsala University in September 2006.

With its roots in clinical pharmacy, a new role in relation to individual patients began to develop in the USA during the second half of the 1970s. A changed role toward patients also began to develop in community pharmacies in Europe during this decennium (Claesson 1989; van Mil 1999). An important landmark was the Standard of Good Pharmaceutical Practice outlined in 1979 by the American Association of Clinical Pharmacy (AACP) and the American Pharmaceutical Association (APA). The development was based on a growing awareness of the need to support the process in order to achieve optimal therapeutic effect from the new advanced medications (Berenguer, La Casa et al. 2004). Thus, when Hepler and Strand launched their new concept in 1990 and called it “Pharmaceutical Care”, the profession had already started to change its work towards a patient-oriented practice.
The term “pharmaceutical care” had been used as early as 1975, but at that time it was used for pharmacy service given to inpatients at hospitals (Mikeal, Brown et al. 1975). The concept of Pharmaceutical Care (and from here on pharmaceutical care will be called PC) did however, mean something different (Hepler and Strand 1990). PC according to Helper and Strand includes a new professional caring attitude, clarified responsibilities, and several structured methods for professionals to use. The concept included a professional philosophy, and the pharmacists were presented as healthcare providers with responsibility for individual patients’ drug-related needs.

In the meantime the Hepler and Strand article was an appeal to all pharmacists, suggesting that this switch in professional role was the chance for pharmacists to survive at all as a profession (Hepler and Strand 1990; Penna 1990). Distributing medications was said not to be a sufficient motivation for defining the pharmacist’s role as a profession. However, the proposed professional changes have brought about a new internal professional split, e.g. pharmacists with a technical focus contra the new caring attitude, and the pharmacist as a shop owner contra being a member of the healthcare team (Almarsdottir and Morgall 1999; Traulsen and Bissell 2004).

The ideas of PC have been adopted and developed by community pharmacists in many countries (van Mil 1999). The evolution will not be presented here, but to grasp the situation today a recent article series entitled “Pharmaceutical care worldwide” in The Annals of Pharmacotherapy will be reviewed. The series includes experiences from Australia, Canada, Germany, the Netherlands, Spain, Switzerland, Sweden, and the USA. The reviews demonstrate a variety of “pharmaceutical care” activities performed at community pharmacies. In general “pharmaceutical care” has been interpreted in a wide sense and used interchangeably for “pharmacy service”, “patient care”, “cognitive service”, or “medication therapy management service”. Few authors seem to used the definition of PC as outlined by Hepler and Strand (Hepler and Strand 1990).

In Australia the pharmacists are considered to be key partners in achieving optimal health outcomes and economic objectives, as defined by the National Medicines Policy (Benrimoj and Roberts 2005). Decisive for the development is a series of five year-long agreements between the Government and the Pharmacy Guild of Australia (community pharmacy owners). The agreements have included strategies for patient care and financial incitements for pharmacy involvement. One of these is that pharmacists are expected to assist people to make informed decisions about their health. A variety of services are provided, for instance drug information, counseling on minor ailments, drug regimen reviews, health promotion, and therapy outcome as well as adherence monitoring.
Canada reports that cognitive services by pharmacists are now becoming more frequent. However, the lack of reimbursement is a problem (Jones, Mackinnon et al. 2005). Services included in the presentation are the counseling and written information provided when new prescriptions are dispensed, home delivery of prescriptions, and monitoring blood pressure. Since 1978 pharmacists in Quebec are paid for writing opinions (recommendations to physicians) and for refusal to dispense potentially harmful prescriptions, however the frequency of these activities is low. New projects include dispensing new medications for only seven to ten days and having the pharmacist monitor effects before the next dispensation.

Pharmacy services in Germany involves the supplying of drugs, providing drug information and advice, screening for diseases, promoting health, and the provision of pharmaceutical care (Eickhoff and Schulz 2006). Many projects have been conducted on PC. One that was especially successful was a project addressing patients with asthma. This was a three-sided cooperation involving community pharmacists, insurance companies, and physicians. The project is now implemented on the national level, which means that pharmacists in Germany now are paid for pharmaceutical care provided to patients with asthma, as defined by the contract. A change in legislation in 2001/2002 was helpful for the development of the asthma program, including financial benefits to patients who join disease management programs.

In the Netherlands pharmacists are paid only for the dispensing of medications. However, all pharmacists regard themselves as healthcare professionals and not as shopkeepers (van Mil 2005). Medical surveillance as a part of dispensing has a long history in Dutch pharmacies. Interactions have been checked since the 1970s, and computerized prospective medication surveillance for all new drugs has been performed since 1990. Since 1995 Dutch pharmacists and local general practitioners have meetings on a regular basis. Other activities are medication analysis based on indicators and individualized information given the first time a drug is dispensed to a patient.

The main task of pharmacies in Spain, according to a law from 1997, is to distribute drugs. However, pharmacies should also provide what is described as “patient care” (Gastelurrutia, Faus et al. 2005). An agreement with the Ministry of Health and an expert panel published in 2001 defined three main services that should be provided. These include giving advice when dispensing drugs, advising patients about minor ailments, and “pharmaceutical follow-up”. “Pharmaceutical follow-up” means monitoring patients to identify and prevent negative clinical outcomes. The quality of the implementation of these services is, however, questioned.

In Switzerland a new remuneration system for community pharmacies was passed in 2001. The new system separates the remuneration for distribution and for pharmaceutical cognitive services (Guignard and
Bugnon 2006). As a result the costs of drugs have dropped and in the meantime pharmacists are better known by their customers and their collaboration with insurers has improved. Examples of activities that are remunerated are checking prescriptions and giving advice, checking risk factors during dispensing, follow-up and maintenance of medical records, generic substitution, quality circles with GPs, and pharmaceutical consultations in nursing homes. The promotion of adherence, PC service for particular diseases, and medical reviews are provided on a small scale and without remuneration.

In Sweden the pharmaceutical care activities include self-care counseling, health promotion, and written self-care information provided in pharmacies and on a website, as well as the identifying, resolving, and documenting of drug-related problems (DRPs) (Westerlund and Björk 2006). Non-individual documentation of DRPs has been possible in all pharmacies’ computers since 2001. Individual PC documentation is slowly being introduced in voluntary patient medication profile programs. Medication reviews by pharmacists working at healthcare centers has been tested. All pharmacies in Sweden belong to The National Pharmacy Corporation, “Apoteket AB”.

In the USA every state has its own regulations for pharmacy and pharmacists (Christensen and Farris 2006). Most states require the maintenance of drug use profiles and check for harmful drug combinations or contra-indications before a drug is dispensed. When new drugs are dispensed, instructions should be given to patients and counseling offered. However, this counseling is included in the dispensing fee and usually limited to focus brief messages about administration of drugs, precautions, and potential adverse effects. Payment for cognitive service is rare but seems to be growing, including features like medication reviews and the resolution of DRPs.

However, new concepts and movements in the healthcare sector have been launched parallel to PC, and two of them will be discussed below.

Evidence-based medicine and patient centeredness

Besides the increasing awareness of quality and safety issues related to healthcare there are two important “social movements” – perhaps better called “social forces “ – that have significantly influenced healthcare science and services in the past two decades – Evidenced-Based Medicine (EBM) and Patient centeredness. The following section will provide a brief overview of these movements, since these concepts are linked to the development of both DTC activities and to pharmaceutical care.

EBM is a concept that in about 15 years has become a cornerstone in healthcare for the decision-making in medical therapy issues (Reilly 2004). It started as a new method to teach medical students how to practice
medicine (Evidence-Based Medicine Working Group 1992; Leape, Berwick et al. 2002; Lambert 2006). The new approach was grounded in problem-based learning and critical appraisal of published therapy studies (Evidence-Based Medicine Working Group 1992). The critical appraisal technique was presented as an effective method of separating scientific evidence from superstition. One characteristic of EBM is a biomedical understanding of health.

Somehow, EBM has been transformed from a way of finding the best evidence and into a clinical discipline (Editorial 1995; Goldenberg 2006). The creators of EBM explained in a commonly cited article that EBM means “integrating individual clinical expertise with the best available external clinical evidence from systemic research” (Sackett, Rosenberg et al. 1996). To support the development there has been a long series of articles (30 papers between 1993 and 2000) that explain how EBM should be used in practice, for instance how to take individual patient data and calculate individual numbers needed to treat or to harm (McAlister, Straus et al. 2000). The studies with the highest grade of evidence according to EBM are the large Randomized Clinical Trials (RCTs). However, whereas the intern validity in RCTs is often high, the external validity may be poor. Thus it is difficult to generalize the results from a RCT to a different patient population (Rothwell 2005).

There is a connection between EBM and the system approach in the Patient Safety movement. This connection is that procedures based on EBM are viewed as obvious ways to improve healthcare and reduce errors (Shojania, Duncan et al. 2002; WHO 2002). However, there is also a connection between the Patient Safety movement and the increased involvement of patients in healthcare from policy-makers, e.g. the UK government’s actions for patient participation (Elwyn and Corrigan 2005).

A precondition making it possible for professionals to practice EBM is easy access to reviewed medical knowledge. There are several journals and websites available, e.g. the Cochrane Institute with its Library plays an important role as a source of evidence-based information (Cochrane Library website; Guyatt, Cook et al. 2004). The construction of computerized decision-aid support is an effort to make evidence-based knowledge available for prescribers (Sjöqvist, Bergman et al. 2002; Bastholm Rahmner, Andersen-Karlsson et al. 2004).

However, the EBM practice has been criticized by clinicians. Examples of the criticisms include suggestions that EBM is impossible to use on individual patients, that it is “cookbook” medicine, that can only be applied on certain kind of knowledge, and that it is a method for healthcare managers to cut down costs (Editorial 1995; Grahame-Smith 1995; Sleigh 1995; van Weel and Knottnerus 1999; Ben-Shlomo 2005; Druss 2005; Glasziou 2005; Kernick 2005; Wilson 2005).
EBM has also been criticized by social scientists (De Vries and Lemmens 2006; Goldenberg 2006; Lambert 2006). They emphasize that EBM is not the only way to gain knowledge in medical questions. It is stressed that EBM knowledge is not objective, which the EBM supporters seem to take for granted. On the contrary, social scientists describe knowledge as a product of its social context. Correspondingly, EBM knowledge applies to a special kind of person – the educated, prosperous, white man – the social peer of the one who is the creator of the knowledge. Furthermore, the concept of EBM is described as changing all the time by an assimilating process; all criticisms are met by incorporating the issues discussed under the wings of EBM (Lambert 2006).

If EBM seeks to empower the physicians (Guyatt, Cook et al. 2004), patient centeredness emphasizes other values. Patient centeredness is defined in different ways in the literature, which is often the case when a new concept is founded. However, common ideas are that the patient’s perspective must clearly be brought into the medical discussion and the patient should participate in the decision-making (Ong, de Haes et al. 1995; Stewart 1995; Mead and Bower 2000; Roter 2000). Mead and Bower highlighted the need of a common definition of patient centeredness. They proposed five essential dimensions of patient centeredness, which include the biopsychosocial perspective, the ‘patient-as-person’, sharing power and responsibility, the therapeutic alliance, and the ‘doctor-as-person’ (Mead and Bower 2000). The term patient-centered has also been used in a broader sense with applications to the health system as a whole, including the access to care, insurance, choice of physician, and waiting times (Epstein, Franks et al. 2005).

Some authors find the term patient centeredness problematic and interpret it as if all power is taken from the physician to the patient. Instead the term ‘relationship-centered medicine’ has been proposed (Quill and Brody 1996; Roter 2000). Roter calls it consumerism when all power is taken by the patient. The opposite situation, which is probably the most frequent, is called paternalistic and exists when the power is taken by the physicians. In both of these models the contribution from one of the partners is lacking and an equalized mutuality model is favored (Roter 2000).

The results from studies of the effects of patient centeredness are not yet conclusive, although there are signs of positive effects. The results depend much on how patient centeredness is measured (Mead and Bower 2002). Good physician-patient communication, and especially agreement between patients and physicians, influenced symptom resolution, functional and physiologic status, and pain control (Stewart 1995). Other reviews have found positive effects on patient satisfaction, understanding of information, physical health and adherence to treatment (Ong, de Haes et al. 1995; Michie, Miles et al. 2003).
When patients and patient representatives were asked about their preferences in taking part in health decisions, they said they wanted to take part in decisions concerning chronic illnesses. However, regarding emergency illnesses they preferred a more paternalistic style, and they wanted the professionals to know to which level patients were prepared to participate (Edwards, Elwyn et al. 2001). It has been proposed that seriously ill patients have impaired cognition, and thus may have difficulties taking part in complex clinical choices (Cassell, Leon et al. 2001). This highlights the fact that it is important for physicians to change their patient relation approach depending on the situation, a feature that was already expressed in a seminal paper published in 1956 (Szasz and Hollender 1956). However, even though the partnership approach in the meeting with the chronically ill patient is acknowledged to be preferable, and the chronically ill patients are increasing in number, the medical education is still designed for acute diseases (Holman 2004). This creates difficulties on a clinical and organizational level, as patient involvement in care is desirable in theory but hard to achieve in practice.

Patient centeredness in healthcare

One of the focuses in this thesis is on how patients are considered when DTC professionals, and respectively pharmacists performing pharmaceutical care, describe their work. Thus, providing a background for this discussion is needed.

It can be concluded that the involvement of patients in healthcare is increasing and that this can be described in various ways. One sign of the increased involvement is the semantic shift from “compliance” to “concordance”, when health professionals talk about whether patients follow therapy instructions or not (Holmström 2002). This semantic shift demonstrates the desire of healthcare professionals to encourage mutual partnerships with the patients. Both “compliance” and the sometimes-used term “adherence” have a tone of obedience, whereas “concordance” implies a decision between equals. Certainly it is not sufficient to just change a word to make changes in healthcare, but the mission of the professionals who proposed the change is obvious (Mullen 1997; Royal Pharmaceutical Society of Great Britain 1997; Blenkinsopp 2001; Bissell, May et al. 2004).

The legislation also supports an increased patient involvement in healthcare. Traditionally the paternalistic relationship with a powerful physician was regarded as the natural state. However, in the 1980s in Sweden the role of the patient was debated and the lack of patient influence was a major issue (Blomqvist and Rothstein 2000; Spångberg Winblad 2003). The discussions led to a strengthening of the patient’s role in Swedish healthcare, which is shown in new legislations and commissionaire reports.
(Swedish Commission 1997; 1999). Here it was clearly stated that patients have the right to take part in treatment decisions, when alternatives were given, and that patients should be given individual information about their health status and about possible diagnosis and treatment methods.

In the UK the Department of Health and the NHS (the National Health System) have established programs to involve patients in healthcare and stimulate shared decision-making in health issues. Actions taken include a program that supports patients living with long-term conditions (The Expert Patient), continuous patient surveys that are published on the Internet, the funding of a task force working for promoting patients’ partnership in medicine-taking (Medicines Partnership) as well as funding of a website (DIPEX) where patients can write about their experiences (Department of Health 2000).

However, the Expert Patient initiative has also been questioned as an example of paternalistic power where the patients are supposed to act in a special way. Furthermore, the lack of strategies to challenge the perceptions among professionals regarding patients with chronic illnesses is criticized (Wilson 2001). Another study concluded that patients that participated on an international website, “X-Online”, did not develop new understandings of their health, meaning that the biomedical model was not challenged (Fox, Ward et al. 2005).

Much of the discussion of patient involvement in healthcare concerns the patients’ opportunities to take part in decisions about their own treatment. Patient preferences in this issue were explored in a European interview study performed in eight countries, among them Sweden. Among 1,000 interviewed Swedish patients, the majority wanted to share the decision-making with their doctor. About 15% of patients wanted to decide themselves and almost 20% wanted the doctor to decide (Coulter and Magee 2003).

Many factors influence patients’ possibilities to participate in decision-making. One factor that is often stressed is the availability of sufficient information (Edwards, Elwyn et al. 2001; Coulter and Magee 2003). However, information may be difficult to find or difficult to understand (Coulter and Magee 2003). In an interview study from the UK patients were satisfied with the information they had been given, although the same patients sometimes expressed that they did not feel that they were in control of their drug use, indicating a lack of information (Granas and Bates 2005). The same authors concluded that some of the decisions patients made concerning their drug use were not the best from a medical point of view, and that these patients needed to be empowered by appropriate information about their drug treatment.

Patient-centered care is not only understood as taking part in individual treatment decisions, but also as public involvement in health policy decisions (Gillespie, Florin et al. 2004). The people in a democratic system already
exercise indirect control on healthcare in democratic elections, but this involvement concerns the direct public participation at local policy level. Patient involvement on policy level is still in its infancy and one problem involves the lack of consensus about what public involvement at this level means (Traulsen and Almarsdottir 2005). Studies suggest that members of the public want to have a counseling role on system and program level, for instance in priority setting (Litva, Coast et al. 2002; Wiseman, Mooney et al. 2003). In the UK, both patient organizations and producers are welcome to follow the process and make comments when the National Institute for Clinical Excellence (NICE) develops guidelines (Pearson and Rawlins 2005). However, experience reveals low input from lay members when they participate on primary care boards. Models of lay involvement must be developed, for instance in situations concerning how information is shared between lay participants and decision-makers (Pickard and Smith 2001; Church, Saunders et al. 2002; Pickard, Marshall et al. 2002; Abelson, Forest et al. 2004).

This was a presentation of knowledge areas related to this thesis. In the next section a basis for the interpretations of the findings in this thesis are reviewed, and after this section the specific methodologies will be revealed.

The social construction of medicine

To be able to understand the interpretations of the findings in a thesis, its basic ontological and epistemological stances must be presented. Probably this presentation is especially important because the research field in which this thesis will be read traditionally has another basis. Medicine is rooted in realism and positivism, and a belief in the objectivity of knowledge, a notion that has been dominant for 300 years and which concentrates on the biomedical part of medicine (Wilson 2000). In contrast, the basic assumptions in this thesis are that multiple realities exist and that we humans create our world by living in the world. Knowledge is created in a social context in which the researcher is integrated. The traditional way of viewing medicine has been questioned by others as being too limited, and of not taking medicine’s complexity into account (Wilson 2000; Goldenberg 2006; Malterud 2006; Tonelli 2006).

A criticism of the positivistic way of understanding knowledge was published as early as 1935 in a book written by the Polish physician Ludwik Fleck (Fleck 1997). This book has been rediscovered in recent decades, and is cited by many researchers, for instance in Swedish dissertations (Liliequist 2003; Hedfors 2005) and by Malterud (Malterud 2006). More recent literature describes the social constructionistic view of science (Collins and Pinch 2002), however, Fleck is interesting because he concentrates on research within the medical field (not reviewed here). He presents
explanatory ideas (of which a few are summarized below) that are easy to understand.

The message is that nothing is obvious and that we construct all knowledge by ourselves. Fleck describes how all facts, including the scientific ones, develop as a result of social activity. He launches two central concepts, ‘thought style’ and ‘thought collective’, which are important features in the shaping of facts. Fleck states that a fact becomes true by social concentration within a thought collective. In principle all humans belong to one or more thought collectives, each with its specific thought style that shapes what is accepted as the truth. The thought style may be described as a gathered intellectual readiness, and strive to look and act in one way and not in another, or as a thought constraint. To belong to a thought collective, a person needs to go through a trainee period during which the thought style of this collective is adopted.

When a ‘fact’ is presented to a person who belongs to another thought collective, this fact can be perceived as a misunderstanding of reality. Fleck states that the larger the difference is between two thought collectives, the less the exchange of thoughts is. A foreign collective’s principles are perceived as illogical, if the principles are observed at all, and their eventual justifications are seen as circles of evidence. However, sometimes it is possible that a person that belongs to different thought collectives can act as a mediator between the collectives, which may be fruitful for the development of new understandings. New basic facts are discovered only with the help of new thinking. This is a statement that shows the connections between Fleck’s theories and the phenomenographic view of learning, even though in phenomenography the expression is that a new relation between the learner and the phenomenon must be established (see below).

The next section describes the specific methodologies that were used in the five papers.

Methodology

In this section the methods that have been used in the five papers are described. The choice of research approach depends on the research question and on what perspective the researchers want to take to answer the research questions. When the research question concerns how common a predefined feature is or the magnitude of a predefined feature, statistical methods are used. They are also used to test hypotheses in order to draw conclusions about, for example, the best intervention. When the research question concerns the meaning of a characteristic, how people perceive a situation, or when the characteristic of a phenomenon is unknown, a qualitative method is chosen.
In this thesis the first paper is based on numerical data and statistical analysis, and the following four papers are based on text data, primarily analyzed by qualitative approaches. The texts are collected in interviews and questionnaires, except in Paper IV, in which four classification systems for drug-related problems were analyzed.

**Analyses of quantitative data**

In Paper I statistics were used to compare mean numbers of used prescribed drugs and mean numbers of potential drug-drug interactions (DDIs) per person among patients living in six European countries. Because several measurements were compared and there was only one dividing variable (country), one-way ANOVA was used.

The reason for using ANOVA was that when multiple observations are performed and compared pair by pair, the random risk of a false positive value (Type I error) increases and thus a single global comparison is preferred (Petrie and Sabin 2000). The ratio of DDIs per patient showed a right-skewed distribution, but due to the high number of patients in each study group normal distribution was used as a good enough proxy. A check-up was done with the non-parametric Kruskal-Wallis test and this gave the same result. Levene’s test showed a probable equal variance for both mean numbers of prescribed drugs and ratios of DDIs per patient, which is required for using ANOVA.

Null hypothesis for both measures were stated: no differences in mean numbers of prescribed drugs per patient among the countries and no differences in ratio of potential DDIs per patient. ANOVA rejected both null hypotheses, demonstrating that at least one of the countries differed in both measurements. The Bonferroni post hoc test showed how occurrence of DDIs differed among countries pair by pair. SPSS (Statistical Package of Social Sciences) was used for all statistical calculations.

In Paper II content analysis was used, a method which is described as quasi-statistical (Malterud 1998). Here key persons from drug and therapeutics committees answered questions in a questionnaire. With content analysis informants that used certain words in their answers were identified and called “patient-aware”. The use of statistics in this paper was confined to the presentation of the fraction of informants in percent that were found to show “patient awareness”.

**Analyses of qualitative data**

The qualitative research is regarded as value-bound, and the methods are often inductive, time- and context-bound, and often follow an emerging design (Dahlgren, Emmelin et al. 2004). Many different approaches exist. However, the analysis phase has many similarities, irrespective of qualitative approach. The material often consists of a text and this text is organized according to a common structure with the aim of creating new descriptions.
and concepts. The analysis process can be described in four steps (Malterud 1998): 1) gain an overview, 2) identify meaning units, 3) abstract the content in the meaning units, and 4) conclude the meaning of this content. Irrespective of choice of method, the researcher must be able to describe the analysis process together with the findings.

**Phenomenography**

Phenomenography is more extensively presented than the other methods. This is because phenomenography has both been used as an analyzing approach in Papers II and III, and ideas from this field have been used in the discussion of possible implications of the findings of this thesis.

Phenomenography is a qualitative research method used to study peoples’ ways of understanding phenomena in the surrounding world (Marton and Booth 2000). The method was developed at the education department of the University of Gothenburg during the 1970s. When studying learning, the researchers found a variation in what and how students learned and that it was possible to divide the outcomes of the learning into a limited number of categories. From these experiences the researchers developed an understanding of how people conceive phenomena in different ways (Marton and Booth 2000). Later on the researchers have explained and developed phenomenography by using concepts from phenomenology. These include the interest in examining the world “as it shows itself to us” and the act of consciousness described as a meeting between the individual and the world (Lepp and Ringsberg 2002).

**Phenomenography as a tool for learning**

The main interest of the creators of phenomenography was the pedagogical view – to describe the outcome of learning. Marton and colleagues have continued on this path and developed the “Variation theory”. Whereas the questions in phenomenography focus on the different ways of experiencing a phenomenon and how these ways are related, the focus in variation theory is on what it is to experience something (Pang 2003). According to variation theory people experience a relationship to an object and this constitutes their conception of the phenomenon. To learn means to incorporate new aspects, hence the relationship between the person and the phenomenon is changed. According to the variation theory the learners can only discern a new aspect when they experience a variation of this aspect. Thus, by describing the variance in how an aspect is perceived the aspect becomes visible.

Phenomenography has sometimes been misunderstood and not used as intended (Larsson and Holmström 2006). This has discredited the method to some extent, according to the creators of the method (Phenomenography website). In such studies the focus has been on the phenomenon as such and not on the ways of understanding the phenomenon or the phenomenon on which the informants are asked to focus has not been sufficiently delimited.
The principles of phenomenography have been found to be useful in areas outside the domain of education, including that of healthcare (Barnard, McCosker et al. 1999). In Sweden phenomenographical studies have explored medicines and medications from patients’ perspectives (Fallsberg 1991; Hansson Scherman 1994) medical students’ understanding of medical practice (Dall'Alba 1998; Dall'Alba 2002), general practitioners’ experiences of asthma management (Stålsby Lundborg, Wahlström et al. 1999), health professionals’ understanding of diabetes care (Holmström, Jonsson et al. 2000; Holmström, Halford et al. 2003), and anesthesiologists’ understanding of their work (Larsson, Holmström et al. 2003; Larsson 2004).

Data collection and analysis in phenomenography

Data in a phenomenographic study commonly consists of texts collected by interviews. The informants are asked to talk about the phenomenon in question in a way that reflects their own experiences. Three questions have been found to be useful to explore conceptions (Holmström, Jonsson et al. 2000; Larsson, Holmström et al. 2003). The first two questions are derived from Dall'Alba (Dall'Alba 1998). The questions are directed at 1) the core of the phenomenon, 2) difficulties with the phenomenon, and 3) successes related to the phenomenon. The informants are asked to give examples to give a rich description of the phenomenon and to help informants focus on their experiences. Open-ended questionnaire answers have also been used for phenomenographic analysis (Dall'Alba 1998; Holmström, Halford et al. 2003; Kjeldmand, Holmström et al. 2006).

The analyzing steps used in Papers II and III in this thesis have been described by Alexandersson (Alexandersson 1994). The process starts with a thorough reading to get familiarized with the material, and then the material is organized according to a specific procedure and successively transformed into a more abstract form. However, in the second step in a phenomenographic analysis, instead of gathering meaning units or statements, “what” and “how” aspects are identified. In the next step aspects are grouped and categories of descriptions are created. The categories are the researchers’ created abstractions of the conceptions.

Finally the structures of categories are examined. This step includes the creation of an outcome space (Marton and Booth 2000). The outcome space shows how the categories relate to each other, often in a hierarchical way; see figures in Papers II and III, pp. 39 and 41. In the figure a category that is more complex is placed above a less complex category. Commonly the findings are regarded to represent how the phenomenon is conceived at the group level. However, new branches of phenomenography have grown, in which individual informants are correlated to single categories (Stålsby Lundborg, Wahlström et al. 1999; Dall'Alba 2002).
Grounded Theory

The analysis in Paper V was inspired by Grounded Theory (GT). GT represents a special qualitative approach and has its roots in social interactionism. The method was developed in USA in the end of the 1960s by Glaser and Strauss (Glaser and Strauss 1967; Strauss and Corbin 1990). The overall purpose is to generate new theories, and the method is said to be useful for studying all kinds of material, even quantitative material. There are two important aspects that constitute the base of GT; they are the social construction of reality and the human ability to generalize (Dahlgren, Emmelin et al. 2004).

The GT approach is characterized by stepwise coding, creation of categories, and a constant comparison during the process, meaning that the researcher goes back and forth and compares created codes and categories with the original text (Malterud 2001; Dahlgren, Emmelin et al. 2004). Coding is done in several steps. First important information from the text is coded and in a second step the codes that are most relevant for the research question are selected and clustered into core categories. Then the text is read again with the core categories as a guide to what the researcher is looking for. In a theoretical coding the researcher tries to find connections between codes and between categories to construct concepts and hypothesis. The process also involves integration into existing theories if possible. Furthermore, the researcher is encouraged to continuously write down reflections, which are used in the analysis.

Trustworthiness in research

The question of trustworthiness is important in all research. To be able to draw conclusions from quantitative research there are many features to consider. The measurement or instrument must be able to measure what it is intended to measure (internal validity), the researcher should not have impact on the result (objectivity), similar results should be gained if the study is repeated under the same conditions (reliability), and the result should be possible to use in other populations (external validity or generalizability) (Hamberg, Johansson et al. 1994). To meet these criteria established methods are used, for example randomization techniques to ensure a representative sample, and statistical tests to explore the risk of randomness in the results.

Four commonly used criteria for trustworthiness in qualitative studies were developed by Lincoln and Guba (Lincoln and Guba 1985; Hamberg, Johansson et al. 1994; Dahlgren, Emmelin et al. 2004). Credibility, which can be compared to “validity”, deals with the question of whether the study really captures what it was intended to capture. This applies to how thoroughly data are collected and analyzed. Dependability refers to the ability of the researcher to adapt to the constantly changing conditions of the
phenomenon studied. This term may be compared to the term “reliability”, although the requirement from quantitative studies that a repeated experiment would bring up the same results is not applicable in qualitative research. Confirmability can be compared to “objectivity” and means that the findings come from the collected data and not from the researcher’s pre-understanding. Consistently following a structured analysis method is one way to fulfill this criterion. Other ways include using two independent persons who perform the coding, or using co-readers. Transferability, which can be understood as “external validity” or “generalizability”, deals with whether the descriptions and interpretations in the study are useful in other contexts. The readers must be the ones who make this judgment and thus the context must be clearly described. Another prerequisite for the readers for evaluating the quality of the research is that the processes and important choices are reported.

Introduction to the papers

The overall aim of this thesis is to increase our understanding of how two professional collectives – the Swedish drug and therapeutic committees and the international pharmacy profession – have approached the safety and quality problems related to medication use in healthcare. However, the focus in the first paper is on one of the many possible causes of unintended drug-related problems – the occurrence of potential drug-drug interactions.

Papers II and III focus on key persons on drug and therapeutics committees (DTCs) and their work. A law passed in 1997 states the goals of the DTCs and the challenge has been made to the DTCs to develop strategies to achieve these goals. Paper II explores how key persons in the DTC perceived the role of the DTC or their own roles five years after the legislation. Paper III explores perceptions of the DTC role two years after the first study.

Papers IV and V focus on pharmacists’ work to improve quality in drug use in a community setting by performing pharmaceutical care (PC). To aid in this, pharmacists have developed classification systems to document drug-related problems. These classification systems also serve as support in the counseling process. For some reason several different classification systems have been developed. Paper IV explores how four established classification systems work in practice, and compares similarities and differences. Paper V continues where Paper IV leaves off. In Paper IV a difference was found in systems’ characteristics, which was assumed to be reflections of the PC goals. Goals are influenced by underlying values and beliefs. Thus, Paper V explores values and beliefs, i.e. ideologies, that are reflected in the studied classification systems.
4. Drug-drug interactions in the elderly (Paper I)

Drugs that are used at the same time may affect each other. When this happens there is a drug-drug interaction (DDI). There are several different mechanisms that can lead to DDIs, but for the patient they appear either as an increased effect, with a risk of adverse drug reaction, or a decreased effect, with less or no therapeutic action. Hence, DDIs constitute one set of problems that may be created when drugs are used. Because the possible effects of many potential DDIs are known, DDIs are potentially preventable and thus important to address. This paper aims to describe the prevalence and type of potential DDIs in a group of elderly people living in Europe as well as describe differences among countries.

Materials and methods

Patients
All patient data came from a European longitudinal multicenter study on pharmaceutical care involving elderly people at community pharmacies, the Elderly study (also called the OMA project, from the German/Dutch word for “grandmother”). Ethical approvals were obtained in each country according to local practice. Results of the study have been published elsewhere (Bernsten, Björkman et al. 2001).

To be included in the study the elderly had to be 65 years or older, use four or more prescribed drugs and live in their homes, taking care of themselves. The participating countries were Denmark, Germany, the Netherlands, Northern Ireland, Portugal, the Republic of Ireland, and Sweden. Patients were randomly invited to the participating pharmacies based on pharmacy records or general practitioners’ records (only in Sweden).

Individual patients’ drug lists were the basis of the present study. These were collected at baseline interviews with the elderly in the pharmacies, and represent all prescribed drugs the elderly themselves said they were using at the time.
Analysis

We used the classification system for potential DDIs, which has been available in Sweden since the mid-1990s (Pharmaceutical Specialties in Sweden 1997). It is based on ATC codes and gathers knowledge from published data and documentation from drug companies. Potential DDIs are classified in categories A, B, C, and D. In this study we concentrated on the prevalence of DDIs classified in categories C and D. Some of the drugs used in the other European countries were not included in the Swedish DDI classification system and were thus not possible to analyze. To minimize this problem these drugs were, if possible, replaced with an appropriate drug registered in Sweden.

All drug data were coded using ATC codes and entered in the statistical computer program SPSS for Windows. Potential DDIs were analyzed in a special software program constructed by one of the authors and based on the Swedish classification system. Patients from the Netherlands were not included in the analysis because drug data were not available in this format. To test for differences among countries ANOVA was used, as presented in the Background section.

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2 Category C contains drug combinations that have potential clinically significance but can be handled by individual dosage adjustments, and category D contains drug combinations that either involve severe risk or are difficult to handle, and thus are recommended to be avoided.
3 Assoc. Professor Johan Fastbom.
Table 1  Demographics on study patients in the six countries.

<table>
<thead>
<tr>
<th>Country</th>
<th>N</th>
<th>Age, years mean (SD)</th>
<th>Percent of women</th>
<th>No of drugs mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>523</td>
<td>74 (6)</td>
<td>57</td>
<td>6.8 (2.3)</td>
</tr>
<tr>
<td>Germany</td>
<td>291</td>
<td>74 (6)</td>
<td>60</td>
<td>7.5 (2.7)</td>
</tr>
<tr>
<td>N. Ireland</td>
<td>189</td>
<td>74 (6)</td>
<td>62</td>
<td>6.2 (2.0)</td>
</tr>
<tr>
<td>Sweden</td>
<td>334</td>
<td>76 (6)</td>
<td>62</td>
<td>7.6 (2.9)</td>
</tr>
<tr>
<td>Portugal</td>
<td>137</td>
<td>73 (6)</td>
<td>50</td>
<td>6.5 (2.0)</td>
</tr>
<tr>
<td>Rep. Ireland</td>
<td>127</td>
<td>75 (6)</td>
<td>54</td>
<td>6.6 (2.2)</td>
</tr>
<tr>
<td>Total</td>
<td>1,601</td>
<td>74.7 (6)</td>
<td>58</td>
<td>7.0 (2.5)</td>
</tr>
</tbody>
</table>

N = number of participating patients

ANOVA. Differences among countries concerning average number of drugs used:
- Denmark, N. Ireland and Portugal differ from Germany and Sweden
- Germany differs from Denmark, N. Ireland and Portugal
- Rep. Ireland differs only from Sweden
- Sweden differs from all countries except Germany

Table 2  Occurrences of potential drug-drug interactions.

<table>
<thead>
<tr>
<th>Country</th>
<th>N</th>
<th>DDI/pat</th>
<th>Range</th>
<th>One or more DDIs (%)*</th>
<th>Two or more DDIs (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>523</td>
<td>0.75</td>
<td>0 - 9</td>
<td>43</td>
<td>19</td>
</tr>
<tr>
<td>Germany</td>
<td>291</td>
<td>1.04</td>
<td>0 - 8</td>
<td>51</td>
<td>28</td>
</tr>
<tr>
<td>N. Ireland</td>
<td>189</td>
<td>0.67</td>
<td>0 - 6</td>
<td>39</td>
<td>17</td>
</tr>
<tr>
<td>Sweden</td>
<td>334</td>
<td>0.84</td>
<td>0 - 6</td>
<td>47</td>
<td>24</td>
</tr>
<tr>
<td>Portugal</td>
<td>137</td>
<td>0.62</td>
<td>0 - 4</td>
<td>43</td>
<td>13</td>
</tr>
<tr>
<td>Rep. Ireland</td>
<td>127</td>
<td>1.05</td>
<td>0 - 5</td>
<td>57</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>1,601</td>
<td>0.83</td>
<td>0 - 9</td>
<td>46</td>
<td>22</td>
</tr>
</tbody>
</table>

N = number of participating patients

* = percentage of patients

ANOVA. Differences among countries concerning average frequency of potential DDIs:
- Denmark and N. Ireland differ from Germany
- Germany differs from Denmark, N. Ireland and Portugal
- Ireland differs from Portugal
- Portugal differs from Germany and Rep. Ireland
- Sweden does not differ from any country
Results
In total 1,601 patients were included in the analysis. Details are presented in Table 1. In total 1,324 potential DDIs were found. Forty-six percent of the patients had ≥1 potential DDIs, and 22% had ≥2 DDIs (see Table 2).

Potential DDIs and their possible effects
This study demonstrates that a substantial number of the elderly were at risk of adverse effects or ineffective drug treatment because of interactions, and therefore needed special attention.

Among the 1,324 potential DDIs about 90% were classified in category C (thus possible to handle), and 10% of the combinations were recommended to be avoided.

In many studies only the DDIs that lead to adverse drug reactions (ADRs) are included. Here we found that 50% of the identified combinations could lead to decreased effect. This implies that some of the elderly used drugs from which they had no benefit.

Comparisons among countries
A second aim of the study was to describe the differences in identified DDIs among patients at a national level. We found statistical significant variations in number of drugs used per person and in number of possible DDIs. A major variation was also found in the types of potential DDIs in various countries. This fact is a reflection of the different therapy traditions in the various countries. Our aim was not to analyze therapy traditions, but exploration of this variability would be an interesting topic for future studies. For more details see Paper I.
5. The role of the drug and therapeutics committees – perceptions of chairs and information officers (Paper II)

A new Swedish law that came into effect in January 1997 gave the drug and therapeutics committees (DTCs) the authority to work for reliable and rational drug use in their counties. The law included no detailed directives and consequently it was up to the DTCs to operationalize the goals and develop strategies for achieving these goals. Owing to the magnitude of drug use within healthcare and its relation to safety, public health and health economics, it was considered important to explore how the DTCs had formed their task. We took a second-order perspective, i.e. focused on peoples’ conception of the phenomenon, and asked key persons in the DTCs about their experiences.

The aim of this paper was to explore how chairs of DTCs perceived the role of the DTC and how information officers of DTCs perceived their roles. A second aim was to determine whether the chairs and information officers included patients in their answers.

Material and method

Questions were sent out to chairs and information officers in the autumn of 2002. At that time there were 38 DTCs in Sweden. The questions were included in a larger questionnaire sent out from the National Board of Health and Welfare addressing the work of the DTCs. Our three questions are presented in Table 3.

To explore variations in conceptions, the answers were analyzed by a phenomenographic approach, as described in the Background chapter. The two groups of chairs and information officers were analyzed separately. For more details of the analyzing process, please see Paper II.

Content analysis was used to determine whether patients were included in the informants’ answers. The informants were regarded as “patient-aware” if they had included the predefined words patient, public, citizen, and elderly in their answers.
Table 3  Questions used to collect information from the respondents.

<table>
<thead>
<tr>
<th>Questions for chairs</th>
<th>Questions for information officers/educators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Briefly describe what you believe to be the Drugs and Therapeutic Committee’s most important task.</td>
<td>1. Briefly describe what you believe to be your most important task in your role as an educator/information officer on pharmaceuticals.</td>
</tr>
<tr>
<td>2. What are the most serious impediments standing in the way of the Drugs and Therapeutic Committee’s performing its task?</td>
<td>2. What difficulties do you believe are inherent in your work as an educator/information officer? Give examples.</td>
</tr>
<tr>
<td>3. Briefly describe a project/activity in which you felt the Drugs and Therapeutic Committee “succeeded” at its task.</td>
<td>3. Briefly describe an occasion or situation in which you felt you “succeeded” in your work as an educator/information officer.</td>
</tr>
</tbody>
</table>

Findings

There were 31 chairs and 43 information officers responding to the questions.

Descriptions of conceptions

Similar conceptions were found in the two studied groups; four qualitatively different conceptions among chairs and three among information officers. The basis for the creation of categories was how the informants related to their primary target group – the drug prescribers (primarily the physicians). The categories of description were related to each other in a hierarchical manner and this is illustrated in the outcome space (see Figure 1).

Each category was given a name to describe its quality and to make it easier to communicate the results. The names should not be regarded as labels that can be put on individual informants. Categories are abstract descriptions and relate to the group as a whole.

Distant

This category was only seen among chairs. Here the prescribers were distant from the informants and the idea was to control the prescribers by regulations and restrictions. “Optimal usage” of drugs was expressed as the goal, which primarily included economical aspects.

Knowledge distributor

In this category the prescribers were conceived as somewhat closer to the informants. They were a visible target group and the task of the DTC was to gather and distribute reliable knowledge. Prescribers were described as passive receivers of this knowledge. The goal was expressed as “optimal usage”, described in a similar way as in the Distant.
**Catalyst**
Here the prescribers were even closer to the informants. Prescribers were receivers of knowledge but were also activated in discussions and projects. The primary goal was said to be good quality in drug use. However, economic aspects were also important and occasionally decentralized budgets were said to be effective.

**Supporter or link**
In this category the prescribers were conceived closest to the informants, at the same level. Prescribers were already working in the same direction as the DTCs and the role of the DTC was to support the prescribers or to serve as a link and mediate information between the field and the policy level. Emphasis was on high quality in drug use, and economic aspects were also acknowledged.

**Patient awareness**
Our definition of a “patient-aware” informant was an informant that included the word patients (or citizens or the equivalent) in their answers. This was not common; 20% of the chairs and 9% of the information officers were found to express patient awareness in their answers.
<table>
<thead>
<tr>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supporter or Link</td>
</tr>
<tr>
<td>Catalyst</td>
</tr>
<tr>
<td>Knowledge Distributor</td>
</tr>
<tr>
<td>Distant (only chairs)</td>
</tr>
</tbody>
</table>

**Figure 1**  Outcome space for chairs and information officers. The same categories were found in both groups, except for the Distant category, which was only seen among chairs.
6. Developing the role of the drug and therapeutics committee – DTC chairs’ perceptions (Paper III)

The findings from Paper II were presented to the chairs in May 2004. The reactions at the meeting gave us reason to believe that the chairs’ perceptions of the DTC role had changed. In order to further explore how chairs perceived the DTC, a new study was conducted two years after the first.

Material and methods

Questionnaires containing the same three questions used two years earlier were distributed to chairs in all DTCs. This was done in the autumn of 2004, and the number of DTCs was then 31.

To get richer descriptions of the conceptions, data triangulation by complementary telephone interviews was used. A strategic sample of six chairs was selected, based on the preliminary analysis of the questionnaire answers. Three preliminary categories were found and two persons with major contributions to each category were recruited. The telephone interviews were semi-structured and based on the same three questions as in the questionnaires. Informants were asked follow-up questions to exemplify and develop their statements. All interviews were transcribed verbatim and then analyzed.

The analyzing method was the same as in Paper II, a phenomenographic approach. However, the final step in the analysis was completed after the telephone interviews; preliminary findings from the questionnaire analysis were used together with the new data from the telephone interviews. In this step the categories were given their final descriptions and the outcome space was built, based on categories’ internal relationships.

Findings

A total of 25 chairs answered the questionnaire and this was judged to be a sufficient number. A total of 20 informants has been proposed sufficient to identify the variation in a group (Sandberg 2000).

Again four qualitatively different conceptions were found (see Figure 2). At first, an attempt was made to find the same categories as in Paper IV. However, the variation in chairs’ conceptions of prescribers was less this
time when compared to the variation in the study done two years earlier (Paper II). This allowed other separating aspects to appear in the foreground. A new separating aspect was which target groups the informants included when they answered the questions about the work of the DTC.

![Diagram of conception categories]

**Figure 2** Outcome space for chairs describing the relations among conception categories.

**Description of conceptions**

*Traditional*

In this category the focus was on the prescribers, as in all categories in the previous study. However, now a variety of methods was described to be used in order to reach the prescribers. Furthermore, the drug industry was described as an obvious competitor of the DTCs. Administrative strategies such as decentralized budgets were not said to be used.

*Influential*

In the *Influential* category physicians were included as important targets together with decision-makers, which suggests a political awareness. Hence, in this conception the responsibility of reaching the DTC goals also stayed among the professionals. The chairs stated that DTCs took the roles of experts who brought cost-effective drug use into the healthcare agenda and supported decision-makers. A variety of methods, including administrative strategies (e.g. decentralized budgets) were said to be actively used.
Patient-aware

Here both prescribers and patients were considered in the DTCs’ task of achieving the stated goals. However, the patient was talked about in various ways, from being actively involved in DTC campaigns to having a more passive role as somebody the doctor takes care of. Decision-makers were mentioned as the DTCs’ assigner, but were not a target group for the DTCs’ activities. Here a variety of methods was also said to be used.

Holistic and cooperative

Here, all actors addressed by chairs in all conceptions were involved (physicians, decision-makers and patients). Patients were described as human beings living in unique contexts. Networking and cooperation across administrative borders were said to be important. It was stated that the old structures within healthcare could be counterproductive when dealing with complicated issues like improved quality in drug use.

Comparison of new conceptions and conceptions identified two years earlier

As presented above, the variation in how prescribers were met was less prominent in Paper III; in all conceptions prescribers were involved in a variety of methods.

Regarding patients, there was a trend toward increased involvement; two of the identified conceptions included patients, whereas none of the conceptions did that in the previous study.

There was also an increased awareness of decision-makers. They were addressed as a target group in two conceptions. In one conception they were not a target group, but mentioned as the assigners of the DTC.

Finally, there was greater agreement on the goals of the DTC. Previously, in some conceptions there was a strong focus on economical aspects of drug use. Now, two years later, all conceptions included both quality and economical aspects in the DTC goals.

Theories from implementation research

Implementation research theories were used as an analyzing framework to interpret the work of the DTCs as stated by chairs. Findings from this analysis are presented in Paper III and in the Discussion section, below.
7. Comparing four classification systems for drug-related problems: processes and functions (Paper IV)

Pharmaceutical care (PC) is a worldwide movement among pharmacists in order to improve quality in patients’ drug use. An essential component of PC is the documentation and classification of drug-related problems (DRPs) (Hepler and Strand 1990). The classification system is used to document and communicate identified DRPs, and serves also as a guide for the pharmacist in the patient encounter.

However, a search in the literature reveals that pharmacists have developed several different classification systems (Kane, Briceland et al. 1993; Berardo, Kimberlin et al. 1994; Kane, Briceland et al. 1995; Caleo, Benrimoj et al. 1996; Chen, Casson et al. 1996; Poirier and Gariepy 1996; Winslade, Bajcar et al. 1997; Westerlund, Almarsdóttir et al. 1999; Krass and Smith 2000; Raynor, Nicolson et al. 2000; Titley-Lake and Barber 2000; Carter, Malone et al. 2001; Kassam, Farris et al. 2001; Kraska, Cromarty et al. 2001; van Mil, Dudok van Heel et al. 2001; Consensus Committee 2002; Gilbert, Roughead et al. 2002; Schaefer 2002).

The fact that several systems have been proposed can be interpreted as a sign of pharmacists’ engagement and internal splits on the issue. A first question is why pharmacists develop new systems instead of using the existing ones. From this question follows another; how do existing systems differ in practice?

Hence, the aim of this paper was to compare four classification systems for documenting DRPs and describe their characteristics in order to understand their similarities and differences.

Material and methods

Selected classification systems

The four studied classification systems were constructed to be used in patient counseling in community settings.

The systems were developed by Strand et al (Cipolle, Strand et al. 1998), a consensus group in Granada, Spain (Consensus Committee 2002), the Pharmaceutical Care Network Europe (version 5.0) (PCNE website), and
Apoteket AB, the National Corporation of Pharmacies in Sweden (Apoteket AB).

In this paper the studied systems are called *Strand, Granada-II, PCNE*, and *Apoteket*, respectively. These systems were chosen because they were all constructed to be used in regular patient encounters in community settings, and were not constructed for a specific project.

**The database**

To make the comparisons among the selected systems possible a model of the patient counseling situation was set up. An existing patient database containing documented problems was used for this purpose. The patient material came from the Swedish branch of the Elderly study (OMA project).

This material consisted of documented DRPs identified during counseling sessions involving a patient and a pharmacist. Identified DRPs were documented by the pharmacists in a classification system called PAS® (Ijben, van Mil et al. 1999) and in short handwritten notes.

The original P-codes (problem codes) from PAS and the handwritten notes were purposefully restructured to make up a handier database.

**The analysis**

The analysis was carried out in a stepwise manner. First documented problems from the database described above were reclassified according to each of the selected systems, one at a time. In the analysis special attention was paid to what kinds of problems were possible and not possible to classify, and to how the classifications were done. This first step ended in a description of four different processes to classify a problem, one to each of the studied systems (see Figure 1a-d in Paper IV).

In the next step the various classification processes were analyzed together with the knowledge of which problems were classifiable and which were non-classifiable. Patterns were searched by comparing similarities and differences to reveal characteristics for each system, which were listed (see Table 4).

Only one person with extensive experience of documenting drug-related problems was chosen intentionally to do all classifications to make sure that it was the differences among systems that were analyzed and not how different persons might interpret the systems. The classifications were based on studies of each system’s classification codes and their definitions, together with available instructions for each system.

**Findings**

The study revealed that the processes of classifying a problem varied among systems. Whereas previous reviews on classification systems have primarily focused on structural aspects of the systems, our findings demonstrate that
the characteristics of a system are influenced both by the structure and by the process of selecting a classification code.

More problems were classified when PCNE and Apoteket were used, compared to the other two systems. This corresponds to the fact that these systems include process-related issues (e.g. patient’s knowledge of drugs and diseases), whereas Granada-II and Strand focus more strictly on therapy outcome.

In Strand patients’ opinions were included in the classification of a problem. Hence, when this system is used therapy changes that patients want to make after discussions with the pharmacist about their drug therapy are documented.

In Granada-II, PCNE, and Apoteket patients’ opinions were not included in the selection of a classification code. Here the pharmacists select a classification code based on their own knowledge of drugs and drug therapy. Hence, when these systems are used bad therapy outcome and hindrances for optimal drug therapy outcome according to available knowledge are documented.

These characteristics of the systems were proposed to reflect different PC goals.

However, the approaches of Granada-II, PCNE, and Apoteket also have other differences. Granada-II has a structured assessment process and focuses on outcome-related issues. PCNE has no structured process and focuses both on process and outcome-related issues. Apoteket has no structured process. The focus is mostly on how patients use their drugs in practice, but also on therapy outcome and on known harmful drug combinations.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Strand</th>
<th>Granada-II</th>
<th>PCNE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus on what outcomes the patient wants to achieve</td>
<td>Focus on effect, safety, and convenience</td>
<td>Focus on clinical outcome of therapy</td>
<td>Focus on drug use and on events known to lead to harm</td>
</tr>
<tr>
<td>Focus on effect, safety, and convenience</td>
<td>A structured assessment process</td>
<td>Focus on effect and safety</td>
<td>Primary focus on safety, but also on effect</td>
</tr>
<tr>
<td>Patient takes part in all decisions</td>
<td>Patient’s opinions of equal importance to professional’s knowledge</td>
<td>Intention is to focus only on clinical outcomes, however, risks are also documented</td>
<td>The professional decides what constitutes a problem</td>
</tr>
<tr>
<td>Categories present what the patients want to change in their drug therapy</td>
<td>Cannot be used as an epidemiological documentation of problems defined by theoretical knowledge</td>
<td>The professional makes the decisions on what constitutes a problem</td>
<td>No structured assessment process, but actual adverse effects are always classified as “Adverse drug reaction”</td>
</tr>
<tr>
<td>Patient behavior has one separate category and shares one category with physician behavior</td>
<td>Patients’ worries are not documented</td>
<td>The outcome of patient behavior is included in categories together with physician behavior and drug “behavior”</td>
<td>Both process and outcome-related issues</td>
</tr>
<tr>
<td>Cannot be used as an epidemiological documentation of problems defined by theoretical knowledge</td>
<td>Patients’ worries are not documented</td>
<td>Similar to an epidemiological documentation of “objective” problems</td>
<td>Classifies “soft” patient-related issues, e.g. insufficient knowledge and when patients complain despite using drugs</td>
</tr>
<tr>
<td>Patients’ worries are not documented</td>
<td></td>
<td>Patients’ worries are not documented</td>
<td>Patient behavior not primarily classified as problems (but in the separate system for causes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient’s opinions not included in classifications</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patients are a source of information</td>
</tr>
</tbody>
</table>
Focus on 1) how patients use their drugs to find deviations from recommendations, 2) patients’ perceptions of therapy failure and adverse reactions, and 3) checking prescription for situations known to be harmful.

- Focus on correct use of medicines and on safety
- No structured assessment process but must explore patient usage of medications before therapy failure and side effects are documented
- The professional decides what constitutes a problem
- Patient’s opinions not included in classifications
- Document what the patient tells about the outcomes without any further exploration except how the drugs are used by the patient
- Several categories address how the patient uses the medications.
- Has a category of “Others” where all kinds of problems related to drug use can be classified.
8. Care ideologies reflected in four classification systems for drug-related problems (Paper V)

Paper IV has shown that the studied classification systems for documenting drug-related problems when counseling patients had various characteristics. These characteristics were suggested to correspond to the goal of the pharmaceutical care. Goals are based on underlying values and beliefs. Therefore, the aim of this paper, Paper V, was to explore the values and beliefs that were reflected in the four selected classification systems.

Materials and methods

The studied systems were the same as those in Paper IV.

The data consist of four interviews with representatives who have major impacts on the construction of the studied classification systems. The representatives had experiences of PC in Minnesota (USA), Spain, the Netherlands, and Sweden. Interviews were chosen for the data collection because interviews are likely to give rich descriptions of the phenomena.

Each classification system was assumed to correspond to one way of perceiving PC. Here the different perceptions of PC will be called Strand/PC, Granada-II/PC, PCNE/PC, and Apoteket/PC.

Interviews

We assumed that the classification systems were a reflection of the PC goal which is integrated in how PC is perceived. Therefore the interviews focused primarily on how the informants described their way of applying PC.

The interviews were semi-structured. All questions except the last were chosen to make the informants focus on their own experiences. They included 1) what is the core of pharmaceutical care? 2) what are the obstacles in performing pharmaceutical care? 3) give examples of successes in applying pharmaceutical care, and 4) how do you define a drug-related problem? Follow-up questions were asked to explore new issues that came up. Interviews were audio recorded and transcribed verbatim.
Analysis

The interviews were analyzed by a method inspired by grounded theory. First the text was read thoroughly to get a general overview. Thereafter the material was systematically organized by coding statements, and codes important to the research aims were grouped in themes and summarized for each informant. Table 5 shows one example of a summarized theme. From the summarized themes, key points were transferred to a matrix (Table 6).

Finally, we sought similarities and differences concerning aspects that could disclose underlying values and beliefs. In this last step findings from our previous study were used (Paper IV). One insight was that the actors involved in the PC process were given different roles in the different systems. These actors were primarily patients and pharmacists, but also physicians. Focusing on these actors seemed appropriate because the way they were involved could probably reveal something about underlying values and beliefs.

Findings

In all four descriptions of PC the patients told the pharmacists about symptoms and how they used their drugs. However, in Strand/PC patients also participated in the evaluation of their drug therapies.

A similarity was that pharmacists in all systems assumed that they had special knowledge that patients could benefit from, although they used their knowledge differently.

Physicians were passive until activated by pharmacists or patients. However, the relations to physicians were expressed to be different in the various PC perceptions. The closest relation was found in Strand/PC, with a falling scale to Granada-II/PC, to PCNE/PC, and to Apoteket/PC where pharmacists were not used to give therapy proposals to physicians.

Ideologies

Our findings suggest that the different classification systems and PC perceptions were based on different care ideologies\(^4\). In all PC perceptions the goal of PC was to achieve optimal drug therapy, which however was differently defined depending on the care ideology.

In Strand/PC patient therapy goals are explicitly expressed, individually set and agreed upon by patient, pharmacist, and physician. The patient’s desires and concerns is the starting point of the therapy discussion. Thus, Strand/PC is based on a patient-centered ideology.

In Granada-II/PC, PCNE/PC, and Apoteket/PC therapy goals are not discussed. However, implicit therapy goals are used by the pharmacists

\(^4\) A set of values and beliefs.
grounded on evidence-based medicine and other established therapy standards. Thus, Granada-II/PC, PCNE/PC, and Apoteket/PC are based on an ideology using a biomedical view of health.

Table 5  An example of a theme, “Goals and outcomes”, with each informants’ summarized statements. This is not the final finding, but a step in the analysis.

<table>
<thead>
<tr>
<th>PC version</th>
<th>Theme “Goals and outcomes”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strand/PC</td>
<td>Drug therapy must have explicit patient-individual goals. The goals are proposed by the PC pharmacists but all parties must agree on the goal (patient, physician and pharmacist). The individual patient’s therapy goals must be established because a DTP* depends primarily on the definition of the goals. Outcome can only be measured if goals are stated. The patient must be aware of the goals to be able to cooperate in meeting these goals.</td>
</tr>
<tr>
<td>Granada-II/PC</td>
<td>Pharmacotherapy follow-up is about achieving expected outcome and avoiding unexpected outcome. Outcome is defined by Donabedian as a change in a patient’s health status as a result of healthcare service. Most therapies have objectives and in order to know whether there is a good outcome, the outcome of therapy is measured by the pharmacist. This can include asking the patient about symptoms or interpreting clinical tests, e.g. blood pressure and lab tests. How therapy goals are set was not mentioned; they seem to be taken for granted and to be equivalent to theoretical optimal outcome.</td>
</tr>
<tr>
<td>PCNE/PC</td>
<td>A good outcome is based on evidence-based medicine and evidence-based pharmacy. Pharmacists assume that following guidelines will lead to optimal outcome. Guidelines are based on clinical outcome whereas humanistic outcome, which is more important, is not addressed. There is a possible conflict between optimal prescribing and improved humanistic outcome. This is a major philosophical dilemma in PC.</td>
</tr>
<tr>
<td>Apoteket/PC</td>
<td>There is information available on how to achieve the best benefits of medications. For example the lowest effective dosages of drugs are stated, drug-drug interactions and double medications should be avoided, and drugs should not be used on incorrect indications.</td>
</tr>
</tbody>
</table>

*Drug therapy problem
Table 6  Key issues in the four studied PC perceptions.

<table>
<thead>
<tr>
<th>Themes</th>
<th>Strand</th>
<th>Granada</th>
<th>PCNE</th>
<th>Apoteket</th>
</tr>
</thead>
<tbody>
<tr>
<td>The focus of PC</td>
<td>To meet patients’ needs related to drug therapy. The meaning of care.</td>
<td>Patients’ needs in relation to drug therapy clinical outcome</td>
<td>Pharmacotherapy outcome.</td>
<td>Identify, solve, follow up, and document DRPs.</td>
</tr>
<tr>
<td>Goal &amp; outcome</td>
<td>Patients have individual goals which must be set and agreed upon. These goals determine the problems, and outcomes are measured against them.</td>
<td>Specific goals not discussed. Following guidelines leads to optimal outcome. Outcomes may vary among patients and are measured.</td>
<td>Specific goals not discussed. Following guidelines leads to optimal outcome.</td>
<td>Specific goals not discussed. Following guidelines leads to optimal outcome.</td>
</tr>
<tr>
<td>DRPs</td>
<td>DTPs* are negative experiences of patients in relation to drug therapy.</td>
<td>Focus not on DRP but on negative clinical outcome of drug therapy.</td>
<td>DRPs hinder optimal effects of drug therapy.</td>
<td>DRPs hinder optimal effects of drug therapy.</td>
</tr>
<tr>
<td>Pharmaceutical knowledge</td>
<td>Patients benefit from good knowledge about their drug therapies.</td>
<td>Patients benefit from good knowledge about their drug therapies.</td>
<td>Patients benefit from good knowledge about their drug therapies.</td>
<td>Patients benefit from good knowledge about their drug therapies.</td>
</tr>
<tr>
<td>Patient role</td>
<td>Patients’ concerns start the PC process. Patients determine which issue is a problem.</td>
<td>Patients receive information about guidelines. Outcome is individual and measured.</td>
<td>Patients receive information about guidelines.</td>
<td>Patients receive information about guidelines.</td>
</tr>
</tbody>
</table>

*Drug Therapy Problems*
<table>
<thead>
<tr>
<th>Cooperation with physicians</th>
<th>Physicians are contacted on therapy issues. Strives for good relationship.</th>
<th>Physicians are easy to contact on safety issues. Tries to propose therapy changes by written recommendations.</th>
<th>Physicians are contacted on technical but not in therapeutic issues. Good relationship desirable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good relationship with physicians on therapy issues is obvious and established.</td>
<td>Physicians are easy to contact on therapy issues. Strives for good relationship.</td>
<td>Physicians are easy to contact on safety issues. Tries to propose therapy changes by written recommendations.</td>
<td>Physicians are contacted on technical but not in therapeutic issues. Good relationship desirable.</td>
</tr>
<tr>
<td>Explore patients’ concerns and help them to set goals and achieve those goals. Use a structured process. Need to adopt PC philosophy and to move over to the care paradigm.</td>
<td>Explore patients’ concerns and help them to set goals and achieve those goals. Use a structured process. Need to adopt PC philosophy and to move over to the care paradigm.</td>
<td>Explore patients’ concerns and help them to set goals and achieve those goals. Use a structured process. Need to adopt PC philosophy and to move over to the care paradigm.</td>
<td>Explore patients’ concerns and help them to set goals and achieve those goals. Use a structured process. Need to adopt PC philosophy and to move over to the care paradigm.</td>
</tr>
<tr>
<td>Tell patients the best way to use drugs. Use computer screening to find patients in need of attention. Measure outcomes to follow up outcomes. Need to change focus from pill to patient.</td>
<td>Tell patients the best way to use drugs. Use computer screening to find patients in need of attention. Measure outcomes to follow up outcomes. Need to change focus from pill to patient.</td>
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<td>Pharmacist activities</td>
<td>Tell patients the best way to use drugs. Use computer screening to find patients in need of attention. Measure outcomes to follow up outcomes. Need to change focus from pill to patient.</td>
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<tr>
<td>Tell patients the best way to use drugs. Use computer screening and pharmacy computer alerts to find patients in need of attention. Need to develop communication skills.</td>
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<tr>
<td>Explore patients’ needs of information about best way to use drugs. Refer patients to physician in clinical inquiries. Need to develop their new role and to improve clinical competence.</td>
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9. Summary of findings

Paper I  When elderly Europeans use many drugs, almost half of them are at risk of unintended adverse effects or poor therapeutic outcomes caused by the drug combinations themselves, and a variation was noted among countries.

Paper II  DTC key persons described the DTC role or their own roles, in four qualitative different ways, based on how the prescribers were addressed. The four conceptions included Distant, Knowledge distributor, Catalyst, and Supporter or link. Variation also existed in the conception of DTC goals; either goals were expressed in economic terms or in both economical and qualitative terms. “Patient awareness” was low.

Paper III  New conceptions of the DTC role were found among chairs compared to those in Study II, suggesting a development of the role. Besides prescribers, patients and decision-makers were also addressed. The new conceptions included Traditional, Influential, Patient-aware, and Holistic and cooperative. High consensus was seen in how prescribers were addressed and in perceptions of goals. “Patient awareness” seemed to have increased, but was not a dominating issue. Both structural changes (top-down model) and how the actors work (bottom-up model) may be used to interpret the development of the role of the DTCs.

Paper IV  Classification systems for documenting drug-related problems have different characteristics, depending not only on the structure of systems but also on the process of classifying a problem. These characteristics were suggested to reflect the goal of the pharmaceutical care.

Paper V  Different care ideologies were reflected in the studied classification systems. One system was based on a patient-centered ideology, whereas three systems were based on an ideology derived from EBM and a biomedical view of the patient.
10. Discussion of methods

Scientific research is a social activity and this applies to both natural and social science (Fleck 1997). This means that the researcher’s interests and preferences influence the research process, from what is interesting to study to the findings. Furthermore, the researcher’s interest is influenced by the various thought collectives to which the researcher belongs, to use Fleck’s vocabulary. This means that my experiences and the context in which I work have had impact on this thesis. For instance, I acknowledge certain qualities in the patient-centered approach and this has probably influenced the perspectives. However I have intentionally tried to be as neutral, as systematic, and as thorough as possible in the analysis processes and in the compilation of final findings.

All research must be of high quality; however the type of quality requirements varies depending on research question and approach. When a study is expected to show whether one intervention is better than another, a quantitative hypothesis testing method is chosen. Here accepted study designs are available and the statistical methods serve as an obvious guarantee of quality. In contrast, when qualitative methods are used there are no statistics to rely on. Instead the quality in the procedures involved in a qualitative study determines the quality of the whole study. By presenting the procedures, the researcher shows that the findings are grounded in the data material, as discussed in the Background section.

In the first paper it is claimed that patients using many drugs commonly are at risk of altered drug effects due to interactions among the drugs they use. This is a statement that is probably not controversial. Another question is how common the potential risk is determined to be. This depends on which system is used to identify potential drug-drug interactions (DDIs). By using the definitions of DDIs that are usually used in Sweden (Pharmaceutical Specialties in Sweden 1997) it was found that 46% of the patients were at risk of DDIs. As a comparison a complementing analysis was done by using a list from Denmark comprising of 45 drug combinations generally accepted as carrying a risk of serious drug reactions (Rosholm, Bjerrum et al. 1998). By this definition 13% of the elderly had one or more of such combinations. Thus, the latter measure represented a selection of more serious drug combinations, whereas in the system we used combinations were included based on wider criteria.
One difficulty that the researcher encounters in qualitative studies is the interpretation of text materials in such a way that the informants’ intentions are understood. Especially complex concepts may have different meanings for different people, which has been explained by Connolly (Connolly 1993). In the studies of DTC roles (Papers II and III) the informants used, for example, the expressions “rational use” and “optimal use” when they wrote about the goals of the DTCs. The question was what they actually meant by these expressions, as the expression could include economic values, quality values or both. To enable the interpretation the answers from the three questions were analyzed as a unit and especially the examples the informant gave on successful activities were of good help.

Sometimes findings from qualitative studies are presented for the informants to reflect upon, as a part of the validation process. Other researchers do not favor this model because the informants do not have the whole picture from all informants (Malterud 1998). In the first study of DTC key persons’ perceptions (Paper II), the findings were presented for chairs after the analysis was completed. The findings were not rejected, but the informants stressed that they now had changed perceptions. These reactions were taken as a validation of the findings.

There are also other implications of the fact that the findings were presented to the chairs. One of the findings in the second study was that “patient awareness” had increased. There is one possibility that the chairs after listening to the presentation become aware of the finding that “patient awareness” was low. When the new questionnaires were received four months after the meeting, some of them could have remembered to focus on patients in their answers because of social desirability (Paper III). However, this is not likely to have happened; the examples given by chairs support the increased consideration of patients in the second study.

In the second DTC study data triangulation was performed (Paper III). The aim of triangulation is not to validate but to enrich the understanding of the phenomena (Malterud 2001). One advantage of interviews is that follow-up questions can be asked to increase the understanding of the informants’ statements (Malterud 1998). The new data collected in telephone interviews did not change the structure of the findings gained from the questionnaire analysis. However, the picture was made clearer.

It was more difficult to disregard my own experiences in the studies on classification systems and different ways to perceive pharmaceutical care (Papers IV and V) than in the studies on DTCs (Papers II and III). I had discovered myself that I approached customers at the pharmacy differently after my perception of the patient as a person instead of a passive participant in the healthcare system. However, I concentrated on being open to what the analysis would reveal. One might say I was ready to explore and notice special kinds of qualities but I did not know how they would look. This
might be compared to the readiness Fleck writes about concerning the thought style.

The analysis of classification systems in Paper IV was difficult because the study material was not a text; it was four different classification systems for drug-related problems and their instructions. The editing (data-based) analysis style which was used in Papers II, III, and V were easier to perform and to present. The identified characteristics of the classification systems in Paper IV could be validated by comparing them with the definitions of classification codes and the instructions that belong to each system. However, the characteristics were not revealed until the analysis had been done and the design of the study was decisive for the identification. It was necessary to get the experience of the practical use of the systems and to contrast them by using the same patient material.

The findings from Paper IV led to the research question that was explored in Paper V. These two studies can be considered to explore two different aspects of the same phenomenon regarded as a triangulation – two kinds of data collection and two kinds of analyzing methods. Hence, in addition to revealing new aspects of the findings, the interview study in Paper V supports the findings in Paper VI.

**Ethical considerations**

The consideration of good ethical practice is important in all studies where individuals participate. In the European study on elderly people (Paper I) ethical approvals were obtained in each country according to local practice. The elderly were given written information about the study and gave written consents in accordance to normal procedures. All data were treated with confidentiality and patients were informed that they could at any time leave the study if they wanted.

In the studies addressing healthcare professionals (Paper II, III, and V), participants where interviewed – either by mail back questionnaires, by telephone, or face-to-face. The subjects were informed of the purpose of the study and that the findings were planed to be published in reports and scientific articles. Participation was voluntary, and the questions addressed professional topics only. Thus, approvals from ethics committees were not considered necessary. This is in accordance to the Swedish law (2003:460) which states that approval from ethics committee is only needed for research that implies physical or psychological influence on the participants.
11. Discussion of findings

The overall aim of this thesis is to increase our understanding of how two professional collectives – the Swedish drug and therapeutic committees and the international pharmacy profession – have approached the safety and quality problems related to medication use in healthcare. The first study illustrates that prescribing of potential harmful drug combinations for the elderly is common in Europe. The study adds to an increasing body of research published during the last two decades, highlighting that drug therapy can possibly be a cause of iatrogenic disease. Iatrogenic disease is a problem that may be one of the most challenging issues to handle in modern healthcare. Moreover, the study shows an example of clinical practice variation – expressed in differences in prescribing patterns across participating countries. Thus, it also serves as an illustration of the main perspective on which this work is based – the perspective of social construction, acknowledging that illness, diagnoses, and healthcare services are shaped within a social and cultural context. The following discussion will focus on the findings of the other four studies exploring the two groups of healthcare professionals’ perceptions of their work, and how efforts towards improved quality and safety in drug use have emerged. The discussion also addresses some of the policies and social forces as well as values and beliefs that have influenced these efforts.

Developing the role of the DTC

The findings of the DTC studies suggest an ongoing development of the perception of the role of the DTC. The perceptions can be seen as a demonstration of how the professionals orient themselves in their context.

Implementation theories were used as an analyzing framework to further scrutinize the work at the DTCs, and this brought new perspectives into the discussion. The two models used were the top-down (Pressman and Wildawsky 1973; Mazmanian and Sabatier 1983) and the bottom-up models (Lipsky 1980).
Implementation of a political decision – or political decision as an “actor” in the social construction

The work of the DTCs was changed by the new law that was passed in 1997. The legislation involved a structural transformation that radically changed the conditions for DTCs’ work, and therefore a top-down explanation can be applied. This new structure consisted of a clearly defined government commission, a goal, and local assigners to work for. The DTC work which earlier had been voluntary was now upgraded. In our second DTC study the chairs stress especially that they were commissioned by the government, indicating that this made the DTCs’ task more important both for themselves and for other people in the context. The financial resources that were allocated for DTCs in relation to the reform were of course also crucial to the development.

However, ideas from the bottom-up model were likely to fit into the professionals’ work better. According to this theory the lower levels in the political system do not consist of neutral bureaucrats that follow instructions. On the contrary, the people here have high expertise and the freedom to shape the activities without central control. This was especially clear in the second DTC study, in which the complementary telephone interviews gave a rich material from the chairs. Concerning the DTCs’ work, the central control was confined to the governmental commission and the stated goals, and the goals can be described as a framework given to the DTCs to interpret. Furthermore, as will be addressed below, the bottom-up model can also be used to explain the background of the DTC law; the professionals’ voluntary DTC work influenced the political level in the recognition of the problems and in the formulation of the policy.

The following findings from the studies will be discussed: 1) a change in perception of target group(s), 2) a change in perception of goals, and 3) variation in how target groups were perceived.

1) A change from focusing on prescribers to also involving other target groups

The fact that prescribers were a target group is not surprising. However, one can reflect over the finding that they were the sole target group in the first study. Probably this is related to how the traditional DTCs were used to working and also to how the law was written – two aspects which probably coexist to some extent.

The DTC law was a part of a major drug policy reform. With this reform the parliament instructed the county councils to take responsibility for cost control and cost-effectiveness of drugs. The county councils were already responsible for organizing and budgeting healthcare, and now the budget for medications was to be integrated. In this context the DTCs were given the task of an assignment of the county councils in order to contribute to the aim
of the reform. It is important to consider that this task could just as well have been given to some other institution, or a new organization could have been established, which is commonly done when new directions are to be implemented (Spångberg Winblad 2003). However, the DTCs had received attention from the government and their work was appreciated. The members of the DTCs were viewed as competent drug experts and some DTCs had developed methods which had been shown to be effective in healthcare (Social Ministry 1996). Probably these aspects were vital factors in the decision to give the assignment of improving drug use to the already existing DTCs, as well as in the writing of the proposition, in which the prescribers were already identified as an obvious target group.

Another aspect which certainly influences the strategies developed by the DTCs, including the focus on prescribers, is the composition of professions in the DTCs. The law stated that pharmaceutical and medical expertise should be given the opportunity to participate in the work of the committees, a probable reflection of the old DTCs. The committees are dominated by medical expertise in the form of specialist physicians, and nurses as well as pharmacists are few, while other professionals such as educators and professionals in media and communications are even more rare (National Board of Health and Welfare 2004a). However, lately new professional groups are incorporated on DTCs, another sign of the ongoing development of the role (Cross 2001; National Board of Health and Welfare 2004a). All chairs in the studies for this thesis were experienced specialist physicians, and the information officers were, with few exceptions, physicians or pharmacists.

The involvement of other target groups in chairs’ perceptions is a sign of a development of the DTCs as such and parallels other changes, for instance the change in perception of goals. Decision-makers were involved, which was evidently in line with the intentions of the law. However, to explicitly consider patients when the tasks of DTCs were described, as was done in two of the perceptions in the second study, was a new approach. We can again use the bottom-up model (Lipsky 1980), and regard the statement which says that the actual policy is formed in the meeting with the public on the ‘street level’. DTCs work on a local policy level and not really at the ‘street level’. Nevertheless, their local character gives them opportunities that a national organization lacks. This seems to be what has happened here; DTCs are developing their local possibilities to come closer to the public.

Another major actor in the drug use domain, the drug industry, was perceived as an obvious counterpart to the DTCs. It was said that the industry played in the same arena but had a different goal than DTCs. This perception is not surprising; the drug industry’s promotion of expensive new drugs is obviously effective (Rosén and Beermann 1999; Morgan, Basset et al. 2005), and their promotion materials, though of high quality, are likely to be biased toward specific drugs (Wazana 2000; Collier and Iheanacho 2002;
The political investment in DTCs can be regarded as a strategy to build up a strong organization for producer-independent information.

2) A change in perception of DTC goals

According to the law, the goal of the DTCs was to work for reliable and rational drug therapy within their counties. “Rational” refers both to quality and cost aspects. However, the first DTC study revealed two different ways to perceive the DTC goal among key persons; one is with emphasis on cost and one addresses both quality and cost. In the second study all perceptions included both quality and cost aspects, which suggests a trend toward consensus among chairs. This change in perception of goals suggests a process of maturing into a more complex role, which probably requires new DTC strategies, for instance involving new target groups. Creating new structures across the bureaucratic healthcare borders is another strategy, which was suggested in one of the perceptions in the second study.

As I understand it, the aim of the new law was primarily to take control over the medication expenditures. This does not mean that the quality of care was ignored; however the emphasis seems in my reading to be set on measures to stop the increasing costs, though without jeopardizing the quality. In this sense the perceptions of goals in the first study, the reduction of drug costs, was in line with the intentions of the law.

The stronger emphasis on drug costs in the first years after the introduction of the legislation can also be interpreted by ideas from Lipsky (Lipsky 1980). He suggested that to survive, bureaucrats tend to focus on the easy tasks. Certainly, to promote the prescription of a less expensive generic brand is easier than to tackle the complex question of quality. Real cost defines itself and is easy to follow up, whereas quality is a complex concept that need to be operationalized.

One contributing factor to the shift towards quality aspects in goal perception was a reform passed in October 2002. From then on the pharmacy staff was obliged to choose the generic brand with the lowest cost at drug dispensing. With this reform the development of the drug expenditures dropped dramatically and in the meantime the DTCs did not have to take time to address the question of generic brands any more. A second contributing factor is the report from the National Board of Health and Welfare that was published in January 2004 (National Board of Health and Welfare 2004a). The report gave a number of proposals addressing improved DTC strategies, including a suggested increased focus on quality. An example of a major action by DTCs addressing quality issues is a national activity focusing on elderly and the quality in their drug use, which was run in 2005.
3) Variation of how target groups are perceived

The task of the DTCs was to develop strategies in order to achieve stated goals. In the first study the perceptions of the task concentrated on how to influence prescribers in the most effective way. The qualitatively different perceptions, the so called categories of description, were named Distant, Knowledge distributor, Catalyst, and Supporter or link, with the latter as the most complex. A more complex perception has been related in phenomenographic studies to increased competence, for example among schoolchildren and engineers (Marton and Booth 2000; Sandberg 2000). Among key DTC persons an increased complexity of perception correlated to an increased usage of pedagogical methods. In parallel there was a change in the relationship between the professionals and the focus of their interest (i.e. the prescribers); when the perception became more complex, the distance to the abstract prescriber was decreased. This is an example of what is taught in the theory of phenomenography (and the variation theory) – that new understanding means incorporation of new aspects that change the relationship to the phenomenon (Marton and Booth 2000; Pang 2003).

In the second study all perceptions concerning prescribers were more complex, indicating a development of how prescribers were perceived by chairs. Now, all of them could be viewed as “catalysts” or “supporters or links, and, for example, plain information was only expressed as one method among others. The usage of interactive approaches is supported by large studies on how to influence professional practice (Thomson O’Brien, Oxman et al. 2001; Thomson O’Brien, Freemantle et al. 2003) and were also recommended by the National Board of Health and Welfare (National Board of Health and Welfare 2004a).

4) Increased consideration of patients

There was an obvious trend towards increased patient awareness among chairs between the two studies. This change is a further expression of the ongoing development of the role of DTC, as has been discussed above.

However, patients were perceived in various ways. There was a gradual scale from patients being considered as passive recipients of care, to being considered a cooperative actor that helps the DTCs to achieve goals set by the DTC, and to being involved patients as human beings living in unique contexts (a perception which clearly sticks out from the rest). It was interesting to note that the latter holistic perception of patients was connected to a view of healthcare bureaucratic borders as being counterproductive for the challenging task of improving the quality of drug use. This perception may be provocative, but it is important to consider and highlights possible difficulties built into the structure of healthcare. In contrast, taking the expert role and giving advice to the decision-maker is a
perceived role that fits well into existing structures of healthcare; this was also outlined in the proposition for the law (Social Ministry 1996).

A reflection concerning the two implementation models, the top-down and the bottom-up, is that neither of them involved the users (the patients); the implementation is viewed as a professional task and the users are viewed as being outside this system. This criticism has already been discussed by other researchers (Winter 1990). This notion, to leave the users outside, was found among key DTC persons. In the first study the task of improving drug use was clearly viewed as a solely professional task, and this notion persisted in two of the perceptions in the second study. By taking this position the responsibility of improved quality in medication use stays among the professionals. My view is that it is valuable to involve the users, both for humanistic and practical reasons. This is primarily because the use of drugs concerns all users’ lives, and secondly, because most of the actual medication use occurs in peoples’ homes, outside of the professionals’ control.

Pharmacists and pharmaceutical care

Helping patients to achieve good drug therapy is a way for pharmacists to develop new professional tasks in a time when the traditional tasks are taken over by other parties. This new role started to emerge in the pharmacy profession in the 1970s, but was given a more pronounced, clearer position when Hepler and Strand described the concept “Pharmaceutical Care” (Hepler and Strand 1990). Today, the pharmacists’ patient counseling activities have developed in different directions. Some of them are still named PC, whereas others have been given other names, e.g. patient care, cognitive service, and medication therapy management service. Different ways to organize the activities have also been developed (Benrimoj and Roberts 2005; Gastelurrutia, Faus et al. 2005; Jones, Mackinnon et al. 2005; van Mil 2005; Christensen and Farris 2006; Eickhoff and Schulz 2006; Guignard and Bugnon 2006; Westerlund and Björk 2006).

The following discussion is based on the two articles focusing on four classification systems and their corresponding perceptions of PC, here called respectively Strand and Strand/PC, PCNE and PCNE/PC, Granada-II and Granada-II/PC, and Apoteket and Apoteket/PC. The following findings are discussed: 1) the classification systems’ different characteristics, 2) PC goals reflected in the different classification systems, and 3) care ideologies in different PC perceptions.

1) Classification systems have different characteristics

The structure of classification systems are different (van Mil, Westerlund et al. 2004). What my study adds is the description of the different processes to
classify a problem, and that the process is also essential for the characteristics of the system. The process can be viewed as a cognitive map corresponding to how a problem is classified. This means that different systems support different kinds of thinking.

There were three main differences in characteristics. First, two of the systems (Strand and Granada-II) include a structured process for the assessment of drug therapy, whereas this is not the case in the PCNE and Apoteket systems, which have few instructions. My conclusion was that a structured process was preferable, and this notion was shared in a study from Portugal (Costa, Santos et al. 2004). A second different characteristic is that PCNE and Apoteket include process-related issues in their systems, e.g. patient’s knowledge of health and drug therapy as well as administrative problems, whereas Strand and Granada-II are more strictly oriented towards outcome-related problems. However because Strand and Granada-II systems include potential problems or risks of problems, there is no total relationship between classified problem and outcome and thus process-related problems are also included.

The third and most important difference was how patients were involved or not involved in the classification of a problem. In short, in Strand the patients participated actively in the classification of a problem, whereas in the other systems the professionals made the classification. I propose that the different characteristics are reflections of different PC goals, and this will be discussed in the next paragraph.

2) Different goals in PC counseling

The different characteristics of the systems suggest a variation of PC goals and that the goals are sometimes explicitly expressed and sometimes implicit, and must be interpreted. These findings lead to the following conclusions: pharmacists have different perceptions of the PC goal, PC goals need to be explicitly formulated, and depending on the goal of the PC, a classification system that supports this kind of PC must be used.

The perception of PC includes a PC goal, and this goal influences how PC is performed. In this discussion it is essential to acknowledge that different goals exist. On one level the goal of PC can include, for instance, personal and professional features, but these kinds of goals are not addressed here. The discussion here concerns what the practitioner wants the PC counseling to lead to concerning the patient’s drug therapy.

The different goals of PC in relation to a patient’s drug therapy can be described as follows. First, on a concrete level there is the goal of the practitioner, which is to contribute his or her knowledge about drug therapy based on EBM and therapy standards, and the goal of the patient, which is to be healthy and feel good. In addition, on an abstract level there is a goal of the PC perception, and this is the goal that is reflected in the classification system. The goal of PC includes the other two goals – the practitioners’ and
the patients’. This can be confusing. To clarify, the different goals and their relations can be described in a formula.

\[
\text{Goal (PC)} = \text{goal (practitioner)} + \text{goal (patient)}
\]

The formula shows that if the patients’ goal is not considered, the goal of the PC is equal to the practitioners’ goal and vice versa. However, if the patients’ goal is considered, the overall PC goal changes to include both the practitioners’ and the patients’ goals. The documentation in the Strand system includes agreed therapy changes, thus, the goal in this PC perception is to help the patients to achieve their own established therapy goals. The Granada-II, PCNE, and Apoteket systems do not document intended agreed changes, thus the goal in these PC perceptions is to help patients to achieve optimal drug therapy according to EBM and drug therapy standards.

However, there were also other differences in the systems’ characteristics, suggesting support of different counseling strategies. For instance, the structured assessment process in the Strand and Granada-II systems supports a structured process in the counseling. The PCNE system has a separate system to classify causes of problems, which supports the pharmacists in finding a cause to resolve the problem. The Apoteket system has a focus on administrative problems, which supports an exploration whether a patient use the drugs as recommended or not. Granada-II, with its intention to document “real” problems that lead to bad outcomes, supports a documentation of problems similar to an epidemiological study.

The various PC perceptions can be interpreted as expressions of multiple pharmacists’ efforts to develop a new role. Patient counseling by pharmacists within the framework of PC is still a young enterprise that has not found its place in society. In this position it is not surprising that various “branches” of counseling activities are formed. On the whole it has been difficult for pharmacists to launch new services and get paid for them (Gastelurrutia, Faus et al. 2005; Jones, Mackinnon et al. 2005; van Mil 2005; Westerlund and Björk 2006). We do not know whether the counseling role will be a professional task of pharmacists in the future, even though this is what many pharmacists desire. It is also impossible to know whether a single counseling model will be formed or whether there will be various counseling models.

The use of a few consensus models and classification systems may be beneficial for the PC counseling and strategically important for pharmacists if they want to integrate patient counseling into their professional duties. From the professional perspective this may also have implications for the survival of the profession. An internal split can have a bad impact on the
professional role (Claesson 1989). This internal professional split and other questions regarding the future of pharmaceutical profession have also been highlighted by others (Traulsen and Bissell 2004).

3) The perception of pharmaceutical care is based on different care ideologies

To understand how goals are formed, underlying ideologies can be studied. Two basic care ideologies became apparent in the analysis. One was the patient-centered ideology, which was reflected in the Strand classification system and presented in its corresponding PC perception. The other was the biomedical-based ideology, which was reflected in the Granada-II, PCNE and Apoteket systems and their corresponding PC perceptions. It may appear strange that the patient-centered ideology in the perception of Strand/PC is presented as a finding, because this ideology is clearly emphasized in the theory of this PC (Cipolle, Strand et al. 1998). However, patient centeredness is one of these misused phrases that represent something people want to be, and might express what they hold on to, even though they do not live up to it. My analysis proposes that Strand/PC is a good example of how patient centeredness should be practiced.

I suggest that different perceptions of PC have developed as a result of the creators’ care ideologies and other possible competing interests in the context of the creators. In the perception of Strand/PC, patient centeredness is a central and prioritized focus, and because pharmacy culture and how patients behave in a pharmacy does not support this thinking, Strand/PC moved out of the pharmacy to separate clinics at healthcare centers. In contrast, the practitioners who work with Granada-II/PC, PCNE/PC and Apoteket/PC did not chose the care ideology first, but wanted to develop a PC that was possible to practice within the culture of community pharmacy. In the pharmacy culture the product has traditionally been in the center, and it has been shown that to shift focus from the drug is difficult (Claesson 1989; Almarsdottir and Morgall 1999). EBM fits easily into this culture, with its focus on knowledge derived from randomized controlled trials on specific drugs and indications and a biomedical view of health.

Different ways to approach patients were addressed as early as 1956 by Szasz and Hollender, who wrote a seminal paper about different relationships between physicians and patients (Szasz and Hollender 1956). Here three different relationship models are described: the activity-passivity, the guidance-cooperation, and the mutual participation. The findings from the descriptions of the various PC perceptions can be recognized in the models; the Granada, PCNE, and Apoteket perceptions of PC can be described in the terms of guidance-cooperation. In this model the

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5 Care ideology means a set of values and beliefs that influence the caring approach in the patient-pharmacist encounter.
professional guides the patient and the patient is expected follow the directions of the professional. In contrast, the Strand/PC can be described in terms of the mutual participation model. In this model the both parties have approximately equal power, are mutually interdependent, and engaged actively in a way that will satisfy both (Szasz and Hollender 1956). Good medicine from the viewpoint of relationship, according to Szasz and Hollender, requires all three different relationships depending on the situation. This statement can also, at least for the two latter models, be applied to the patient-pharmacist relationship. The guidance-cooperation model was said to be required in the initial stages of, for instance, a newly diagnosed diabetes mellitus. This relationship must however change to the mutual participation model to support the patient in managing his/her own health.

It is difficult for professionals to work in a patient-centered way. Studies show that even when professionals have such intentions this is difficult (Rosenvist 2002; van Dam, van der Horst et al. 2003). Pharmacists find it hard to change to a more caring role (Almarsdottir and Morgall 1999). Obviously this is nothing that professionals just adopt because they have the intention. This must be practiced, and new strategies are necessary. In medicine there are good examples of approaches aiming at training doctors to involve patients in a holistic way (Charon 2001; Ahlzen and Stolt 2003; Kjeldmand 2006).

Increasing patient centeredness in healthcare

There are many signs of a movement towards increased patient centeredness in healthcare, as presented in the Background section. However, there are also ideas which if too strongly emphasized involve a risk of decreased consideration of patients as subjects.

First and foremost, this discussion seems to concern the professionals’ basic perceptions of health and how they are constituted in healthcare – the biomedical view and the holistic view. These two perceptions can be understood as two different thought collectives, to which the professionals belong more or less. If a person belongs strongly to one thought collective he or she will understand phenomena according to the thought style of this collective (Fleck 1997).

The biomedical view of health is important, but too limited. This notion is increasingly argued for in the literature and is also the basis of the patient-centered movement (Bensing 2000; Mead and Bower 2000; Wilson 2000; Hetlevik 2004; Goldenberg 2006; Kjeldmand 2006; Lambert 2006; Malterud 2006; Tonelli 2006). The importance of involving patients in healthcare is also stressed in Swedish law (Swedish Commission 1997; 1999). In the
The biomedical view that has been dominant for the last 300 years, diseases are addressed in the same way as natural phenomena are addressed in natural science, and a positivistic view of knowledge is dominant (Wilson 2000). This is also the view of health that is constituted in healthcare. EBM is based on this traditional positivistic view, and thus fits easily into the existing healthcare system. Probably this is one explanation of why EBM has been accepted quickly by professionals, and has in just a few years been incorporated into the curriculum of medical schools (Green 2000; Holman 2004). In contrast, knowledge areas that aim at increasing the holistic view and a partnership approach play only a minor role in medical school curricula (Ahlzen and Stolt 2003; Holman 2004).

An increased involvement of patients in healthcare is widely requested but obviously hard to put into action. Studies show that comprehensive cultural changes in healthcare are difficult (Lindberg 2003). Leape and Berwick state in regard to a change to a safer system: “The primary obstacles to achieve these results for the patients who depend on physicians and health care organizations are no longer technical; the obstacles lie in beliefs, intentions, cultures, and choices” (Leape and Berwick 2005). Regarding increased patient centeredness the question is how a holistic view of healthcare can be implemented among healthcare professionals. Fleck teaches that to be able to gain new knowledge, new thinking must develop (Fleck 1997). The development of new thinking is also important according to Lipsky’s ideas, which say that the actions taken by professionals in their work are partly unconscious (Lipsky 1980). One way can be to make conscious the ideas professionals are using and to present alternative ideas to stimulate new thinking. To help this development, theories from phenomenography can be used.

**Describing the variation in order to contribute to new ways of thinking**

Theories of phenomenography state that people act in accordance with their understanding of the world, and that understandings (or conceptions/perceptions) are inseparably intertwined with the person’s life experiences and actions (Marton and Booth 2000). The understandings influence what a person will focus on, i.e. which aspects will be in the foreground and which will be in the background. In learning, the experiences a person has influence what is learned. Learning is about changing the relationship between the person and the phenomenon, and may be done by incorporating new aspects of the phenomenon. However, new aspects can only be seen if there is a variance in them, otherwise the aspects remain
unobserved. Thus, to reflect on variation of conceptions is a way to gain new understanding (Marton and Booth 2000; Pang 2003).

Ideas from phenomenography can be used to describe the professionals’ understandings of health. The categories would then be the holistic view and the biomedical view, and in an outcome space I would place the holistic category above the biomedical. This is because the holistic understanding includes a biomedical, social, and psychological view, and thus is more complex than the biomedical understanding. Concordantly, a holistic view of health is the preferred one, and knowledge from biomedical studies should be used as one source of information together with other sources. This approach is also proposed by practitioners and researchers (Greenhalgh 1999; Mäkelä 2004; Goldenberg 2006).

One way to broaden our thinking is to bring in thoughts from one thought collective to another (Fleck 1997). This is what my thesis tries to do – to bring in new perspectives – by applying research methods that are not commonly used in the medical field. This is done by describing the different ways of how professionals perceive their tasks, and hopefully aspects are revealed that have not been visible before. By reflecting on these aspects new understandings of the work are possible.

Conclusions and implications

The opening paper in this thesis describes how drug therapy potentially can lead to harmful effects for patients. These findings add to the literature stating that drug-related problems are a public health issue that demands our attention. To gain understanding of how this issue is tackled in society, two professional groups aiming at improving drug therapy were studied. These were drug and therapeutics committee (DTC) members and pharmacist in community settings performing pharmaceutical care (PC).

Perceptions among key persons on DTCs reveal an ongoing development of the role of the DTCs, including a more complex notion of the DTC goals and strategies. The trend was to focus both on improving economic and quality aspects of medication use and to consider new target groups for DTC activities. Patients were considered but there was some uncertainty about how they were to be involved, and involving patients as subjects was not a major concern.

Counseling patients in community settings is a new professional task for pharmacists, and thus this role is also evolving. Different ways to perform PC have been developed based on different care ideologies and other possible interests. One of the studied PC perceptions (the Strand) was based on a patient-centered ideology, whereas the other perceptions (the Granada-II, PCNE, and Apoteket) were primarily based on an ideology expressed in EBM, one which includes a biomedical understanding of health.
Although legislation and research promote the involvement of patients in healthcare, this study demonstrates that the involvement of patients as subjects was not the dominant approach among professionals working for improved drug use at different levels in society. Rather, their work was primarily based on the biomedical view of health which has existed for the last 300 years, in which there is a risk of decreased consideration of patients as subjects. This finding suggests that we are still at the beginning of a development towards a patient-centered perspective in healthcare.

To support this development, which is strongly encouraged by legislation and research, comprehensive strategies supporting this change are necessary. Future activities should focus on challenging traditional thought patterns and care approaches at different levels of healthcare organizations as well as on changes at educational institutions.

Hopefully this thesis introduces new perspectives and ideas that will stimulate professionals, decision-makers, and the general public to fruitful discussion and development of healthcare in a patient-centered direction.
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