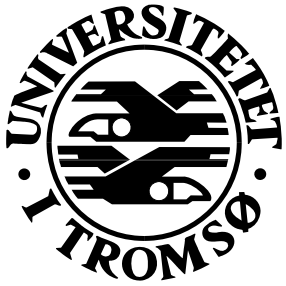
Clinical audit of structured pharmaceutical care plans recorded within a hospital pharmaceutical care service

A research project

A partial fulfilment of the Norwegian degree

Master of Pharmacy

University of Tromsø, May 2008



Project Investigator: Kari Jansdotter Husabø
Academic Supervisor: Steve Hudson
Co-Supervisor: Carl Fenelon
Academic Co-Supervisor: Thrina Loennechen

Project Location: University of Strathclyde, Glasgow

Acknowledgements

I would first of all like to thank my fellow researchers Marit, Reidun and Maren for a tremendous support all through the project. It has been a lot of fun! A special thanks to Marit who has coped with me through this last part of the project. I would also like to thank Mona and Ingrid for support and a nice time all through our stay in Scotland.

I would like to thank my supervisor Professor Steve Hudson for having patience with me and helping me through the project. I would also like to thank my co-supervisor Carl Fenelon for letting me come to his ward and for helping me with the project. A special thank goes to Lee Stewart for making me feel welcome at his ward, and for supervising me through this project. Ian Thompson, you've been really helpful for four girls with no clue when it comes to computers. I would also like to thank Susan McKellar for helping us with everything, both with the project and everything else. Thanks to Amir and Sue for analysing the data for the prescribing survey.

In addition I would like to thank my mother for being the best mother a girl could wish for.

Abstract

Background: Pharmaceutical care is delivered in various ways and settings. There is a need for ways of describing the care delivered to be able to compare the care delivered in different settings.

Aim and objectives: The aim of the project was to compare the prescribing activity and delivery of pharmaceutical care in two clinical settings. In order to quantitatively compare the pharmaceutical care activity, a categorisation system for pharmaceutical care issues previous developed at University of Strathclyde was used. This categorisation system was modified as part of this and three other projects before it was used.

Methods: The categorisation system was developed through literature review and discussions between the four researchers. Categorisation of care issues was used to quantitatively describe the delivery of pharmaceutical care at a Care of the Elderly ward. The data was also used to statistically compare the delivery of pharmaceutical care with another ward at the same hospital. Two separate projects surveyed the prescribing activity at the two wards, and the results from these are included in this project.

Results: The comparison of pharmaceutical care between the two wards showed that the pharmacists had different focus in the delivery of care. Differences in prescribing activity were also showed between the two wards.

Discussion: The difference in pharmaceutical care activity can be explained by differences in patient population, prescribing activity and pharmacist preferences. The data collection was based upon documentation made by the pharmacists during their work in the clinical setting. Variations in recording can have contributed to the differences seen.

Conclusion: The categorisation system can be used to describe and compare delivery of pharmaceutical care in different settings.

Abbreviations

κ	Cohen's kappa
95% CI	95 % Confidence Interval
ADR	Adverse Drug Reaction
APhA	American Pharmaceutical Association
CF	Carl Fenelon
CMP	Clinical Management Plan
CNS	Central nervous system
COPD	Chronic obstructive pulmonary disease
CVS	Cardiovascular system
GI	Gastro-intestinal
GP	General Practitioner
IL	Ingrid Lian
IQR	Inter Quartile Range
KJH	Kari Jansdotter Husabø
LOS	Length of (hospital) Stay
LS	Lee Stewart
MBC	Marit Bergheim Christensen
MCMB	Multi-compartment Medicines Box
MI	Myocardial infarct
MRR	Maren Rambøl Ruud
NHS	National Health Service
NSF	National service framework
OTC	Over the counter
PMP	Patient Medication Profile
POD	Patient's own drugs
PWDT	Pharmacist's Workup of Drug Therapy
ROH	Reidun Os Husteli
RPSGB	the Royal Pharmaceutical Society of Great Britain
SH	Steve Hudson
SOP	Standard operating procedure

Table of Contents

List of Tables

List of Figures

List of Equations

1 Introduction

1.1 The history of pharmaceutical care

Clinical pharmacy emerged as a profession in the US during the mid 60s. The development of clinical pharmacy was partly a result of a change in the pharmacist's role in the community. Earlier the pharmacist had been an advising, producing and dispensing health care provider in the pharmacy, but during the middle of the 20th century many things changed. The pharmaceutical industry started to manufacture drugs on a large scale, and the need for local production in the pharmacy decreased. In 1951 the prescription only legal status was introduced in the US, limiting the amount of drugs that could be bought over the counter (OTC). There were similar developments in the UK through the Medicines Act 1968, confirming a trend to address patient safety by increasing controls over medicines distribution. The American Pharmaceutical Association (APhA) Code of Ethics from 1922 prohibited the pharmacist from discussing the therapeutic effect and the composition of a prescription with the patient until 1969, when the Code of Ethics was changed.[1] These circumstances contributed to making the role of the pharmacist mainly one of dispensing. Many pharmacists wanted to use their knowledge to the best advantage of the individual patient and the population as a whole; the development of clinical pharmacy was a way of doing this.

Clinical pharmacy has many various definitions.[2] The National Health Service (NHS) in Scotland defines it as "a discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients".[3] After its introduction clinical pharmacy was performed in many different settings in many different ways, while the focus of the services was often technical (e.g. pharmacokinetics, parenteral nutrition, adverse drug reactions) on the drug and not necessarily on the whole patient.[1, 4] The need for a more holistic approach to the pharmaceutical care of the patient was discussed during the 70s and 80s.[5] The concept of pharmaceutical care was developed as a contribution to this discussion. The term pharmaceutical care was

first introduced in 1980, but the definition and the concepts which are most widely used today were formulated and presented by Hepler and Strand at the "Pharmacy in the 21st Century Conference" in 1989.[2, 6] This definition was later published in the seminal article "Opportunities and responsibilities in pharmaceutical care".[4] With this article the concept of pharmaceutical care, as understood worldwide today, was born; but its implementation is far from universal and so remains not as highly developed in reality.

1.2 What is pharmaceutical care?

According to Hepler and Strand the mission of pharmacy practice is more than just clinical pharmacy. They describe pharmaceutical care as the philosophy of pharmacy practice which, until then, had been missing from clinical pharmacy.[4] Their main objection to clinical pharmacy practice was its pre-occupation with the drug, as opposed to the patient. Hepler and Strand define pharmaceutical care as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life".[4]

There are some aspects of this definition which are worth mentioning and which highlight the differences between clinical pharmacy practice and pharmaceutical care. Firstly, the definition focuses on the responsibility. This is an important feature of pharmaceutical care. The practitioner of pharmaceutical care has responsibility for the patient and the quality of care the patient receives. To fulfil this responsibility there must be a focus on patient outcomes, as underlined in the definition. The quality of care delivered cannot be evaluated without knowing the outcomes. Secondly, the definition addresses he patient's needs directly, and also it does not define the provider of pharmaceutical care. These features of the definition have two implications. First of all this means that pharmaceutical care is patient focused. It is the patient, with his or hers beliefs, diseases and drug related needs, which are the centre of attention. The definition can even be understood as a description of what the patient receives and not what the practitioner delivers.[7] Secondly this means that pharmaceutical care is not primarily about pharmacists. It is a system for delivering patient care in the use of

medicines. It requires co-operation between health professionals and has to be integrated with the rest of the health care system to work optimally.[2, 4]

These features of pharmaceutical care; the responsibility of the patient and the focus on the patient and the patient outcomes are what separate the meaning of 'pharmaceutical care' from what is understood by the term 'clinical pharmacy'. At the same time, clinical pharmacy is an important and integral part of the delivery of pharmaceutical care.[2]

Other definitions of pharmaceutical care have been published since 1989, for instance a redefinition made by Cipolle, Strand and Morley. In this definition pharmaceutical care is described as "a patient-centred practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment".[8] Even though the words are different the contents are mainly the same. This definition focuses to a greater degree on the responsibility and commitment of the practitioner. The word outcome is left out, but the importance of outcome is still implied.[2] The International Pharmaceutical Federation has added *maintain* patient's quality of life to the original definition.[9] Even though newer definitions of pharmaceutical care have been published, the Hepler and Strand definition remains the one that is most often cited.

1.3 The need for pharmaceutical care in health care

Pharmaceutical care is, as described above, a quality assurance system. One of the main reasons for development of this system was an identified need in the society for more effective and safer use of drugs due to more potent drugs and a high incidence of medication errors.[4] Pharmaceutical care is a complex system where many health professionals contribute to the total care received by one patient. This makes it difficult to directly measure the influence of the pharmacist in the system. Consequently the research literature on pharmacist-provided pharmaceutical care is drawn to examining the outcome of defined clinical pharmacy services. The impact of a service can still be difficult to measure and it is often hard to define appropriate measures of the outcomes. This means that the research often has focused on the structure and the process of health care,

with an underlying assumption of increased outcomes being achieved by increased quality of the structure or the processes of care.[10]

Even with these challenges much research is published on the contributions of clinical pharmacy to the health care of both inpatients and outpatients. A systematic review of the literature published between 1985 and 2005 concerning clinical pharmacist contributions on processes and outcomes of care in hospitalised adults was published in 2006.[11] The review included 36 articles, mainly from the US, which were divided into three categories based on type of service they evaluated; Patient care unit pharmacist participation on rounds (1), Admission or discharge medication reconciliation (2) and Drug class-specific pharmacist services (3).

Pharmacist participation on ward rounds

The review found that participation of a pharmacist on rounds (10 studies included) contributed to reduced occurrence of adverse drug events (both preventable and not preventable), shorter or no difference in length of stay, reduction in medication errors and reduced total average costs.

Admission and discharge medication studies

The review included eleven studies that examined the impact of admission or discharge medication reconciliation, two considered admission and nine considered discharge interventions. One of the studies showed that medication histories taken by a pharmacist, compared to histories taken by nurses, resulted in more accurate medication and allergy information, but this didn't lead to any differences in identification of drug interactions or adverse drug reactions (ADRs). For the discharge counselling the studies reported that the patients who received counselling showed increased medication adherence, increased compliance and higher knowledge about their medication after discharge compared to the control groups. One of the studies showed fewer preventable adverse events and preventable medication-related emergency department visits or hospital readmissions 30 days after discharge for the intervention group, despite no difference in medication compliance between the two groups.

Pharmacy services focused on drugs/drug classes

The review included 15 articles evaluating drug class-specific pharmacist services. Four of the articles examined the impact of pharmacist-led inpatient anticoagulation services. They reported either no difference or better anticoagulation, especially concerning excessive anticoagulation, shorter time from blood drawing to dose adjustment and shorter length of hospital stay (LOS). Four of the studies evaluated the impact of antibiotic therapy and infectious disease consultations. One of these studies showed decreased cost of antibiotics, with no change in mortality, clinical response or LOS. Another study showed reduction in mortality, LOS and antimicrobial cost when a pharmacist approved restricted and non-formulary antimicrobial agents and assisted with changes in therapy and culture report interpretation. The last seven studies evaluated the value of therapeutic drug monitoring of aminoglycosides, vancomycin and phenytoin. Pharmacist-led aminoglycoside monitoring was reported to result in shorter febrile periods, faster returns to normal vital signs and shorter LOS. Three of the studies reported a non-significant reduction in nephrotoxicity as an ADR to aminoglycosides. Monitoring of vancomycin led to a reduction in vancomycin-related renal impairment. One study evaluated therapeutic monitoring of phenytoin, and reported better monitoring with fewer unnecessary assays and a reduction in incorrect drawing and handling of blood samples, and a reduced number of seizure-related re-admissions.

Most patients in a hospital will have diseases and use drugs in addition to those related to the reason of admission, consequently a pharmacist can meet all kinds of problems at a specific ward. This range of opportunities will call for delivery of different kinds of services by the pharmacist. All of the services evaluated in the articles included in the review are natural parts of the delivery of pharmaceutical care at a hospital ward. They comprise some of the tools and methods the pharmacist uses in the delivery of patient specific care, and are examples of pharmacist services shown to increase the quality of patient care. A survey of the clinical pharmacy services delivered to all hospital trusts in one NHS region in the UK has been carried out.[12] This survey showed that lack of resources makes it necessary for the pharmacy manager to choose between if all wards should be covered by a clinical pharmacist, or if some wards should be prioritised and hence would be visited by a pharmacist more often while other wards didn’t get

covered at all. This choice would of course affect what kind of services the clinical pharmacist would manage to deliver at the ward, and the survey showed that some of the services mentioned above, for instance discharge planning and counselling, were underrepresented in the hospitals.

In summary, research is often focused on defined services delivered by pharmacists, and not on pharmaceutical care. The services evaluated aren't necessarily patient focused, but when they exist as part of a system, for instance in pharmaceutical care, they still contribute to the individualisation of drug therapy and hence to putting the patient's needs in their focus.

1.4 The process of pharmaceutical care

Pharmaceutical care is based on collaboration between the patient, the practitioner and other health professionals. Pharmaceutical care involves three major functions[4]:

1. Identifying potential and actual drug therapy problems
2. Resolve actual drug therapy problems
3. Prevent potential drug therapy problems

The three functions are performed in order to reach the goal of the pharmaceutical care system, namely achieving definite outcomes that improve or maintain a patient's quality of life.[4, 9] This requires a logical and structured way of how pharmacists and other health care providers think and act; furthermore a possible means of structuring the deeds in order to perform the three functions is proposed by Cipolle, Strand and Morley.[8, 13] This way of structuring the provision of pharmaceutical care is called the Pharmacist's Workup of Drug Therapy (PWDT). It has been developed in the US where pharmaceutical care is more developed and has been delivered for a longer time and in a more extensive way, within both primary and secondary care settings, than in the UK. This can be an advantage because the system has been modified and improved based on experience from clinical use. On the other hand the US health system is very different form the NHS in the UK, and this could represent a problem in using this system. In any case, the PWDT is a well-developed way of structuring the

delivery of pharmaceutical care. It consists of three parts, the assessment, care-plan development and follow-up evaluation, which will be described in the following sections.

1.4.1 The assessment

The purpose of the assessment is to decide if the patient's drug-related needs are being met. If they are not met a potential or actual drug therapy problem exists. A patient's drug-related needs are described as all the health care needs of the patient related to drug therapy.[13] In order to evaluate if the patient's drug-related needs are met the practitioner has to assess what the patient's drug-related needs are. In the first part of the assessment the practitioner collects relevant patient specific data. This data includes the patient's demographics, medication experience and relevant clinical information, see table 1.

Table 1 The assessment: Patient specific data

Patient demographic	Medication experience	Relevant clinical information
Name	Drug history	Presenting complaints
Date of birth/age	Current medical conditions with related drug therapies	Relevant laboratory values
Gender		Medical history
	Allergies	
	Drug sensitivities	
	Social drug use	
	Patient beliefs	

This information and other relevant information provided by the patient are used to evaluate if all the patient's drug-related needs are being met and to identify potential or actual drug therapy problems. Drug therapy problems often evolve as a result of unmet drug-related needs. A drug therapy problem is defined as "any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy".[13] A drug therapy problem consists of an actual undesirable event or the risk of an undesirable event, one or more possible associated drugs and a relationship between the suspected drug(s) and the event. All three aspects of

the drug therapy problem must be identified in order to find a solution of the problem. To be able to recognise an undesirable event the practitioner and the patient must know what to expect from the drug therapy (e.g. what kind of effect could be anticipated?) and how these expectations relate to time (e.g. when can effect be anticipated?).

Drug therapy problems are identified through answering the following questions:

Indication

- Are all drugs indicated?
- Are all indications appropriate treated?

Effectiveness

- Are the drugs selected the most effective?
- Are the selected drug dosages effective/producing the desired effect?

Safety

- Is the patient experiencing any adverse drug reactions?
- Is the patient experiencing any toxicity?

Compliance

- Is the patient compliant?
- Is the patient best equipped to be compliant?

If the answer to any of these questions is no, a drug therapy problem is identified. The order of the questions is logical, and they should be answered according to this order to avoid unnecessary work.

1.4.2 The care plan

The care plan is a tool the practitioner uses to resolve and prevent drug therapy problems in order to achieve the goals of therapy. The first thing the practitioner has to do is to determine the goals of therapy; this is done in co-operation with both other health professionals and the patient. The goal of therapy should be stated on the care plan as a clear statement to the patient, the practitioner and other health professionals. To have a clearly defined and measurable goal of therapy is crucial in evaluating the actual outcomes from the drug therapy. The goal of therapy forms the basis of the care plan and the choice of interventions to resolve/prevent drug therapy problems.

The drug therapy problems should appear in prioritised order on the care plan. The practitioner has to recommend interventions to resolve/prevent the drug therapy problems identified in the assessment. Both goal of therapy, drug therapy problems, recommended interventions to resolve/prevent the drug therapy problems, the follow-up schedule and actual outcomes are documented on the care plan.

1.4.3 Follow-up evaluation

The follow-up evaluation is scheduled according to the timeframe for expected effect and/or adverse effects of the patient's drug therapy. The purpose of the follow-up evaluation is to determine the patient outcomes and compare the results with the goals of therapy. The practitioner and the patient should also use the follow-up to assess if any new drug therapy problems have evolved since the last meeting. Interventions to resolve or prevent these should be implemented. The follow-up evaluation makes the delivery of pharmaceutical care a continuous and dynamic process, where the changing drug-related needs of the patient guide the care.

1.4.4 The pharmaceutical care process in UK hospitals

It can be seen that the PWDT is more suited in the chronic disease management setting in primary care for which it has been developed. The structure of the PWDT implies that it is created with a practitioner-patient counselling appointment in mind. The idea is that the practitioner and the patient arrange a meeting. During this meeting the practitioner collects the relevant information about the patient, and a care plan is created from this data in co-operation with the patient. An important function of the PWDT is the follow-up of the patient, and this requires that the patient and the practitioner have the opportunity to meet at least once more for a planned follow-up. This situation does not apply to hospitals. Patients are often hospitalised at short notice, and the main goal of the hospitalisation is to receive full medical care and not just to receive pharmaceutical care.

In hospitals a member of the hospital staff (often doctor or nurse, less often the pharmacist) writes observations/decisions in the notes and collects relevant patient specific data from the patient. The clinical pharmacist shares and reads the patient's case notes to elicit the data. Increasingly it is recognised that a pharmacist or a pharmacy technician should take the patients' drug histories on admission. Studies show that, compared with drug histories taken by doctors or nurses, this would increase the accuracy and completeness of the history and decrease the potential of unintended errors in prescription of drugs on admission.[11, 14] Drug history taken on admission as part of a clinical pharmacy service is also shown to decrease mortality rates[15], and is recommended as a service hospitals in UK should provide.[16]

Even though the hospital environment deviates from the setting in which the PWDT was developed, most parts of the PWDT would still be useful with some adjustments. The assessment and the creation of the care plan would be an important part of the delivery of pharmaceutical care in any setting, even though other health care professionals perform some parts of the assessment. The planned follow-up cannot be performed in most hospital settings, but the practitioner is able to do some follow-up during the patient stay in the hospital, especially at long-stay wards. All in all, the PWDT describes a good and structured way of delivering pharmaceutical care that could and should be used in UK hospitals. Care plans used in teaching at Universities and in practice in hospitals in Scotland contain most of the parts of the PWDT[3], see example of care plan used in the Glasgow Royal Infirmary (Appendix I).

1.5 Pharmaceutical care and medicines management – the situation in the UK

Each of the four constituent countries of the UK has its own health service known as the NHS (for England), the NHS Wales, the NHS Scotland and the Health and Social Care in Northern Ireland. The health service is responsible for the primary and secondary health care in its area, and in Northern Ireland the health service is responsible for the social care as well. Each of the health services produces individual guidelines and reports to guide the delivery of health care to the public,

but reports produced in one of the health service can be used by other health services as well.

There has been a lot of focus in the media and among the public on injustices and discrimination in the NHS, this phenomenon is referred to as the “postcode lottery”, where postcode refers to living address. “The postcode lottery” is a nickname for accentuated differences in guidelines for treatment and the timeframe for delivery of care both between different NHS trusts and different health services. With the first core principle of the NHS being “The NHS will provide a universal service for all based on clinical need, not ability to pay”[17] such differences are clearly unacceptable.

In order to serve patients in a better and more modern way a need to reform the NHS has been identified. With the government willing to increase the investments to the health services the command paper “The NHS Plan: a plan for investment, a plan for reform” was issued. By implementing this plan the NHS seeks to change into a health service designed around the patient, where all patients receive the same high quality of care.[17]

Pharmacists, both in the community and in hospitals, are recognised as an important profession in the delivery of the NHS Plan. Two reports have been issued to describe the contribution the pharmacy profession can make. “A Spoonful of Sugar. Medicines management in NHS hospitals” focuses on raising the profile of medicines management in hospitals by recommending changes to the use of staff, to the organization of processes involving medicines and to the pharmacy services delivered in the hospital.[16] “Pharmacy in the future. Implementing the NHS Plan” focuses on future changes that need to be done in the community pharmacies in order to realise the NHS plan.[18]

The NHS in Scotland issued in 2000 its own report “Our National Health: A plan for action, a plan for change” on the changes that need to be done in the NHS Scotland.[19] The report “The Right Medicine. A Strategy for Pharmaceutical Care in Scotland” was issued one year later as a response to the recommendations in “Our National Health” to make a strategy for the pharmacy contribution in implementing this plan.

Some of the recommendations in “A Spoonful of Sugar” and “The Right Medicine. A Strategy for Pharmaceutical Care in Scotland” will be described below as they are important in the future development of pharmaceutical care in UK hospitals. The two most important changes are re-designing the services and the introduction of non-medical prescribing.

1.5.1 Medicines management

In the UK, the health services use the term medicines management in addition to the term pharmaceutical care. Medicines management has no generally accepted definition, and it is described in different ways throughout the NHS.[16, 20] Medicines management is a wider term than pharmaceutical care. It comprises all of the processes within the NHS that relates to drugs, from their production to their administration and review. Medicines management is also linked to the control of expenses, and is viewed as a potential tool to control the costs.[21] It is not always easy to understand the difference between pharmaceutical care and medicines management.[21, 22] It would be reasonable to say that the process of pharmaceutical care can contribute to raising the quality of some parts of the medicines management in UK hospitals because pharmaceutical care seeks to improve the outcomes of drug therapy, which is the same goal as for medicines management.[23] At the same time, medicines management includes services that are not a part of pharmaceutical care, like production, logistics and economics, and it is not clearly defined which services should be viewed as part of any medicines management system and which should not. The use of the term medicines management is further complicated by the fact it is sometimes used in the context of clinical services to help patients manage their medicines; a totally different use of the term to that used in the hospital setting.

Medicines management and pharmaceutical care are recognised as important in the reforming of the NHS of England and Wales and of Scotland.[16-19, 24] However, while the NHS in England and Wales focuses on medicines management, the NHS in Scotland focuses on pharmaceutical care.[23] In this project the term pharmaceutical care will be used, both because it is most closely linked to the

aim and objectives of the project and because it is the preferred term in the NHS Scotland where the project is executed.

1.5.2 Re-designing the service

One of the biggest changes to the medicines management in the NHS is the re-design or re-engineering of the pharmacy services. These changes are implemented to contribute in achieving the aims of "The NHS Plan" and "Our National Health" in England and Scotland respectively.[16, 24] Re-designing the services comprise both the introduction of new services and a redistribution of health care staff. Many of the proposed changes require investment in both new personnel and equipment, and this is an obstacle to their implementation. A short description of the changes a re-design of the service will result in follows below.

Patient's own drugs (POD)

Patients are encouraged to bring their own medicines into the hospital on admission. A pharmacist or a pharmacy technician should review the drugs and assess the suitability for re-use according to hospital guidelines. This will reduce the patients' confusion as the same drugs (the same tablets in the same packages) are used in and out of hospital. POD has also a potential for saving money because drugs are not unnecessary destroyed.[16]

Self administration

A system, which enables the patients to administer their own drugs while in hospital, should be introduced. This requires the drugs to be kept in a bedside locker, and it requires an assessment of the patients' ability to manage their own drugs. Self-administration has many advantages. It enables the health care team in the hospital to review compliance problems during the hospital stay, it encourages the patient to undertake an active role in his/hers health and it makes the administration of drugs as required better because the patient can take the drugs when he/she needs it.[16, 18]

One-stop dispensing/Original pack dispensing

In order to adhere to EU requirements, a patient information leaflet has to be available for all drugs administered. This means that rather than administer drugs

from bulk, packets of 28 tablets should be dispensed in hospitals. This will make the discharge process faster as the patient doesn't have to wait for the discharge prescription to be dispensed by the pharmacy before going home. Dispensing more then the usual amount of one week consumption will give the patient drugs for a longer period of time after discharge, making it more likely that the GP has received the discharge information from the hospital when the patient comes to collect a new prescription, avoiding unintentional changes in prescribing.[16, 18]

Medication review on admission

It is a recognised that pharmacists or pharmacy technicians should take the patient's drug history on pre-admission or admission wards in order to get the patient's medicines right early in the stay and by this avoid medicine errors.[14, 16, 18] According to the National service framework (NSF) for older people all elderly people should have a medication review on admission to identify medication related problems.[25]

1.5.3 Non-medical prescribing

The aims of the modernisation of the NHS include easier access to first line healthcare, a reduction in waiting time for healthcare and a health service designed around the patient. Introduction of prescribing by healthcare professionals other than doctors and dentists, generally termed non-medical prescribing, is seen as an integral part of achieving these aims and in realisation of the plan.[16, 24, 26] The legal framework for introducing non-medical prescribing is set in the Health and Social Care Act 2001, and as a result of this 'supplementary prescribing' by pharmacists and nurses was introduced in 2003 and 'independent prescribing' was introduced in 2006.[26, 27] In order to become a prescriber, pharmacists have to complete a prescriber programme accredited by the Royal Pharmaceutical Society of Great Britan[28], today 25 Universities offer such programmes, either to become a supplementary prescriber or to convert from supplementary to independent prescriber.[29] The first programmes to educate independent prescribers directly are commencing in 2008.

A prescribing pharmacist has the responsibility to up-date skills and knowledge through continued professional development and the prescribing has to be in accordance to the pharmacist Code of Ethics.[27, 28] The prescriber has to know when his or her competence isn't good enough, and refer the patient to the independent prescriber or other health professionals when appropriate. An accurate and comprehensive record of consultation and prescribing for an individual patient should be maintained.[28] Patient safety is of high importance, and increasing the number of prescribers for one patient can be a source of drug therapy problems, for instance has the number of prescribers been shown to be an independent risk factor for adverse drug events.[30] A close relationship between the different prescribers and the patient has to be in place in order to ensure safe prescribing.

Supplementary prescribing

Supplementary prescribing is defined by the Department of Health as: "a voluntary prescribing partnership between an independent prescriber and a supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement".[26] In order to function as a supplementary prescriber the pharmacist has to arrange a partnership with a doctor or dentist. The prescribing partners have to agree on a Clinical Management Plan (CMP) for each patient. A CMP is a patient specific record, and it sets the range the supplementary prescriber has to work within. It has to include the conditions under which the supplementary prescriber has to refer the patient to the independent prescriber and the date of commencement and review by the independent prescriber.[26] Because a patient-specific CMP has to be made, supplementary prescribing is most useful in the treatment of long-term medical conditions where the prescribing partners has access to a shared medical record, and therefore it is not suitable for emergency or acute prescribing situations.[26, 31]

Independent prescribing

The definition of independent prescribing is "prescribing by a practitioner (e.g. doctor, nurse, pharmacist) responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the

clinical management required, including prescribing".[28] Pharmacist independent prescribers can legally prescribe all licensed drugs. The UK Department of Health regard pharmacist independent prescribing as most useful for pharmacists that work remotely from a doctor and who is competent to diagnose, assess and make independent treatment decisions. It is not considered useful for treatment of patient with complex medical conditions or several co-morbidities.[31]

Pharmacist prescribing in hospitals

The need to have a Clinical Management Plan for each patient makes supplementary prescribing of limited use to hospital pharmacists. Independent pharmacist prescribing constitute a possibility to save resources because the clinical pharmacist will be able to make changes in the prescribing directly, instead of making recommendations to the prescriber who will later implement the changes. Pharmacists will also have the possibility to prescribe drugs on admission after taking the drug history. Today drugs are often prescribed before a complete drug history is taken, and the pharmacist has to make recommendations to the responsible prescriber to correct errors in prescribing made at admission. Pharmacist prescribing should be introduced if they cover service needs or if they contribute to a more effective use of recourses at the hospital.[28] The categorisation system used in this project might be a tool in identifying if the work the pharmacist is doing would be more effective if he or she undertook a prescribing role.

1.6 Documentation in Pharmaceutical Care

Accurate documentation is important in pharmaceutical care, and the importance will only increase as more pharmacist become prescribers. Documentation is mandatory in pharmaceutical care for legal and ethical reasons, and for quality assurance functions.[13, 32] When the pharmacist assumes responsibility for the patient and patient outcomes from drug therapy he/she agrees to make decisions and recommendations regarding the health of the patient. These decisions and recommendations have to be recorded along with commenced interventions and actual outcomes. Formal documentation is viewed as one of the key concepts that form the basis of pharmaceutical care.[33] There are various reasons to record

the pharmaceutical care delivered. Documentation is important for the continuity of patient care, and is essential in communication with other health professionals.[34] A complete documentation simplifies the delivery of care from the patient's health care team, as all members know what the others are doing, and it makes pharmaceutical care an integrated part of the health care of the patient. The documentation can also be used in research, education and to evaluate the quality of care delivered.[3, 34] American literature underlines the importance of documentation in the prospect of reimbursement of pharmaceutical care services.[34] All NHS services are free of charge, however, documentation in pharmaceutical care have economical aspects in the UK as well. It can be used as justification in delivery of services paid by the NHS and in negotiating for increased funding for clinical pharmacist posts. As UK community pharmacists start to deliver new clinical services, they will have to document in order to receive payment for their services.

While there are guidelines on documentation of pharmaceutical care planning in Scotland[3], there are no UK wide standards or guidelines on how or what to document when providing pharmaceutical care in secondary care. The Royal Pharmaceutical Society of Great Britain (RPSGB) has developed a set of guidelines on recording of interventions with a focus on community pharmacy.[35] It is stated in these guidelines that a local or employer's policies should prevail, but in the absence of a policy the guideline could function as a minimum requirement independent of the practice setting. With the goal of the NHS being to give the same kind of care to all patients, independent of postcode or ability to pay, there should be an interest for making a standard for documentation of pharmaceutical care. A standardised way of documenting pharmaceutical care will make the evaluation of the quality of care easier. It will make it possible to compare services that are delivered in different settings, and make it possible to share the documentation between different levels of care, for instance between primary and secondary care.[35] Focus on documentation of pharmaceutical care can help raise the status of clinical pharmacists as a provider of care and as an important and integrated part of the health care team. Documentation is a demand for prescribing pharmacists, as described above.

There are many aspects of documentation that have to be considered, and a description of the most important features covered in existing guidelines is described below.

1.6.1 What should be documented?

A requirement in the documentation of pharmaceutical care should be that another person than the provider is able to tell what has been done by reviewing the documentation.[36] The reviewer should be able to understand the reason for a recommendation or an intervention, and should also be able evaluate the quality of care given without the need to gather additional data. It is not easy to know what to document, and this is a skill that develops by experience with care planning.[13] It is important that the documentation is complete, but it is just as important not to document unnecessary information.[13, 35]

More detailed lists of what might be necessary to record exist.[32, 35] A pharmacist is not required to record all activities, and the extent of the documentation will vary depending on the situation.[35] A study has shown that clinical pharmacists prioritised to record care issues they consider clinical important or clinical interesting for other pharmacists. Furthermore, situations where a doctor was contacted, especially if the advice given was not accepted, and situations where there was possibility of further developments or problems was considered important to record.[37] The situations mentioned by the pharmacists in the study coincides with situations the RPSGB recommend pharmacists to consider as worth recording.[35]

1.6.2 How should pharmaceutical care be documented?

Different systems for documenting of pharmaceutical care have been proposed. A common feature of most of the systems is to divide the record into history, assessment and plan.[13, 33, 38] The documentation system SOAP (Subjective, objective, assessment and plan) used by doctors is proposed as a possible tool for pharmacist documentation.[33, 38] However, this system is not developed specifically for clinical pharmacists' use, and a system that takes drug-related problems and not just medical problems into account would be preferable. Use of standardised forms to record patient information is recommended.[33] The PWDT

integrates recording as part of the pharmaceutical care process, and documentation of the assessment, the pharmaceutical care plan and the follow-up evaluation is emphasised.[13] In Scotland a similar documentation system, the Patient Medication Profile (PMP), is used.[3] The PMP comprises patient details, reason for admission, drug and medical histories, results from investigations, patient's risk factors affecting medication use, diagnosis, pharmaceutical needs and a pharmaceutical care plan. In the pharmaceutical care plan each identified drug therapy problem is recorded as a pharmaceutical care issue. Desired outcome, action and actual outcome are recorded for each care issue. The pharmaceutical care plan can be evaluated by comparing desired and actual outcomes and it forms a basis for peer review.[3] An example of a PMP can be seen in Appendix I.

The composition of these two systems, the PMP and the PWDT, guides the structured and logical process of pharmaceutical care delivery. This increases the usefulness of the information gathered through the systems, both for the pharmacists and for potential reviewers, and helps the pharmacist avoid omission of important information.

1.6.3 Where should pharmaceutical care be recorded?

In the systems described above data is recorded separately from the patients' medical record, and the pharmacist is often the only one to use the information. Some parts of the information are important to share with other parts of the health care team. This might be done in order to record advice given to patients, to improve communication and to record advice given to other health care professionals. Increasingly it is recognised that pharmacists can, after adequate training, record important issues and problems in patient medical notes shared with other health care professionals.[32, 35]

1.6.4 Clinical Audit

"Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change".[39] Clinical Audit is recognised as an important tool

in the clinical governance in the NHS. It has received a lot of attention the latest years as a higher demand for local trusts to perform regular clinical audits has been issued by the NHS.[40]

A clinical audit comprises five stages[39]:

1. Preparing for audit - through choosing an appropriate audit topic or issue
2. Selecting criteria – i.e. what standard or criteria for best practice will the chosen topic be evaluated against
3. Measuring performance – the clinical practice as is measured through data collected from the setting
4. Making improvements – the need to make improvements is identified through comparing the measured performance (Stage 3) with the set criteria (Stage 2).
5. Sustaining improvement – this is done through re-auditing the same topic after implementation of changes.

The data for the audit is often gathered by reviewing documentation produced in the setting. This makes consistent and accurate documentation even more important.

It is important to remember that a clinical audit is not research, because no hypothesis is tested, it is merely a review of the clinical performance measured up against a set criteria, with an objective to improve the clinical performance.

In this project a clinical audit will be performed as a peer review without any objectives to improve the care delivered. This means that the clinical audit is done to describe the delivery of pharmaceutical care at one ward and compare it to another ward. It is not done to measure the delivery of pharmaceutical care at the ward against any predefined standards.

1.7 Care of the elderly

An estimation of the population of Scotland in June 2006 showed that of the 5,116, 900 inhabitants, 16.4 % (837 968 persons) were over 65 years.[41] This

number is expected to increase by almost 45 %, to 1,200,000, in 2030.[42] The elderly are for many reasons high consumers of health services, and they require special focus regarding health and drug therapy. It is important to remember that the elderly is a heterogeneous population group and functional age is often a better measure than chronological age for the physiological changes expected for an individual patient.[43] Still some common physiological and psychological features develop because of age. These features are important to take into consideration when caring for older patients and will of course influence the delivery of pharmaceutical care. In recent years the Department of Health in UK has increased the focus on ways to improve the quality of use of medicines for and by older patients. Older patients are more prone to drug-related problems, partly as a result of age-related physiologic changes leading to alteration of pharmacokinetic and pharmacodynamic parameters.[44] Assessing the risk of medicines-related problems, and preventing and solving these, is identified as an important function in improving the quality of drug use among the elderly.[25]

Pharmacokinetic changes

The pharmacokinetics of drugs change in many ways during ageing. Absorption after oral administration of drugs might be altered due to changes in the GI tract, e.g. increased gastric pH, increased intestinal transit time, and decreased intestinal blood flow.[44] This rarely alters the bioavailability of drugs, but the rate of absorption can be reduced.[45] Bioavailability of high extraction drugs, for instance propranolol and simvastatin, will be greatly increased with a small decrease in hepatic first pass drug metabolism, which makes a greater than predicted part of the orally administrated dose systemic available.[43]

Changes in body composition, with increased total fat content and decreased total body water and lean body mass, alter the volume of distribution. This will result in a relative smaller distribution volume for water-soluble drugs, for instance digoxin, which in turn gives a higher plasma concentration of the drug than anticipated from the dose. Cardiac output decreases and peripheral vascular resistance increases with ageing resulting in diminished blood flow to organs, another source of changed drug distribution. Altered protein binding also affects distribution; this can arise because of changed protein concentration, co-administration of other drugs or disease states.[44] Changes in unbound fraction

are important in interpretation of the plasma concentration of a drug since it is only unbound drug that is available for pharmacologic effect. For instance, a reduced albumin concentration will give increased unbound fraction of phenytoin, which in turn will lead to a decrease in phenytoin plasma concentration, but the unbound plasma concentration is unchanged because unbound clearance is not affected. Most changes in distribution are probably only of significance during acute drug administration because the plasma concentration of drug at steady state is mainly dependent upon unbound clearance.[45]

The most important pharmacokinetic change with ageing is the change in clearance of drugs. Clearance of drugs can be affected by many factors, and in the elderly many of these factors co-exists. Hepatic drug metabolism is influenced by hepatic blood flow, disease states, co-administration of drugs and liver mass. A decreased hepatic metabolism of some drugs is seen with age, morphologic changes of the liver are the most likely cause.[45] Alcoholic liver disease is a special concern in Scotland. Even though alcohol abuse is less of a problem among the elderly, 4 % of women and 20 % of men over 65 years had excessive alcohol consumption in 2001.[46] Decreased liver function can both contribute to decreased metabolism of drugs; low-extraction ratio drug is of special concern, and increased bioavailability, as seen above. The impact changes in liver function has on metabolism of drugs in an individual patient is often difficult to predict. Kidney function decreases progressively with age and makes administration of drugs, especially drugs that are mainly excreted renally, a challenge. Glomerular Filtration Rate decreases with approximately 1 % each year after a person is 20 years[43], this proportional deterioration with aging makes it possible to make a rough estimation of the renal clearance of drugs as long as some kidney function remains. The methods used to estimate renal function are less accurate in the lower range of kidney functionality, so both severe kidney failure or fast changes in kidney function makes prediction of appropriate dose to an individual patient difficult. Decreased clearance of drugs make it necessary to decrease dose and/or increase dosing intervals to avoid toxicity, and as an approximation a 50% reduction in starting dose is recommended.[47]

Pharmacodynamic changes

The pharmacodynamic changes that develop with age are more difficult to predict and there are limited information about these changes. The changes can be divided in two main groups; changes secondary to changes in specific receptors and target sites, and changes due to decreased homeostatic reserve.[45] Older patients tend to have increased response to some drugs, indicating increased receptor sensitivity. This applies especially to drugs affecting the central nervous system (CNS), with an increase in both effect and side effects.[44] It is recommended to use centrally acting drugs with caution in the elderly.[47] The effect of other drugs, for instance β-adrenoceptors, is reduced possibly due to decreased density of receptors.[45] The body's ability to maintain homeostasis decreases with age and this result in a vulnerability to drug induced insults. For instance, older people have decreased orthostatic circulatory response, resulting in increased susceptibility to orthostatic hypotension as an adverse drug reaction of drugs with anti-hypertensive effects. Decreased postural control results in increased postural sway, which in turn can increase the risk of fall as a side effect of drugs. Many drugs can lead to confusion in the elderly, which can be misdiagnosed as a real condition and not as an adverse effect of the drug.[45]

Older people has in summary risk of increased drug levels, increased half-life of drugs, increased sensitivity to drugs and a decline in physiological functions that makes them more vulnerable to both disease and adverse drug events. A survey of adverse events of drugs as main hospitalising reason in England showed that 59 % of the patients admitted due to an adverse event was over 60 years.[48] Many diseases become evident at an earlier stage in older patients and they present themselves with other symptoms than in the younger age groups, reflecting the organ system with the lowest reserve to deal with disease. Older patients are also more likely to suffer atypical symptoms of adverse drug reactions.[44] Prescribing guidelines underlines the need to balance the benefit of drugs against the increased risk of adverse drug reactions when prescribing for older patients.[47] This should not be interpreted as an advice to avoid prescribing of beneficial drugs to older patients, as under use of medicines has a high prevalence and is connected with adverse health outcomes in this patient group.[49] A problem in prescribing is that guidance on treatment involves extrapolation of data derived from a younger or healthier age group, and there is a need for more information

about risks and benefits of drugs when used in the older age group. Prescribing calls for caution, especially when prescribing drugs known to have a high risk of adverse drug effects among elderly, for instance NSAIDs and benzodiazepines, with increased focus on choice of doses and monitoring for adverse drug reactions.

Older people have an increased risk of developing drug related problems, and some of the features known to contribute to this increased risk are[25]:

- Co-morbidity, co-existence of many chronic diseases, with an increased risk of drug-disease interactions
- Poly pharmacy (taking more than 4 drugs), with an increased risk of drug-drug interactions
- Many different care givers
- Discharge from hospital
- Atypical symptoms of disease and adverse drug events
- High risk drugs
- Increased susceptibility to adverse drug reactions
- Reduced mental function

In addition to the challenges in drug therapy mentioned above is compliance of special concern when caring for older people. Studies shows that age is not a risk factor for non-compliance per se, but many of the features more common among the elderly, for instance many diseases and prescribers at the same time, poly-pharmacy and reduction of functions like strength, flexibility, hearing and vision can make it necessary to make arrangements to increase compliance.

The pharmacist has an important role in caring for the older patient, both in the pharmacy and as part of the health care team at a hospital or nursing home. The NHS has as mentioned above recognised the unexploited knowledge and resources the pharmacists constitute. This will contribute to a better use of pharmacists, which in turn hopefully will result in safer and more effective care for the older patient. Despite better use of pharmacist and increased focus on problems in drug-use among the older patients many avoidable ADRs and medication errors still occur both in hospitals and in the community.

2 The project – aim, objectives and setting

2.1 Aim

The aim of the project is to compare two clinical settings in terms of the profile of pharmaceutical care delivered and the profile of medication use. The findings will be reported in a way which allows quantitative comparison of pharmaceutical care issues addressed by the clinical pharmacy service in a proposed reporting system.

2.2 Objectives

1. Review the literature on medicines use in care of the elderly during hospitalisation, and the clinical pharmacy documentation used in inpatients and at the point of discharge from hospital in Scotland. Review the literature on pharmaceutical care issue categorisation systems and the literature on introduction of non-medical prescribing in the UK.

2. Describe the operational delivery of the clinical pharmacy service at the ward using a process map that is validated by pharmacists involved in care delivery.

3. Modify existing categorisation system used at University of Strathclyde to increase the robustness and clinical usefulness. Develop a guideline for use of the system. Test utility and validity of the modified system.

4. Report on the care issues during a prospective survey phase of the study. Validate the clinical interpretation of the care issues.

5. Demonstrate inter-rater reliability in the categorisation of the care issues in the survey.

6. Apply data from the findings of a parallel survey of prescribing activity that aims to interpret the prescription turnover and quantify exposure of each patient to medication during their stay.

7. Evaluate proposed templates of parameters of pharmaceutical care activity in order to report on their validity and utility for reporting care plans.

8. Draw conclusions on the role of the audit findings in defining future application of non-medical (including pharmacist) prescribing.

2.3 Study Design

2.3.1 Study setting

The data collection for the study took place at two of four Medicine for the Elderly wards at the Glasgow Royal Infirmary, namely ward 18 and 19. These two wards share the same staff and can be viewed as one entity that will be referred to as Ward 18/19 in this project. Ward 18/19 is a mixed-gender ward with 27 beds distributed between three single rooms and six four-bedded rooms. The ward provides general care for the older person, which means the patient composition is heterogeneous regarding disease, social and functional status. The clinical pharmacy service is provided by one pharmacist, Lee Stewart (LS), who visits the ward Mondays to Thursdays from 8.30 a.m. to 1.00 p.m., a maximum total of 18 hours per week. If the pharmacist for some reason is unable to cover the ward, for instance due to illness or a meeting, another pharmacist will not visit the ward and the patients will not receive any clinical pharmacy services in that period of time.

2.3.2 Ethical approval

The chair of the local Ethics Committee at the Glasgow Royal Infirmary approved the project as an audit, so neither ethical approval nor patient consent was needed.

3 Methods

3.1 Review of literature

Structured search in the Medline and Embase databases was performed in order to find relevant literature on all subjects covered in the introduction. The searches were mainly conducted by MeSH terms, but searches in free text were also necessary both to ensure that the newest articles were included in the search and because some of the relevant search terms weren't indexed as MeSH terms. For the most relevant articles, the 'find similar' function in Ovid (Medline) and the reference list were used to identify other articles about the same subject. All subjects were also searched for in the Pharmaceutical Journal. Google was used as a last option if search in the sources mentioned above and below was insufficient.

A need for the researcher to get familiar with the health system in the UK was identified. Knowledge about the British health system was gained through browsing the most important health and pharmacy web pages in the UK, including the homepages of the Department of Health, the NHS (both England and Scotland), the Royal Pharmaceutical Society of Great Britain and the British Medical Journal. These sites were also used to find guidelines and reports on medicines management, pharmaceutical care, care of the older person, documentation in hospitals and non-medical prescribing.

Literature on pharmaceutical care and care of the older person was also sought in books on these topics.

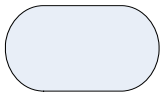
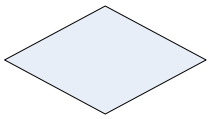
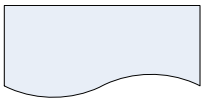
3.2 Process map

In this project a process map was used to describe the operational delivery of pharmaceutical care at Ward 18/19.

A process map is a flow chart where actions are represented by different symbols; each symbol contains one step of the total process. The shape of the

symbol communicates what type of action it contains, see table 2. Variation in the delivery of the process will exist because one step isn't performed the same way each time. The process map describes the process as it is performed most of the time.[50]

Table 2 Process map: Description of symbols[51]

Name of symbol	Shape of symbol	Meaning of symbol
Process		Represents a step in the process (an activity or task)
Terminator		Represents the first and the last step of the process
Predefined process		Represents a predefined process, i.e. a set of steps that that combine to create a sub-process that is defined elsewhere (usually on a different page of the same map).
Decision		Represents a decision, the outcome of the decision dictates the next step.
Document		Represents production of a document
Connector		An arrow that connects the different boxes in the process map. Can be doubled-headed.

Process mapping is a general tool in production systems to identify where in a process the benefit of changes would be greatest, where the main aim is to improve the quality and efficacy of the process examined.[52] It is often combined with other improvement methods, for instance the plan-do-study-act cycle, in order to make the most of the different methods.[50] In health care process mapping is often used to map the patient journey, or a part of the patient journey, in order to identify bottlenecks, duplication of efforts and other parts of the

journey where the quality needs to be increased or where resources can be saved. The process map is developed through discussions between key persons in the patient journey, and is a useful tool because persons involved in different stages get the complete picture of the journey. The process map is a description or a map of the patient journey as it is at that point in time, and acts at a starting point for identifying troublesome parts of the journey and for generating ideas to improve the journey.[50, 52] When suitable changes are identified these are implemented and evaluated through other improvement methods.[50]

In this project the process map was used to describe the processes the pharmacist at Ward 18/19 perform from the identification of a new patient to the discharge of the same patient. The researcher observed the delivery of pharmaceutical care at Ward 18/19 and gained knowledge about the actions the pharmacist undertakes through this. The shadowing lasted until the researcher had a clear idea of what the pharmacist does in relation to the patients at the ward. The researcher developed a draft of process maps based on the observations made, and the pharmacist reviewed and gave feedback on these. The researcher amended the process maps according to the feedback from the pharmacist. This feedback/amendment-loop continued until the pharmacist and researcher agreed that the process maps describe a true, clear and complete picture of the pharmacist's actions at the ward.

3.3 Modification of the categorisation system for pharmaceutical care issues

Different systems have been developed in order to categorise pharmaceutical care issues.[53] A categorisation system developed at the University of Strathclyde is used in this project. This system is triangularised and consists of the Drug Therapy Problem or Drug Related Problems categories initially developed by Strand et al.[4, 13, 54], check and change categories developed through a PhD at the University of Strathclyde[55] and Quality Assurance Descriptor categories developed at the University of Strathclyde.[7]

There are many reasons for categorisation of care issues. Cipolle et al. recommend to do it as a integrated part of the pharmaceutical care process

because it helps in structuring the thought process of the practitioner.[13] Categorisation of pharmaceutical care issues makes it possible to quantitatively compare pharmaceutical care delivered in different settings or by different practitioners, and can be used as a tool in structuring the description and documentation of the care delivered.[53] It can also be used to evaluate the quality of the pharmaceutical care delivered.[55] In this project the categorisation of care issues is used to quantitatively describe the pharmaceutical care provided at Ward 18/19 at Glasgow Royal Infirmary, and to statistically compare these results with the results from a parallel project at a General Medical ward at the same hospital. The parallel project was carried out by Marit Bergheim Christensen (MBC).

In Scotland the delivery of pharmaceutical care is structured by the PMP. As seen in the introduction, an important part of the PMP is the pharmaceutical care plan. When developing a pharmaceutical care plan the pharmacist has to identify the patient's pharmaceutical care issues. A pharmaceutical care issue is defined as "an element of a pharmaceutical need which is addressed by the pharmacist"[3], where a pharmaceutical need is "a patient's requirement for a pharmaceutical product or service".[3] A pharmaceutical care issue is sometimes referred to as a drug therapy problem or a drug related problem.[4, 7] In this project the term (pharmaceutical) 'care issue' refers to the problem identified by the clinical pharmacist, and 'drug therapy problem' refers to one part of the categorisation system used in the project. All care issues identified *and* resolved by the clinical pharmacist can be categorised in this categorisation system.

The categorisation system used at the University of Strathclyde is complex, with many different categories and subcategories. It was going to be used in four other projects at the same time as this project was carried out, namely the projects for fulfilment of the Master in Pharmacy degree at the University of Tromsø of Maren Rambøl Ruud (MRR), Reidun Os Husteli (ROH), Ingrid Lian (IL) and MBC. At the start of the projects all five researchers found it hard to understand and use the system. There was a guideline for use of the system and a short description in an article recently published from the University of Strathclyde.[7] However, inconsistencies were apparent to the researchers, and after preliminary categorisation of care issues from old care plan a need to

amend the system to make it more logic and easier to use was identified. There was also a need to resolve some of the definitions and make the total system more clinical useful. The four researchers MMR, ROH, MBC and KJH, referred to as the research group, added this to the objectives of their protocols. The research group also added the development of a guideline for the use of the categorisation system to their objectives. MBC and KJH were to collect care issues from Glasgow Royal Infirmary, while MMR and ROH were to collect care issues from Ayr Hospital to use in the audit of delivery of pharmaceutical care in different settings.

The research group came up with suggestions of changes to the original system through review of literature, trail categorisation of care issues and many long discussions. Feedback on the proposed changes was obtained through discussions with Professor Steve Hudson (SH) and Carl Fenelon (CF). The PhD student Tobias Dreischulte also contributed to the discussion. An amended categorisation system was agreed upon. The research group developed a guideline with both a description of the amended categorisation system and a manual for use of it. IL and SH gave feedback on the readability of the guideline, and ambiguities in the language and in the directions for categorisation were clarified. The research group also developed a set of examples for categorisation of both common and complex care issues. The guideline is included in Appendix II.

Categorising a larger number and wider range of care issues during the prospective data collection and categorisation phase of the project tested the utility of the amended system, as described more thoroughly below. The validity of the categorisation system was tested through an assessment of inter-rater agreement between KJH and MBC. The utility and validity of the system was also established through a focus group, as described below.

3.4 Data collection and Categorisation

3.4.1 Inclusion of patients

Patients admitted to the Medicine for the Elderly wards 18 and 19 at the Glasgow Royal Infirmary from the 11th of January 2008 were included. Only patients who

received a care plan by the clinical pharmacist at the ward were included in the project, because the data necessary for the project was derived directly from the patients' care plans. The inclusion ended when 100 patients had been recruited. All the patients who were admitted to the wards in the inclusion period, but weren't included were counted. New patients admitted to the ward in the inclusion period were identified by reading the nurses' admission/discharge diary, reading the bed map at the ward and talking to the clinical pharmacist.

3.4.2 Data collection

Dates of admission and discharge/death, reason for admission and place of discharge to for the patients admitted in the inclusion period were obtained from the nurses' admission/discharge diary, the care plans, the ward clerk's diary and the discharge prescriptions.

Care plans for included patients were obtained from the clinical pharmacist at the ward after discharge or death of the patient. Discharge prescriptions for patients discharged to primary care were obtained from the dispensary filing system at the hospital. Patients do not receive a discharge prescription when discharged to another ward or hospital. If no discharge prescription could be found for a patient the researcher assumed to be discharged to primary care the medicines dispensed to the patient on discharge were identified through the dispensary computer system. All documents were anonymised and given an identification-number before they were removed from the hospital. The researcher kept a list of patient names and date of birth linked to this number at the hospital to make it possible to collect additional data about the patients at a later point of time if this was needed.

3.4.3 Identification of Care Issues

Care issues were identified through reading the care plans. Clinical interpretations and clarification of the care issues were obtained through discussions with the pharmacist at Ward 18/19 when needed. If an identified care issue didn't have a documented outcome, the researcher would use these

discussions to clarify if this was because the pharmacist had forgotten to write the outcome down. If this were the case the researcher would document the outcome stated by the pharmacist. When a care issue involved a recommendation to a prescriber about changes to the patient's drug therapy and nothing were documented about the outcome on the care plan, the discharge prescription was used to identify if the change had been made to the patient's drug therapy.

3.4.4 Quantitative description and comparison of pharmaceutical care delivery

Development of a database

A database for categorisation of care issues was developed in Access© from a database used earlier at the University of Strathclyde. The original database already contained entries for past medical history and basic patient characteristics, for instance age and gender. The database was amended by Susan McKellar and the research group to include entries for categorisation of care issues, drug history sources, patient length of stay, place of discharge to, number of care issues not categorised and tick boxes for recommendation and interaction, as described below.

The categorisation system used to categorise the care issues cannot capture if the care issue includes a recommendation made by the pharmacist to the prescriber. In order to count the total number of recommendations made and the proportion of these the prescriber acted upon a tick box named 'Recommendation?' was added in the database. This box was ticked each time the care issue included a recommendation made by the pharmacist to the prescriber, regardless of outcome.

The categorisation system does not capture when the pharmacist identifies a care issue related to a drug interaction. The research group wanted to find out to which extent the clinical pharmacists focus on interactions, because of a suspicion that queries about interactions is under-represented in the pharmacists' work. A tick box called 'Interaction' was added in the database to be able to count this type of care issues. This box was ticked each time the identified care issue was related to an interaction.

Categorisation
Patient information and past medical history were entered into the Access© database. All care issues with a known outcome were entered into the database and categorised according to the guideline for categorisation of care issues. Identified care issues without known outcomes were counted and the number was entered into the database. Boxes were ticked for each care issue when appropriate, as described above.

Appropriate queries were made and run in the Access© database in order to obtain data that described the included patients and the pharmaceutical care delivered to these patients. The data is presented in the result section.

The results were statistically compared with the results from the project of MBC. The comparison focused both on the delivery of pharmaceutical care per patient and the distribution of care issues into subcategories in the total delivery of pharmaceutical care. Fischer's exact test for 2x2 tables was used to compare if there was any differences in the distribution of care issues in the different categories and subcategories between the two wards. This was done by comparing the proportion of one subcategory to the proportion of the rest of the care issues in the same category. This was done for each subcategory. A 95 % Confidence intervals were calculated for the proportions by using the modified Wald method. GraphPad QuickCalcs was used to perform these calculations.[56] The t-test was used to compare patient characteristics and the delivery of pharmaceutical care per patient between the two wards. The researcher aimed to highlight similarities and differences in the delivery of pharmaceutical care at the two wards on background of differences in patient characteristics, prescription turnover and way of documenting the pharmaceutical care delivered.

3.5 Demonstration of inter-rater agreement

In this project the inter-rater agreement or inter-rater reliability between KJH and MBC was assessed through calculating Cohen's kappa (κ) for different parts of the categorisation system. This was used to test the validity of the categorisation system. It also gave a basis for assessing the legitimacy of the comparison of

delivery of pharmaceutical care at the two wards, which was executed through comparison of categorised care issues.

Cohen's kappa is a number that tells something about how good the agreement between two raters is when they are assigning information to predefined categories, see table 3.

Table 3 Values of κ[57]

Value of κ	Strength of agreement
< 0.20	Poor
0.21 – 0.40	Fair
0.41 – 0.60	Moderate
0.61 – 0.80	Good
0.81 – 1.00	Very good

Cohen's kappa incorporates both the observed agreement and the agreement expected by chance, i.e. if the raters randomly assigned the information into the categories. This means that result can be negative if the agreement is less than what would be expected by chance.[57] The equations for calculating Cohen's kappa and the standard error for Cohen's kappa can be seen in Equation 1 and 2.

Equation 1 Cohen's kappa

$$\kappa = \frac{p_o - p_e}{1 - p_e}$$

κ	= Cohen's kappa
p_o	= Relative observed agreement between raters
p_e	= Relative agreement expected by chance
1	= Maximum possible observed agreement

Equation 2 Standard error for Cohen's kappa

$$se(\kappa) = \sqrt{\frac{p_o(1 - p_o)}{n(1 - p_e)^2}}$$

se(κ) = standard error κ

Cohen's kappa is calculated by assigning the categorised information into a table like table 4.

Table 4 Example of table for structuring data for calculating κ

		RATER B Category 1	Category 2	Category 3	Total
RATER A	**Category 1**	**5**	0	1	6
	Category 2	2	**10**	0	12
	Category 3	1	0	**6**	7
	Total	8	10	7	25

Relative observed agreement (p_o) is calculated by dividing the number of subjects the raters agreed on (the sum of the numbers in the boxes along the diagonal line in table 4) with the total number of subjects that were assigned to categories, see equation 3.

Relative agreement expected by chance (p_e) is calculated by adding the expected number in each of the boxes along the diagonal in table 4 to each other and dividing this sum by the total number of subjects that were assigned to categories. The expected number in a box is obtained by multiplying the total row sum with the total column sum for the box, and dividing this number by the total number of subjects, see equation 4.

Equation 3 Calculation of p_o

$$p_o = \frac{(5+10+6)}{25} = \frac{21}{25} = 0.84$$

Equation 4 Calculation of p_e

$$p_e = \frac{(\frac{8\times 6}{25} + \frac{10\times 12}{25} + \frac{7\times 7}{25})}{25} \approx 0.35$$

Equation 5 Calculation of κ

$$\kappa = \frac{(0.84-0.35)}{(1-0.35)} = 0.75$$

Equation 6 Calculation of se(κ)

$$se(\kappa) = \sqrt{\frac{0.84(1-0.84)}{25(1-0.35)^2}} = 0.11$$

In this example the Cohen's kappa was calculated to be 0.75 with a standard error of 0.11, as seen in equation 5 and 6.

A limitation with Cohen's kappa is that the expected frequencies in the boxes along the 'agreement' diagonal depend on the distribution of subjects in the different categories. This means that one kappa can't be compared with another kappa unless the data it was calculated from had the same distribution pattern in the different boxes.[57]

In this project the Cohen's kappa for the amended subcategories of the categorisation system was calculated. To test the total system at once would require a very big table because of the many categorisation options for one care issue, and this would in turn require that both raters categorised a large number of care issues. This was avoided by calculating the Cohen's kappa separately for the main categories, the Quality Assurance Descriptors (both 'Time Perspective' and 'Degree of Change') and the subcategories of the main categories. This made it possible to tell how large the inter-rater agreement is in different parts of the system. The Cohen's kappa was not calculated for the 'Drug Therapy Problem' categories because this part of the categorisation system is tried out in big degree, and a high degree of inter-rater agreement was assumed.

The care issues for testing of Cohen's kappa were chosen randomly among the total care issues identified from the care plans by MBC and KJH. A sample of 50 care issues that already were categorised were chosen from each rater's database, and the other rater categorised these care issues as well. The care issues were taken out of its context when the other rater was to categorise them, so if any clarification about the background of the care issue was needed this was sought from the other rater. The raters were careful not to reveal their own categorisation of the issue in these discussions, but only explained the clinical context. If the raters disagreed on any of the main categories the assigned 'Time Perspective' would still be included in the calculation of Cohen's kappa for the 'Time Perspective', because the raters considered it as possible to evaluate the 'Time Perspective' for the care issue independent of the main category.

3.6 Survey of prescribing activity

A separate project undertook a survey of prescribing activity on Ward 18/19 in the same period of time as the prospective phase of the project of KJH. The MPharm

student Amiruddin Bin Ahmad Ramly (ABAR) executed this project. Discharge prescriptions and care plans were collected by KJH for this project as well. Both projects included the same patients. The aim of this project was to compare the pharmacy service at the Care of the Elderly ward with the General Medical ward in terms of profile of medication use and drug therapy problems. This was done through a survey of prescribing activity in order to measure the prescription turnover and to quantify the exposure of medicines of each patient on admission, during their stay and at discharge at Ward 18/19.

The calculations were done using a system developed by CF; a description of the calculated parameters can be seen in table….in the result section. These parameters and parameters describing the patients at the wards were statistically compared with the data from a corresponding project executed at the General Medical ward by Chan Sue Li (CSL) in the same period of time. The distribution of prescribed drugs were also characterised according to which drug class they belong to, using the classification system for drugs in the British National Formulary.[58] This MPharm project was supposed to include data from KJH's study, but differences in timeframe for the projects didn't allow this.

3.7 Focus groups

Focus group is a group interview technique for qualitative data collection. The objective of the method is to explore the participants' opinions, experiences, prioritising, perspectives and thoughts about a subject through a structured interview. It is used to identify and explore relevant questions in a field of interest, and is often used in market research and politics to gather information about consumers' or electors' opinions respectively. The method can also be used to ensure content validity of a structured instrument. It is usually used as a tool in exploratory and descriptive studies in combination with other research methods.[59] The data generated through focus groups is influenced by interactions between the participants. Hence, both the composition of participants and the size of the group will affect the data. A homogenous group is considered more productive, there is a greater likelihood that all members participate in the discussion and the discussion will have more depth. On the other hand, a homogenous group will reduce the generalisability of the results, but if the focus group is supposed to be

an ‘expert panel’ this is not of big concern as generalisability is not an objective. A possible solution to capture both the productivity of the homogenous group and the diversity of the heterogonous group is to have more than one focus group, with homogenous composition of the group, but heterogeneity between the groups. A small group size will increase the portion of members participating in the discussion and the possibility of in-depth discussions, but most likely decrease the numbers of topics discussed.[59]

The interview should be focused on subjects important to the participants, and not only the subjects the researchers believe to be important. It is normal to use an interview or topic guide to structure the discussion, but there has to be room to discuss the subjects the participants find most important. This will result in an open discussion of predefined subjects where one of the researchers functions as facilitator/moderator in order to guide the discussion and encourage the members to participate.

The validity of data generated through focus groups is ensured if all members of the group have expressed their views and felt they were able to influence the direction of the discussion. If this is fulfilled the data should be an accurate reflection of the group’s opinion. It can be hard to know if the reliability or the reproducibility of the data is ensured, because group dynamics will influence the data. If the data is a reflection of all of the group member’s experiences and opinions this should be enough to consider the data reliable.

The focus group in this project

The research group arranged one focus group together. The focus group was used to ensure the validity and utility of the modified categorisation system and to receive input on amendments that can make the system better and easier to use. The research group also wanted to use the focus group to get feedback on the results from the categorisation and to explore possible future areas of utilisation for the system. An overview of the participants and investigators (the research group) can be seen in table 5. All the participants except SH work at a ward audited in one of the four projects. The focus group meeting was estimated to last 90 minutes. The guideline and a kind request to read it through before the

meeting was sent to the participants beforehand. The participants with positions at University of Strathclyde have previous knowledge of the system.

Table 5 Focus group: Participants and investigators

Initials	Title	Workplace
LS	Clinical pharmacist	Glasgow Royal Infirmary & University of Strathclyde
CF	Clinical pharmacist	Glasgow Royal Infirmary & University of Strathclyde
SH	Professor of pharmaceutical care	University of Strathclyde
CW	Clinical pharmacist	Ayr Hospital
KW	Clinical pharmacist	Ayr Hospital
MBC	Investigator	University of Tromsó
MRR	Investigator	University of Tromsó
ROH	Investigator	University of Tromsó
KJH	Investigator	University of Tromsó

The meeting was started by a short introduction of the system that gave the participants an opportunity to clarify aspects of the system they found unclear. Microsoft Power Point © was used as a topic guidance to structure the meeting. This made it possible for the inexperienced research group to maintain the attention and focus of the participants and on the same time present some of the results from the categorisation of care issues. A couple of slides with either description of the categorisation system or presentation of results from all four wards were followed by one or two questions for the participants to answer. The members of the research group led one part of the meeting each. The research group had a tight time-schedule, where only discussion in relevance to the project could be encouraged.

The focus group meeting was tape-recorded. A summary of the topics discussed and opinions expressed was transcribed afterwards. All of the free dialogue was fully transcribed, but the parts of the meeting that were merely presentation of the system or the results presented by the research group were just shortly described. This gave a consistent documentation of the opinions expressed by the participants of the focus group.

3.8 Future applications of non-medical prescribing

After the introduction of non-medical prescribing in the UK a way of deciding if it will add value to the use of recourses and to patient care if the pharmacists in a certain setting become prescribers is needed. The categorisation of care issues might be a way of describing the work undertaken by the pharmacist in a manner that can support such a decision. The researcher will in this project evaluate, with input from the focus group, if the results from the categorisation of care issues can be used as a decision support when introduction of pharmacist prescribing is considered in a clinical setting. The researcher will also try to assess if Ward 18/19 at Glasgow Royal Infirmary would benefit from a pharmacist prescriber.

4 Results

4.1 Literature review

Relevant articles, guidelines and reports on most subjects were found through Medline, Embase, Pharmaceutical Journal and the web-pages mentioned in the introduction. Most of the literature that was found is included in the reference list. The books "Pharmaceutical Care Practice. The Clinician's Guide" and "Research Methods in Pharmacy Practice" were read thoroughly. Literature on care of the older person was found in pharmacokinetic and therapeutic books, as seen in the reference list. To find literature or guidelines on documentation/recording of pharmaceutical care in Scottish hospitals turned out to be a challenge, and it was necessary to include literature on documentation/recording from the US.

4.2 Qualitative description of pharmaceutical care

The process maps were developed after the researcher had spent three days shadowing LS's work at the Care of the Elderly ward, in addition to the time spent at the ward when the researcher was there to collect data for the study. Originally two process maps, one describing admission and patient stay and one describing discharge, were made. Through discussions with LS a decision to make a separate process map for the provision of the Multi-compartment Medicines Box (MCMB) was made, because this is a complex process where many health institutions in primary care are involved. All three process maps have been discussed with LS, and after some amendments the researcher and LS agreed that they describe the pharmaceutical care at Ward 18/19 as it is delivered most of the time. The process maps describes the delivery of pharmaceutical care to each patient by the clinical pharmacist on the ward, and do not give a complete picture of the total pharmaceutical care delivered to the patient because this involves other health professionals in addition to the pharmacist. A description is written in addition to each of the process maps to describe the processes more thoroughly.

In order to prioritise which patients it is most important to see during the day the clinical pharmacist at Ward 18/19 starts the day by identifying the new patients at the ward and the patients that are ready for discharge.

Description of pharmaceutical care at admission and during patient stay

A PMP is initiated for each newly admitted patient. This document is started by filling in the information available in the patient's notes onto the first page, see appendix I. If some important information is missing this is, when possible, obtained from other sources and added both to the patient's notes and the PMP. If the patient's drug history isn't signed for by another pharmacist at the hospital LS takes an accurate drug history by using available sources, as described in table 6. After the drug history is complete, it is compared to the drugs and doses prescribed on admission, and discrepancies that seem unintentional and inappropriate are discussed with the prescriber at the ward. Any ambiguities in the patient's drug chart is also discussed with the prescriber and clarified. LS also clarifies with the patient or the patient's family how the patient's medication is managed at home pre-admission, see table 6. This gives a basis to decide if arrangements of any compliance aids are necessary, see table 7 for examples of compliance aids.

The pharmacist assesses if the patient is receiving all drugs necessary to treat the medical conditions, and that the patient is not receiving any unnecessary or inappropriate drugs. The need for initiating or stopping drug therapy is discussed with the prescriber. All identified problems, actions and outcomes regarding the patient's drug therapy are written as pharmaceutical care issues on the patient's pharmaceutical care plan, which is on page two of the PMP, see appendix I. The pharmacist also assesses if the patient needs any clinical monitoring to determine the effect of drugs or the need for new drugs, or to avoid adverse drug reactions. Monitoring needs are written on the care plan as a care issue and are followed-up during the patient's stay.

Through the patient's stay at the ward LS sees the patient and/or goes through the patient's notes in order to keep up to date on results from tests, changes in drug therapy and change in goals of therapy, and in order to monitor the patient's lab values, all of which can change the patient's drug therapy needs. All changes

in the patient's drug therapy needs are discussed with the prescriber at the ward. When the pharmacist discusses an identified need to change the patient's drug therapy with the prescriber, and a change is agreed on, the pharmacist will later go through the patient's drug cardex to see if the change was actually made. When a change hasn't been made the pharmacist has to discuss the issue with the prescriber once more.

How often and how much time LS uses on a patient depends both on to which extent the pharmacist believes the patient will benefit from pharmaceutical care and on how much time there is available. LS sees all of the patients at the ward at least twice a week.

Table 6 Description of some of the actions and decisions in figure 1

Actions/Decision	Assessed through
Verify drug history and allergies.	• Notes • GP letter • Patient • Patient's family • GP • Community pharmacist • Nursing home
Do the drugs and dosage prescribed on admission match the drugs and dosage from the confirmed drug history and do the changes seem appropriate or intentional?	• Presenting complaints • Results from tests • Past medical history • New diagnosis after admission
How does the patient manage the medication at home?	• Living arrangements (e.g. nursing home, alone, with family etc.) • Abbreviated mental test • Patient understanding of drugs • Patient ability to administer drugs • Physical status (vision, strength, ability to open things)
Is the patient medication needs met?	• Medical history • Drug history • Presenting complaints • Results from tests

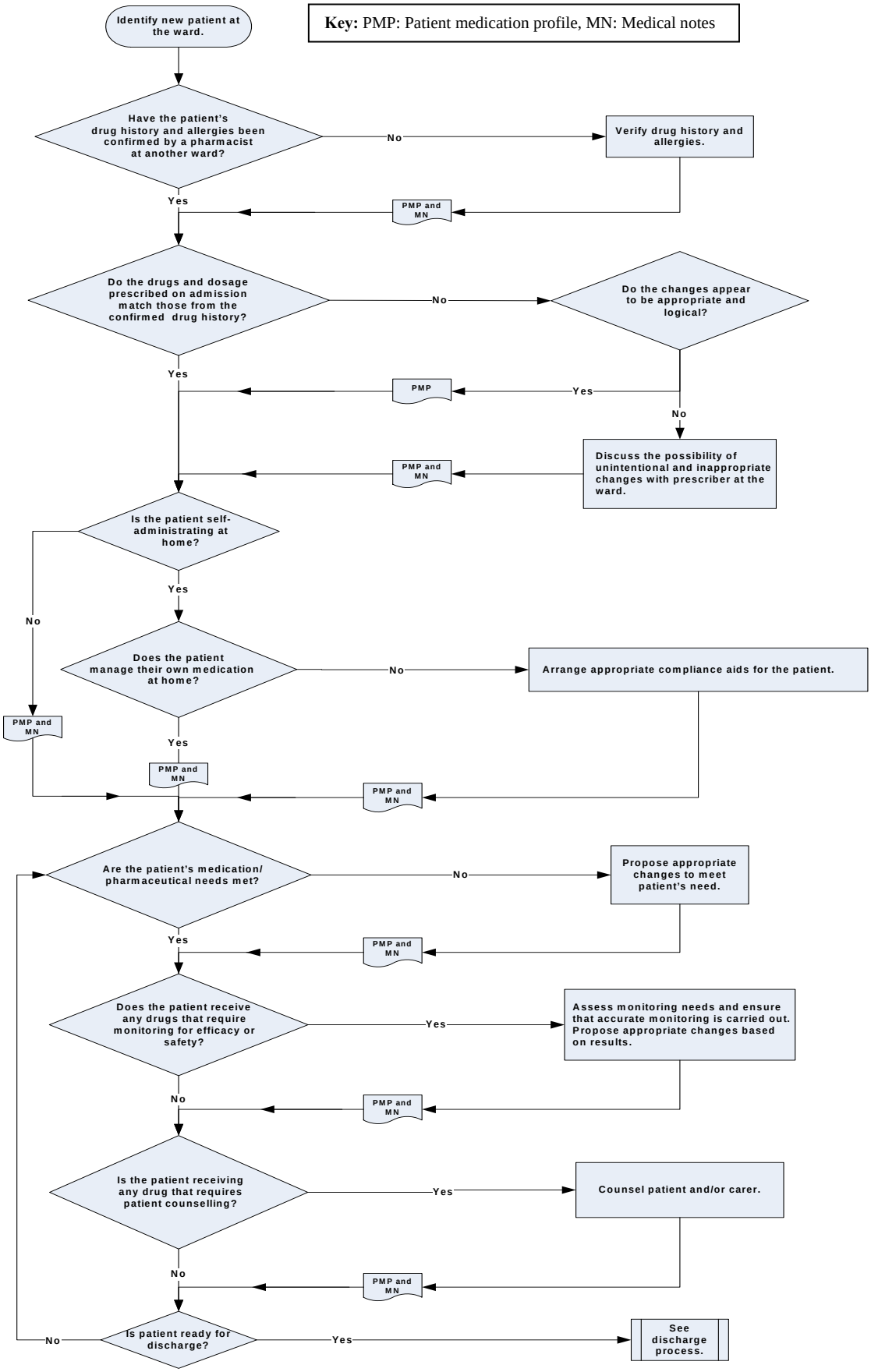


Figure 1 Description of pharmaceutical care at admission and during patient stay

Table 7 Description of available compliance aids

Available compliance aids	Description
Multi-compartment Medicines Box Synonyms: Dosette, PlusPak, Medidos etc.	Box with the tablets and capsules in different rooms according to the time and the day they are supposed to be administered. Can either be filled in the pharmacy or at home. Contains drugs for one-week consumption. Exists as many-time use or disposable box.
Large print label	Label (with instructions for drug use) with increased size of letters to ensure readability for visually impaired patients.
Medication reminder card	Card with information about when to take medication.
Easy-open containers	Medicines in containers without childproofing. Blister packs are not appropriate as it often is hard to squeeze out the tablets.
Inhaler devices	Spacers that excludes the need for coordination between release and inhalation of the dose.

Description of pharmaceutical care at the patient's discharge from the ward

When a patient is going home LS screen the discharge prescription if he is at the ward. If he has not been able to do it, the dispensary will screen the prescription and compare it with patient's care plan before dispensing the drugs. Any discrepancies between the discharge prescription and the drugs the patient has been prescribed during the hospital stay that doesn't seem appropriate or intentional are discussed with the prescriber that wrote the prescription. Any messages to the patient's General Practitioner (GP) regarding the patient's drug therapy are written on the discharge prescription, and a copy of the prescription is sent to the GP. When necessary, and there is enough time to do it, the patient and/or the patient's carer is counselled on changes in the patient's drug therapy before the discharge. If the patient is transferred to another ward at the Glasgow Royal Infirmary the care plan is transferred along with the patient. If the patient is transferred to another hospital with a clinical pharmacist, unresolved care issues are forwarded, usually orally. If the patient is going to a hospital without a clinical pharmacist only very important unresolved care issues would be transferred.

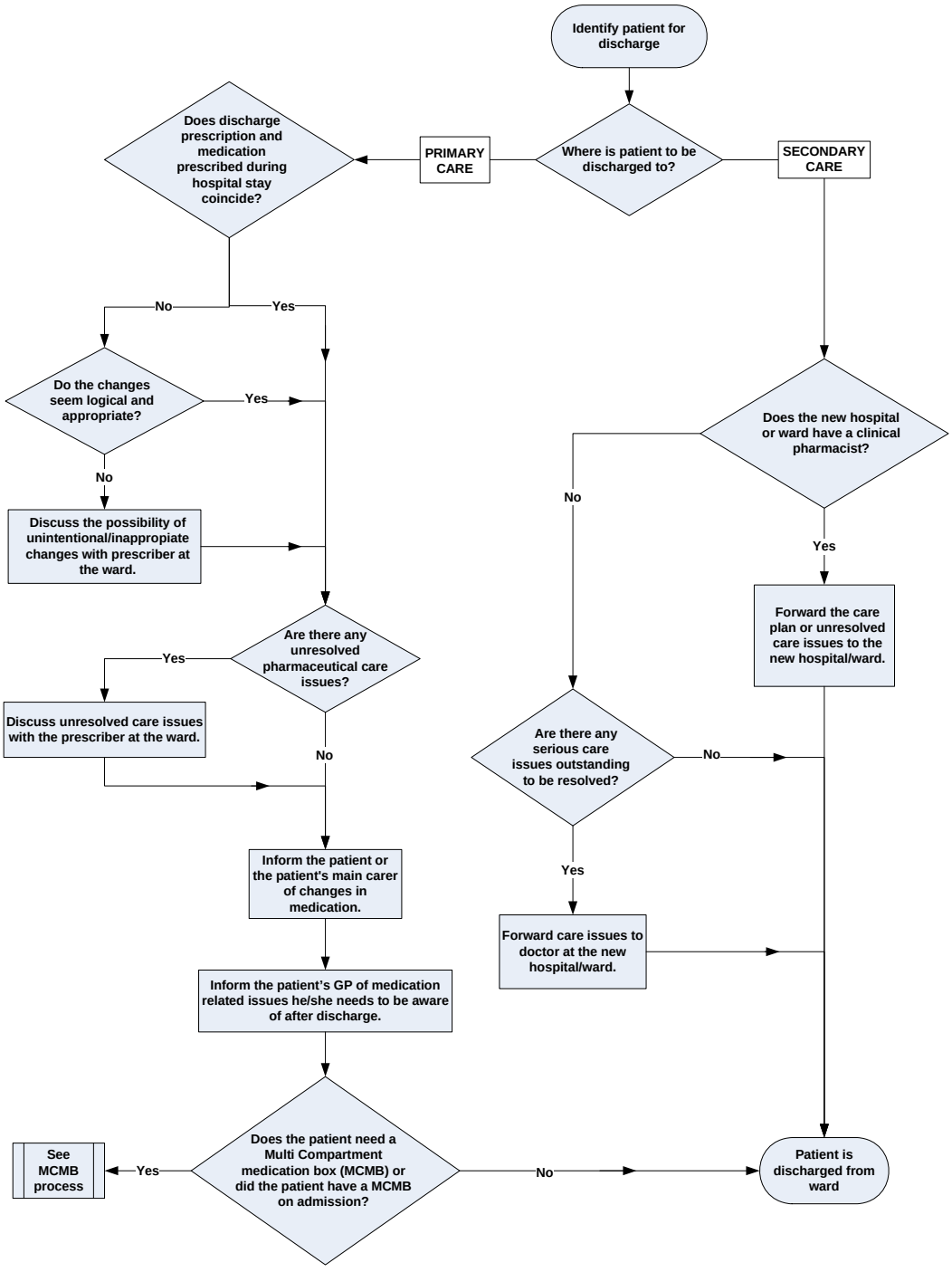


Figure 2 Pharmaceutical care at the patient's discharge from the ward

Description of Multi-compartment Medicine Box process

If LS identifies a need to get a MCMB for a patient that didn't have one on admission this has to be arranged. LS first calls the patient's preferred pharmacy to make arrangements. Most of the time the first choice of pharmacy hasn't got the capacity to fill a MCMB for any new patients, but suggests another nearby pharmacy that might still have availability. When a community pharmacy that is willing to fill the MCMB for the patient is found LS faxes the patient's medication list anonymised to the pharmacy. Then LS calls the GP to make sure that 'once weekly' is written on the patient's future prescription. This is done so the pharmacy gets refund for its service of filling the box. LS then talks to the patient to make sure he or she is able to understand the MCMB. If the patient doesn't seem to understand which compartment to administer on what time of the day and week the pharmacist has to arrange for someone else to administer the patient's medicines, either a family member or the patient's home help.

For some patients the need to get an MCMB comes from their need to have the home help administer their drugs, because they will only do it if the drugs are in an MCMB. If the patient had an MCMB on admission the pharmacy that normally fills the box is called when the patient is ready for discharge. LS writes on the care plan of all patients with an MCMB that they have an MCMB, so when the dispensary at the hospital is dispensing the discharge prescription the medicines are put in an MCMB.

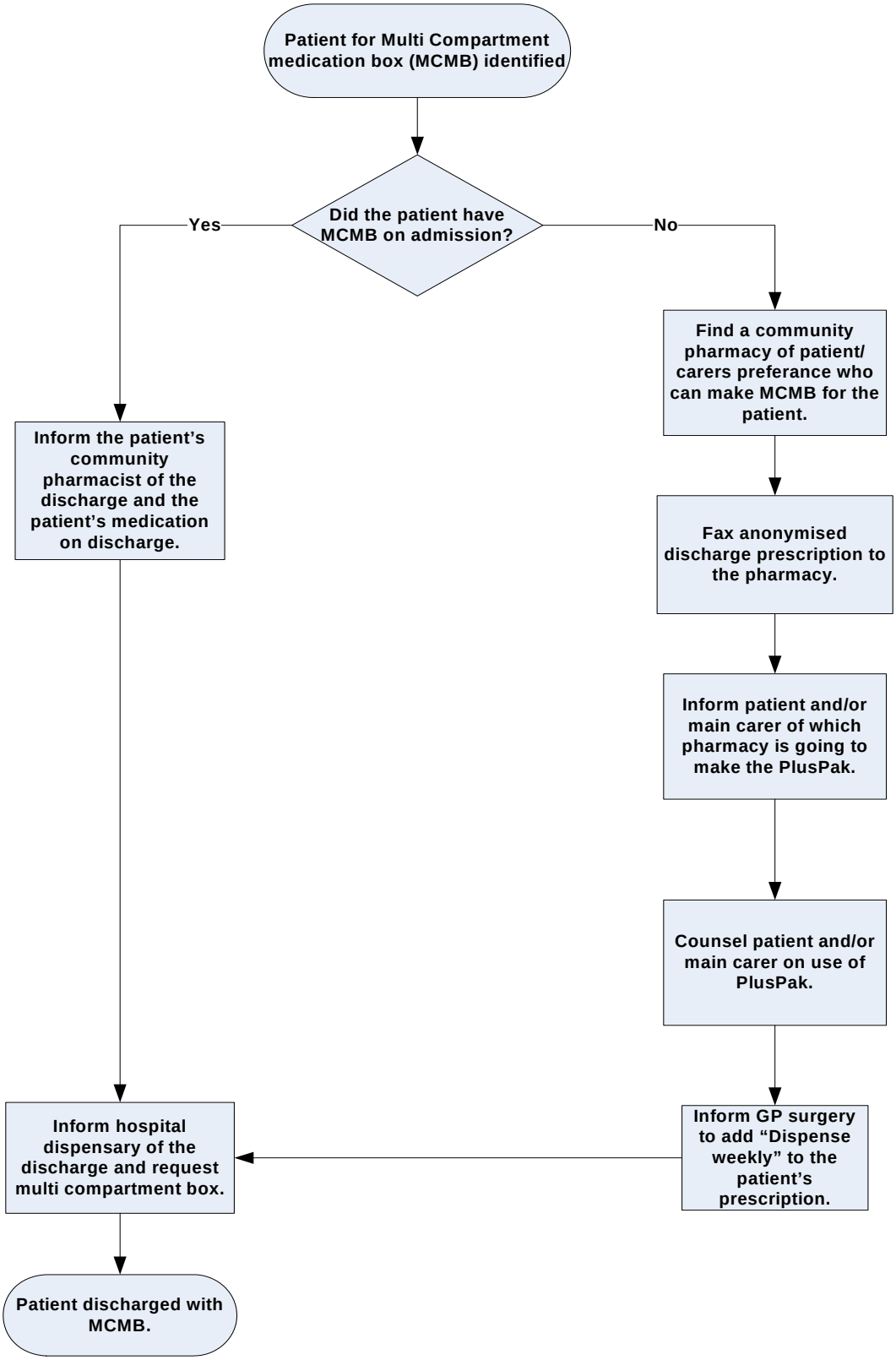


Figure 3 Multi Compartment Medicine Box Process

4.3 Modification of the categorisation system

The research group developed a guideline for the modified system. The guideline is a free-standing text developed in collaboration, and it can be found in Appendix II. Since the guideline both describes the theory behind the categorisation system and the practical use of the system in detail, this information will not be repeated in the main text of this project. The general features of the modified categorisation system and changes made by the research group to the previous system are discussed below. For a more in-depth description of the modified system, see the guideline in Appendix II.

4.3.1 A short description of the modified categorisation system

In the modified categorisation system each care issue is:

1. Categorised into one of the three main categories ‘Check’, ‘Change in Drug Therapy Processes’ or ‘Change in Drug Therapy’, and into a subcategory of the selected main category
2. Categorised into one or two ‘Quality Assurance Descriptor’ categories; all care issues is categorised into a ‘Time Perspective’ category, while ‘Change in Drug Therapy’ is categorised into a ‘Degree of Change’ category as well

Care issues categorised as ‘Changes in Drug Therapy’ is:

3. Categorised into a ‘Drug Therapy Problem’ category

A short summary of the categorisation of a care issue can be seen in table 8.

Table 8 Summary of categorisation of a pharmaceutical care issue

	Pharmaceutical Care Issue			
Main category	Check	Change in Drug Therapy Process	Change in Drug Therapy	
Drug Therapy Problem	-	-	Drug Therapy Problem	
Quality Assurance Descriptor	Time Perspective	Time Perspective	Time Perspective	Degree of Change

4.3.2 The Check category

A care issue identified and resolved by the pharmacist can be either a ‘check’ or a ‘change’. A ‘check’ is a care issue where nothing related to the patient is changed. One example of a check is monitoring of blood pressure after a thiazide is withheld, but where the outcome is that blood pressure is still controlled and no changes need to be done. A check can be categorised into four different check categories according to the type of inquiry; medication need, safety, effectiveness and compliance, see table 9. Each check category corresponds with one or two Drug Therapy Problem categories, and which check category the care issue belongs to is given by the description of the corresponding Drug Therapy Problem categories, see table 11.

The research group made only one change to the subcategories of checks. There used to be a fifth category; ‘Formulary adherence inquiry’. This subcategory was removed, and in the modified system only care issues involving a recommendation made to change drug therapy on basis of formulary adherence where the change were actually acted upon will be categorised.

4.3.3 The Change categories

A check can lead to a change. All care issues are categorised as either a check or a change. When an initial check leads to a change (for instance monitoring of effect which leads to a change of dose), the care issue is only categorised as a change.

A care issue that results in a change either undertaken by the pharmacist or recommended by the pharmacist and undertaken by someone else is categorised as a change. The change can be of many different types, and in the modified system the change category is divided into two categories; ‘Change in Drug Therapy Process’ and ‘Change in Drug Therapy’, see table 9 for a overview of what falls into the two categories. The research group divided the original change category into these two categories in order to differentiate between changes made in the patient drug therapy or done to enhance compliance, where the extent of the change is easily measured, and changes made to other processes related to the care of the patient, where the extent of the change is hard to

assess and where the care issue can't be assigned to a drug therapy problem category.

Table 9 Main categories with subcategories

Check	**Change in Drug Therapy Process**	**Change in Drug Therapy**
	Changes made to	**Changes made to**
Medication need inquiry	Clinical (shared) record of patient characteristics	Drug selection (starting new or changing drug)
Effectiveness inquiry	Clinical (shared) record of drug history	Dose
Safety inquiry	Continuity of information/care between clinical settings	Route/dose form
Compliance inquiry	Level of patient monitoring	Dose interval/timing
	Health care team member(s) information/education	Duration
		Stop drug temporarily/permanently
		Patient or Carer Level of Education (Understanding/Compliance)

The research group has made some changes to the subcategories of 'Changes' in order to make them more logical and useful. A comparison between the old and the new system can be seen in table 10.

Table 10 Changes: Comparison between the old and the new subcategories

NEW SYSTEM	OLD SYSTEM
Change in Drug therapy process **Changes made to:**	**Changes** **Changes made to:**
Clinical (shared) record of patient characteristics	Patient characteristics
Clinical (shared) record of drug history	History (indications, contra-indications)
Continuity of care between clinical settings	Continuity of care
Level of patient monitoring	
Health care team member(s) information / education	
Change in Drug Therapy **Changes made to:**	
Drug selection (starting new or changing drug)	Drug Choice
Dose	Dose
Route/Dose form	Route/Dose form
Dose interval/timing	Dose interval / timing
Duration	Course duration
	Drug use precautions e.g. potential interactions
Stop drug temporarily / permanently	Stop drug pending review
Patient or Carer Level of Education (Understanding / Compliance)	Patient comprehension Patient agreement / participation Patient expectations of treatment

The subcategory 'Drug use precautions e.g. potential interactions' was removed because the research group found it confusing. It was not obvious what kind of care issues that would fit into this category, as all changes that happens because of a suspected interaction also could go into other change categories, for instance 'Dose', 'Dose interval/timing' or 'Level of patient monitoring'. The research group sought to ensure that each care issue only had one categorisation possibility in the system.

The original subcategories 'Patient comprehension', 'Patient agreement/participation' and 'Patient expectations of treatment' were merged to one subcategory; 'Patient or Carer Level of Education (Understanding/Compliance)'. This was done because the research group found it hard to differentiate between care issues that increased patient

agreement/participation and care issues that increased compliance, because the outcome of patient counselling or education is hard to measure or evaluate. With the old system these care issues would be categorised as if the intention of the pharmacist was the actual patient outcome, but the pharmacist will rarely assess if the patient actually had gained for instance increased participation, so the real outcome is rarely known. The new subcategory 'Patient or Carer Level of Education (Understanding/Compliance)' takes into account that it is hard to evaluate a change in understanding in a patient, and only describes the action of the pharmacist, with the intentional patient or carer outcome in parenthesis. The new subcategory has added Carer in addition to Patient in order to emphasise the importance of carer involvement and education, and to be able to categorise the care issues that comprise counselling of the patient's carer. The research group chose to have this subcategory in the 'Change in Drug Therapy' instead of the 'Change in Drug Therapy Process' category because it can be categorised according to the 'Drug Therapy Problem' part of the categorisation system.

Some of the names of the subcategories are also changed to make it clearer what kind of care issues that falls into that specific category as seen in table 10.

4.3.4 Drug Therapy Problems

A care issue can be categorised into one of seven Drug Therapy Problem categories, where each category states one possible origin of the care issue.[13] When a care issue is categorised into one of the seven categories the reason/most likely reason for the care issue is stated. This system is an adjustment of the eight categories of Drug Related Problems initially developed by Hepler and Strand.[4, 54] The only difference between the two categorisation systems is that Drug Related Problems identifies 'interactions' (drug-drug, drug-food and drug-laboratory interactions) as a separate category, whereas Drug Therapy Problems has included interactions in three other subcategories, 'Adverse Drug Reaction', 'Dose too high' and 'Dose too low', according to the ultimate result of the interaction, see table 11. The original Drug Therapy Problem categorisation system is patient centred, and was developed to help focus the pharmacist's role on the patient, as opposed to the drug.[54] Only 'Change in Drug

Therapy' is categorised into this category in the categorisation system used in this project.

The research group has added an extra subcategory named 'Unclassified', to describe changes made in the patient's drug therapy that is not done to individualise the therapy, but in order to adhere with local or national formulary. This category is included because the pharmacist's contribution to adherence with local/national formulary is an important part of a pharmacist's responsibility as a health care professional. To fully characterise the work undertaken by the clinical pharmacist this has to be a part of the categorisation system, even though it's not a part of the pharmaceutical care delivered to an individual patient.

The research group has also made some changes to the nature of the care issues belonging to each category in order to make the categories more logical. For instance was 'The duration of therapy is too long' originally included in the 'Dose too high' subcategory.[13] The research group found it more logical to include this care issue in the 'Unnecessary medication use' subcategory. By changing this, a care issue concerning too long drug therapy will be categorised the same way independent of if the drug is for short-term or long-term use. The same was done for care issues concerning too short duration of drug therapy, where the original subcategory was 'Dose too low', and the subcategory in the modified system is 'Need for additional drug therapy'.

Some additional common causes of the 'Drug Therapy Problem' have been added into the description of the subcategories in order to increase the understanding of where an identified care issue belongs. The added common causes are written in bold in table 11.

Table 11 'Check' categories coupled to Drug Therapy Problem categories

Check categories	Drug therapy problem categories	Common causes
Medication needs	Unnecessary drug therapy	There is no valid medical indication for the drug therapy at this time Multiple drug products are being used for a condition that requires fewer drug therapies The medical condition is more appropriately treated with non drug therapy Drug therapy is being taken to treat an avoidable adverse reaction associated with another medication Drug abuse, alcohol use, or smoking is causing the problem The duration of therapy is too long
	Need for additional treatment	A medical condition requires the initiation of drug therapy Preventive drug therapy is required to reduce the risk of developing a new condition A medical condition requires additional pharmacotherapy to attain synergistic or additive effects The duration of drug therapy is too short to produce the desired response
Effectiveness	Ineffective drug	The drug is not the most effective for the medical problem The medical condition is refractory to the drug product The dosage form of the drug product is inappropriate The drug product is not an effective product for the indication being treated **The time of dosing or dosing interval is not the most effective** **Route of administration is not the most effective**
	Dosage too low	The dose is too low to produce the desired response The dosage interval is too infrequent to produce the desired response A drug-drug/food/lab/disease interaction reduces the amount of active drug available

Table 12 (continued) 'Check' categories coupled to 'Drug Therapy Problem' categories

Safety	Adverse drug reaction (anticipated/unanticipated)	The drug product causes an undesirable reaction that is not dose-related A safer drug product is required due to risk factors A pharmacodynamic drug-drug/food/lab/disease interaction causes an undesirable reaction that is not dose-related The dosage regimen was changed too rapidly The drug product causes an allergic reaction The drug product is contraindicated due to risk factors **The time of dosing or the dosing interval is not the safest.** **Route of administration is not the safest**
	Dosage too high	Dose is too high The dosing frequency is too short A drug-drug/food/lab/disease interaction occurs resulting in a toxic reaction to the drug product The dose of the drug was administered too rapidly
Compliance	Inappropriate compliance	The patient prefers not to take the medication The patient forgets to take the medication The drug product is too expensive for the patient The patient cannot swallow or self-administer the drug product appropriately The drug product is not available for the patient **The time of dosing or the dosing interval is decreasing compliance**.
	Unclassified i.e. Non-DTP	Formulary adherence, e.g. generic switch

4.3.5 Quality assurance descriptors

The systematic role of the pharmacist can be seen as a process in the quality system feedback loop.[7] The delivery of pharmaceutical care can be pictured as a closed feedback loop, which consists of design, delivery and evaluation of care, as described in figure 4. The expectations to care set by the clinical standards

and the goals of therapy guide the design, delivery and evaluation of the patient's care.

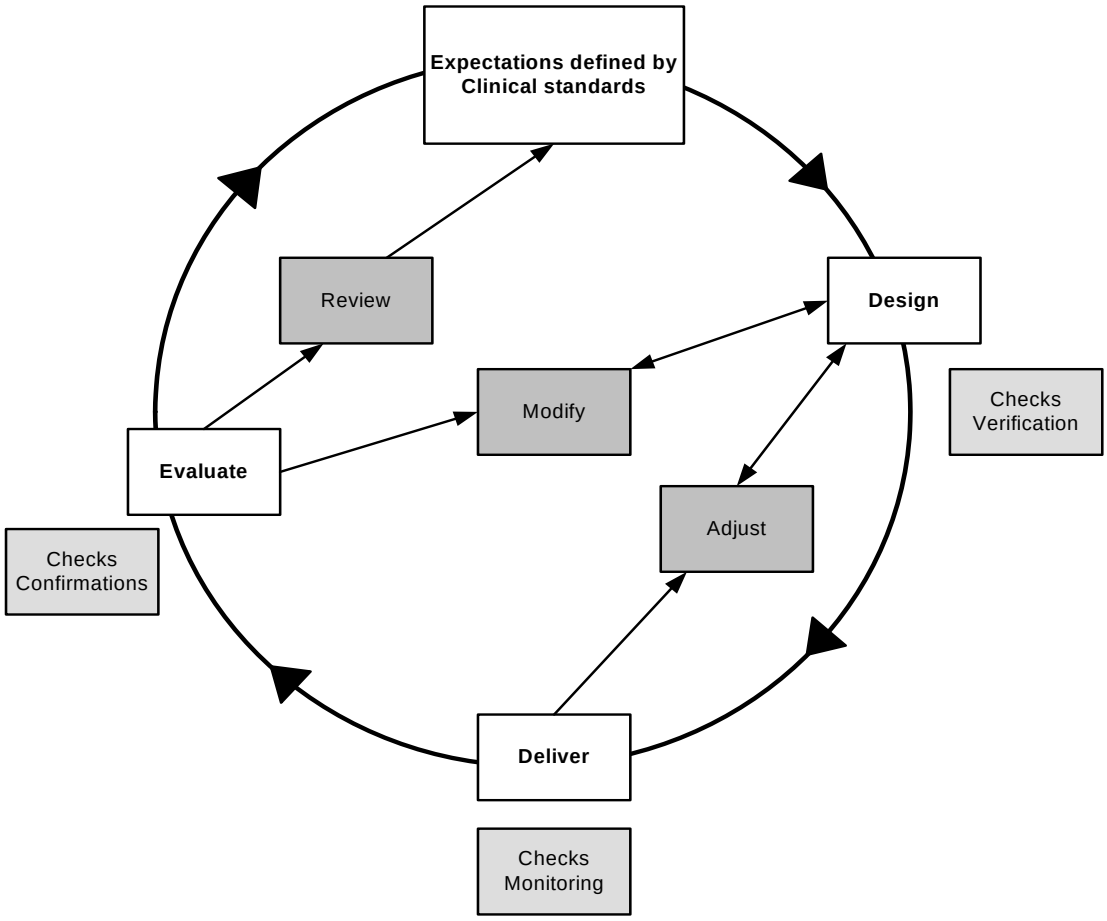


Figure 4 Pharmaceutical care model: Quality Assurance Feedback Loop

A care issue can arise at different times during the patient treatment journey described by the feedback loop, and care issues can be categorised according to what time they arise. The category describing care issues according to where in the quality feedback loop they arise is named 'Time Perspective'. The category describing the care issue according to the nature of the outcome is named 'Degree of Change' These two categories are together called 'Quality Assurance Descriptors' to underline that they describe care issues in connection with the Quality Assurance Feedback Loop, see figure 4.

Time Perspective

A care issue can be identified at the start of treatment (design), as a treatment continues (delivery) or after a course of treatment (evaluation), and all care issues can as a result be categorised according to what time in the quality assurance feedback loop they arise. This category is called 'Time Perspective',

and has three subcategories that describes the time perspective according to the feedback loop, see table 12. This is a modification of the original system, where only care issues categorised as 'Checks' were categorised according to where in the quality assurance feedback loop the care issue was identified.[7] This category was therefore named 'Quality Assurance Descriptor for Checks' in the original system. The research group changed the categorisation system to be able to characterise all care issues according to where in the patient's treatment they arise. The research group saw no logic in that the 'Time Perspective' only would add value to the characterising of care issues categorised as 'Checks', and made this change to the system to underline the importance of the time aspect for both checks and changes.

Table 12 Quality Assurance Descriptor – Time Perspective

Time Perspective	Description
Verification Verification of appropriateness of medications in the proposed treatment plan	Checks at the start of the treatment to make sure that, for each medicine, the patient: is on the right medicine is on the right dose is not on unnecessary medication doesn't have any new needs for additional medication is not receiving a combination of interacting medicines understands how to take their medication and what it will do to them
Monitoring Implementation of treatment is appropriate and checking for safety and effectiveness	Checks as treatment continues which should ensure that, for each medicine, the patient: is on receiving medication as intended continues to be on the most suitable dose has no symptoms of unwanted(adverse) effects understands how to take their medication
Confirmation Checking that medication is producing positive outcomes	Confirmation and documentation to identify that medication is: resulting in expected effects on the patient's condition not failing to control condition not producing unwanted effects requiring clinical review.

Degree of Change

Care issues that are 'Change in Drug Therapy' will have a change in the patient's treatment or education as outcome. The category 'Degree of Change' describes the extent of the Change (the outcome of the care issue) compared to the patient's original treatment plan, see table 13. The research group chose to exclude the 'Change in Drug Therapy Process' from being categorised according to the 'Degree of Change' category because the outcome of this kind of care issues is often hard to assess. There would be a need to speculate about what exactly the outcome of the care issue would be, and what degree of change it comprises. This is a change from the original system where all care issues categorised as 'Changes' would also be categorised into this quality assurance category.[7] This category was original named 'Quality Assurance Descriptors for Changes'.

Table 13 Quality Assurance Descriptors – Degree of Change

Degree of Change	Description
Adjustment	A recommended change to patient behaviour, treatment regimen or process of continuity of care that individualises pharmaceutical care within the agreed treatment plan.
Modification	A change to the patient treatment that is not anticipated and leads to a change of the patient's treatment plan.
Review	A re-assessment of the patient's treatment, and leads to a change in the expectations defined by clinical standards i.e. change in the expectations to the outcome of the treatment.

Combination of 'Time Perspective' and 'Degree of Change'

At what time in the feedback loop the pharmacist identifies a need to change the drug therapy of a patient will influence what 'Degree of Change' the change in

drug therapy will be, as can be seen in figure 4. This is a new part of the categorisation system, because in the original system changes weren't categorised according to when in the patient's treatment they were identified, hence it wasn't necessary to make a connection between 'Time Perspective' and 'Degree of Change'.

The connection between 'Time Perspective' and 'Degree of Change' can be summarised as follows:

- A **'Verification'** can lead to an **'Adjustment'** or a **'Modification'**
- A **'Monitoring'** can lead to an **'Adjustment'**
- A **'Confirmation'** can lead to a **'Modification'** or a **'Review'**

The reason for a connection between the 'Time Perspective' and 'Degree of Change' is that not all kind of changes can be performed at all times during a patient treatment, for instance during monitoring a confirmation of the patient's treatment would be needed in order to do a change outside the treatment plan (a 'Modification').

4.4 Quantitative description of pharmaceutical care

The researcher went to Ward 18/19 once or twice a week in the first part of the data collection period to collect data. This was done to obtain a reliable list of patients' admittance and discharge or death dates, as there was no complete record of this at the ward. When only three of the included patients were left at the ward the researcher stopped going to the ward on a regular basis, but arranged for LS to inform the researcher when the last three patients had left the ward, so the researcher could come back to collect the last remaining data.

The data were collected according to the description in the methods section. The researcher had a list over all the included patients, with room to tick of for collected care plans and discharge prescriptions. This list made it possible for the researcher to know if some of the data was lacking for any of the patients. For some of the patient's there were no discharge prescriptions even though they had

supposedly been discharged to their home. A search through the data system of the dispensary showed that none of these patients had actually been dispensed anything on discharge. An effort was made to find out the real place of discharge to for these patients, as there was obviously an error in the original source used to find this information. No effort to calculate how much time LS spent at the ward during the data collection period was made, as this was not one of the objectives of the study. LS had bedside teaching of Master of Science in pharmacy students during the normal working hours in the data collection period.

The inclusion period lasted from 11th of January until 27th of February when 100 patients had been admitted and care planned. The last included patient was discharged from the ward the 11th of April. Two patients were admitted during the inclusion period without being care planned. The clinical pharmacist saw them, but there was no record of what kind of pharmaceutical care they received and they were not included in the project. As the pharmacist saw both patients, the exclusion of these two patients would probably not influence the results of the audit of delivery of pharmaceutical care at the ward in any notable extent. Two patients were admitted twice during the inclusion period. The first patient was only discharged for six days before being readmitted. This patient was counted as one patient because the stay at home was short and the pharmacist continued on the same PMP. These two hospital stays can be considered one episode of care. The second patient was home for almost a month before being readmitted. This was considered two episodes of care, and the patient was counted as two patients.

The data from the 100 included patients will provide a good description of the pharmaceutical care delivered at Ward 18/19 in the study period.

The researcher read all of the collected care plans to identify care issues. LS helped the researcher to understand indistinct handwriting and ambiguous shorthand. Clinical interpretation of care issues where either the outcome or the background of the care issue was hard to understand was also sought from LS. The researcher had to contact LS for all except two care plans to clarify either handwriting or clinical interpretation.

4.4.1 Description of included patients

The most common presenting complaints among the patients were confusion, shortness of breath, falls and pain, see table 14. The presenting complaints are usually exacerbation of a chronic disease, for instance shortness of breath due to worsening of the patient's COPD, symptoms of an acute disease, for instance confusion as a symptom of urinary tract infection or consequences of an incidence, for instance pain as a result of a fall. Many of the patients presented with a combination of different symptoms, and these form the basis for the investigations and treatment that are initiated at the hospital.

The most common chronic medical conditions of the included patients were hypertension, chronic obstructive pulmonary disease (COPD), previous stroke or cerebral vascular accident (CVA) and Ischemic heart disease, previous myocardial infarct (MI) or angina, see table 14. These are common diseases in the general public and most have increased prevalence among the older population in Scotland.[60] Both common presenting complaints and common chronic conditions will affect the requirements of knowledge of the clinical pharmacist at a hospital ward.

The pharmacist at Ward 18/19 takes the drug history of new patients if this is not already done by a pharmacist at another ward in the hospital. This can be time consuming, but it's an important contribution to avoid errors in the continuity of care between primary and secondary care. As seen in table 14 the pharmacist used a total of 154 drug history sources to take the drug history of the included patients, and in over 40 % of the instances more than one source was used. The pharmacist did the drug history for 66 % of the patients. The average number of drugs on admission per patient was high at the ward, with a mean (SD) of 8.3 (3.4), as seen in table 16. Taking the drug history would probably require a lot of the pharmacist's time. Almost 90 % of the patients used more than four regular drugs on admission. Taking more than four drugs is a normal indication of risk of drug related problems, but a recent study has shown that the number of drugs a patient has on admission is directly correlated to the number of drug related problems, and that no real cut-off value can be determined.[61]

Table 14 Patient characteristics for the 100 included patients

Characteristic	Prevalence
Presenting Complaints	
Confusion	26.0 %
Shortness of breath	25.0 %
Fall	21.0 %
Pain	18.0 %
Most prevalent Chronic Diseases	
Hypertension	39.0 %
Ischemic heart disease/angina/MI	36.0 %
COPD	27.0 %
Stroke/CVA	24.0 %
Place of Discharge to	
Primary Care	72.0 %
Secondary Care	18.0 %
Died	10.0 %
Most common drug history sources	
Total number of drug history sources = 154	
Discharge letter	8.4 %
Patient	11.0 %
GP	15.6 %
GP letter	18.8 %
Notes	27.9 %
Other	18.2 %
Number of Drug History Sources Used	
1 source	59.0 %
2 sources	30.0 %
3 sources	9.0 %
4 sources	2.0 %

Key: COPD: Chronic obstructive pulmonary disease, MI: Myocardial infarct, CVA: Cerebral vascular accident

There was an even distribution of gender in the included patients, with 49 % females. The mean (SD) age of the included patients was 80.9 (7.1) years, as seen in table 15. This is quite a high mean, with a small standard deviation, as would be expected at a Care of the Elderly ward. The mean LOS in the ward is 14 days. The high standard deviation implies large differences in LOS between the patients; the wide range, from 2 to 74 days, supports this assumption, and the

median of 11 days would probably be a better measure for the central tendency description of the length of stay.

Table 15 Patient characteristics and pharmaceutical care activity

Parameter (per patient) (n = 100)	**Mean (SD)**	**95 % Confidence Interval**	**Median (IQR)**	**Range**
Age	80.9 (7.1)	(79.5, 82.3)	80 (76, 86)	82-98
Length of Stay	14.3 (11.8)	(11.9, 16.6)	11 (7, 16)	2-74
Number of diagnoses	4.2 (2.1)	(3.7, 4.6)	4 (2.8, 5)	1-14
Number of drugs on admission	8.3 (3.4)	(7.6, 9.0)	8.5 (6, 11)	2-18
Total care issues	9.7 (5.5)	(8.6, 10.8)	9 (6, 12)	1-32
Care issues not categorised	3.6 (2.9)	(3.1, 4.2)	3 (2, 5)	0-15
Checks	6.4 (3.4)	(5.7, 7.1)	6 (4, 8)	0-17
Changes in Drug Therapy Processes	1.9 (2.4)	(1.4, 2.4)	1 (0, 3)	0-13
Changes in Drug Therapy	1.4 (1.6)	(1.1, 1.8)	1 (0, 2)	0-8

Key SD= Standard Deviation; IQR= Inter Quartile Range, Number of drugs on admission: Not including as required medication.

4.4.2 Description of pharmaceutical care through categorisation of care issues

Evaluation of the care plans for the 100 included patients identified a total of 972 care issues. Of these 65.8 % were categorised as ‘Checks’, 19.3 % as ‘Changes in Drug Therapy Problems’ and the resulting 14.8 % were categorised as ‘Changes in Drug Therapy’, as seen in table 16. This gave an average (median) of 9.7 (9) care issues per patient. The range of care issues per patient was 1 to 32. This highlights the big difference in delivery of pharmaceutical care to

individual patients; some have many care issues that need to be resolved, while others don't. The big difference in number of care issues per patient might also be a result of the big differences in length of stay and number of chronic diseases per patient, as seen above.

Table 16 Pharmaceutical care issue distribution in main categories

Main categories (n=972)	**Number**	**%**
Checks	640	65.8 %
Changes in Drug Therapy Processes	188	19.3 %
Changes in Drug Therapy	144	14.8 %
Total	**972**	**100 %**

The number of care issues per patient in the main categories can be assumed to be normal distributed as the means and medians are quite close together. Averages of 3.6 care issues per patient were not categorised. These are care issues identified by the pharmacist that either weren't resolved, or that were resolved, but where the outcome was never documented.

Checks

Safety inquiries are the most common checks in Ward 18/19, where 40.8 % of the checks are of this type, as seen in table 17. The least common subcategory of checks is compliance inquiries, which make up 14 % of the total number of care issues categorised as checks. Even though this is the smallest subcategory this is probably a quite high proportion compared to other wards, because it is limited how many compliance inquiries it is possible to make per patient.

The Time Perspective subcategories describe at what time during a patient's treatment feedback loop a care issue is identified. As seen by table 17, almost 46 % of the checks are 'Verifications'. In a hospital setting this are checks that are done either at the first meeting between the pharmacist and the patient, usually during the first days after the patient's admission, or they are done to ensure safety and effect when a new drug therapy is started. The largest subcategories of 'Checks' at this point of time are the 'Safety inquiry' and 'Compliance inquiry', which constitute 15.5 and 12.8 % of the total number of checks respectively. Almost all of the 'Compliance inquiries' are done as a

'Verification' action, most of these involve checks performed by the pharmacist immediately after admission to ensure that the patient has appropriate arrangements to manage the medicines at home.

Table 17 Distribution of 'Check' in subcategories and 'Time Perspective'.

	TIME PERSPECTIVE			
CHECKS (n=640)	**Verification** n (%)	**Monitoring** n (%)	**Confirmation** n (%)	**Total** n (%)
Medication need inquiry	58 (9,1 %)	54 (8,4 %)	59 (9,2 %)	171 (26.7 %)
Effectiveness inquiry	55 (8,6 %)	64 (10,0 %)	0 (0,0 %)	119 (18.6 %)
Safety inquiry	99 (15,5 %)	160 (25,0 %)	2 (0,3 %)	261 (40.8 %)
Compliance inquiry	82 (12,8 %)	5 (0,8 %)	2 (0,3 %)	89 (13.9 %)
Total	294 (45,9 %)	283 (44,2 %)	63 (9,8 %)	640 (100.0 %)

Around 44 % of the check are categorised as 'Monitoring', which means they are performed during the delivery of the patients' treatment. These checks are monitoring actions performed to ensure effective and safe treatment of the patient during the patient stay at the hospital. The largest subcategory of checks in the monitoring phase is 'Safety inquiry', which makes up 25 % of the total 'Checks' and 61.3% of the 'Checks' performed during the monitoring phase. This was followed by 'Effectiveness inquiry', which make up 10 % of the total 'Checks'.

Only around 10 % of the checks are 'Confirmations', and of the confirmations are 'Medication needs inquiries' the biggest subcategory. 'Medication needs inquiries' constitute 9.2 % of the total 'Checks' and hence over 90 % of the 'Checks' performed as a 'Confirmation' of the patient's drug treatment. These care issues are mainly confirmation that short-term therapy is stopped when not needed anymore.

Change in Drug Therapy Process

The distribution of care issues categorised as 'Changes in Drug Therapy Processes' were uneven, with three of five subcategories contributing to over 95 % of the total care issues in this category, as seen in table 18. 'Clinical (shared) record of drug history' was the largest subcategory, 120 of the care issues were in this category, which is over 10 % of the total 972 care issues. These care issues were identified after taking drug history, and involved identification an error in the prescription of a drug that resulted in a change back to the pre-admission regimen.

Table 18 Distribution of 'Change in Drug Therapy Process' in subcategories and 'Time Perspective'

	TIME PERSPECTIVE			
CHANGES IN DRUG THERAPY PROCESS (n=188)	**Verification** n (%)	**Monitoring** n (%)	**Confirmation** n (%)	**Total** n (%)
Clinical (shared) record of patient characteristics	4 (2.1 %)	0 (0.0 %)	0 (0.0 %)	4 (2.1 %)
Clinical (shared) record of drug history	117 (62.2 %)	3 (1.6 %)	0 (0.0 %)	120 (63.8 %)
Continuity of information/care between clinical settings	0 (0.0 %)	42 (22.3 %)	0 (0.0 %)	42 (22.3 %)
Level of patient monitoring	6 (3.2 %)	13 (6.9 %)	0 (0.0 %)	19 (10.1 %)
Health care team member(s) information /education	2 (1.1 %)	1 (0.5 %)	0 (0.0 %)	3 (1.6 %)
TOTAL	129 (68.6 %)	59 (31.4 %)	0 (0.0 %)	188 (100.0 %)

None of the 'Changes in Drug Therapy Processes' were done at the confirmation stage in the feedback loop. This is a result of the nature of the care issues in this category; none of them can be a confirmation of the safety and effect of the patient's treatment. As seen by table 18, 68.6 % of the 'Changes in Drug Therapy

Process' were done as a 'Verification' of the patient's treatment. These were mainly changes to either record of patient characteristics or record of drug history, which were done at the first meeting between the pharmacist and the patient. 'Continuity of information/care between different clinical settings' was the largest subcategory during the monitoring phase, with 22.3 % of the 'Changes in Drug Therapy Processes' in this category. This is natural as continuity of care is something that is ensured during the patient treatment and the patient stay in the hospital, and is expected to be a large part of the pharmacist work on a Care of the Elderly ward. 'Level of patient monitoring' is done both during the 'Verification' (3.2%) and during the 'Monitoring' (6.9 %) stage. This means that the pharmacist identifies the need for improved patient monitoring both at the start of a new drug treatment, for instance when initiating a drug where therapeutic drug monitoring is needed, and as treatment continues, for instance due to the development of side effects where increased monitoring is needed.

Change in Drug Therapy

Only 144 (14.8 %) of the total 974 care issues were 'Changes in Drug Therapy', as can be seen in table 19. In this category is 'Stop drug temporarily/permanently' and 'Drug selection (starting new or changing drug)' the two largest subcategories; they constitute 25.7 % and 21.5 % of the care issues in this category respectively. None of the 'Changes in Drug Therapy' were categorised as 'Duration'.

Of the 'Changes in Drug Therapy' 75.7 % were done as a result of 'Verification' actions. The most frequent changes at this point in the patients' treatment feedback loop were stopping of a drug (20.8 %), starting or changing a drug (18.1 %) or changes to the patient's dose (16.0 %). Only 20.1 % of the changes were done as a result of 'Monitoring' of the patient during the delivery of treatment, and of these did 'Patient or Carer Level of Education (Understanding/Compliance' constitute over 50 %. Only 4.2 % of the 'Changes in Drug Therapy' was done as confirmation actions, and all of these involved stopping of a drug. The need to stop a drug was either due to accomplishment of the treatment goal for a short-term therapy where the drug was no longer needed, or the drug had to be stopped because of intolerable adverse drug reactions.

Table 19 Distribution of 'Changes in Drug Therapy' in subcategories and 'Time Perspective'

CHANGES IN DRUG THERAPY (n = 144)	TIME PERSPECTIVE			Total
	Verification	Monitoring	Confirmation	
	n (%)	n (%)	n (%)	n (%)
Drug selection (starting new/ changing drug)	26 (18.1 %)	5 (3.5 %)	0 (0.0 %)	31 (21.5 %)
Dose	23 (16.0 %)	4 (2.8 %)	0 (0.0 %)	27 (18.8 %)
Route/dose form	5 (3.5 %)	0 (0.0 %)	0 (0.0 %)	5 (3.5 %)
Dose interval/timing	18 (12.5 %)	0 (0.0 %)	0 (0.0 %)	18 (12.5 %)
Duration	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Stop drug (temporarily/ permanently)	30 (20.8 %)	1 (0.7 %)	6 (4.2 %)	37 (25.7 %)
Patient or Carer Level of Education (Understanding /Compliance)	7 (4.9 %)	19 (13.2 %)	0 (0.0 %)	26 (18.1 %)
Total	109 (75.7 %)	29 (20.1 %)	6 (4.2 %)	144 (100.0 %)

In order to get the full clinical picture of the care issues categorised as 'Change in Drug Therapy' the subcategories need to be combined with the 'Drug Therapy Problems' subcategories. This opens for many possible combinations of categories, as seen in table 20. The most frequent combinations are patient/carer counselling due to identified or risk for inappropriate compliance (18.1 %), starting of new drug due to need for additional drug (16.7 %) and stopping of drug as a result of unnecessary drug therapy (12.5 %). Changes in dose were also among the most common; 14.6 % of the 'Change in Drug Therapy' involved reduction of dose, either through total dose reduction (12.5 %) or by increasing the dosing interval (2.1 %). Care issues concerning too low dose constituted 13.2 % of the 'Change in drug therapy', and these issues were resolved through an increase the total dose directly (6.3 %) or by reducing the dosing interval (6.9 %). In sum, 27.2 % of the 'Changes in Drug Therapy' involved a change of dose.

Table 20 Distribution of care issues in the combination of 'Change in Drug Therapy' and 'Drug Therapy Problem' categories

	n (%)	DRUG THERAPY PROBLEMS (n = 144)							
		Unnecessary drug therapy	**Need for additional drug therapy**	**Ineffective drug**	**Dosage too low**	**ADR**	**Dosage too high**	**Inappropriate compliance**	**Unclassified**
CHANGES IN DRUG THERAPY	Drug selection (starting new or changing drug)	0 (0.0 %)	24 (16.7 %)	2 (1.4 %)	0 (0.0 %)	4 (2.8 %)	0 (0.0 %)	0 (0.0 %)	1 (0.7 %)
	Dose	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	9 (6.3 %)	0 (0.0 %)	18 (12.5 %)	0 (0.0 %)	0 (0.0 %)
	Route/dose form	0 (0.0 %)	0 (0.0 %)	2 (1.4 %)	0 (0.0 %)	2 (1.4 %)	0 (0.0 %)	0 (0.0 %)	1 (0.7 %)
	Dose interval/timing	0 (0.0 %)	0 (0.0 %)	2 (1.4 %)	10 (6.9 %)	3 (2.1 %)	3 (2.1 %)	0 (0.0 %)	0 (0.0 %)
	Duration	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
	Stop drug temporarily/permanently	18 (12.5 %)	0 (0.0 %)	2 (1.4 %)	0 (0.0 %)	10 (6.9 %)	3 (2.1 %)	0 (0.0 %)	4 (2.8 %)
	Patient or Carer Level of Education (Understanding/Compliance)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	26 (18.1 %)	0 (0.0 %)
Total		18 (12.5 %)	24 (16.7 %)	8 (5.6 %)	19 (13.2 %)	19 (13.2 %)	24 (16.7 %)	26 (18.1 %)	6 (4.2 %)

'Inappropriate compliance' (18.1 %), 'Adverse drug reaction' (16.7 %) and 'Need for additional drug' (16.7 %) were the largest subcategories when looking at the 'Drug Therapy Problems' subcategories separately, as seen in table 20. Six (4.2 %) of the 'Changes in Drug Therapy' involved non-adherence with local or national formulary.

Table 21 Distribution of 'Changes in Drug Therapy' in subcategories and 'Degree of Change'

CHANGES IN DRUG THERAPY (n = 144)	DEGREE OF CHANGE			Total
	Adjustment	Modification	Review	
	n (%)	n (%)	n (%)	n (%)
Drug selection (starting new/ changing drug)	29 (20.1 %)	2 (1.4 %)	0 (0.0 %)	31 (21.5 %)
Dose	27 (18.8 %)	0 (0.0 %)	0 (0.0 %)	27 (18.8 %)
Route/dose form	5 (3.5 %)	0 (0.0 %)	0 (0.0 %)	5 (3.5 %)
Dose interval/timing	18 (12.5 %)	0 (0.0 %)	0 (0.0 %)	18 (12.5 %)
Duration	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Stop drug (temporarily/ permanently)	23 (16.0 %)	12 (8.3 %)	2 (1.4 %)	37 (25.7 %)
Patient or Carer Level of Education (Understanding /Compliance)	26 (18.1 %)	0 (0.0 %)	0 (0.0 %)	26 (18.1 %)
Total	128 (88.9 %)	14 (9.7 %)	2 (1.4 %)	144 (100.0 %)

The category 'Degree of Change' describes in what degree the outcome of a change in drug therapy could be expected in relation to the patient's treatment plan. In Ward 18/19 nearly all of the 'Change in Drug Therapy' were 'Adjustment' (88.9 %) and hence expected inside the limits of the patient's treatment plan, as seen in table 21. For changes not expected according to the treatment plan there were 9.7 % 'Modifications', and only 1.4 % 'Reviews'. All of the 'Review' and nearly all of the 'Modifications' care issues involved stopping of a drug, the rest of the 'Modification' involved start of a new drug.

Table 22 'Degree of Change' coupled to 'Time Perspective'

	DEGREE OF CHANGE (n = 144)		
	Adjustment	**Modification**	**Review**
TIME PERSPECTIVE	n (%)	n (%)	n (%)
Verification	99 (68.8 %)	10 (6.9 %)	N/A
Monitoring	29 (20.1 %)	N/A	N/A
Confirmation	N/A	4 (2.8 %)	2 (1.4 %)
Total	128 (88.9 %)	14 (9.7 %)	2 (1.4 %)

Key: N/A: Not applicable according to the quality assurance feedback loop.

The care issues categorised as 'Change in Drug Therapy' can also be described according to the combination of the 'Time Perspective' and the 'Degree of Change' subcategories, as seen in table 22. In the 'Verification' stage in the delivery of the patients' treatment plan about 90 % of the changes were 'Adjustments', while around 10 % were 'Modifications'. Only six 'Change in Drug Therapy' were done as a result of 'Confirmation' of the patients' drug therapy, two of these care issues included a request made to the prescriber to review the patient's treatment, the rest were 'Modifications' of the patient's treatment.

The combination of 'Time Perspective' and 'Degree of Change' can be connected to the Quality Assurance Feedback Loop, as seen in figure 5. This visualises the 'Changes in Drug Therapy' according to where in the Quality Assurance Feedback loop they arise and the extent of the change of the outcome.

Pharmaceutical Care Profile Distribution of Changes		n (%)
1	Adjust an initial design	99 (68.8 %)
2	Modify an initial design	10 (6.9 %)
3	Adjust during monitoring	29 (20.1 %)
4	Modify after evaluation	4 (2.8 %)
5	Review after evaluation	2 (1.4 %)

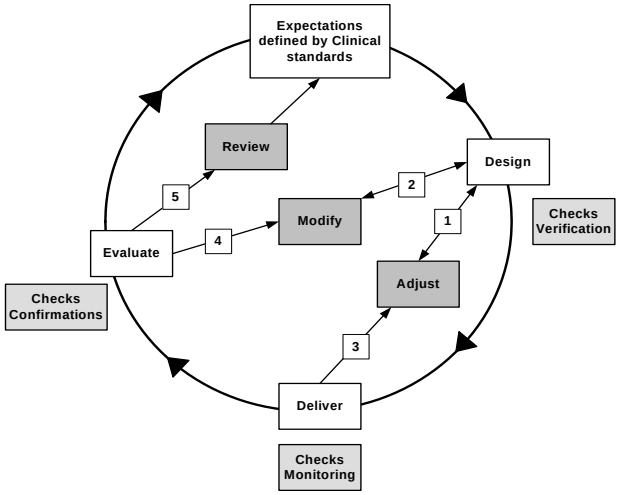


Figure 5 Connection between Quality Assurance Descriptors and the feedback loop

Quality Assurance Descriptors

When categorising and describing care issues according to where in the patients' quality assurance feedback loop they arise, it can be interesting to compare the proportion of different outcomes of the identified care issues at each stage during the delivery of pharmaceutical care.

Table 23 Main categories distributed according to 'Time Perspective' subcategories

	Main categories	Number	Proportion (%)
Verification	**Check**	294	55.3 %
	Change in Drug Therapy Process	129	24.2 %
	Change in Drug Therapy	109	20.5 %
	Total	**532**	**100.0 %**
Monitoring	**Check**	283	76.3 %
	Change in Drug Therapy Process	59	15.9 %
	Change in Drug Therapy	29	7.8 %
	Total	**371**	**100.0 %**
Confirmation	**Check**	63	91.3 %
	Change in Drug Therapy Process	0	0.0 %
	Change in Drug Therapy	6	8.7 %
	Total	**69**	**100.0 %**

As can be seen in table 23, 532 care issues were identified at the 'Verification' stage. Over 50 % of these were 'Checks', and the rest was even distributed between 'Changes in Drug Therapy Processes' (24.2 %) and 'Change in Drug Therapy' (20.5 %). This means that when the pharmacist first sees the patient or when a new drug therapy is started almost half of the identified care issues lead to a change, either to the patient's drug therapy or to the processes of the patient treatment.

During the delivery of the patient treatment at the hospital, at the 'Monitoring' phase in the quality assurance feedback loop, 76.3 % of the 371 care issues were 'Checks' and only 7.8 % were 'Change in Drug Therapy'. Of the 29 'Change in Drug Therapy', 19 (65.6 %) were care issues concerning patient compliance or education as seen in table 23. So even though the pharmacist at Ward 18/19 identifies a great need for monitoring of the patient's treatment, few of these monitoring actions result in changes to the patient drug therapy.

Only 69 of the total of 974 were care issues identified at the evaluation or 'Confirmation' stage of the delivery of the patients' treatment, 91.3 % were 'Checks', the rest were 'Changes in Drug Therapy'. This means that the pharmacist most of the time just makes sure that a drug therapy is stopped, either when effect is achieved and it is not needed anymore, or when the patient experiences an intolerable adverse drug reaction, as opposed to the pharmacist actively recommends stopping the drug therapy.

Recommendations and interactions

The researcher wanted to quantify how many recommendations the pharmacist made to the prescriber, and what proportion of the recommendations that were acted upon by the prescriber. As can be seen in table 24, 289 of the care issues involved a recommendation made by the pharmacist and of these, 17.3 % were not acted upon. There can be many reasons that a recommendation made by the pharmacist is not acted upon, for instance can new clinical data make another choice the most suitable for the patient. Over 40 % of the recommendations involved recommendations to 'Change Drug Therapy Process', this mainly

involved prescription of drugs omitted on admission. The rest of the recommendations led to a change of the patient's drug therapy.

Table 24 Recommendations made by the pharmacist to the prescriber

	Recommendations n (%)
Checks	50 (17.3 %)
Change in Drug Therapy Process	121 (41.9 %)
Change in Drug Therapy	118 (40.8 %)
Total	289 (100.0 %)

The researcher also wanted to quantify the number of care issues that involved an interaction, either a screening of drugs because the patient was on a drug known to contribute to many interactions or an identified interaction. Of the 972 care issues only 28 involved an interaction, this is 2.9 % of the total care issues.

4.4.3 Quantitative comparison of the delivery of pharmaceutical care between two clinical settings

One of the aims of this study was to compare two clinical settings in terms of the profile of pharmaceutical care delivered. The delivery of pharmaceutical care at the Care of the Elderly ward, referred to as Ward B, was statistically compared with a General Medical ward at the same hospital, referred to as Ward A. The audit of delivery of pharmaceutical care was performed simultaneously at the two wards, and both studies included 100 patients. One clinical pharmacist delivered the pharmaceutical care at Ward A during the study period. The pharmacists at Ward A and B both cover their ward for approximately the same number of hours during the week. The comparison of the wards focused on patient characteristics, delivery of pharmaceutical care per patient and on the total pharmaceutical care activity as seen through distribution of care issues in different categories. The study on Ward A was performed by MBC, and the results were calculated by KJH and MBC in cooperation. KJH and MBC will be referred to as the investigators in

this section. KJH shadowed the pharmacist at Ward A together with MBC prior to the study period in order to get familiarised with the clinical setting.

Table 25 Comparison of Patient Characteristics and Pharmaceutical care activity

	Ward A			Ward B			
Parameter (per patient) (n = 100)	**Mean (CI)**	**Median (IQR)**	**Range**	**Mean (CI)**	**Median (IQR)**	**Range**	**p-value (t-test)**
Age	64.1 (61.2, 66.9)	66 (54, 74)	26-98	80.9 (79.5, 82.3)	80 (76, 86)	82-98	p < 0.001
Length of Stay	11.8 (9.7, 13.9)	8 (5, 14)	1-53	14.3 (11.9, 16.6)	11 (7, 16)	2-74	p = 0.12
Number of diagnoses	2.0 (1.8, 2.3)	2 (1, 3)	0-6	4.2 (3.7, 4.6)	4 (2.8, 5)	1-14	p < 0.001
Total care issues	3.6 (3.0, 4.2)	3 (1, 5)	0-17	9.7 (8.6, 10.8)	9 (6, 12)	1-32	p < 0.001
Care issues not categorised	0.5 (0.4, 0.7)	0 (0, 1)	0-3	3.6 (3.1, 4.2)	3 (2, 5)	0-15	p < 0.001
Checks	1.8 (1.4, 2.1)	1 (0, 2)	0-11	6.4 (5.7, 7.1)	6 (4, 8)	0-17	p < 0.001
Changes in Drug Therapy Processes	0.3 (0.1, 0.4)	0 (0, 0)	0-3	1.9 (1.4, 2.4)	1 (0, 3)	0-13	p < 0.001
Changes in Drug Therapy	1.6 (1.2, 1.9)	1 (0, 2)	0-9	1.4 (1.1, 1.8)	1 (0, 2)	0-8	p = 0.64

Key CI = 95% Confidence Interval; IQR= Inter Quartile Range

All of the parameters compared in table 25, except 'Length of Stay', have similar means and medians. For the parameters with similar means and medians the data is assumed to have a normal distribution and a t-test would be suitable to statistically compare the means.

The comparison of patient characteristics between Ward A and B showed that the mean age at Ward A (64.1 years) was higher than mean age at Ward B (80.9 years). This is expected when comparing a ward that only admits patient over 65 years with a ward that is non-selective regarding age. The mean length of stay

was higher than the median length of stay on both wards; this indicates a skew of the data as a result of that some patients have a very long stay at the ward. The wide range and relative narrow inter quartile range at both wards confirm this. The t-test shows that the mean isn't different between the two wards, even though the mean of Ward A is outside the 95% confidence interval of Ward B, and the mean of Ward B is outside the 95% confidence interval of Ward A. This supports the assumption of non-normal distribution of the patients' length of stay. The number of diagnosis per patient is also different between the two wards, the patients at Ward A had a mean of 2.0 diagnosis and the patients at Ward B had a mean of 4.2 diagnosis. This is an expected difference when comparing two wards where the patient population have statistically different age. Ward A is an all male ward, as compared to Ward B where there the included patients had an even distribution between the genders.

The delivery of pharmaceutical care per patient between the two wards was statistical significant different for 'Total care issues', 'Care issues not categorised', 'Checks' and 'Change in Drug Therapy Process'. The biggest differences were seen with 'Total care issues' and 'Check'. The patients at Ward A had a mean of 3.6 care issues and of these were 1.8 care issues a 'Check', while the patients at Ward B had a of mean 9.7 care issues and of these were 6.4 a 'Check'. There was no difference in the number of 'Change in Drug Therapy' per patient.

A comparison of the distribution of care issues into different subcategories in the main categories was performed by using Fischer's exact test for 2x2 tables. The results are shown in table 26 and table 27.

The distribution of care issues differed between the wards in all main categories, as seen in table 26. The proportion of care issues in 'Checks' and 'Change in Drug Therapy Process' were higher in Ward B, while the proportion of care issues in 'Change in Drug Therapy' was higher in Ward A.

The distribution of care issues in subcategories of 'Checks' showed similar proportions in all subcategories except 'Compliance inquiry', where Ward B (13.9%) had a higher proportion than Ward A (3.4%). In 'Changes in Drug

Therapy Processes' Ward A had a higher proportion of 'Health care team member(s) information/education' (29.6 %) compared to Ward B (1.6 %). Ward B had a higher proportion of 'Clinical (shared) record of drug history' (63.8 %) when compared with Ward A (25.9%). The distribution of care issues in subcategories of 'Change in Drug Therapy' was not different between the two wards.

Table 26 Pharmaceutical Care Issues: Comparison of Ward Settings 1

	WARD A		WARD B		
	n	**% (95 % CI)**	**n**	**% (95 % CI)**	**p-value (Fischer's exact test)**
Checks	**177**	**49.3 % (44.2, 54.5)**	**640**	**65.8 % (62.8, 68.8)**	**p < 0.0001**
Medication need inquiry	60	33.9 % (27.3, 41.2)	171	26.7 % (23.4, 30.3)	p = 0.0729
Effectiveness inquiry	41	23.2 % (17.5, 29.9)	119	18.6 % (15.8, 21.8)	p = 0.1988
Safety inquiry	70	39.5 % (32.6, 46.9)	261	40.8 % (37.0, 44.6)	p = 0.7957
Compliance inquiry	6	3.4 % (1.4, 7.4)	89	13.9 % (11.4, 16.8)	p < 0.0001
Changes in Drug Therapy Processes	**27**	**7.5 % (5.2, 10.8)**	**188**	**19.3 % (17.0, 22.0)**	**p < 0.0001**
Clinical (shared) record of patient characteristics	2	7.4 % (1.0, 24.5)	4	2.1 % (0.6, 5.5)	p = 0.1658
Clinical (shared) record of drug history	7	25.9 % (12.9, 44.9)	120	63.8 % (56.7, 70.4)	p = 0.0003
Continuity of information/care between clinical settings	4	14.8 % (5.3, 33.1)	42	22.3 % (17.0, 28.8)	p = 0.4595
Level of patient monitoring	6	22.2 % (10.3, 41.1)	19	10.1 % (6.5, 15.3)	p = 0.1000
Health care team member(s) information/education	8	29.6 % (15.7, 48.7)	3	1.6 % (0.3, 4.8)	p < 0.0001
Changes in Drug Therapy	**155**	**43.2 % (38.2, 48.4)**	**144**	**14.8 % (12.7, 17.2)**	**p < 0.0001**
Drug selection (starting new or changing drug)	36	23.2% (17.2, 30.5)	31	21.5% (15.6, 29.0)	p = 0.7820
Dose	26	16.8% (11.7, 23.5)	27	18.8% (13.2, 26.0)	p = 0.7621
Route/dose-form	5	3.2% (1.2, 7.5)	5	3.5% (1.3, 8.1)	p = 1.0
Dose interval/timing	11	7.1% (3.9, 12.4)	18	12.5% (8.0, 19.0)	p = 0.1226
Duration	0	0.0 % (0.0, 2.9)	0	0.0 % (0.0, 3.1)	p = 1.00
Stop drug temporarily/permanently	55	35.5% (28.4, 43.3)	37	25.7% (19.2, 33.4)	p = 0.0792
Patient or carer level of education (Understanding/compliance)	22	14.2% (9.5, 20.6)	26	18.1% (12.6, 25.2)	p = 0.4311

Key: 95% CI: 95% Confidence interval

Table 27 Pharmaceutical Care Issues: Comparison of Ward Settings 2

	Ward A		Ward B		
	n	% (95% CI)	n	% (95% CI)	**p value (chi square)**
Checks					
Verification	59	28.8% (26.8, 40.6)	294	45.9 % (42.1, 49.8)	p = 0.0027
Monitoring	113	63.8% (56.5, 70.6)	283	44.2 % (40.4, 48.1)	p < 0.0001
Confirmation	5	2.8% (1.0, 6.6)	63	9.8 % (7.8, 12.4)	p = 0.0018
Total	177	100.0 %	640	100.0 %	
Changes in Drug Therapy Process					
Verification	10	37.0 % (21.5, 55.8)	129	68.6 % (61.7, 74.8)	p = 0.0022
Monitoring	17	63.0 % (44.2, 78.5)	59	31.4 % (25.2, 38.3)	p = 0.0022
Confirmation	0	0.0 % (0.0, 14.8)	0	0.0 % (0.0, 2.4)	p = 1.0
Total	27	100.0 %	188	100.0 %	
Changes in Drug Therapy					
Verification	47	30.3 % (23.6, 38.0)	109	75.7 % (68.1, 82.0)	p < 0.0001
Monitoring	92	59.4 % (51.5, 66.8)	29	20.1 % (14.4, 27.5)	p < 0.0001
Confirmation	16	10.3 % (6.4, 16.2)	6	4.2 % (1.7, 9.0)	P = 0.0474
Total	155	100.0 %	144	100.0 %	
Adjustment	132	85.2 % (78.7, 90.0)	128	88.9 % (82.6, 93.1)	p = 0.3919
Modification	23	14.8 % (10.0, 21.4)	14	9.7 % (5.8, 15.8)	p = 0.2192
Review	0	0.0 % (0.0, 2.9)	2	1.4 % (0.1, 5.2)	p = 0.2311
Total	155	100.0 %	144	100.0 %	

Key: 95% CI: 95% Confidence interval

The distribution of ‘Checks’ into the subcategories of ‘Time Perspective’ showed that the proportion of ‘Checks’ identified at the design or evaluation stage (‘Verifications’ and ‘Confirmations’) were higher in Ward B (45.9 %) than in Ward A (28.8 %), as seen in table 27. The proportion of ‘Checks’ identified during the patients’ treatment (‘Monitoring’) was higher in Ward A (63.8 %) than in Ward B (44.2 %). This shows that the pharmacist at Ward B perform a higher proportion of the checks at the first meeting with the patient or when a new drug therapy is started than the pharmacist at Ward A, while the pharmacist at Ward A perform a higher proportion of checks during the patients treatment. Ward B had a higher proportion of ‘Confirmation’ (9.8 %) than Ward A (2.8 %).

The distribution of ‘Changes in Drug Therapy Process’ in subcategories of ‘Time Perspective’ shows that neither of the wards had any ‘Confirmations’. A higher proportion of ‘Verification’ was seen at Ward B when compared with Ward A, this was mainly due to the large number of ‘Clinical (shared) record of drug history’ at Ward B, as most of these would be identified at the first meeting between the pharmacist and the patient. Ward A had a higher proportion of ‘Monitoring’ than Ward B, and this was mainly a result of identified need of improved patient monitoring or of information to other members of the health care team during the patients’ treatment.

The distribution of ‘Changes in Drug Therapy’ in subcategories of ‘Time Perspective’ showed that the proportion of ‘Verification’ was higher in Ward B (75.7 %) than in Ward A (30.0 %), while the proportion of ‘Monitoring’ was higher in Ward A (59.4 %) than in Ward B (20.1 %). The proportion of ‘Confirmation’ was higher in Ward A (10.3 %) than in Ward B (4.2 %).

The distribution of ‘Changes in Drug Therapy’ in subcategories of ‘Degree of Change’ showed no difference between the two wards.

4.5 Inter-rater reliability test

Calculating Cohen's kappa for the categorisation of 100 care issues assessed the inter-rater agreement between MBC and KJH. The raters chose to randomly select 50 care issues among each of the raters care-issues instead of choosing care issues with a even distribution between the different categories. This was done in order to ensure that rater number two didn't know anything about the categorisation made by rater number one, and hence avoid rater number two trying to adjust the categorisation of the care issues to fit a certain pattern. As a consequence of this the distribution of care issues among the different categories was random and not very even, as seen in table 28. This table shows the categorisation performed by the rater the care issues was collected from, so each of the raters has categorised 50 of these care issues. The tables showing the results from the inter-rater reliability testing is presented in tables in Appendix III.

Table 28 Distribution of care issues for inter-rater reliability testing

		Time Perspective			
		Verification	**Monitoring**	**Confirmation**	**Total**
Checks		26	34	3	63
Changes in Drug Therapy Process		7	4	0	11
Changes in Drug Therapy	**Adjustment**	6	17		23
	Modification	0		3	3
	Prompt a review			0	0
Total		40	54	6	**100**

The raters only disagreed on the main category of one of the hundred care issues. This gave a Cohen's kappa of 0.96, which is ranged as very good inter-rater agreement, as seen in table 29. This is as expected because as long as the rater knows the background and the outcome of the care issue, the assignment into the main categories is mostly straightforward with little need of clinical judgement.

Table 29 Results from inter-rater reliability testing

Parameters	Main categories	Main categories w/ subcategories	Check subcategories	Time Perspective	Degree of Change
P_o	0.99	0.96	0.95	0.85	1.00
P_e	0.48	0.15	0.33	0.47	0.80
κ	0.96	0.95	0.93	0.72	1.00
SE(κ)	0.019	0.023	0.041	0.067	0.0
95 % CI	0.94 - 1.02	0.91 – 1.00	0.85 – 1.01	0.58 – 0.85	-
Strength of agreement	Very good	Very good	Very good	Good	Very good

When assessing the main categories with subcategories the raters disagreed on the subcategory for three of the checks, in addition to the previous mentioned disagreement on the main category. This gave a Cohen's kappa of 0.95, which is rated as very good inter-rater agreement. The Cohen's kappa for the care issues both raters agreed on were 'Checks' were calculated separately in order to see if the inter-rater agreement were substantially lower in this main category, compared to the overall Cohen's kappa for all the main categories with subcategories. This Cohen's kappa were calculated to 0.93 with a 95 % confidence interval of 0.85 – 1.01. This is also rated as very good inter-rater agreement.

The Cohen's kappa for 'Time Perspective' was calculated to be 0.72, which is rated as good inter-rater agreement. The 95 % confidence interval is broad (0.59 – 0.85), and extends from moderate to very good inter-rater agreement. The raters disagreed on the 'Time Perspective' of 15 of the 100 care issues. After evaluation of the care issues the raters disagreed on it were found that eight were 'Checks' and seven were 'Changes in Drug Therapy', none were 'Changes in Drug Therapy Processes'. This gave an observed agreement in 'Time Perspective' of 87.1 % (8 disagreements of total 62 'Checks') for 'Checks' and 73.1 % (7 disagreements for the total 26 'Change in Drug Therapy') for 'Change in Drug Therapy'. This gave a observed agreement of 80.5 % for the total changes ('Change in Drug Therapy Process' and 'Change in Drug Therapy'). The reasons for disagreement in the categorisation were misunderstandings (the

background of the care issue had not been described thoroughly enough), different interpretation of the 'Time Perspective' when results for a test was needed before review of changes in drug therapy could be performed or care issues that only involved monitoring for a need for drug without any drugs involved at the time.

The raters agreed on the categorisation of all care issues categorised in to 'Degree of Change', hence the Cohen's kappa for 'Degree of Change' was calculated to be 1.00. The distribution of care issues according to the different subcategories of 'Degree of Change' were skewed, with 23 of the 26 'Changes in Drug Therapy' categorised as 'Adjustments'. The remaining three 'Degree of Change' were categorised as 'Modification', and none were of the subcategory 'Review'.

A Cohen's kappa over 0.60 for all parts of the system that were tested means that the inter-rater agreement in the system in total are good, and that a comparison between the categorisation data from Ward 18/19 and from the General Medicines ward can be carried out.

4.6 Comparison of prescription activity

The prescription survey performed at Ward A and B had an earlier deadline than the audit of the delivery of pharmaceutical care. As a result six patients that were included in the audit were not included in the prescription survey (three at each ward), because they were still in the ward when the prescription survey had to finish the data collection. Even though the prescription survey and the audit of delivery of pharmaceutical care didn't include exactly the same patients the numbers from the prescription survey can be used in the combined comparison of prescription activity and the delivery of pharmaceutical care between the two wards. The studied prescription parameters are described in table 30.

Table 30 Description of studied prescription turnover parameters

Parameter	Description
Medicines courses prescribed	Number of medicine courses the patient was administered during the patient stay. A medicine is counted as one medicines course irrespective of how many times it is dosed per day. A change in dose or route of administration is counted as a prescription of a new medicine course.
Course-days (days)	Sum of the duration of all the patient's medicine courses (during the hospital stay)
Prescription courses active daily	The average number of prescriptions active daily. Calculated by dividing Course-days by length of stay.
Mean duration of prescriptions (days)	The patient's course-days divided by number of medicine courses prescribed.
Medicines courses discontinued	Number of medicine courses discontinued during the patient stay. Includes medicine courses not prescribed on admission that patient used at home. A change in dose is also counted as discontinuation of a drug.
Medicines courses started	Number of medicine courses started during the patient stay. A change in dose is also counted as starting a new drug.
Medicine course changes	The sum of medicines courses discontinued and the medicine courses started during the patient stay.
Medicine courses on admission	The sum of medicines the patient received on admission (i.e. the first day in the hospital)
Medicine courses on discharge	The sum of medicines courses the patient received at discharge (i.e. number of medicines courses on the discharge prescription).
Medicine courses on admission and discharge	The sum of the medicines courses on admission and the medicine courses on discharge.
External prescribing turnover (/day)	Medicine courses on admission and discharge divided by number of course-days.
Internal prescribing turnover (/day)	Rate of change in the medicines during the stay. Calculated by dividing medicine course changes by number of course-days.
Total prescribing turnover (/day)	The overall rate of changes of medicines. Calculated by adding the internal and external prescription turnover.
Prescribing actions within the stay as a proportion of all actions	Internal prescribing turnover divided by total prescribing turnover.
Numbers of courses needed to monitor per change	Mean number of medicines courses divided by total changes initiated by the pharmacist.

The prescription activity per patient at Ward A was compared with Ward B as part of the prescribing survey. The differences between the wards were determined statistical significant if the mean value for both wards were outside the 95% confidence interval for the other ward. Three prescription parameters were found to be significant different between the two wards; the number of medicine courses, the number of drugs on discharge and the number of course-days, as seen by table 31. The average course-days per patient are directly dependent on the average number of medicines courses. The patients' exposure to changes in medication as described through the prescription turnover (both internal and total) was not different between the two wards. This means that the patients' experienced the same degree of changes in proportion to total-course days at both wards. The numbers for prescriptions active daily per patient is also very similar at the two wards, but a statistical analysis could not be performed for this parameter because the patient specific data was not available.

The data from the audit of pharmaceutical care activity can be described and discussed more thoroughly when combined with the data from the prescription survey. In order to get the data from the audit of pharmaceutical care to fit in with the system of prescribing activity the total number of changes per patient were calculated by summing the 'Changes in Drug Therapy Processes' and the 'Changes in Drug Therapy'. This parameter was different between the two wards. The number of courses needed to monitor per change was 6.6 at Ward A and 4.6 at Ward B.

Table 31 Comparison of prescription and pharmaceutical care activity

	Ward A		Ward B	
	Mean (CI)	**Median (IQR)**	**Mean (CI)**	**Median (IQR)**
Length of stay (days) **(n=97)**	11.3 (9.4, 13.2)	8 (5, 15)	13.2 (11.5, 14.9)	11 (7, 17)
Length of stay (days) **(n=100)**	11.8 (9.7, 13.9)	8 (5, 14)	14.3 (11.9, 16.6)	11 (7, 16)
Total medicines courses (course)	11.9* (10.7, 13.1)	11 (7, 16)	15.3* (14.05, 16.5)	15 (11, 18.5)
Total course-days (course-days)	99.4* (79.7, 119.1)	68 (28, 149)	119.5* (99.6, 139.3)	91 (55, 192)
Prescriptions active daily (courses)	8.8		9.1	
Mean duration of prescription (days)	7.0 (6.1, 7.9)	7 (6, 8)	7.4 (6.6, 8.2)	6.5 (4.4, 9.5)
Medicines courses at discharge	7.4* (6.5, 8.3)	7 (4, 11)	9.0* (8.3, 9.6)	9 (6.5, 11)
Internal prescription turnover (/day)	0.16 (0.13, 0.19)	0.11 (0.63, 0.21)	0.14 (0.12, 0.15)	0.74 (0.11, 0.18)
Total prescription turnover (/day)	0.39 (0.34, 0.45)	0.35 (0.21, 0.50)	0.35 (0.31, 0.39)	0.31 (0.20, 0.46)
Prescribing actions within the stay as a proportion of all actions	41.0%		40.0%	
Care issues (per patient)	3.6* (3.0, 4.2)	3 (1, 5)	9.7* (8.6, 10.8)	9 (6, 12)
Checks (per patient)	1.8* (1.4, 2.1)	1 (0, 2)	6.4* (5.7, 7.1)	6 (4, 8.5)
Changes (total) (per patient)	1.8* (1.4, 2.2)	1 (0, 3)	3.3* (2.7, 4.0)	2 (1, 5)
Number of courses needed to monitor per change (courses/change)	6.6		4.6	

Key * Significantly different ($p<0.05$), CI: 95% Confidence interval, IQR: Inter Quartile Range

The prescription survey also described the prescribing at the ward according to the BNF categories, as seen in table 32. This parameter wasn't compared with Ward A.

Table 32 The most frequent prescribed medicines courses according to BNF category at Ward B

BNF Category	Number of medicines courses	%
Cardiovascular system (CVS)	461	31.1%
Central nervous system (CNS)	262	17.7%
Gastro-intestinal (GI) system	184	12.4%
Respiratory system	148	10.0%
Infections	144	9.7%
Others	284	19.2%
Total	1483	100.1 %

A total of 1483 medicines courses prescribed were prescribed for the 97 patients included in the prescription survey, 31.1 % were in the BNF category cardiovascular system. The second and third most prescribed BNF category were Central nervous system (17.7%) that include for example analgesia and sedatives, and Gastrointestinal system (12.4 %).

4.7 Focus Group

The general impression from the focus group was that all participants felt comfortable to share their view on the topics. All participants commented on most of the topics addressed during the meeting, even though some contributed more to the discussion than others. None of the moderators had any previous experience with focus group. PowerPoint was used as a way of directing the conversation, and this worked to a certain degree. It was easy to get the participants attention and to stop discussions that didn't relate directly to the topic of the focus group when changing the slide. Still it was obvious that the moderators could have been more proactive when asking direct questions, because some of the main questions remained uncommented. This might have

been a result of the dynamics between the moderators, who are students, and the participants, who are experienced pharmacists. All participants work in either secondary care or an academic institution, so the results from the focus group will not have generalisability to primary care.

Some of the focus group was (unnecessary) used to explain presented graphs and tables that were unclear to the participants. Another general problem during the presentation was confusion regarding the meaning of the various 'Quality Assurance Descriptors', and a lot of time was used to explain this part of the categorisation system.

The transcribing of the focus group turned out to be a time consuming process. The sound-quality on the tapes was low, and both participants and moderators mumbled and talked all at once in parts of the meeting. In addition there was general background noise and some loud coughing. This made it hard for the research group to transcribe. The research group decided not to transcribe the meeting fully, but focus on getting a comprehensive context with a more thoroughly transcription where the conversation was found to be most interesting. All members of the research group transcribed one part each.

4.7.1 General results form the focus group

One of the aims of the focus group was to find out if the guideline was understandable and useful, and if it explained the categorisation system in a meaningful way.

'It's not something you could start intuitively' (LS)

The general response from the participants was that the 'Check' and 'Change' part was easy to understand, as opposed to the 'Quality Assurance Descriptors'. Even after reading the guideline many times this part of the system wasn't clear for all the participants. Even the participants who have been working with the system earlier had problems understanding some of the changes the research

group had made to the system. The participants expressed a concern that this could lead to problems with inter-rater reliability.

The participants felt that the names of some of the categories were confusing, especially the names for the 'Quality Assurance Descriptor' categories. The main problem was that some of the categories have names that are the same as words the pharmacists' would use in their everyday language, but in the categorisation system they had a specified and sometimes slightly different meaning.

'Some of the language you use, there are lots of words that could mean the same thing, but are taken to mean different things.' (LS)

The research group wanted to focus the meeting around changes made to the system, and a systematic discussion of each part was performed.

Changes

The participants approved of the division of the 'Changes' category into two categories. Some of the participants questioned if all of the subcategories in 'Changes in Drug Therapy Process' in reality are changes. The main objections were towards the subcategory 'Health team member information/education', where the arguments were that this is something outside the drug therapy process and on the same time there were arguments that this *is* the drug therapy process. In general the participants didn't see this as a change. A proposal to change the name of the main category to a name that incorporated the real nature of care issues categorised in it was proposed to solve this problem. The name 'Contributions to Drug Therapy' was agreed on. This main category was to continue to be under the general heading of 'Changes' in order to avoid creating a completely new category.

One of the participants raised the question if the subcategory 'Patient/Carer level of education' was misplaced under the main category 'Changes in Drug Therapy'. An argument from one of the other participants was made that since this subcategory can be categorised as one of Cipolle and Strand's 'Drug Therapy Problem' it should be categorised as a 'Change in Drug Therapy'. This was agreed on by the other participants. One of the findings from the categorisation

was that none of the care issues were categorised in the subcategory ‘Duration’. The research group wanted to know if the participants could agree to remove this category, and that all care issues concerning duration rather were categorised as either stop or start drug therapy, or if they saw value in keeping it. The general view from the participants was to keep the category, but specify the definition of the three subcategories so it was clear which care issues to put where.

In the ‘Drug Therapy Problem’ category the research group had added the subcategory ‘Unclassified’, in order to capture changes in the patient’s drug therapy made to adhere to local or national formulary. The research group was insecure if this really is a care issue, as it is not patient specific. The participants all agreed on that this is an important contribution to the total health care, and that it should be categorised as a care issue. They underlined that it is something they spend a lot of time on doing. A suggestion was made to change the name of the subcategory to something more specific to avoid people just putting everything that don’t fit elsewhere into it. One of the participants that have used the system earlier had previously categorised this kind of care issues as ‘Ineffective drug therapy’, because it is ineffective to the total health care system. A suggestion to change the name of this subcategory to ‘Ineffective/Inappropriate drug therapy’ was made on this basis. On the other hand did some of the participants have objections to changing an already much used system. Nothing final came out of this discussion.

Time Perspective

Some of the participants found the name ‘Time Perspective’ a bit unfocused. The name should reflect the connection of the care issue to a place in the quality assurance feedback loop, rather than only connecting the care issue to the time aspect. There was a lot of confusion regarding this part of the categorisation system.

‘Verification…..which mean…….you lost me completely.’ (GJ)

The participants that had used the original system earlier were uncertain if the change of the system to a system where all of the care issues are categorised

into this category (as opposed to only the ‘Checks’), possibly had contributed to making the system less comprehensive.

‘I think you…probably…….making it more difficult for people…putting it here… This is very, very far from the ….original system.’ (SH)

A suggestion to change the names of the subcategories to ‘Design stage’, ‘Delivery stage’ and ‘Evaluation stage’ was made. This would avoid using everyday words that could mean different thing to different people, and at the same time the names would describe more accurately where in the quality assurance loop the care issue was identified. After this was agreed on the participants that had used the system earlier could see the value of categorising *all* care issues according to when in the quality assurance loop they were identified.

Degree of Change

In the discussion of ‘Degree of Change’ the confusion from the ‘Time Perspective’ continued. The participants that had used the system earlier had a quite different understanding of what care issues would go into the different subcategories than what were described in the guideline. The lack of a treatment plan for patients admitted to hospital were recognised as a problem when categorising care issues into this category. Some of the participants thought the name ‘Degree of Change’ sounded a bit too static, but no suggestions for another name were made.

As a comment to the ‘Degree of Change’ category this was said: ‘…but that would give you quite a lot of insight into opportunities of pharmaceutical prescribing.’ (SH)

Interactions and Recommendations

Some of the participants didn’t approve of using the term ‘Recommendation’ when describing a suggestion made to a prescriber concerning a patient’s drug therapy. The main objection was that it wouldn’t give an accurate picture of the interaction between the pharmacist and the prescriber. When a pharmacist makes a recommendation, a discussion between the pharmacist and the prescriber would follow. In this discussion there could emerge new information

that could make another option the most appropriate for the patient. This would be documented as a recommendation that weren't acted upon. The participant's objected to this wording, as the clinical discussion that followed the suggestion wouldn't be mentioned and it would only be a recommendation not acted upon. The term 'Recommendation' appeared ill-defined to the participants.

The participants didn't see any reason to record how many care issues were concerned with a interaction, their main focus would be on categorising the outcome of the interaction rather than that there was or could be an interaction. At the same time did some of the participants mention later in the meeting that they probably weren't documenting checking for interactions in a great enough degree.

Documentation

The recording of the delivery of pharmaceutical care was discussed throughout the whole focus group, often on the initiative of the participants. The results from the categorisation of care issues are based on the pharmacists' own recording, and the participants agreed that they didn't document everything they did. The mentioned situations where recording would be less likely and reasons for not recording were;

- if something happened ad hoc
- it is a large effort writing everything down, this is time that could be spent doing other things
- checks would probably not be written down that often, this includes confirmations that drug therapy is stopped when appropriate
- changes made on the drug chart in order to give information to other health care team members would most likely not be written in a handwritten care plan as well, but with electronic prescribing and electronic care plan this is easier.
- 'Continuity of care between different settings' would probably not be written down that often because the patient is going home
- checking for interactions would very rarely be written down

The participants agreed that a problem with comparing the results would be that the extent of documentation is very individual, and there is a need to get more consistency in order for the categorisation system to capture the real delivery of pharmaceutical care.

‘Obvious you would get documented problem, individual practice is various at the moment.’ (SH)

Results from categorisation

Some of the results from the categorisation were presented during the meeting. The research group had chosen to do this in order to give a basis for discussion of the system, because the results would both illustrate examples of where different care issues would be categorised and what kind of data it is possible to generate through the system. The participants were asked to give comments on the similarities and differences between the wards.

The research group presented the wards by different parameters, including the most common chronic conditions among the patients. The participants felt that presenting diagnosis would be a better way of the describing what the pharmacist at the ward is doing, because this would be the most important for the patient’s hospital stay. Not time to follow-up on identified care issues were stated as a reason for the care issues with unknown outcome.

Some of the participants were surprised so few of the care issues were categorised as ‘Review’. Other reasoned that this would be expected because the patients often are admitted to the hospital in order to review of the treatment, and that the patients on some of the wards often have a short stay with only simple treatments that follows a predefined guideline. If the pharmacists had followed the prescribers on ward round the opportunity to prompt a review would probably be more pronounced. The participants agreed that ‘Review’ would be more common when auditing pharmacist working with the patients long term, for instance in primary care.

Summary of the system

As a summary of the system this was said:

‘I think you got the basis of a degree of describing a lot of the activity of pharmaceutical...pharmacist contributions to care.’ (CF)

‘It’s useful for a pharmacist to see as well. You need to start to think is that because of my patient case load, or is it because that’s something I don’t do often enough?’ (LS)

‘The negative is that’s quite complex.’ (LS)

A concern about potential inter-rater agreement as a result of the complexity of the system problems was expressed, and encouragement to make the system as intuitive as possible was made.

On the potential uses of the system this was said:

‘Pharmacist can benchmark their practice and see what they need to be working on. (…)It makes you thinking: it makes you thinking about process, it’s make you thinking about the patient actually going home and evaluating the outcome in another term. So there’s a lot of potential benefits.’ (LS)

The use of the categorisation system to expose pharmacist to what they and other do/document were proposed. A point was also made of the importance of documenting for instance continuity of care for legal reasons, in order to show that all information is passed on. The categorisation system was also viewed as a potential means of giving pharmacist a language to describe what they do, and that this would help in developing the services of clinical pharmacy. The categorisation system could also help in reviewing both practice and documentation of practice, and set focus on what should be documented and what is unnecessary documented.

5 Discussion

5.1 The modified system

The original system for categorisation of care issues was greatly changed during this project. The utility of the modified system was tested through categorisation of all the care issues identified from the care plans. An inter-rater reliability test was conducted in order to establish the validity of the system. The utility and validity were also established through a focus group. The experiences from the categorisation, the results from the inter-rater reliability testing and the feedback from the focus group will be discussed below. Problems with the categorisation system and possible solutions to these will be described.

5.1.1 Experiences from categorisation of care issues

The assignment of categories to most of the care issues was found to be achievable in practice, even though some of the care issues required some thinking before suitable categories were assigned. In order to avoid the categorisation system to be too complex it has to be accepted that not all care issues fit smoothly into the categories. Still, some problems were encountered quite often, and are worth describing.

It became clear from the care plans both from the wards at Glasgow Royal Infirmary and the wards at Ayr Hospital that the pharmacists themselves have quite different perspective of what a care issue is, and this gave unexpected problems when categorising. To decide what should be considered a care issue, and when it was appropriate to divide the care issue into more than one care issue based on the pharmacist intentions when identifying the care issue was often problematic (as described in the guideline in Appendix II). If the categorisation system is to be used further it needs to be defined more clearly what should be considered a care issue, and in what situations it would be correct to divide one care issue into more care issues. As the system is now it requires that the persons that use it work in close liaison, so problems with

defining the care issues can be discussed and agreed upon during the categorisation process.

The categorisation of care issues into ‘Time Perspective’ and ‘Degree of Change’ categories gave particular problems. It was hard to assign a ‘Time Perspective’ when the care issue didn’t involve a medicine, but only a potential need for one. This was a problem because the description of the subcategories of ‘Time Perspective’ is directly connected to the drug therapy, and doesn’t take into account situations where the drug isn’t started yet, as seen in table 12. This problem was also encountered when assigning a ‘Time Perspective’ to many of the ‘Change in Drug Therapy Process’ as these often doesn’t include a specific drug either. The descriptions of the subcategories of ‘Time Perspective’ need to be changed in order to include situations where the care issue involve no drug therapy or not started drug therapy. These descriptions would have to focus on the various situations this would apply to, for instance deciding the need for a new drug from one test, through monitoring of the patient or as a result of a change of indication. These situations are potential sources for disagreement between different raters.

A problem with the ‘Time Perspective’ category in general is that it was created with the quality assurance of the patient’s treatment in focus, but when applied to a hospital setting it has to take into account at what time the pharmacist first meet with the patient. This means that it becomes a combination of focusing on the patient and the pharmacist. This is not consistent with the philosophy of pharmaceutical care, which is defined as patient focused. It is also a source of difficulties when assigning a ‘Time Perspective’ to the care issues, because the rater has to decide if the focus should be on the patient’s treatment or on when the pharmacist and patient first met.

The definition of the subcategories of ‘Degree of Change’ relates to the treatment plan of the patient, as seen in table 13. In a hospital setting there are rarely treatment plans for individual patients. This means that the rater has to know what changes to expect in the treatment of a specific diagnosis, which requires clinical experience. The researcher of this project has a limited degree of clinical experience, as would be expected for a student. As a result of this it turned out to

be a challenge to assign a ‘Degree of Change’ to the care issues categorised as ‘Change in Drug Therapy’. Another problem with this category is that the ‘Degree of Change’ for care issues categorised as ‘Patient or Carer Level of Education (Understanding/Compliance)’ is hard to assess irrespective of clinical experience. To be able to categorise these care issues the rater would have to speculate about what degree of change in the patient’s compliance the education resulted in.

As a result of assigning all the care issues into the ‘Time Perspective’ category there was made a connection between which subcategories of ‘Time Perspective’ could lead to which subcategories of ‘Degree of Change’, as seen in figure 4 and 5. During the categorisation of ‘Change in Drug Therapy’ care issues, it turned out that this connection not always applied. The researcher had to change the original assigned categories in order to comply with this connection for some of the care issues. This was mainly a problem when a change in the patient’s drug therapy was done during the patient’s treatment at the hospital (‘Monitoring’). According to the connection, a ‘Change in Drug Therapy’ can only be an ‘Adjustment’ when done during the patient’s treatment.

When a need to change the drug therapy outside what would be expected from the treatment plan during the patient’s treatment at the hospital there will not necessarily be a ‘Confirmation’ of the patient’s treatment before the change is carried out, and hence a ‘Monitoring’ can lead to a ‘Modification’. This is partly a result of that some of the big decisions regarding the patient’s treatment will be left for the patient’s GP to make. There was also a problem when the pharmacist recommended to the prescriber to stop a patients short-term treatment because it was no longer needed. This would be a care issue identified at the ‘Confirmation’ stage. It could be expected that the patient’s treatment plan would include that short-term treatment was to stop when it was no longer necessary, hence it would be an ‘Adjustment’. The connection between ‘Time Perspective’ and ‘Degree of Change’ only allows for ‘Modification’ or ‘Review’ of the patient’s drug therapy to happen at the ‘Confirmation’ stage.

5.1.2 Feedback from the focus group

The participants of the focus group found the categorisation system complex, this applied especially to the ‘Quality Assurance Descriptors’. This part was unclear to the participants even after reading the guideline many times. The research group has worked with the system for more than seven months, and still there was a need to use the guideline quite frequently during the categorisation process. This is one of the main problems with the system, because it means that a lot of effort has to put into understanding it before it can be used, as also mentioned during the focus group.

The system might be easier to use and understand by changing some of the names of the categories and subcategories, as suggested during the focus group. This might make the system more intuitive and hence more comprehensible. The proposed change from ‘Change in Drug Therapy Process’ to ‘Contribution to Drug Therapy’ would probably make it easier to understand the nature of care issues assigned to this category.

A change of name of the subcategories of ‘Time Perspective’ to ‘Design stage’, ‘Delivery stage’ and ‘Evaluation stage’ was proposed at the focus group. These names would connect the subcategories closer to what they actually describe, namely at what time during the quality assurance of the patient’s treatment they arise. This could potentially lead to some problems when assigning the ‘Time Perspective’ according to when the pharmacist met with the patient for the first time. Care issues identified at the first meeting would be categorised as ‘Design Stage’, even though this isn’t necessarily at the design stage of the patient’s treatment. It was not completely clear from the focus group if the participants wanted the change of name to apply to the ‘Time Perspective’ of all care issues, or just the changes. Using the same name for the subcategories of ‘Time Perspective’ of all care issues would be least complex. The name of the category ‘Time Perspective’ would also have to change to a name that connects it better with what it describes, and a proposal of ‘Quality System Position’ has been made to the research group by SH.

5.1.3 Inter-rater agreement testing

The inter-rater agreement between MBC and KJH was rated as very good for most part of the system. This is a surprising finding when taking into account the problems encountered during the categorisation. A Cohen's kappa of 1 in the 'Degree of Change' category was especially unexpected, but for this category the high Cohen's kappa can be a result of an uneven distribution of care issues, with none categorised as 'Review'. The high inter-rater agreement in general can also be explained by the close cooperation between the two raters during the study and categorisation period. The interpretation of different care issues with regard to the categorisation has been discussed thoroughly during the work with modification of the categorisation system and the development of the guideline. It is possible that during this development phase the raters have unconsciously agreed on a pattern for categorisation of some types of issues, even though this isn't mentioned in the guideline.

Even though the raters did agree on the categorisation of most of the care issue, this doesn't necessarily mean that the system is working. It might mean that both the raters make the same kind of 'mistakes' when categorising. There is a need to assess the inter-rater agreement between raters that haven't been involved in amendment of the system or development of the guideline. This will make it possible to assess if the guideline can function as an understandable guide to use of the categorisation system and to evaluate if the categorisation system in itself is comprehensive.

The only category with a Cohen's kappa under 0.80 was the 'Time Perspective'. This was one of the categories the researcher found hardest to categorise the care issues into, as described above. The categorisation of changes into the 'Time Perspective' category was a one of the modifications the research group made to the categorisation system. The raters had an observed agreement of 87.1 % for the 'Checks' and 80.6 % for the total changes in this category. This shows that the agreement was quite similar for the categorisation of both 'Checks', which was part of the original system, and total changes, which was part of the changes made to the system. The researcher found it hard to assign a 'Time Perspective' category to the 'Changes in Drug Therapy Process', so it was

surprising that the agreement between the two raters were absolute in this category. There were only ten care issues from this category in the random selection of care issues for inter-rater reliability testing, so this might explain why no discrepancies were found between the raters. The high disagreement when assigning a 'Time Perspective' to a care issue implies that a better guideline and more intuitive names of the subcategories is needed in order to increase the inter-rater agreement. As seen above a change of names has been proposed for the subcategories, and there would be a need to assess if this increases the inter-rater reliability in the 'Time Perspective' category.

The general responses from the focus group was that the changes to the original categorisation system has made the system more logical, and with the proposed changes of the names of categories and subcategories it will be a more comprehensive and useful system for categorisation of the delivery of pharmaceutical care.

5.2 Data collection for the project

The data to this project was collected through identifying patients' characteristics and care issues from care plans collected from the clinical pharmacist at the ward. Self-reporting has the advantage of the possibility of collecting large amounts of data without a big input of time or effort. This is especially true when the self-reporting system is the regular recording system used in the clinical setting, as here. This means that the clinical pharmacist that was studied didn't have to increase the amount recording in order for the audit to be carried out. A disadvantage with the self-reporting system is that it requires interpretation of both handwriting and clinical background to the care issues, which is time consuming for both the pharmacist and the researcher.

A problem with self-reporting is that clinical pharmacists are shown not to document everything they do, and as a result their input to patient care is under-estimated.[37] This was also one of the conclusions from the focus group, where the participants mentioned various examples of care issues they would be less likely to record. Common features for care issues that wouldn't be documented regularly were that they were checks, that they were identified and resolved

instantly or that they happened at the end of the patient's stay. The two main reasons stated by the participants of the focus group for not recording care issues were that it takes a lot of time and that care issues would not be recorded if the pharmacist didn't think there would be any use for the documentation later on, for instance if the patient was going home soon. Another probable reason is that the pharmacist forgets to write down the care issue or the outcome if the care plan is not present when the care issue is identified and/or resolved.

The problem with under-reporting can be avoided by observing the pharmacist instead of relying on the documentation produced by the pharmacist, but direct observation has some disadvantages as well. First of all, it is a lot more time consuming than self-reporting. Secondly, it is shown that a person who knows a study is taking place is likely to change its behaviour, a phenomena known as the Hawthorne effect.[59] The extent of an observer's influence on the behaviour of the research object is unclear. It is not unreasonable to assume that the Hawthorne effect is less pronounced when the study doesn't include direct observation and doesn't interfere with the object's normal activities, which is the case when data is collected through self-reporting.

The under-documentation will affect the interpretation of the results from both the quantitative description of Ward 18/19 and the comparison of pharmaceutical care activity at the General Medical ward and Ward 18/19. The results will to some degree be a description and comparison of degree of documentation and not pharmaceutical care delivery. The under-documentation will probably also affect the interpretation of the comparison of prescribing activity between the two wards, as the prescription data is derived from the care plans as well. If the pharmacist doesn't record all care issues, all the changes in the patient's drug therapy are probably not recorded either. This could have been avoided by collecting the data directly from the patient's drug charts, instead of from the care plans.

5.3 A description of pharmaceutical care delivered at a Care of the Elderly Ward

The pharmacist has many responsibilities when providing care for a patient, as seen in the process maps and the corresponding descriptions of the delivery of pharmaceutical care at Ward 18/19. A general impression from the shadowing is that the pharmacist rarely has time to provide all the services described in the process maps to each patient, even if they are needed. This is supported by the results from the quantitative evaluation of the delivery of pharmaceutical care. For instance according to figure 3 the pharmacist should counsel either the patient or the patient's main carer on changes made to the patient's drug therapy during the hospital stay. The pharmacist should also counsel patients if they receive a drug that requires patient counselling, for instance an inhaler, according to figure 1. Both of these would be care issues categorised as 'Patient or Carer Level of Education (Understanding/Compliance)' and 'Monitoring'. As seen in the results only 19 care issues were categorised as this combination. This is lower than expected from the description in the process maps, as 72% of the patients were discharged to primary care and the prevalence of for instance COPD was 27 % among the included patients. The process maps presented in the result section is probably mainly a description of how the delivery of pharmaceutical care at Ward 18/19 ideally would be for all patients. The reasons that not all patients receive all services would include short patient stay, not enough pharmacist resources and that the patients at the ward would have individual needs. Still, it would be wrong to exclude any of the actions presented in the process maps because all of the services are delivered by the pharmacist, but usually not to all of the patients.

The lack of time makes it necessary for the pharmacist to prioritise the delivery of pharmaceutical care. This prioritising is on two levels; which patients are most important to see, and what is most important to do for the prioritised patients. At Ward 18/19 all patients are supposed to be seen by the pharmacist, so the main prioritising is regarding what the most important care issues for each patient is. There are no guidelines on what minimum clinical pharmacy service the patients are entitled to when admitted to Glasgow Royal Infirmary, so this is for the pharmacists to work out themselves. It would probably be hard to develop a guideline or standard operating procedure (SOP) for the delivery of

pharmaceutical care, as all patients would present with different needs and issues. Still, the lack of guidelines will make the delivery of pharmaceutical care very different at different wards. It would be the pharmacists' preferences that will dictate what to prioritise, and this would ultimately result in differences between the wards based on the pharmacists' professional judgment. A SOP should be based on clinical evidence from trails, and include services shown to benefit the patient or the health system. If there were a SOP for the delivery of pharmaceutical care it would be possible to perform a clinical audit of the delivery of pharmaceutical care in order to assess and ensure the quality of the pharmaceutical care delivered. The SOP would set the predefined standard of which the current practice would be compared against. The categorising system could most likely be used in the interpretation of the collected data and in the comparison of the delivery of pharmaceutical care against the predefined standards. As long as no standards of what should be delivered exist the categorisation system can only be used to describe the work of the pharmacist and compare this with the delivery of pharmaceutical care in other settings or by other pharmacists. The system cannot be used to assess the quality of the delivery of pharmaceutical care.

5.3.1 Quantitative description of delivery of pharmaceutical care

Checks

The quantitative description of the pharmaceutical care delivered at Ward 18/19 showed that the pharmacist identified a total of 972 care issues for the 100 included patients. The included patients had an average of 8.3 regular drugs on admission, and almost 80% had over 4. The average age was 80.9 years and the average number of diagnosis was 4.2. All of these contribute to an increased risk of drug related problems, and the high total number of identified care issues would be expected. 65.8% of the identified care issues were categorised as 'Check'. This is quite a high proportion, but at a Care of the Elderly ward this would be expected because the changes in physiological function, pharmacokinetics and –dynamics that develop with age increases the need to calculate dose based on changed metabolism and excretion functions, and increases the need to monitor for adverse drug reactions. Consequently, 40.8% of the checks were 'Safety' inquiries, and 61.3% of these were done during delivery of the patients' treatment.

Monitoring for adverse drug reactions is time consuming, and would require follow-up all through the patient's stay at the ward.

Change in Drug Therapy Process

The distribution of care issues in the 'Change in Drug Therapy Process' showed that the pharmacist use a lot of time on taking the patient's drug history and correcting omissions or errors in the prescribing made on the patient's admission. A total of 120 care issues in the 'Clinical (shared) record of drug history' subcategory is a high number, and give an average of 1.2 changes in the drug therapy based on drug history per patient. Taking drug history is one of the services that are shown that pharmacists do more accurately than other health professionals, and it is an important pharmacy service in the hospital setting. This is one of the services the clinical pharmacists are supposed to deliver to all patients at Glasgow Royal Infirmary. A potential problem with the pharmacist being the person who takes the patients' drug history is that the wards have a limited pharmacist covering. At Ward 18/19 this results in that if a patient is admitted Thursday afternoon the pharmacist will not be able to see the patient and take the drug history before Monday morning, almost half a week later. This can lead to errors in prescribing persisting for an unnecessary long time. This could be avoided by either increasing the pharmacist covering, or by appropriate training of other health professionals in taking drug history, for instance nurses.

During the focus group the pharmacists told that care issues in 'Change in Drug Therapy Process' often wasn't written on the care plan, which would mean that there probably should be higher total number of care issues in this category. This would most likely not apply to the 'Clinical (shared) record of drug history' because this is regarded as important for the pharmacists themselves in their delivery of pharmaceutical care, and they would most likely write all the available information on the care plans.

Change in Drug Therapy

The categorisation of 'Change in Drug Therapy' shows the full complexity of the categorisation system, as each care issue is assigned four different subcategories in order to fully describe its nature. This complexity, and especially the assignment of both a 'Change in Drug Therapy' and a 'Drug Therapy Problem'

subcategory to each care issue, makes it difficult to say something in general about these care issues. Still, the categorisation showed that the care issues categorised as ‘Change in Drug Therapy’ were mainly change of dose (27.2%), stopping (25.7%) or starting (21.5%) of a drug. When a need to change the dose was identified this was both because the dose was too low and too high, this highlights that prescribing of sub therapeutic doses to older patients are a problem even at a specialised geriatrics ward.

Only 4.2% of the changes in the category ‘Change in Drug Therapy’ were made because non-adherence with local or central formulary was discovered. This is surprising because the participants at the focus group underlined that this was something they regarded as important, and that they spent a lot of time doing this. The proportion of changes made as a result of inappropriate compliance is high at the ward (18.1%), as would be expected at a Care of the Elderly ward for reasons described in the introduction.

The ‘Degree of Change’ subcategories describes to what extent the ‘Change in Drug Therapy’ could be expected in relation to the patient’s treatment plan. As seen in table 21 almost 90% of the ‘Change in Drug Therapy’ was expected changes, while the rest was either ‘Modification’ or ‘Review’. The fact that all care issues categorised as ‘Review’ or ‘Modification’ were either a start or a stop of a drug can be explained by that changes outside the initial treatment plan would rarely involve a change in dose or route of administration. It could also be explained by the fact that none of the patient’s at the ward had a treatment plan, so only changes that obviously couldn’t have been a part of the patient’s treatment plan would be categorised as ‘Modification’ and only situations where the care issue stated that a prescriber was contacted to re-assess the patient’s treatment would be categorised as ‘Review’.

Quality Assurance Descriptors

Of the total of 972 care issues 532 were identified at the ‘Verification’ stage, while 371 were identified at the ‘Monitoring’ stage. In the ‘Check’ category there was an even distribution of care issues identified at the ‘Verification’ stage (45.9%) and during the ‘Monitoring’ stage (44.2%). Still, at the ‘Verification’ stage almost 45% of the identified care issues led to a change, either in the processes or in the

patients' drug therapy, while at the 'Monitoring' stage only 23.7% led to a change. Of this it can be seen that most care issues are identified at the 'Verification' stage, and that a high proportion of these lead to a change.

This indicates that the pharmacist takes a proactive role when reviewing the patient's drug therapy on admission or when a new drug is started during the stay, and that this contributes to many changes in the patient care. During the 'Monitoring' phase a smaller proportion of identified care issues lead to a change, and the identified need to change is mainly 'Change in Drug Therapy Process' (15.9%) or 'Change in Drug Therapy' based on identified inappropriate compliance (5.1%). Most patients have been on the drugs for some time when admitted, so if the pharmacist at the ward detects for instance an adverse drug reaction immediately after admission these would be categorised as 'Verification'. Hence, during the 'Monitoring' phase ideally only newly developed adverse drug reactions should be detected. The low proportion of 'Change in Drug Therapy' can be due to the fact that identification of a need to make changes to a patient's drug therapy during the 'Monitoring' phase often would require monitoring for a longer period of time. With a median length of stay of 11 days there would probably in most instances be too short time to detect for suboptimal effect or adverse drug reactions.

During the 'Confirmation' stage over 90 % of the care issues was categorised as 'Check'. This is a high proportion, and means that the pharmacist instead of taking an active part in the 'Confirmation' of a patient drug therapy only checks that it is done. This might be due to a choice that 'Confirmation' of short-term drug therapy can be left for the doctors to sort out, and that the pharmacist feels that his time is better spent by doing something else.

The combination of 'Time Perspective' and 'Degree of Change' shows that almost 70% of the care issues were 'Adjustment' of an initial design, which in the hospital setting would mean 'Adjustments' at the first meeting between the patient and the pharmacist or when a new drug is started. Only a total of six 'Change in Drug Therapy' were done as a confirmation, and some of these were probably in reality done during the 'Monitoring' phase because a real 'Confirmation' or 'Review' (as described in the guideline) of the patient's drug therapy was never carried out.

The combination will give more value if more possible combinations are taken into account in the guideline. This combination will not be discussed further here, because of the changes the researcher had to do in the original assigned categories in order to fit with the guideline, as described above.

Interactions

Only 2.9% of the care issues were stated to involve an interaction. This is quite low, especially when the high average number of drugs on admission per patient is taken into account. The participants at the focus group said this would probably be underrepresented in the documentation, because usually only the outcome of the interaction would be written on the care plan with no mentioning of that an interaction was the reason. Even though the outcome of has to be regarded as the most important part of a care issue involving an interaction, it still is interesting to see if this is something the clinical pharmacists focus on. Pharmacists have a unique knowledge of the pharmacokinetics and –dynamics behind an interaction, and will apply this when resolving care issue and by this contributing to the patient care. As long as interactions not are a part of the categorisation system, it will be up to the individual researcher to decide if this should be evaluated.

Prescribing at the ward

The prescription survey found that most of the prescriptions at Ward 18/19 were from BNF category cardiovascular system. This is not surprising when comparing this list with the most common chronic medical conditions for the patients at the ward; hypertension, previous stroke and ischemic heart disease were all among the three most prevalent. The two BNF categories that followed cardiovascular system were central nervous system and gastrointestinal system. None of the most common conditions would have any obvious drugs prescribed from these medicines categories. The prescriptions from these categories would mainly be to treat conditions where the patient not necessarily has a diagnosis. Examples of this would be pain, insomnia and constipation.

5.4 Non-medical prescribing

One of the objectives of this project was to assess if the categorisation system can be used as a tool to evaluate if the patient care in a clinical setting would benefit from a prescriber clinical pharmacist. In order to evaluate if initiating pharmacist prescribing in a clinical setting would directly increase the quality of patient care, a randomised controlled trail would have to be carried out. There are many aspects that would have to be taken into account, for instance the interactions between the doctor and the pharmacist and the impact of introducing more prescribers at a ward. In primary care the number of prescribers for one patient has been shown to be directly related to the number of reported adverse drug reactions[30], and this might apply to a hospital ward as well.

The categorisation system can on the other hand be used to evaluate if introducing a pharmacist prescriber can save resources in form of saved pharmacist and doctor time in the clinical setting. As seen through the categorisation of the care issues at Ward 18/19, 10% of the identified care issues involved the omission of, or errors in prescription of drugs on admission. In addition it was seen that almost 90% of the 'Change in Drug Therapy' was expected inside the patients' treatment plan. For each of these care issues the pharmacist has to contact the prescriber to change the prescription. Each time the pharmacist has recommended a change there would be a need to go through the drug chart to see if the agreed change was actually carried out by the prescriber. If not, the pharmacist would have to talk to the prescriber once more to ensure the change is made. The high number of changes made to the patients' drug therapy based on errors or omissions made on admission or that could be expected from the patients' treatment plans would support that resources would be saved at Ward 18/19 if the pharmacist was a prescriber. On the other hand, the proportion of recommendations not acted upon (17.3%) indicates that for some reason or another, the prescriber doesn't always make the change recommended by the pharmacist. These can be recommendations based on drug history or on the clinical assessment of the patient. The reasons for not making the change can be many, for instance pure forgetfulness, but it can also be that the prescriber didn't agree with the pharmacist. For a prescribing partnership between a pharmacist and a doctor prescriber at a clinical setting to work out, there would have to be a

guideline or SOP for the prescribing at the ward. This would not be a Clinical Management Plan, as these are patient specific. It should be a general outline of which of the prescribers are responsible for what, and in what situations the pharmacist has to contact the main prescriber at the ward before doing any changes to a patient's drug therapy.

The categorisation system can be used to evaluate if the introduction of a pharmacist prescriber will save resources in form of saved time in a clinical setting. How much time that will be saved, and if the introduction of a prescriber will give rise to duplication of efforts in other parts of the process of prescribing for a patient, can not be evaluated through the categorisation system. It is not possible to set a cut-off between which results will support introduction of a pharmacist prescriber and which will not, and this would be for the management at the hospital or the hospital pharmacy department to decide. In order to see if resources actually were saved an evaluation after introduction of a pharmacist prescriber would have to be carried out.

5.5 Comparison of pharmaceutical care and prescribing activity between Ward A and Ward B

The mean number of 'Total care issues', 'Care issues not categorised', 'Checks' and 'Change in Drug Therapy Process' per patient were all higher at Ward B than at Ward A. Some of the observed difference is probably partly due to differences in degree of documentation between the two pharmacists. The fact that it was no difference in the number of 'Change in Drug Therapy' per patient, where the documentation rate probably would be quite similar between the two wards, supports this. The structure of documentation was quite different between the two pharmacists. This was seen when reviewing the care plans. Still the difference in mean total care issues and mean checks per patient is quite high and indicates a real difference in the delivery of pharmaceutical care per patients at the two wards.

The distribution of care issues in main categories showed that there was a higher proportion of 'Check' in Ward B than in Ward A. This can be explained by a difference in recording of care issues, as mentioned earlier. Still, there would

probably be a need to monitor patients at Ward B more closely to ensure safe treatment, as older and frail patients are known to be more susceptible to adverse drug reactions. The proportion of ‘Change in Drug Therapy’ was higher in Ward A than in Ward B. The number of ‘Change in Drug Therapy’ per patient wasn’t different between the two wards, as seen above, so the differences in distribution of care issues are mainly a result of that there were identified a higher total number of care issues at Ward B.

The higher proportion of ‘Compliance inquiry’ at Ward B compared to Ward A could be explained by a higher priority in performing this kind of checks at Ward B than at Ward A. Ward B is a Care of the Elderly ward, and older patients have often reduced mental or physical function combined with many diseases and poly-pharmacy, all of which can lead to problems with compliance.

The higher proportion of ‘Health care team member(s) information/education’ at Ward A is probably not only a result of differences in documentation. The researchers discussed what they had observed during their shadowing, and concluded that this was probably a result of differences in the delivery of pharmaceutical care at the wards. At Ward A the patients’ drug chart is by the patients’ beds, and this result in more direct interaction both between patients and pharmacist, and prescriber and pharmacist than at Ward B. This gives more opportunities to discuss issues regarding a patient direct with the prescriber as they arise, and probably contributes to the higher proportion of education/information related care issues. Still, this subcategory was mentioned by the participants of the focus group as one where the care issues would often not be recorded on the care plan. The total number of ‘Change in Drug Therapy Process’ was very low at Ward A, and a small deviation in recording in one of the subcategories will impact greatly on the proportions. The pharmacist at Ward B put a large effort into taking an accurate drug history for new patients, and this is reflected in a higher proportion of this subcategory of care issues than at Ward A.

The distribution of ‘Check’ in subcategories of ‘Time Perspective’ showed that a higher proportion of ‘Check’ is performed at Ward B at the ‘Verification’ stage than at Ward A, and that a higher proportion of ‘Check’ is performed during the ‘Monitoring’ stage at Ward A compared with Ward B. This is consistent with the

impression the investigators got through shadowing the pharmacists. The difference in proportion of 'Confirmation' might be due to differences in documentation, because the numbers are very low, and omission of recording of these checks would affect the proportion in big degree.

The same distribution was seen for 'Checks' and 'Change in Drug Therapy' in 'Verification' and 'Monitoring' when comparing the two wards. Ward B had the highest proportion of 'Check' and 'Change in Drug Therapy' at the 'Verification' stage, while Ward A had the highest proportion of 'Check' and 'Change in Drug Therapy' during 'Monitoring'. It would seem logical that a high proportion of checks at a certain stage during the patient's drug treatment would result in a high proportion of changes at the same stage. This difference in proportion shows that the pharmacist at Ward B does most of the changes in a patient drug therapy either at the first meeting or when a new drug is started. The pharmacist at Ward A does most of the changes later in the patient stay at the hospital.

For the 'Confirmations' the opposite pattern was seen. Ward B had the highest proportion of 'Check', while Ward A had the highest proportion of 'Change in Drug Therapy', at this stage. This inconsistence, where a high proportion of 'Check' doesn't lead to a high proportion of 'Change in Drug Therapy' can be a result of a low degree of documentation of 'Checks' done at the 'Confirmation' stage in Ward A. This was mentioned in the focus group as a type of care issue where the pharmacist often would just do a mental note, for instance when confirming that a drug therapy had been stopped when not needed anymore. The difference in proportions indicates that the pharmacist at Ward A is more proactive than the pharmacist at Ward B when monitoring the drug therapy, and more often propose to change it when necessary at the 'Confirmation' stage, as opposed to just checking that it is actually changed when appropriate.

The prescription survey showed that there was a difference in the mean number of medications during the hospital stay and the mean number of medicines on discharge per patient, which all were highest in Ward B. These differences can be part of the explanation for the differences between the wards in 'total care issues', 'Check' and 'Change in Drug Therapy Process' per patient. A high prescribing activity at a ward will give rise to an increased need to monitor the

patients. The mean total-course days per patient were also different between the wards, indicating difference in exposure to medicines between the two patient populations.

In summary the comparison of the two wards showed that the two pharmacists have different focus in their delivery of pharmaceutical care. The pharmacist at Ward A interacts more directly with the prescribers and nurses at the ward, and as a result has a higher focus on education or information to the rest of the health care team than the pharmacist at Ward B. The pharmacist at Ward B does much of the delivery of pharmaceutical care during the first meeting with the patient, and has a high focus on taking of drug history in comparison with the pharmacist at Ward A. The pharmacist at Ward B identified more care issues per patient; these were mainly 'Check'. The pharmacist at Ward B also identified more care issues that weren't categorised than the pharmacist at Ward A, and this could indicate that the pharmacist at Ward A doesn't write things down until they are actually done. This would give a large potential for forgetting to record care issues, which would result in an under-estimation of the delivery of pharmaceutical care at this ward.

5.6 Summary of the potential future uses of the system

The total categorisation system is complex. This was experienced both through the initial work with modification of the system and when using the system to categorise care issues. This was also one of the things the participants of the focus group found negative with the system. That the system is complex has both advantages and disadvantages. The advantage is that it is possible to describe the delivery of pharmaceutical care detailed through the categorisation of the identified care issues. The disadvantages are that the system is hard to understand, and this might give problems with inter-rater agreement. The complexity of the system limits it potential for routinely use. It would for instance be too time consuming for a clinical pharmacist to use it to systemise the care issues on a daily basis. Clinical pharmacists could probably use parts of the system to structure their work, in the same way as the original idea with the Drug Related Problems was.[4] The complexity also makes it hard to interpret some of the results. Care issues categorised as 'Change in Drug Therapy' are assigned

four categories each, and the possibilities for combination of these categories make the total description of the delivery of care difficult.

The total system could probably only be used by researchers. A limitation for the use of the system today is that individual pharmacists document what they do to very various degrees. The system might have potential to increase the degree of documentation because results derived from the system hopefully would make the pharmacists realise what could and should be documented.

The categorisation system can, as seen through this project, be used to compare the delivery of care in two different clinical settings. If there was some clinical standard for what a clinical pharmacist should deliver to the patients, the system could be used to compare what the pharmacist actually delivered with the clinical standard. This would make the basis for identifying what parts of the delivery of pharmaceutical care that could be changed in order to increase the quality in a clinical setting. After the changes the delivery of pharmaceutical care in the clinical setting could be assessed once more, and this would evaluate the impacts on quality of the changes made. The system can also be used to support a decision of if introduction of a pharmacist prescriber in a clinical setting will contribute to saving resources in the setting.

6 Conclusion

The categorisation system modified as part of this project is complex, which can make it difficult to use. Hopefully the recommended changes in the names of some of the subcategories and main categories will make it more intuitive and easier to use. The inter-rater agreement was good for one part of the system and very good for most parts. The evaluated raters had been working close through both the process of modifying the system and in the categorisation process. There is a need to assess the inter-rater agreement for persons that has not used the system to such a large extent if the system is going to be used routinely.

The categorisation system was used to describe the delivery of pharmaceutical care at one ward, and to compare this data with corresponding data from another ward. This comparison showed that the delivery of pharmaceutical care was different between the two wards. This can be a result of differences in the patient populations at the two wards or different professional priorities made by the clinical pharmacists. Since the data collection in this project relied on the pharmacists' self-reporting, the difference can also be a result of different approach and extent of documentation between the two pharmacists studied. It is not possible to know if the observed difference is due to a real difference in delivery of pharmaceutical care or just a result of difference in level of documentation. This could have been avoided by observing the clinical pharmacists directly.

The project has shown that it is possible to use the system to statistically compare the delivery of pharmaceutical care in two different clinical settings. The system can potentially be used to assess if the delivery of pharmaceutical care meet predefined standards, but no such standards exist at the moment. The system can also be used to give data to support a decision about whether or not a clinical setting will benefit from having a clinical pharmacist.

7 Appendix

7.1 Appendix I. Example of care plan (PMP) from Glasgow Royal Infirmary

CARE OF THE ELDERLY: PHARMACEUTICAL CARE PLAN

Patient Details:	**Ward:** 18/19 ❑ 20/21 ❑	**Admitted:** / /	**GP Details:**
	PODs: in ❑ useable ❑	**Weight:** kg	
	Allergies:		
	Compliance issues:		

Active Problems/Diagnoses		**Past Medical History**	
PC:			
Δ/Ix:			

Medication O/A Source; Pt Letter GP Notes		**Lab Results**						
		Date	O/A					
		Cr						
		Urea						
		K						
		Na						
		Ad Ca						
		Date	O/A					
		Bili						
		AST						
		ALT						
		GT						
New Medication		**ALP**						
		Alb						
		Date	O/A					
		WBC						
		Hb						
		Plt						
		MCV						
		INR						
		TDM						
		Date						
		Drug						
		Dose						
		Est						
		Level						

L Stewart/GRI/June07

No.	Date	Care Issue & Desired Outcome	Plan & Action Taken	Actual Outcome
1		Establish how medication managed at home pre-admission		
		Patient for discharge	Screen Rx Counselling Contact Community Pharm. Other	❑ ❑ Patient ❑ Carer ❑ Details: ❑ Details:

7.2 Appendix II. Guideline for categorisation of care issues

GUIDELINE FOR CATEGORISATION OF PHARMACEUTICAL CARE ISSUES

1. Introduction

Pharmaceutical care is delivered by a team of health care professionals. The focus of the categorisation system described here is pharmaceutical care contributions made by the pharmacist within that context.

To better comprehend this guideline it is important to have an understanding of how the pharmacist provides pharmaceutical care. This is a cyclical process and will briefly be described here.

The pharmacist initiates this process by gathering relevant information about the patient's drug treatment and medical history, which reveals pharmaceutical care issues. The pharmacist handles the care issues by doing checks leading to three different results:

1. The care issue is found not to be an actual or potential drug therapy problem that needs further follow up at this point.
2. There is an identified need to take action(s) to prevent future drug therapy problems.
3. A drug therapy problem is identified and there is a need for a change in the patient's drug therapy at this point

2. Definition of a pharmaceutical care issue

A pharmaceutical care issue is an identified concern regarding a potential or actual drug therapy problem. A drug therapy problem is patient specific, and so does not include non-adherence to local formulary choices that are based on cost controls.

3. The categorisation system – a short summary

The categorisation system is developed to describe pharmaceutical care. This is done by analysing each care issue and assigning them into categories. This categorisation process provides a basis for quantitative description of the pharmacist's contribution to pharmaceutical care, which makes it possible to compare pharmaceutical care provided by a pharmacy service across different settings.

Each care issue is described according to a triangularised system which consists of multiple categories. The advantage of combining different categorisation systems into one triangularised system is that the categories supplement and support each other, and therefore they capture the different dimensions of the pharmaceutical care issues.

Each care issue is categorised in three such dimensions;

(1) As either a *Check* or a *Change*[1]*;* where a *Change* may be a *Change in the Drug Therapy Process* or a *Change in Drug Therapy*, depending on the outcome.

The care issue is further categorised into

(2) *Quality Assurance (QA) Descriptors*[1]*,* which indicate a care issue's position in the process of delivering pharmaceutical care. If the care issue is a *Change in Drug Therapy* this category also describes the extent of the change made.

The third dimension in the system is

(3) *Drug Therapy Problem*[2] and only a care issue identified as a *Change in Drug Therapy* will be categorised as such.

If the outcome of the care issue is unknown, the care issue is incomplete and can not be categorised in the categorisation system.

Table 1. Categorisation set-up

#	Check	Change in Drug Therapy Process	Change in Drug Therapy	DTP	Quality Assurance Descriptors	
					Quality System Position	Degree of Change

The different parts of the triangularised system with its categories are described below.

4. 'Check' and 'Change' categories

4.1 Checks

When a care issue is identified, the pharmacist has to perform checks in order to detect required actions to prevent future drug therapy problems or required changes in drug therapy addressing actual drug therapy problems. If the check leads to neither an action nor a change the care issue is categorised as a *Check*. A care issue categorised as a *Check* is assigned to one of four subcategories*; "medication needs", "effectiveness", "safety"* or *"compliance"*, based on the reason for the inquiry as summarised in table 2.

The pharmacist's intentions behind making the check constitute the basis for the number of care issues identified and for the categorisation of the identified check(s). A check performed by a pharmacist may be an inquiry which addresses both effectiveness and safety, (for instance when INR or lying/standing blood pressure is measured). In that case the care issue will be divided into two care issues; one check of effectiveness and one check of safety.

If the pharmacist recommends making a change in the patient's drug therapy in order to resolve or prevent a drug therapy problem, but the responsible prescriber either doesn't agree with the change or agrees but forgets to make it, the care issue will be categorised as a check because no change in the patient drug therapy is carried out.

Table 2. Checks

Check	Code
Medication need inquiry	**MED**
Effectiveness inquiry	**EFF**
Safety inquiry	**SAFE**
Compliance inquiry	**COMP**

4.2 Changes

The category *Change* is divided into two types of subcategories; *Change in Drug Therapy Process* and *Change in Drug Therapy.* The *Change in Drug Therapy Process* category includes care issues relating to changes in the care process, and this means that the impact of the outcome often is hard to determine or is too speculative to lead to a *Drug Therapy Problem* category. The *Change in Drug Therapy* category, on the contrary, includes changes related to drug therapy, non-compliance and prescription, where the outcome can be assigned a recognisable *Drug Therapy Problem* category.

Even though all changes are inevitably the result of a check, such checks will not be categorised since their relevance is superseded by the resulting change. The care issue will be adequately described by the resulting categories of *Change*, *Quality Assurance Descriptors* and *Drug Therapy Problem.*

5. Change in Drug Therapy Process

The pharmacist performs different actions to address the pharmaceutical care needs of the patient. Not all of these actions result in a change to the patient's drug therapy. Nevertheless it is important that these actions are quantified, as they comprise a great part of the pharmacist's delivery of pharmaceutical care.

The category *Change in Drug Therapy Process* describes the actions the pharmacist performs to prevent potential drug therapy problems and to identify actual drug therapy problems (Table 3).

Table 3 Change in Drug Therapy Process categories

Changes made to	Code
Clinical (shared) record of patient characteristics	**CHAR**
Clinical (shared) record of drug history	**DH**
Continuity of information/care between clinical settings	**CONT**
Level of patient monitoring	**MON**
Health care team member(s) information/education	**INF**

5.1 Explanations of the *Change in Drug Therapy Process* subcategories

Clinical (shared) record of patient characteristics

This and the next subcategory describe actions that may affect the patient's drug therapy since his/her treatment is based on available patient information. For instance, it is important to note in the patient's record if he/she is allergic to penicillins, in case an antibiotic treatment is required later. These actions help to avoid potentially preventable drug therapy problems in the future.

If the pharmacist corrects or up-dates the patient's shared records, for instance adds two drugs that the patient is allergic to, this will be recognised as one care issue. If drug therapy changes have to be made as a result of the corrected or up-dated record, this is recognised as one care issue for each drug that is changed.

Clinical (shared) record of drug history

When the pharmacist takes the drug history, discovers errors in prescribing on admission and proposes/makes a change to the drug therapy based on this, this is interpreted as one pharmaceutical care issue for each drug that is changed.

Continuity of information/care between clinical settings

This subcategory encompasses the actions the pharmacist undertakes to ensure continuity of care and transfer of relevant information between clinical settings, including making new arrangements for the patient with other health care institutions. The clinical settings include all healthcare institutions that have responsibility for the patient's health care.

A number of care issues might be included globally in a document transferring the patient's care between clinical settings. If the pharmacist prepares or advises on the document, but doesn't follow-up on the recommendations made, that would be a single care issue. This is because the care issues have unknown outcomes, and therefore can't be categorised. We can only categorise the action of the pharmacist in terms of making the recommendation.

Level of patient monitoring

Some care issues can result in the identification of a need to increase/improve patient monitoring. This increased/improved patient monitoring doesn't have to be performed by the pharmacist, but he/she must initiate it or advice about it.

Health care team member(s) education / information

This subcategory describes care issues where the pharmacist contributes by providing information or education to other health care personnel regarding the patient's drug therapy.

6. Change in Drug Therapy

A care issue that is categorised as a *Change in Drug Therapy* (Table 4) includes changes to;

- the drug therapy of the patient
- the patient/patient's carer understanding of the drug therapy or disease
- the patient's adherence to their treatment plan, that is patient compliance

Pharmacists, unless they are acting as prescribers themselves, will in most cases make a recommendation to the patient's prescriber, and the care issue will be categorised as a *Change in Drug Therapy* if the recommendation is accepted and carried out.

The outcome of changes made to the patient/carer understanding/compliance is hard to measure, but it is included in the *Change in Drug Therapy* subcategory because it can be categorised as a *Drug Therapy Problem,* and it can be viewed as a categorisation of the intention of the effort made by the pharmacist.

Table 4. Change in Drug Therapy categories

Changes made to:	Code
Drug selection (starting new or changing drug)	**SEL**
Dose	**DOSE**
Route/dose form	**FORM**
Dose interval/timing	**INT**
Duration	**DUR**
Stop drug temporarily/permanently	**STOP**
Patient or Carer Level of Education (Understanding/Compliance)	**EDU**

7. Drug Therapy Problems (DTP)

The categories of Drug Therapy Problems are those defined in the book *Pharmaceutical Care Practice – The Clinician's Guide* [2] by Cipolle et al. The categories are given examples here to include a broader range of care issues. In addition they are modified to enhance the correlation between the heading of the DTP subcategories and the type of care issues included in them. An additional subcategory *Unclassified* has been added in order to categorise care issues where the change is not patient specific. For instance due to non-adherence with local formularies and with only cost-control implications, rather than medication safety or effectiveness.

Only *Change in Drug Therapy* types of care issue will be categorised into Drug Therapy Problem categories. The combination of the *Change in Drug Therapy* subcategory and the *Drug Therapy Problem* subcategory will describe the nature of the change made to the patient's drug therapy, see table 5 below.

Table 5. Categories and common causes of drug therapy problems

Drug Therapy Problem		Common causes of drug therapy problems	
1	**Unnecessary drug therapy**	a	There is no valid medical indication for the drug therapy at this time
		b	Multiple drug products are being used for a condition that requires fewer drug therapies
		c	The medical condition is more appropriately treated with non drug therapy
		d	Drug therapy is being taken to treat an avoidable adverse reaction associated with another medication
		e	Drug abuse, alcohol use, or smoking is causing the problem
		f	The duration of therapy is too long
2	**Need for additional drug therapy**	a	A medical condition requires the initiation of drug therapy
		b	Preventive drug therapy is required to reduce the risk of developing a new condition
		c	A medical condition requires additional pharmacotherapy to attain synergistic or additive effects
		d	The duration of drug therapy is too short to produce the desired response
3	**Ineffective drug**	a	The drug is not the most effective for the medical problem
		b	The medical condition is refractory to the drug product
		c	The dosage form of the drug product is inappropriate
		d	The drug product is not an effective product for the indication being treated
		e	The time of dosing or dosing interval is not the most effective
		f	Route of administration is not the most effective
4	**Dosage too low**	a	The dose is too low to produce the desired response
		b	The dosage interval is too infrequent to produce the desired response
		c	A drug-drug/food/lab/disease interaction reduces the amount of active drug available

Table 5 (cont.) Categories and common causes of drug therapy problems

5	**Adverse drug reaction**	a	The drug product causes an undesirable reaction that is not dose-related
		b	A safer drug product is required due to risk factors
		c	A pharmacodynamic drug-drug/food/lab/disease interaction causes an undesirable reaction that is not dose-related
		d	The dosage regimen was changed too rapidly
		e	The drug product causes an allergic reaction
		f	The drug product is contraindicated due to risk factors
		g	The time of dosing or the dosing interval is not the safest.
		h	Route of administration is not the safest
6	**Dosage too high**	a	Dose is too high
		b	The dosing frequency is too short
		c	A drug-drug/food/lab/disease interaction occurs resulting in a toxic reaction to the drug product
		d	The dose of the drug was administered too rapidly
7	**Inappropriate compliance**	a	The patient prefers not to take the medication
		b	The patient does not understand the instructions
		c	The patient forgets to take the medication
		d	The drug product is too expensive for the patient
		e	The patient cannot swallow or self-administer the drug product appropriately
		f	The drug product is not available for the patient
		g	The time of dosing or the dosing interval is decreasing compliance.
8	**Unclassified i.e. Non-DTP**	a	Formulary adherence, e.g. generic switch

8. Quality Assurance Descriptors

A patient's drug treatment can be regarded as a cyclical process, which encompasses the design, delivery and evaluation of the treatment plan according to expectations predefined by clinical standards. Figure 1 shows the pharmacist's systematic role as a contribution to increase the quality of this cyclical process. At each step during the cycle the pharmacist (and other health care team members) is in a position to perform checks to confirm the quality of the delivery of the treatment plan. Whenever the checks reveal deviations from the expectations established in the plan, changes to the treatment or the treatment plan are proposed or executed. This process can be viewed as a feedback loop, where changes are integrated into the cycle.

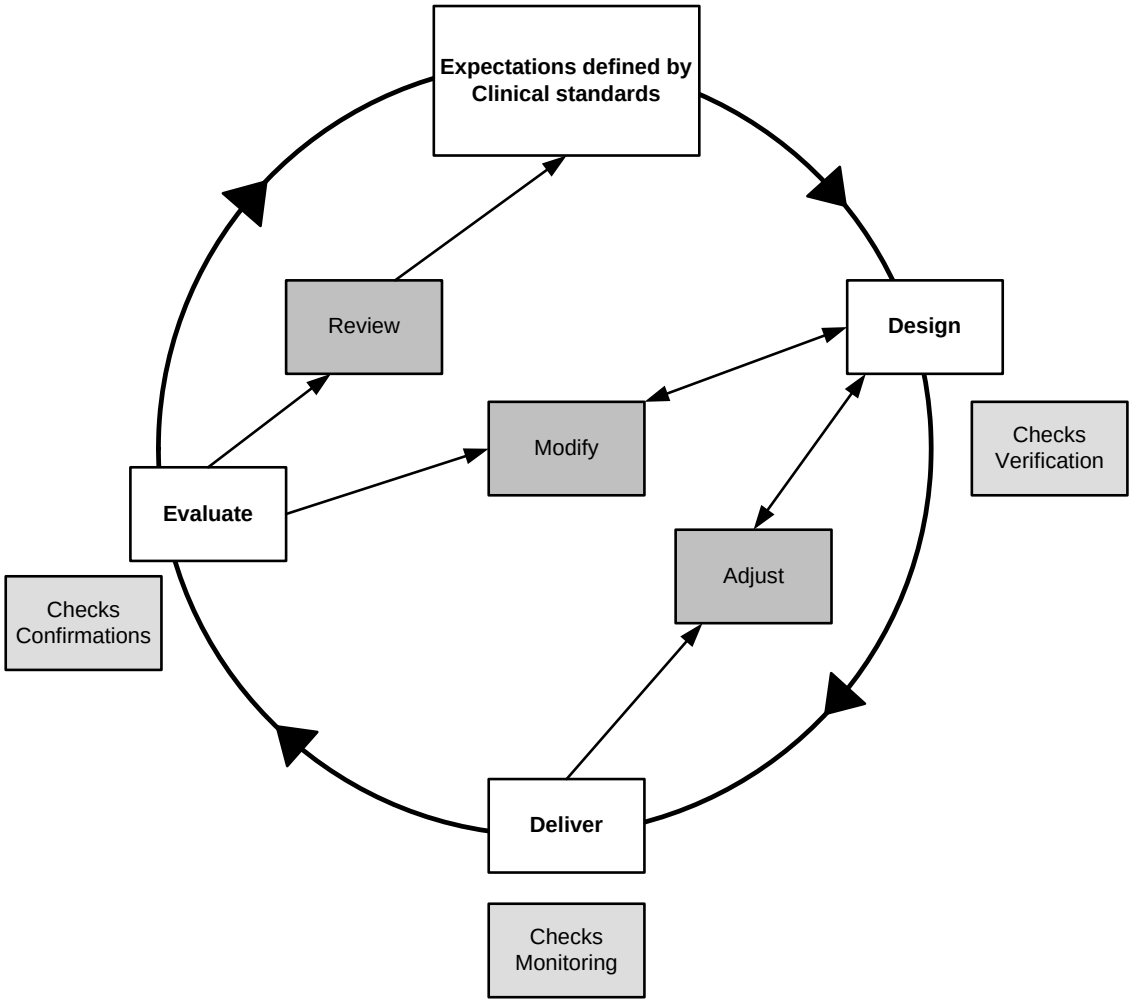


Figure 1 Pharmaceutical care model

The Quality Assurance (QA) Descriptors identify both the points in the feedback loop at which the care issues (the *Checks* or *Changes*) are implemented and the

extent of changes in drug therapy. To emphasise what they describe, the subcategories for *QA Descriptors* are designated *Time Perspective* and *Degree of Change*.

All care issues will be categorised according to the *QA Descriptor Time Perspective*. This *QA Descriptor* adds a time perspective in the treatment cycle to the triangularised system. If the care issue is a *Change in Drug Therapy* it will be categorised according to the *QA Descriptor Degree of Change* as well. This *QA Descriptor* describes the extent of the change made (Table 6).

Table 6. Summary of which care issues are categorised into the two different Quality Assurance Descriptors subcategories

Quality Assurance Descriptors	
Time Perspective	**Degree of Change**
Check Change in Drug Therapy Process Change in Drug Therapy	Change in Drug Therapy

8.1 Time Perspective

The subcategories of *Time Perspective* are **Verification, Monitoring** and **Confirmation**, see table 7. These subcategories relate to the point in the system feedback loop where the initial check that identified the care issue was made.

Table 7. Categorisation of checks according to quality system feedback loop

Time Perspective	Code	
Verification Verification of appropriateness of medications in the proposed treatment plan	**VER**	Checks at the start of the treatment to make sure that, for each medicine, the patient: • is on the right medicine • is on the right dose • is not on unnecessary medication • doesn't have any new needs for additional medication • is not receiving a combination of interacting medicines • understands how to take their medication and what it will do to them
Monitoring Implementation of treatment is appropriate and checking for safety and effectiveness	**MON**	Checks as treatment continues which should ensure that, for each medicine, the patient: • is on receiving medication as intended • continues to be on the most suitable dose • has no symptoms of unwanted(adverse) effects • understands how to take their medication
Confirmation Checking that medication is producing positive outcomes	**CON**	Confirmation and documentation to identify that medication is: a. resulting in expected effects on the patient's condition b. not failing to control condition c. not producing unwanted effects requiring clinical review.

Verification

A 'Verification' is either done at the start of a new patient treatment or when the pharmacist first assesses the patient and the medication, see table 7.

- In chronic disease management, for instance by a clinical pharmacist at an outpatient clinic or a community pharmacy, 'Verification' is done at the first episode of care with the pharmacist. That may or may not be at the start of the patient's treatment but must be undertaken for the pharmacist to assure himself or herself that the proposed treatment plan is suitable for the patient's need.

- When the patient is seen in an interim episode of care interrupting chronic disease management, for instance by a clinical pharmacist at a hospital ward during an acute admission, the verification category will relate to when the pharmacist first saw the patient. 'Verification' of the patient's drug treatment is done at admission, or when a new drug is started. All checks at this point in care should be categorised as 'Verification' even if the treatment has been going on for a long time prior to the hospitalisation.

Monitoring

'Monitoring' is done during the patient's treatment (during the delivery of the treatment plan) with the goal of assuring the medication process is being implemented as intended and within general expectations of signs of benefits and absence of adverse effects, see table 7.

Confirmation

'Confirmation' is an evaluation of the patient's treatment to assure that expected effects are achieved, adverse effects avoided or suitably managed and that the condition is treated optimally, see table 7. This category usually applies to care issues concerning the continuing evaluation of a chronic disease, an acute exacerbation of a chronic disease, or an acute episode of disease

8.2 Degree of Change

The *Degrees of Changes* are **Adjustment**, **Modification** and **Prompt a Review**, see table 8. These three subcategories describe the extent of the change made. Both **Adjustment** and **Modification** may take place at the start or during treatment, while **Prompting of a Review** results from a failure in treatment and so only occurs after a trial period of treatment, see figure 1.

Since it is difficult to distinguish between the extents of changes made in *Change in Drug Therapy Process,* only *Change in Drug Therapy* will be categorised into *Degree of Change.*

Table 8. Categories of changes according to the extent of the change in the quality system feedback loop

Degree of Change	Code
Adjustment	**ADJ**
Modification	**MOD**
Review (prompt a review)	**REV**

If a *Check* leads to a *Change,* the *Time Perspective* (i.e. at what time in the treatment cycle the check is done) will influence the choice of the subsequent *Degree of Change*. As seen in figure 1 and table 9, a **Verification** can lead to either an **Adjustment** or a **Modification**. A **Monitoring** issue can only lead to an **Adjustmen**t. If a need for a bigger change in the treatment is identified, a **Confirmation** of the whole treatment of the patient is needed before a decision to either 'modify' or 'review' the treatment can be made. A **Confirmation** can lead to either a **Modification** or a **Review**, depending on the outcome of the 'confirmation'.

Table 9. Categories of changes according to the time aspect in the quality system feedback loop, linked to preceding check

Time Perspective	Code	Degree of Associated Change	
Verification	**VER**	**ADJ**	**MOD**
Monitoring	**MON**	**ADJ**	
Confirmations	**CON**	**MOD**	**REV**

Adjustment

Adjustment is defined as a recommended change to patient behaviour, treatment regimen or process of continuity of care that individualises pharmaceutical care *within* the agreed treatment plan. 'Adjustments' are anticipated within the protocol/clinical management plan, and the regimen is not markedly changed to an alternative treatment regimen. Most supplementary prescribing decisions made by pharmacists would probably fall into this category.

Modification

Modification is a change to the patient treatment that is not anticipated and leads to a change of the patient's treatment plan.

Prompt a Review

A **Review** is a re-assessment of the patient's treatment, and leads to a change in the expectations defined by clinical standards i.e. change in the expectations to the outcome of the treatment. Because the pharmacist is not able to review the treatment alone, but has to recommend a review to the patient's main prescriber, the qualified term category is termed 'Prompt a Review'. 'Prompt a Review' is done as a part of the evaluation of the patient's treatment. This will be done more often in an outpatient setting or in a pharmacy where the patient comes regularly.

References:

1. Hudson SA, McAnaw JJ, Johnson BJ. The Changing Roles of Pharmacists in Society. IeJSME. 2007; 22-34
2. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice. The clinician's guide. 2nd ed: McGraw-Hill; 2004

7.3 Appendix III. Distribution in Cohen's kappa

Table 33 Main categories: Distribution of care issues for kappa

		Researcher MBC			
		Checks	Changes in Drug Therapy Process	Changes in Drug Therapy	Total
Researcher KJH	Checks	63	1	0	64
	Changes in Drug Therapy Process	0	10	0	10
	Changes in Drug Therapy	0	0	26	26
	Total	63	11	26	100

Table 34 Time Perspective: Distribution of care issues for kappa

		Researcher MBC			
		Verification	Monitoring	Conformation	Total
Researcher KJH	Verification	33	9	0	42
	Monitoring	3	49	0	52
	Confirmation	0	3	3	6
	Total	36	61	3	100

Table 35 Main categories with subcategories: Distribution of care issues for kappa

			Researcher MBC																
			Checks				Changes in Drug Therapy Process					Changes in Drug Therapy							
			MED	EFF	SAFE	COMP	CHAR	DH	CONT	MON	INF	SEL	DOSE	FORM	INT	DUR	STOP	EDU	Total
Researcher KJH	Checks	MED	18		2														20
		EFF	1	7				1											9
		SAFE			28														28
		COMP				7													7
	Changes in Drug Therapy Process	CHAR					0												0
		DH						6											6
		CONT							2										2
		MON								0									0
		INF									2								2
	Changes in Drug Therapy	SEL										6							6
		DOSE											2						2
		FORM												1					1
		INT													7				7
		DUR														0			0
		STOP															4		4
		EDU																6	6
	Total		19	7	30	7	0	7	2	0	2	6	2	1	7	0	4	6	100

Table 36 Check with subcategories: Distribution of care issues for kappa

			Researcher MBC Checks				
			MED	EFF	SAFE	COMP	Total
Researcher KJH	Checks	MED	18	0	2	0	20
		EFF	1	7	0	0	8
		SAFE	0	0	28	0	28
		COMP	0	0	0	7	7
		Total	19	7	30	7	63

Table 37 Degree of Change: Distribution of care issues for kappa

		Researcher MBC			
		Adjustment	Modification	Review	Total
Researcher KJH	Adjustment	23	0	0	23
	Modification	0	3	0	3
	Review	0	0	0	0
	Total	23	3	0	26

8 References

1. Jones RM, Rospond RM. Patient Assessment and the Pharmaceutical Process. In: Patient Assessment in Pharmacy Practice. Baltimore: Lippincott Williams & Wilkins; 2003. p. 2-8.

2. Hepler CD. Clinical pharmacy, pharmaceutical care, and the quality of drug therapy. Pharmacotherapy. 2004 Nov;24(11):1491-8.

3. Clinical Resource and Audit Group. Clinical Pharmacy in the Hospital Pharmaceutical Service: A Framework for Practice. 1996 July.

4. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990 Mar;47(3):533-43.

5. Christen C. Clinical pharmacy and medication safety. Ann Pharmacother. 2006 Nov;40(11):2020-1.

6. Brodie DC, Parish PA, Poston JW. Societal needs for drugs and drug-related services. Am J Pharm Educ. 1980 Aug;44(3):276-8.

7. Hudson SA, McAnaw JJ, Johnson BJ. The Changing Roles of Pharmacists in Society. IeJSME. 2007;1:22-34.

8. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice.: McGraw-Hill; 1998.

9. The World Heatlh Organization. Developing Pharmacy Pracitce. A focus on Patient Care.; 2006.

10. Tulip S, Campbell D. Evaluating pharmaceutical care in hospitals. Hospital pharmacist. 2001;8:275-9.

11. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: a systematic review. Arch Intern Med. 2006 May 8;166(9):955-64.

12. Fitzpatrick RW, Boardman HF. A survey of the provision of clinical pharmacy services in relation to existing published standards. Pharm World Sci. 2005 Jun;27(3):191-6.

13. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice. The clinician's guide. 2nd ed: McGraw-Hill; 2004.

14. McFadzean E, Isles C, Moffat J, Norrie J, Stewart D. Is there a role for a prescribing pharmacist in preventing prescribing errors in a medical admission unit? The Pharmaceutical Journal. 2003;270:896-9.

15. Bond CA, Raehl CL. Clinical pharmacy services, pharmacy staffing, and hospital mortality rates. Pharmacotherapy. 2007 Apr;27(4):481-93.

16. Audit Commission. A spoonful of sugar. Medicines management in NHS hospitals. London; 2001 December.

17. Department of Health. The NHS Plan : A plan for investment. A plan for reform; 2000 July.

18. Pharmacy in the Future - Implementing the NHS Plan. 2000 September.

19. Our national health: A plan for action, a plan for change.; 2000.

20. Medicines management services - why are they so important? MeReC Bulletin. 2002 May;12(6):21-4.

21. Tweedie A, Jones I. What is medicines management? The Pharmaceutical Journal. 2001 February 24;266(7136):248.

22. Barber N. Pharmaceutical care and medicines management--is there a difference? Pharm World Sci. 2001 Dec;23(6):210-1.

23. Simpson D. What is medicines management and what is pharmaceutical care? The Pharmaceutical Journal. 2001 February 3;266(7133):150.

24. The Right Medicine: A Strategy For Pharmaceutical Care In Scotland; 2002 December.

25. Department of Health. National Service Framework. Medicines and Older People. Implementing medicines-related aspects of the NSF for Older People. London; 2001 March.

26. National Prescribing Centre. Supplementary Prescribing. A resource to help healthcare professionals to understand the framework and opportunities. Liverpool; 2003 March.

27. National Prescribing Centre. Maintaining Competency in Prescribing. 2nd ed. Staffordshire; 2006.

28. Royal Pharmaceutical Society of Great Britan. Pharmacist prescriber pack.

29. Royal Pharmaceutical Society of Great Britan. Postgraduate courses. [cited 25.02.2008]; Available from: http://www.rpsgb.org/registrationandsupport/postgraduatecourses/

30. Green JL, Hawley JN, Rask KJ. Is the number of prescribing physicians an independent risk factor for adverse drug events in an elderly outpatient population? Am J Geriatr Pharmacother. 2007 Mar;5(1):31-9.

31. Department of Health. Medicine Matters; 2006 July.

32. ASHP guidelines on documenting pharmaceutical care in patient medical records. Am J Health Syst Pharm. 2003 Apr 1;60(7):705-7.

33. Koda-Kimble MA, Young LY, Dradjan WA, Guglielmo BJ. Assessment of Therapy and Pharmaceutical Care. In: Applied therapeutics The clinical use of Drugs: Lippincott, Williams & Wilkins.; 2005. p. 1---17.

34. ASHP guidelines on a standardized method for pharmaceutical care. American Society of Health-System Pharmacists. Am J Health Syst Pharm. 1996 Jul 15;53(14):1713-6.

35. The Royal Pharmaceutical Society of Great Britain. Guidance on Recording Interventions. 2006.

36. Currie JD, Doucette WR, Kuhle J, Sobotka J, Miller WA, McDonough RP, et al. Identification of essential elements in the documentation of pharmacist-provided care. J Am Pharm Assoc (Wash). 2003 Jan-Feb;43(1):41-7; quiz 8-9.

37. Boardman H, Fitzpatrick R. Self reported clinical pharmacist interventions under-estimate their input to patient care. Pharm World Sci. 2001 Apr;23(2):55-9.

38. Canaday BR, Yarborough PC. Documenting pharmaceutical care: creating a standard. Ann Pharmacother. 1994 Nov;28(11):1292-6.

39. National Institute of Clinical Excellence. Principles for Best Practice in Clinical Audit. Oxon; 2002.

40. The Royal Pharmaceutical Society of Great Britain. Practice and Quality Improvement Directorate. Guide to Audit. The Pharmaceutical Journal. 2005 August;275:203-4.

41. General Register Office for Scotland. Mid-2006 Population Estimates Scotland. Edinburgh; 2007.

42. Scottish Executive. Adding Life To Years: Report of the Expert Group on Healthcare of Older People. 2002 January

43. Rowland M, Tozer TN. Age and Weight. In: Clinical Pharmacokinetics Concepts and Applications. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 1995. p. 230-45.

44. Koda-Kimble MA, Young LY, Dradjan WA, Guglielmo BJ. Geriatric therapy. In: Applied therapeutics The clinical use of Drugs. 8th ed: Lippincott, Williams & Wilkins.; 2005. p. 99-1--17.

45. Walker R, Edwards C. Geriatrics. In: Clinical Pharmacy and Therapeutics. 3rd ed: Churchill Livingstone; 2003. p. 127-39.

46. National Health Service Scotland. The Health and Well-being of Older People in Scotland. Edinburgh; 2001.

47. British National Formulary 53. 53rd ed. London: BMJ Publishing Group Ltd. and RPS Publishing; 2007.

48. Patel H, Bell D, Molokhia M, Srishanmuganathan J, Patel M, Car J, et al. Trends in hospital admission for adverse drug reactions in England: analysis of national hospital episode statistics 1998-2005. BMC Clinical Pharmacology. 2007.

49. Spinewine A, Schmader KE, Barber N, Hughes C, Lapane KL, Swine C, et al. Appropriate prescribing in elderly people: how well can it be measured and optimised? Lancet. 2007 Jul 14;370(9582):173-84.

50. National Health Service. Institute for Innovation and Improvement. Improvement Leaders' Guide. Process mapping, analysis and redesign. General improvement skills. 2005.

51. Microsoft Office Visio ©. 2003.

52. Catalyze Ltd. Process Mapping in the NHS. 2002.

53. Hoth AB, Carter BL, Ness J, Bhattacharyya A, Shorr RI, Rosenthal GE, et al. Development and reliability testing of the clinical pharmacist recommendation taxonomy. Pharmacotherapy. 2007 May;27(5):639-46.

54. Strand LM, Morley PC, Cipolle RJ, Ramsey R, Lamsam GD. Drug-related problems: their structure and function. Dicp. 1990 Nov;24(11):1093-7.

55. McAnaw JJ. Development of Novel Approaches to Demonstrate the Quality of Drug Therapy Use [PhD]. Glasgow: University of Strathclyde; 2003.

56. GraphPad Software. GraphPad QuickCalcs. 2005.

57. Altman DG. Some common problems in medical research. Practical Statistics for Medical Research. London: Chapman & Hall; 1991. p. 396-439.

58. Ramly ABA. Medicines Management in the Hospital Service [MPharm final year research project]. Glasgow: University of Strathclyde; 2008.

59. Smith F. Research Methods in Pharmacy Practice. London: Pharmaceutical Press; 2002.

60. Scottish Executive. The Scottish Health Survey. Summary of key findings. Edinburgh; 2003.

61. Viktil KK, Blix HS, Moger TA, Reikvam A. Polypharmacy as commonly defined is an indicator of limited value in the assessment of drug-related problems. Br J Clin Pharmacol. 2007 Feb;63(2):187-95.