Part IV

Conclusion and summary
Conclusion of this Dissertation

Until the first World War community pharmacy in The Netherlands was primarily a product oriented institution. Then the professionalism of pharmacists declined and they seemed to concentrate especially on the trade aspects because of the increased industrial production of medicines. After the Second World War pharmacy started to change slowly in the direction of service and advising on pharmacotherapy, and reprofessionalisation began. In the 1990s the move towards pharmaceutical care (a patient oriented care model) started in community pharmacy, and most of Dutch community pharmacy is now becoming patient and care oriented. The current change is strongly supported by the Royal Dutch Society for the Advancement of Pharmacy (KNMP) and by the type of pharmacy education provided by the Groningen and Utrecht universities, where pharmacotherapy, clinical pharmacy and social pharmacy are major topics in the curriculum.

One of the bottlenecks for the implementation of pharmaceutical care is the availability of clinical data to the pharmacist. In 1999 the KNMP has reached an agreement with the Dutch government that the Dutch pharmacist will be part of the WGBO. This means that pharmacists will soon be acknowledged care providers by law, and this also enables a free exchange of data between medical and pharmaceutical practitioners.

How valuable is pharmaceutical care to society? In the TOM and OMA studies described in this dissertation and also in many articles and abstracts, it has been proven that the provision of pharmaceutical care has a positive influence on different outcomes of patient care. Although most studies have not yet been published in the major biomedical journals, it has clearly been established that the provision of pharmaceutical care has its value in the case of general ambulatory care, psychiatry, HIV infections, asthma, diabetes, hypertension, and hyperlipidaemia.

It can therefore be stated with confidence that pharmaceutical care definitely improves the outcomes of care. Although there are differences in opinion on the definition of pharmaceutical care world-wide, most western countries now embrace the basic pharmaceutical care concept where the patient is the core of the pharmacist’s activities. The opportunities to provide pharmaceutical care, however, depend on several circumstances.

There is quite a difference between pharmacy practice internationally, and a number of country specific barriers have to be overcome. Although small pharmacies, with only one pharmacist and no other staff certainly have low thresholds for their clients, their structure and financial capacities to provide pharmaceutical care most probably are limited. Pharmaceutical care certainly demands extra time, and often also extra staff for it to be properly implemented. There are educational demands to be met as well as demands in the field of knowledge and attitude. Many professional organisations around the world are now addressing these barriers.
The search for definite answers to the question of whether changed pharmacy practice in The Netherlands is possible, a practice in which the community pharmacist has expanded his/her role and influences outcomes in a positive sense, clearly has not ended with the TOM and OMA studies. More research into the outcomes and especially in relation to the processes of pharmaceutical care should be performed.

10.1 **The TOM and OMA Studies**

In a number of publications, Donabedian presented a model for assessing the quality of health care. Looking at pharmaceutical care and at both studies presented in this dissertation, his division of the care-process into structure, process and outcomes is helpful for these type of studies.

10.1.1 The structure

In chapter 8 of this dissertation it has been established that pharmacy in The Netherlands is basically well structured for the provision of pharmaceutical care.

The relatively large Dutch pharmacies do offer opportunities to provide pharmaceutical care. The staffs in pharmacies are relatively well trained in counselling and pharmacotherapy, although pharmacists have their doubts about the possible role of assistant pharmacists in the pharmaceutical care process. The layout of Dutch pharmacies is spacious compared with pharmacies in many other countries and counselling has for the last twenty years been part of the activities. There are relatively good relationships with GPs, a well functioning medication surveillance system and most Dutch clients visit the same pharmacy. Almost all pharmacies have a special counselling room. However, during the TOM and OMA studies it became apparent that the Dutch pharmacist is not accustomed yet to document interventions and outcomes in a structured way.

Before and during the TOM and OMA studies attention was paid to the structure by giving additional education to the pharmacists, and helping them to implement the study protocol in their pharmacies. The importance of documentation was stressed as well as the need for a quiet environment for providing care and working in a structured way (see chapter 3).

A major handicap for the interpretation of the results for the TOM and OMA studies was the limited documentation in some of the participating pharmacies, in spite of the extensive training-programme. However, during the studies it became clear that the Dutch computer software has not yet been developed appropriately for proper documentation and that the pharmacy staff needs additional training on this topic.

10.1.2 The process

The initial thoughts expressed in section 3.2.2 about separating two types of reference pharmacies for both studies did not prove to be helpful. The fact that intervention pharmacists provided e.g. care to asthma patients had no or little influence on their care towards the elderly population in their pharmacy. Similarly no influence on asthma patients could be recognised in those pharmacies were care was provided to elderly using 4 or more medicines.
Although the processes for the TOM and OMA study have been thoroughly described (see Chapter 3), they have not been implemented as well as they should have been, in spite of the training sessions before and during the studies. From the pharmacists’ reports on the frequency of the consultations, there are indications that the implementation of the process has not been as good as desired. The underlying documentation was not filled out well and more attention should have been paid to the documentation of process-indicators.

The pharmacists participating in the TOM and OMA studies were provided with a structured approach to medication analysis, which in fact is a protocollled way of dealing with potential drug related problems in complex medication regimens, using drug use profiles. If and how this protocol was used, could not be assessed. The latter effect became visible when comparing the number of drug related problems encountered. According to the OMA pharmacists’ documentation the number of problems decreased throughout the study, but when the intervention and reference groups were compared at the end of both studies, no difference in the number of drug related problems experienced by the patient could be established. The reasons for this discrepancy can be twofold. Either the pharmacists have not addressed the drug-related problems as experienced by the patients (but mainly the ones they could detect with a potential clinical significance), or the willingness to document decreased during the study. In future studies it is advised that special attention be paid to the way process indicators are established and documented.

10.1.3 The outcomes

The major interesting part of any study into the effect of care processes are the outcomes. In spite of the deficiencies in the TOM and OMA study concerning the structure and process and the relative high drop-out rates, the inclusion of reference groups in the study ensured that changes in outcome could be established between the intervention and reference groups. These changes must have been a result of the process (which perhaps was not exactly the process as planned for the study) and the slightly adapted structure in the participating pharmacies.

As illustrated by chapter 3 of this dissertation, much energy was put into establishing the proper outcomes to be monitored before the study, both final outcomes and intermediate outcomes. But because of the quality of the available data, no highly sophisticated statistical procedures have been applied.

In his major publication in 1993 about outcomes in pharmacoeconomic research, Kozma presented his ECHO-model. This model seems to be very suitable to analyse the outcomes of pharmaceutical care research as well. The model divides outcomes of care into economic, clinical and humanistic. If this model is used to analyse the results of the OMA and TOM studies, then the following picture emerges.

Economic: No comprehensive pharmacoeconomic analysis was performed but some indicators changed in a positive sense in the OMA study, like the number of visits to the GP, the number of visits to a specialist and the number of hospital admissions.

Clinical: There are clear indications that certainly in the case of the TOM study (asthma) some clinical outcomes improved. This finding was supported by the changes in drug use. In the OMA study the intervention has not resulted in changes in the number of dispensed...
daily dosages of benzodiazepines, and only in a non-significant change in presumed compliance calculated from the dispensed daily dosages. Other clinical outcomes were not included in the assessments because of the character of the intervention.

Humanistic: The provision of pharmaceutical care improved the satisfaction with care of patients and professionals alike. In the TOM study there are indications that the patients’ quality of life improved but not to a clinically or statistically significant degree. In the OMA study a change in quality of life could not be established, probably due to the low sensitivity of the instrument, minor changes in this outcome and the high drop-out rate.

10.2 Considerations for Pharmaceutical Care Research

Research in the field of pharmaceutical care, which is a form of pharmacy practice research, is relatively new. According to Cotter and Mays, pharmacy practice research can be defined as ‘the research into the protection, development and justification of pharmacy roles and services’. Systematic major research in this field is rare, although many smaller research projects are being performed, mainly in the United Kingdom.

The definition of pharmaceutical care research can be formulated as ‘the investigation of pharmaceutical needs of individuals and the community and the effectiveness and efficiency of the provision of pharmaceutical services and care to meet those needs’. It is a form of research, which is clearly based upon the patients’ viewpoint, a logical result of the definitions of pharmaceutical care. Systematic research in this field is at this time only being performed in a few centres, in Europe mostly by members of the Pharmaceutical Care Network Europe, or in a few universities in Northern America and Australia. Sometimes pharmaceutical care research includes the pharmaco-economic evaluation of the intervention, to estimate the possible beneficial effects to society of the pharmacists’ actions, but that clearly remains a difficult topic.

The standard way of academically investigating a problem runs through 4 phases: designing, implementing and collecting data, analysing data, and reporting. During the design-phase two main questions have to be answered, as follows:

- what is to be found out (the research question) exactly and
- what is the best strategy to answer this question.

In the case of pharmaceutical care research in practice, the researchers can hardly influence experimental conditions and there is a large possible variety in outcomes. The outcomes are partially subjective and include a large array of humanistic variables. This also implies that many instruments should be used to measure outcomes, or a limited number should be chosen in the knowledge that not all results of the application of pharmaceutical care, or the fulfilment of all pharmaceutical needs of patients, will be measured. This influences the answers to both questions posed above.

In 1997 the Cochrane Centre published a review (last amended in 1999) in which they stated that only a limited number of studies which could be analysed in the field of pharmacy practice and studying outcomes, supported the expanded roles of pharmacists in patient counselling and physician education. The reviewers had doubt about the generalisability of the studies and the poorly defined nature of the interventions tested. The lack of studies including cost assessment and patient outcome data indicates that more
rigorous research is needed to document the effects on outpatient pharmacist interventions. An article with a similar content by Kennie et al. appeared in 1998 in the Annals of Pharmacotherapy. Nevertheless the authors of the Cochrane review conclude that ‘Pharmacists should continue their roles in delivering patient counselling regarding drug therapy and educating physicians about drug therapy. A limited literature supports further expansion of pharmacist roles to include therapeutic management of patients independent of physicians and patient counselling on general health issues other than those specifically related to drug therapy.’

The TOM and OMA studies described in this dissertation suffer from some of the flaws mentioned in both reviews above. This is not surprising because they were started in 1994, at a time that outcome research in pharmacy and pharmaceutical care were relatively new. Nevertheless, the chance that the presented findings are a result of the implemented care is high, because of the availability of reference data. However, there are some other reasons why pharmaceutical care research in practice can not always meet the demands of a well-designed clinical study.

10.2.1 Monitoring the process
Pharmacy practice is far from a sterile laboratory. Pharmacists and patients both are human and only the drug is an unchangeable entity. The human influences on any process in care can hardly be standardised. Before and during the TOM and OMA studies, the pharmacists were not only educated on the content of the care to be provided, but also on documenting and using the different documentation forms. Nevertheless there are indications that the documentation was insufficient and that the intervention was not implemented fully as planned. Therefore it would certainly be very useful if the process of the provision of pharmaceutical care and its documentation during studies are closely monitored and documented by an independent supervisor, equal in position to the clinical monitor in clinical studies.

An interesting recent development is the publication by Odedina and Segal of an instrument for measuring the pharmacists’ activities. This instrument would enable researchers to establish a level of the provision of pharmaceutical care in a pharmacy and monitor how far the implementation process has progressed. Odedina used a multiple-item scale to assess behavioural activities in pharmaceutical care. The scale was proven to be valid, reliable and sensitive. The authors assume pharmaceutical care to be a combination of drug use assessment, counselling and therapeutic outcome monitoring. However, the scale seems sensitive to bias. It will only be valid if the pharmacists abstain from formulating socially desirable answers to the questionnaire. Additionally the questionnaire is quite complex and country (USA) specific. Semantic and cultural translation does not seem an easy task.

10.2.2 Data Quality
Drug data from pharmacies, although very helpful, are not always complete. Drug data used in the TOM and OMA study suffered especially from the fact that the real daily use by the patient was obviously not always in concordance with the daily use as entered into the pharmacy’s database. Monitoring e.g. compliance on the basis of such incomplete data then
becomes difficult. The mentioned independent supervisor could also be helpful to detect and repair such discordance at an early stage.

Furthermore the collection of quality humanistic data especially is quite a challenge when an interviewer is involved. In pharmaceutical care research the pharmacist will often take part in the data collection. The chances to receive biased answers under these circumstances are high. The interpretation of a question by the interviewer or even the reader adds to the variability and influences the quality of the data and therefore the results. The validation of data collection instruments and methods is of uttermost importance under practice circumstances.

10.2.3 Availability of validated and practical instruments

Although some outcomes (economic, clinical and some humanistic) can be measured and can provide a firm basis for research, the assessment of other humanistic outcomes is not standardised. Control groups must always be included in pharmaceutical care research because healthcare is changing continuously, and other factors (outside of the pharmaceutical care intervention) may also affect the outcomes.

Currently the emphasis of pharmaceutical care research is heavily placed upon sociological outcomes, and suitable instruments for the assessment of the effects of pharmaceutical care in this field are only now in the process of being developed. Therefore a number of additional challenges can be foreseen when collecting, analysing and interpreting the data.

For one main outcome, the health related quality of life (HRQL), well established research instruments exist, which sometimes have a validated derived linear scale. However, that instruments are designed for assessing the effects of medical care, which often has a more outspoken impact on the life of the patient. Instruments to measure other humanistic outcomes like satisfaction of patients and professionals for the time being cannot be interpreted in such a way, if available, and inclusion of reference groups into studies remains essential.

Bentley et al. have researched if the concept of quality of life is clear to pharmacists in community practice. They concluded that there are still a number of questions that must be answered before HRQL questionnaires can become clinical tools in the practice of pharmacy. The issues that pharmacists try to affect when providing pharmaceutical care are the perceived health status of the patient, in combination with limits to functional (dis)abilities. But some find this a debatable viewpoint because essentially there are many different concepts regarding the health related quality of life, originating from different approaches. When choosing an instrument, these differences in approaches must also be taken into account.

If the current validated instruments are used, one needs quite a large number of study-subjects in order to demonstrate changes in quality of life over time, significant at a 95% confidence level. In the case of generic instruments the link with clinical significance is difficult to establish. This is especially the case for the provision of pharmaceutical care, because it seems not to influence one single domain, but all (or most) domains simultaneously to a small extend, unless a clear disabling disorder is being addressed.
Apart from isolated attempts to construct pharmaceutical care specific instruments for outcome assessment, a more integrated approach was taken at the Working conference of the Pharmaceutical Care Network in January 1999 in Hillerød, Denmark. Some of the workshops resulted in instruments, which are now being validated. The proceedings of the Working Conference will be published by the end of 1999. In the mean time a publication has appeared in Germany about the PCNE Attitudes Towards Medicines Questionnaire, which was developed during that conference.

10.2.4 Process and outcome documentation

There are no well-designed validated instruments to document the care process. Although one could use the SOAP-notes approach initially developed for medicine, the content of each element (subjective, objective, assessment and plan) still can not be documented in a way that would enable statistical analysis. Medicine also is still struggling to find appropriate Electronic Medical Record (EMR) systems.

During our studies the PAS® system was developed (see appendix 2), as an attempt to document elements of the consultation process and to be able to analyse these elements using statistical methods. The results of the evaluation of this instrument indicated that this system was not very valid, although in retrospect the validation method was not optimal either because the cases offered to code were probably too concise and left room for different interpretations.

A concise structured documentation system for pharmaceutical care activities has been developed by the Dutch Scientific Institute for Pharmacy Practice (WINAp), and installed on the major Dutch pharmacy computer-systems. This system is designed to monitor the performance of the pharmacy. This could be an extremely efficient documentation system, however, in practice this system is seldom used because the pharmacy-staff in The Netherlands is not accustomed to documenting care-activities.

The International Classification of Primary Care (ICPC) is a classification system and research tool developed in an EC project to classify simultaneously three of the four elements of the problem-oriented construct-SOAP. It is a biaxial classification system developed to order medical concepts into classes, which have been chosen on the basis of their relevance for family practice to code GP-patient encounters and other actions in general practice of medicine. In 1998 a reduced version of the ICPC coding system was published which could be helpful in the documentation process for certain aspects of pharmaceutical care in community pharmacy.

Documentation and process implementation could possibly be improved by providing payment to pharmacists for the time invested. However, in studies where this has been done, the documentation quality was reasonable but still not optimal, according to the researchers. In Quebec (Canada) the available funds for remuneration of pharmaceutical care are hardly being used by the pharmacists.

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* More information on the validation and a brief report of the meeting can be found at the internet at http://www.pharmakon.dk/Interna/pcne.htm.
† Information obtained at discussions within the Pharmaceutical Care Network Europe.
10.2.5 Good examples

Potential researchers will not be able to identify many examples of pharmaceutical care research by performing literature searches, due to a certain lack of publication platforms and the erratic use of the term ‘pharmaceutical care’ in databases like Medline or Embase. Additionally, full descriptions of methodologies have not often been published, possibly because publishers (and therefore authors) seem to concentrate on the clinical or economic outcomes rather than on the process.

As remarked by Kennie, it is true that published studies relating to pharmaceutical care do not always meet the same stringent scientific criteria, which can be applied to studies under laboratory circumstances or in a clinical environment. This is possibly also one of the reasons that it appears to be difficult to find a publication platform for pharmaceutical care research, apart from national pharmaceutical journals. Researchers in different countries are still searching for independent peer reviewed international biomedical journals, which are willing to accept their major publications on the results of their studies, some already concluded in 1996.

Furthermore, a number of projects have been performed with the state or professional pharmacist organisations as the major sponsor. Reports on the effects of those projects have primarily been prepared for the principals or authorities, and have not (yet) appeared in the major biomedical journals (e.g. the projects of the University of South Australia by Gilbert and the University of Sydney by Benrimoj et al.). Parts of such projects have, however, sometimes been presented as posters or short communications in national and international pharmaceutical conferences, but not in full in peer reviewed biomedical literature.

For the time being personal communications seem the best way to obtain information about pharmaceutical care research methodology. Apart from the Pharmaceutical Care Network Europe (PCNE), other possible platforms for obtaining such information include the annual International Conference on advances in Pharmaceutical Care and the PharmCare discussion list of the PharmWeb Internet-server in the UK. Increasingly national and international pharmacy conferences also offer opportunities for the exchange of methodologies, especially during the short communications or poster sessions.

10.3 The future of pharmaceutical care and pharmaceutical care research

Although different opinions exist on the definition of pharmaceutical care, the concept has a future in community pharmacy and probably in hospital pharmacy as well. In the latter case the care will be provided through a clinic, as can be seen in many places in the US, and increasingly in the UK.

How easy is it to establish the effect of pharmaceutical care, assuming that the process control is optimal? This largely depends on the outcomes that can be selected for the study. Looking at the literature, and comparing the results of the OMA and the TOM study, it seems that establishing the effect of the provision of pharmaceutical care to a clinically well-defined population is relatively easy. Providing pharmaceutical care to a defined group of patients (e.g. certain age groups, pregnant women, elderly using 4 or more medicines) becomes more difficult. This is due to the fact that the clinical outcomes to be studied are...
more difficult to identify. When the effects of interventions to all patients in a pharmacy (for instance the effects of counselling at first and second delivery of a specific medicine) is to be studied, the researchers must rely almost solely upon economic and humanistic outcomes. In the latter case the indications for drug use and thus the clinical outcomes can be manyfold. It is therefore not surprising that articles describing significant changes in final clinical outcomes of care as a result of pharmaceutical care interventions usually deal with clearly identifiable diseases and clinical outcomes. Publications on comprehensive pharmaceutical care concentrate on humanistic outcomes, or on models calculating possible economic benefits.

However, the processes that can lead to the optimal outcomes of pharmacotherapy need to be refined further. Disease specific pharmaceutical care remains a topic requiring more research, during which protocols can be developed and tested for implementation. But protocols can only be developed if standards for optimal care exist. The medical profession is still struggling to describe standards for the optimal treatment of diseases. Many standards of care are country (or health system) specific and are in a constant state of revision. It seems desirable to develop standards for pharmaceutical care, which are more independent of such changes. The Dutch institute WINAp is currently trying to define disease specific pharmaceutical care standards, based upon the Dutch Pharmacy Norms and additional requirements.

The concept of comprehensive pharmaceutical care, as described by Cipolle, Strand an Morley, offers the opportunity to provide patients with pharmaceutical care irrespective of medical standards, but based upon drug use and medication related errors. In community pharmacy practice this seems a very useful approach, also because the pharmacist in most countries, including The Netherlands, often lack the indication for drug use. The effects on final outcomes of this form of pharmaceutical care, however, are hard to establish. There have been efforts to link the occurrence of drug related problems (basically a process indicator) to the clinical and/or economic outcome of care, but such studies include many gross assumptions of the impact of drug related morbidity on hospital admissions and other costs. The studies also usually assume that drug related morbidity is preventable, which is not always the case. Additionally, the frequency of drug related problems would differ between countries due to differences in the implemented systems for prescribing by physicians and medication surveillance in pharmacy. Results of national studies therefore are not representative for other health systems.

The future will be for both types of pharmaceutical care. Where a diagnosis and a good pharmacotherapeutic treatment standard exists, the pharmacist could use that standard to underpin a process of care which will influence a clearly defined outcome; including the same (usually clinical) outcome the standard addresses.

In the case of multimorbidity, or if the goals of the pharmacotherapy are unknown, the comprehensive approach has its value as well, not only to improve patient satisfaction but also to prevent and correct medication related errors and their impact on outcomes. In this latter case it seems especially necessary to establish what drug related problems are

‡ Several minutes of the WINAp steering group meetings throughout 1998.
preventable, and the consequences of preventable drug related morbidity in terms of economical, clinical and humanistic outcomes.

10.4 References to Chapter 10


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