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

A research project

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Abstract

Background

Pharmaceutical care as a health care service has already made its mark and been shown to make an important contribution to the health care system. However, there is still a demand from the NHS among others, that pharmacist to a greater extent must document their provision of pharmaceutical care. Tested out in this project, is the application of a Care Issue Categorisation System.

Aims

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, and a modified categorisation system will be use to accomplish this.

Method

A literature review were performed on pharmaceutical care, medicines management, common chronic diseases etc. Process maps were produced to describe the delivery of pharmaceutical care at the General Medical Ward at Glasgow Royal Infirmary. An existing categorisation system was modified and a guideline developed and both used for the analysis of documentation made by the pharmacists. Inter rater agreement on the categorisation system was tested and pharmaceutical activity was compared between two wards.

Result

The existing categorisation system was modified in several parts and tested by four investigators. Process maps and analysis of the care issues documented reveal that there was a inconsistency between the pharmacist's provision of care and documentation. The comparison between two wards showed that the pharmacists had different priorities and documentation.

Conclusion

The modified categorisation system is tool that has the potential to aid future documentation of pharmaceutical provision of patient care.

Comparison of pharmaceutical care activity between two ward showed that pharmacists are contribution to pharmaceutical care but that there are differences in their priorities and documentation of care issues

List of abbreviations

ADR – adverse drug reaction

CF – Carl Fenelon

CI – confidence interval

CMP – Clinical Management Plan

DT – drug therapy

DTP – Drug Therapy problem

GP – general practitioner (doctor)

HDL – High density lipoprotein

IL – Ingrid Lian

IQR – inter quartile range

KH - Kari Husabo

LS – Lee Stewart

MBC - Marit Bergheim Christensen

MRR – Maren Rambol Ruud

NHS – National Health Service

NICE - National Institute for Clinical Excellence

QAD – Quality Assurance Descriptors

ROH – Reidun Os Husteli

SD – standard deviation

SIGN – Scottish Intercollegiate Guidelines Network

ST – Steve Hudson

TD – Tobias Dreischule

Type 1 – type 1 diabetes mellitus

Type 2 – type 2 diabetes mellitus

UK – United Kingdom

Ward A – General Medical ward

Ward B – Care of the Elderly ward

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1 Introduction

1.1 Background

Many lifesaving medicines work in a way that too much or too little can be the difference between successful treatment, unsuccessful treatment or toxicity. It is because of the recognised need to help patients get the *most benefit* from their medicines, and to *minimise* the associated risk, that the practice of pharmaceutical care have become increasingly meaningful.

After the suggestion, by the UK government, through the NHS in 2000, of implementing medicines management services [1], pharmacists and technicians have to an ever-increasing extent found their rightful roles, and are becoming an increasingly important part of the health care team in hospitals.

Pharmaceutical care as a health care service has already made its mark and been shown to make an important contribution to the health care system. However, there is still a need to continuously improve the work that is done. Among the elements that need to be addressed, are the ways in which pharmacists document their work. Although there are guidelines in how to perform pharmaceutical care, there is no doubt that there is great variety in how pharmacists proceed. In order to review and analyse the work carried out by pharmacists in pharmaceutical care practice, it would be advantageous that the documentation of the work in different settings is done in a similar, and therefore a standardised way. One way to make this happen is to have an organised, and well-functioned care plan. This should be designed in a way that easily shows what the pharmacists is implementing and contributing towards inpatient care. Tested out in this project, is the application of a Care Issue Categorisation System.

1.2 Pharmaceutical Care

Over the past four decades there has been a clear tendency for pharmacy practice to extend its line from the original medicine supply, towards that involving a comprehensive focus on patient care. The pharmacist's role has consequently evolved from that of a compounder and supplier of pharmaceutical products, to that of provider of patient care.

The practice of Clinical Pharmacy can be defines as "…a discipline concerned with the application of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients." [2] Pharmaceutical care is used to refer to the pharmacist's contribution to patient care resulting from the practice of clinical pharmacy. [2]

This expansion to patient centred care comprises a new *responsibility* for the pharmacist, and that is to ensure the effectiveness and safety of a patient's drug treatment in the best possible way. By providing patients with counselling, drug information and to monitoring their drug therapy, the pharmacist can make a vital contribution to the outcome of drug therapy and to the patients' quality of life.[3]

The most generally accepted philosophy of Pharmaceutical Care was defined in 1990 by Hepler and Strand as;
"The responsible provision of drug therapy for the purposes of achieving definite outcome that improve a patient's quality of life". [4]
The International Pharmaceutical Federation (FIP) adopted this definition in 1998 but added one amendment: "…*achieving definite outcomes that improve* ***or maintain*** *a patient's quality of life*". [3] The definition has been redefined later by Cipolle, Strand and Morley; "Pharmaceutical care is a patient-centred practice in which the practitioner assumes responsibility for a patient's drug related needs and is held accountable for this commitment " [5]

These concepts of pharmaceutical care describe what the patient deserves to receive from care. However it doesn't mention the pharmacist's role in particular. Because of this fact, pharmaceutical care is open as a team responsibility involving a group of health care professionals and it can be delivered in different ways and settings. The term is in general referring to quality of medicines use and the focus is on achieving

the best outcomes for the patients by assuring optimal drug therapy. The Scottish Executives have further stated in their report "The Right Medicine – a Strategy for Pharmaceutical Care in Scotland: "*Pharmaceutical care reflects a systematic approach that makes sure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons."* [6] The pharmacist's role in this patient-care process is to determent whether the patients drug-related needs are met by taking responsibilities for these latter actions . [7]

In Scotland pharmaceutical care, through the practice of clinical pharmacy, has evolved trough gradually steps taken during the last 30 years. The development started with the "Aberdeen system" for prescription and administration recording, and went further with ward pharmacy and drug information services, to modern clinical pharmacy practice as we now it today. [2]

As pharmaceutical care has infiltrated the health care system, one can see that many different definitions and meanings of the term have been presented. In spite of this, there is one principal counting for all; the patient is the main focus and the responsibility lies in optimising his/her drug therapy.

1.3 **Medicines management**

Medicines management has been adopted rather than pharmaceutical care by the Department of Health in England and Wales. And although the terms are related they are not quite synonymous.[8]
Medicines management comprises the initiatives to improve the means of the supply and use of medicines. [7] It describes how the work and collaboration between health care professionals (physician, nurse, technicians and pharmacist etc) can be organised to achieve and deliver *pharmaceutical care* and hence best outcome for the patients.

In their report "A Spoonful of Sugar – Medicines Management in the NHS "The Audit Commission defines; "Medicines management in hospitals encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care" [1]

The purpose of medicines management is to optimise the way that medicines are used, both by individual patients and the National Health Service (NHS), and this is done by a wide range of activities. *"Medicines management services are processes based on patient need that are used to design, implement deliver and monitor patient-focused care."* [1]The services include *all aspects* of the supply and use of medicines, that is, from a patient's medication review to a health promotion programme. Risk management (e.g. reducing errors caused by prescribed medicines) and disease prevention strategies (e.g. immunisation) are ways in which medicines management services are improving the health of the public. [1]

Several studies over the last few years have shown that pharmacists make a contribution in improving patient care as member of the health care team providing medicines management service, although there is emphasised that more research is needed with larger sample sizes and more areas, to better understand the role of the clinical pharmacist. Reduced medication errors, improved accuracy of drug history documentation, reduced prescribing costs, decreasing the potential risk to patients and patient discharge counselling, are among variables that have been tested and where it have been shown that pharmacists contribute to improvement and positive outcomes.[1, 4, 8-10]

1.3.1 Why do we need pharmaceutical care and medicines management?

The most frequently used form of treatment in any health care setting is drug therapy. The use of medicines has grown substantially as the population has aged and the prevalence of chronic diseases has proliferated.[3] Also new "life-style medicines/ailments" and an increasing amount of over-the-counter drugs (OTC) have been marketed in the recent decades and to an ever increasing extent. This gives reasons for why pharmacists, in particular, have an important contribution to make by giving information about use and effects of these drugs, not just to inpatients but to all patients and the public in general. However, this report will further focus on situations occurring in the hospital setting, where the latter account for a smaller part of the larger picture.

There are several reasons why pharmaceutical care and medicines management are needed in hospital;

With today's exploding development in new drugs, ensuring the safe and effective use of the medicines is a complex and growing challenge. Due to the ageing population with multiple diseases and polypharmacy, combined with advanced drug regimens, patients may have difficulties managing their own drug regimens.[1, 11] Issues that need to be addressed here are for one the fact that up to 50% of patients (especially the elderly) do not or cannot take their medicines as prescribed. Some 6-17% of older inpatients experience some kind of adverse drug reactions while in hospital, and drug related problems are implicated in 5-17% of actual hospital admission in this group. [12]

Unintentional changes in medication after discharge from hospital are a common risk. The prescriber not having the immediate access to accurate information about either the medicine or the patient, causes most errors. Hand-written prescriptions or patients notes also contribute to errors, as they may be illegible, incomplete, subject to transcription errors or using inappropriate abbreviations. [1] Continuing the implementation of Medicines Management can improve this lack of good communication between health care personnel. [6]

It must also be kept in mind the importance of assuring the most *rational use* of medicines. This implies the need to ensure that patients receive the appropriate drug for their clinical needs, in the doses that are effective and safe for each individual, for an appropriate period of time and at the most economical cost possible for both them and the community [3].

All these examples of contributions emphasise the importance of Medicines Management and the collaboration between different health care personnel. Pharmaceutical care in terms of evaluating and monitoring drug regimens, informing the patient about medicines effect and use, and the follow-up of the patient are also of obvious importance here. There is no doubt that when medicines are used for the greatest possible benefit of each individual patient, and of society as a whole, this will gain in improved health care as well as cost savings. [3]

1.4 **The hospital pharmacist specialisation.**

There has been a great development over the past 30 years in both the role of the pharmacist as carer for patient and in the general knowledge about diseases and drugs. This has led to a significant vigilance where it has been realised that the traditional roles of the physician prescribing and the pharmacist dispensing is no longer sufficient to ensure the safety, effectiveness and compliance to drug therapy.
Errors related to medicines use are costly for the domestic economy in terms of hospitalisations, laboratory tests and remedial therapy [3]

To an ever-increasing extent the impact drug therapy can have on patient care has been made visible; interaction, administration problems, adverse drug reactions, compliance and educational needs. This has led to the opening and widening of the need for clinical pharmacists to improve the use of medicines. Due to the increasing complexity of drug therapy management, pharmacists have established clearer roles in the health care team, optimising the patient drug therapy by identifying and resolving drug therapy problems and preventing new problems from occurring. [1, 5, 6]
In UK the last twenty years, hospital pharmaceutical services have had a considerably development with clinical pharmacy services being established as an important part of hospital healthcare. Through the practice of clinical pharmacy the pharmacists provide services intended to deliver pharmaceutical care to hospital patients.[13, 14]

1.5 **Pharmaceutical Care Issues and Drug Therapy Problems**

The pharmacist initiates his/her provision to pharmaceutical care by gathering information about the patient's drug treatment and medical history. Through an assessment, pharmaceutical care issues will be revealed.
A pharmaceutical care issue is an identified concern regarding a potential or actual drug therapy problem which is addressed by the pharmacist.
When a patient's drug related needs are not being met they usually result in drug therapy problems. (DTPs)

"A drug therapy problem is 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" [5]

The most common cause of adverse incidents in hospital patient is a complication arising from the use of medicines. The drug-related problems may be caused due to the effect of the drug, patient factors or other idiosyncratic factors. The way in which drugs are administered will also make an impact and might be a contributing factor. [11] Cipolle, Strand and Morley have stated that: *" Identifying drug therapy problems is to pharmaceutical care what making a medical diagnosis is to medical care",* [5] in other words, the most important contribution the pharmacist can make. And further to take the responsibility to resolve and prevent them.

1.6 Pharmaceutical care provided by the hospital pharmacist.

In the absence of a standard description of pharmaceutical care, or consistent level of staffing in the NHS, different hospitals and primary care services have adopted different levels of care provision. (ref bok R)

The American Society of Health-System Pharmacists, ASHP published a document in 1996 [15] where they presented guidelines on a standardised method for pharmacists providing pharmaceutical care. Their document described a method based on function that they thought all pharmacists should perform for individual patients in organised health systems. The reason for this was the recognition of considerable variation in pharmacists' provision of pharmaceutical care. With a

standardised method it would be a consistency in the provision of pharmaceutical care in any practice setting. The aim with these guidelines was among many to assist pharmacists in implementing pharmaceutical care in their work sites. Also that these methods would establish consistent documentation so that information concerning the patient and his/her drugs could be shared between pharmacists and other health care personnel. Following are the points which the ASHP believed should be included in the standardises methods of pharmaceutical care;

- Collecting and organising patient-specific information,
- Determining the presence of medication-therapy problems,
- Summarising patients' health care needs,

- Specifying pharmacotherapeutic goals,
- Designing a monitoring plan,
- Developing a pharmacotherapeutic regimen and corresponding monitoring plan in collaboration with the patient and other health professionals,

- Initiating the pharmacotherapeutic regimen,
- Monitoring the effects of the pharmacotherapeutic regimen, *and*
- Redesigning the pharmacotherapeutic regimen and monitoring plan[15]

Today it points to that this standardised method is implemented among the pharmacists in different degree and manners in the clinical settings.

As emphasised, the pharmacist is a member of a health care team providing pharmaceutical care. The pharmacist's task and hence responsibility in the delivery of pharmaceutical care, if first and foremost to ensure safety and effectiveness regarding the patient drug therapy. This means to ensure that a patient is given drug(s) that is appropriately *indicated*, the most *effective* available, the *safest* possible, and most convenient for the patient. [3]

The pharmacist's contribution can further be divided into 3 main processes in order to fulfil this accountability;

1. Identifying potential and actual drug therapy problems
2. Resolving actual drug therapy problem
3. Preventing potential drug therapy problems.[6, 8]

There are many ways in which all of these tasks can be performed, depending on the individual situation of each patient. However, they all involve assessment, monitoring and follow-up of the patients in order to be accomplished. Assessment is a key word in the approach to patient care, and means in this setting "the identification and

review of an individual patient's pharmaceutical care issues". [2] The assessment comprises medication history, evaluating prescribed drugs, monitoring drug therapy, consulting clinical records and liaising with the patient, carer and other health care members [2]

As a general there are however some important points regarding these 3 main processes:

Identifying a drug therapy problem requires the pharmacist to spot the association between a patient medical condition (signs, symptoms, abnormality etc), physical condition (e.g. allergy etc) and his/her drug therapy.

Resolving a drug therapy problem requires the pharmacist to know how, or be able to find out how, to deal with the unmet needs of the patients' drug therapy and disease state. This most often involve a discussion and cooperation with other health care members.

*Preventin*g drug therapy problems is also a major task for the pharmacist. When it comes to drug therapy it is important that the patient receive appropriate preventive medications if necessary. (e.g. aspirin to prevent myocardial infarct in high risk patient) [5] Also assuring that the patient does not receive any medicines which cause interaction, side-effects or are contraindicated etc. are part of the prevention of drug therapy problems.

Moreover, the pharmacist plays an important role in ensuring that the patient gets the information they need and understands how to use their medicines and by this have the best starting point to achieve the best outcome. In addition monitoring of drug therapy, general patient education and follow-up of the patient, in order to ensure the best therapeutic outcomes, are also all included in the preceding processes. All together these are contributions to pharmaceutical care made by the pharmacists on the wards.

A more detailed description of how the different tasks are performed will be described in the process maps presented in under the Results.

1.7 Categories of Drug Therapy Problems

It was in 1990 that a research group at the Peters Institute of Pharmaceutical Care at the University of Minnesota defined and developed the categorisation of drug therapy problems [5] The research group categorised patient problems involving medication into 7 different types of drug therapy problems. (Table1) The same classification of drug therapy problems, with small adjustments, will be used in this project. The categories are adopted from the book "Pharmaceutical Care Practice – the Clinician's guide".[5] All together these seven categories sum up the problems that drugs might cause, but also how drugs can solve them; by changing and optimise the drug therapy.

Table 1.Categories of drug Therapy Problems[5]

Drug Therapy Problem	DTP
Unnecessary Drug therapy	DTP 1
Needs additional drug therapy	DTP 2
Ineffective drug product	DTP 3
Dosage too low	DTP 4
Adverse drug reaction	DTP 5
Dosage too high	DTP 6
Non-compliance	DTP 7

Looking at the different drug therapy problems one can see that they also cover the four aspects of *indication*, *effectiveness*, *safety* and *compliance* (table 2).

Table 2. Relating DPTs to Indication, Effectiveness, Safety and Compliance 5

INDICATION	▪ Unnecessary Drug therapy ▪ Needs additional drug therapy
EFFECTIVENESS	▪ Ineffective drug product ▪ Dosage too low
SAFETY	▪ Adverse drug reaction ▪ Dosage too high
COMPLIANCE	▪ Non-compliance

For further details on the subcategories of the DTP see Appendix and “Guidelines – Suggested Categorisation for Pharmaceutical Care Issues”

1.8 Why categorise Drug Therapy Problems?

The Guideline – “Suggested Categorisation for Pharmaceutical Care Issues” will describe the process of categorising care issues into different categories, a triangularised system. Following are a sum up of why Drug Therapy Problems are divided into 7 different categories.

Drug therapy problem encompasses the drug, the patient and the medical problem that links them together. Despite the fact that there is a huge number of different drugs and prescriptions, and quite a number of acute and chronic diseases, which theoretically could have given unmanageable numbers of drug therapy problems, there are only *seven* main groups of drug therapy problems. [5]

Categorising drug therapy problems into these different categories is advantageous for many reasons. With different categories, a systematic process of problem solving can be developed and aid the pharmacist in obtaining the overall positive health outcomes of each individual patient. And by this, ease the work done by pharmacist in pharmaceutical care. On a population level the categorisation of DTP could help pharmacoepidemiologists in developing a national database concerning DTPs and make the documentation clearer. [5]

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Furthermore, these categories will help to clarify the professional responsibilities of the pharmacist working with pharmaceutical care as a team member. Dividing DTP into different categories put care issues, such as noncompliance, into a visible clinical perspective. Another function of this categorisation is that it gives the pharmacist a vocabulary that coincides with that used by other health care professionals. By defining the pharmacist’s function in terms of identification, resolution and prevention of DTP, his/her function is placed in a patient-care context consistent with the responsibilities of other healthcare professionals.[5]

1.9 The Care Plan

In Scotland, many pharmacists in the hospitals are trained and encouraged to provide a care plan for patients in their care. The care plan will state the care issues regarding the patient medical condition(s) and drug therapy. A planned action to be taken, together with the outcome of the former, should also be included in the care plan.

"The concept of a pharmaceutical care plan is the use of a document as a clinical tool that identifies potential problems with a patient's medicines. It records the pharmacist's action with patients, nurses and doctors to address those problems." [7]

The main purpose of the care plan is, in co-operation with the patient, to determine how to best manage his/her medical conditions in the best way by using drug therapy.[5] The documentation within the care plan first of all points out the desired outcome of the patient's drug therapy and describes the actions taken to accomplish this. By committing to writing the care issues addresses by the pharmacist in the care plan the work done is validated, and hence the care plans can be assigned a "quality assurance document". [14] The monitoring and follow-up of the patient is also an important part of the pharmaceutical care, which should be included within the care plan to determine the outcomes of the drug treatment at a clinically appropriate time.

As mentioned at the beginning, the care plan has a standard template in general, but how it is used and how the documentation is performed differs widely among the individual pharmacists. This can probably not be avoided, but by improving the documentation by making it more consistence, clearer and hence valuable for other health care member, this could result in a tool for better continuity of care between secondary and primary settings.

1.10 Documentation in pharmaceutical care - amendment ahead

Compared to the pharmacists' traditional role, the practice of pharmaceutical care still needs to continue finding its way and become recognised. For the time being pharmacists have not to a considerable extent undertaken the responsibility to

document, monitor and review the care they are giving. Nonetheless, accepting to do this is essential to the practice of pharmaceutical care. [6, 7]

In the review article " The Changing role of pharmacists in society " there is a stated demand for pharmacists taking action in helping improving the system that they are working in by, among other things, documenting problem solving, improving teamwork and continuity of care. [7] Also the Scottish Executive has stated in their report "The Right Medicine. A strategy for pharmaceutical care in Scotland" that the actions the pharmacist performs in clinical health care, needs to be recorded in order to develop and ensure the improvements in pharmaceutical care in Scotland.[6] Most reports and document guidance today regarding documentations is made for the community pharmacy systems. However, it is emphasized in the recent document from the Royal Pharmaceutical Society of Great Britain – "Guidance on Recording Interventions", that documentation on the actions pharmacist perform applies equally to wherever a pharmacist practices. [16]

1.10.1 Why is documentation important?

As continuity of care and good communication between health care personnel within and between clinical settings are key elements in good pharmaceutical care practice, this would depend on reliable records. [16]

The Royal Pharmaceutical Society of Great Britain implies several reasons why pharmacist should make an effort to document the work they are doing. Firstly, to ensure patient safety and to improve the quality and continuity of care. Secondly to have an accurate document available on closer inspection when decisions made regarding a patient are questioned (e.g. changes made in prescribing). By documenting the contribution and actions made by pharmacists in the health care services, evidence of the value a pharmacist represents as a member of the health care team, is also identified (e.g. improvement in patient care through their clinical input to patient assessment) [16]

Documentation further points out the extent of responsibility the pharmacists have taken for their professional actions and is an important component in demonstrating how professional judgement is put into practice. Moreover it is emphasized that any situation where the pharmacist makes a significant contribution to patient care should

be included in the documentation, not only prescription interventions. These situations would, among others, include alterations that are of clinical significance and could be regarded as having direct impact on patient care, and alterations that lead to learning and improvement of standards of care. [16]

By making a standard way of documenting their identification of care issues and problem solving, pharmacists will also have to be aware of what kind of action they are taking in the care plans. Whether they are making an impact on the patient behaviour or the drug therapy etc. The suggestion in this research project to categorise the different care issues into Check or Changes categories (Strand, McAnaw)[17], Drug Therapy Problems (Cipolle, Strand)[5], and Quality Assurance Descriptors (McAnaw, Hudson)[7] will also make it clearer for the pharmacist and others interested, what exactly is happening in the care plan. In other words, what the pharmacist is identifying, resolving and preventing in the patient's drug therapy will be made visible, and also when in the treatment cycle it is done. (see Appendix 2)

1.11 **The General Medical Ward**

The General Medical Ward at the Glasgow Royal Infirmary, is also known as the Cardiac and Diabetic ward. Patients are admitted to this unit either directly from referral from the Acute Receiving Unit, the Coronary Care Unit (CCU), from the diabetic clinics or after a planned admission that have come via a GP referral to a hospital internal specialist. In general the patients admitted here suffer from different diseases. Most of them have some form of cardiovascular complication, alone or in addition to other diseases and internal medicine exacerbations. Many of the patients at this ward are transferred further to other wards for continuity of care.

The pharmacist at the General Medical Ward works as a member of the health care team. The responsibilities of the pharmacist lie in checking and optimising the patients' drug therapy to ensure safe and effective use of medicines for the patients at this ward. Further description of the tasks performed by the pharmacist will be viewed under process maps.

1.12 Comorbidity and Complications – reasons for acute exacerbation

The term “co-morbidity” means that more than one illness affects an individual, and that each of the illnesses may influence the course and management of the others. [18] Those who suffer multiple illnesses often suffer them simultaneously. Each condition can seldom be treated in isolation from the others. There has been recognised an urgent need to know much more about the optimal management of patients with comorbidity. Their complex needs lead to greater dependence on hospital stay to support them. Joint working between primary and secondary healthcare teams can be one way to best achieve this.[18]

1.13 Chronic disease management and hospitalisation

Chronic disease is a condition that last 3 months or longer and requires ongoing medical care. [19] As people live longer the prevalence of chronic diseases are increasing. The modern healthcare has realised that responding well to the needs of these patients is important in order to optimise their quality of life and prevent future burden both for the patients and the health services.

A definition of chronic disease management is: “A system of coordinated healthcare interventions and communications for populations with long-term conditions in which patient self-care is significant.”[18]

Chronic diseases include diabetes, asthma, arthritis, heart diseases, depression, psoriasis etc. Their degree and severity vary, but for many these conditions have a great impact on a person’s life. Chronic diseases of different kind are reported in about 60% of adults. The Department of Health stated in 2004 that people with chronic diseases are significantly more likely to see their GP, as they account for about 80 % of GP consultations. On average they are admitted as an inpatient twice as often, and stay in hospital longer than people without chronic disease. Moreover, 15% of people with three or more problems account for 30% of inpatient days. [20]

The NHS Improvement Plan in 2004 highlighted the need for effective management of chronic diseases as a national priority to provide better services and quality care for patient with long-term conditions. The aims is both to enhance benefits for the patients but also to create a more efficient health service that would be able to meet

the needs for all the patients it serves.[21] There is strong evidence that improved management of these conditions would lead to fewer admissions to hospitals/ inpatient care. By slowing the progression of a disease this can delay and prevent the need for treatment in hospital. For example, better management of high blood pressure and high cholesterol in patients with heart disease means that fewer of these patients will be readmitted with heart failure and require heart surgery.[20] Most of the interventions aimed at the managing and preventing of chronic diseases are delivered in the primary and community settings. However an effective approach to chronic management requires a system that works across primary and secondary care and social services as an integrated system. [19, 20]

Further, the Department of Health emphasises that ” improving approaches to chronic disease management is not just an issue for primary care organisations, but will also impact on secondary and emergency care through: reducing waiting lists; improved management of demand; development of the workforce; improved medicines management; and freeing up resources to improve other services.” [19]. By achieving these outputs it is expected that quality of care and health outcomes for patients will be improved. [19]

Health promotion that is focused on *preventing* the wider population from developing chronic disease is also of huge importance in containing the prevalence of chronic disease. [19] In relevance to the General Medical ward, high alcohol intake, obesity and smoking are risk factors for both diabetes and cardiovascular disease. These are concerns, which mainly are dealt with in primary care based services through GP and specialist practice nurses and practice pharmacists (primary care pharmacists). Still there is connection to secondary care through continuity of care, by referring inpatients with these problems to smoking cassation, health counsellors and outpatient clinics etc. and provide them with necessary information and education while inpatient.

1.14 Diseases on the General Medical Ward

Since 59 % of the patient at the General Medical Ward during the survey period suffered from cardiovascular disease and 17% had the diagnosis diabetes mellitus, the comorbidity of these chronic diseases will be reviewed. The complication arising from diabetes mellitus will also be presented.

1.14.1 Diabetes mellitus

Epidemiology and aetiology

Diabetes Mellitus is among the most common chronic disorders in the UK. It is characterised by varying degrees of insulin hyposecretion and/or insulin insensitivity and associated with hyperglycaemia. The two main types of diabetes mellitus are type 1 and type 2. Type 2 is the most common affecting approximately 75% of all patient with the disease in most populations. It usually occurs in patients over the age of 40 years and the incidence of type 2 increases with age and with increasing obesity. Type 1 may present at any age but there approximately 50-60% present before 20 years of age. The aetiology differs between the two types. In short; with type 1 the β cells in pancreas are destroyed due to autoimmune or idiosyncratic reasons. This usually leads to absolute insulin deficiency. With type 2 there is a decreased production of insulin and/or an insulin resistance. [22]

Approximately 3.5% of the population the UK suffer from diabetes mellitus (10 percent from Type 1 and 90 percent from Type 2) and the prevalence is rising. [23] It is estimated that there will be three million people with diabetes in the UK by 2010. The potentially consequences for the health service will be increased workload and financial costs. The identification of diabetes and the importance of this to the health of the nation have been acknowledged by all four nations of the UK. It has been accepted that the primary care will be the organ that will provide the majority of routine clinical care for this patient group [24] Still, the hospital health care team have an important responsibility in ensuring safe and effective treatment of patients admitted with exacerbation of their diabetic disease, diabetes complicating a cardiovascular condition and combination of other complications, such as infections.

1.14.2 Complications of diabetes mellitus

The initially treatment aims of diabetes mellitus are in general to relieve of the signs and symptoms of the disease. (polydipsia, polyuria, weight loss and ketoacidosis) However, since this is a chronically disease, in long-term the treatment aims would also be to prevent the development, or slow the progression of possible complications of the disease.[25, 26]

The two controllable factors that influence the development of diabetic complications are persistent hyperglycaemia and hypertension. These can further be divided into those caused by microvascular disease and those secondary to macrovascular disease.[22] These latter will briefly be presented in what follows.

1.14.3 Microvascular diseases

Microvascular disease refers to damages to the small blood vessels supplying the eyes, kidneys and nerves. [27]

1.14.3.1 Retinopathy

Retinopathy is one of the long-term complications the diabetic patients risk. It is caused by changes in the blood vessels of the retina. These changes can either be that the blood vessels are blocked, swell and leak fluid or that abnormal new blood vessels grow on the surface of the retina. If left untreated this damage vision, and in the working population diabetic retinopathy is the leading cause of blindness. To reduce the risk it is important to keep blood glucose, blood pressure and blood fat levels under control. People with diabetic should have their eyes screened every year. [26 28, 29]

1.14.3.2 Diabetic Neuropat

Neuropathy causes damage to the nerves that transmit impulses to and from the brain and spinal cord, to the muscles, skin, blood vessels and other organs. [26 30] Diabetic neuropathies are very heterogeneous and include focal neuropathies (entrapment syndromes and mononeuropathies), distal sensory polyneuropathy, and autonomic neuropathy. [30] Further, only distal sensory polyneuropathy, will be looked into.

Diabetes is the most common cause of neuropathy in the Western world. A large cross-sectional study of 6487 diabetic patients in the UK found the prevalence of diabetic neuropathy to be 28.5%. The prevalence increased with the duration of the disease. The most common neuropathy was distal sensory polyneuropathy, with a prevalence of 54% in patients with type 1 diabetes, and 45% in patients with type 2 diabetes. [31] Distal sensory polyneuropathy ("glove and stocking" sensory symptoms) is a length-dependent process, with the most distal portions of the longest nerves affected earliest. Thus, the earliest symptoms typically involve the toes, and then ascend. The pain is particularly troubling to most patients, and it is common for such patients to present primarily because of pain in the feet. It can be the most disabling of all diabetic complications, and is a cause of considerable morbidity. Distal sensory polyneuropathy also predisposes patients to neuropathic foot ulcer. Foot problems are the complication which accounts for the highest inpatient hospital bed occupancy in diabetic patients.[22, 31]

Despite research, there is still no conclusive proof of what causes diabetic neuropathy. However both metabolic and vascular factors appear to be involved in the pathogenesis. Hyperglycaemia causes chemical changes in nerves that can impair their ability to transmit signals. Hyperglycaemia can also harm the blood vessels that carry oxygen and nutrients to the nerves. [26,31] The necessary way to diminish the risk of developing neuropathy, or prevent it becoming worse, is to control the blood glucose level. [30]

1.14.3.3 Nephropathy / kidney disease

Nephropathy or kidney disease is a serious condition where the kidney becomes damaged and more protein than normal is excreted in the urine. Over time, the kidney's ability to function begins to decline, which may eventually lead to chronic kidney failure and in the worst case end-stage renal disease. Diabetes is the major cause of kidney failure. [21, 22, 32] Like retinopathy and neuropathy, nephropathy is also caused by damage to the small blood vessels. [26] The earliest clinical evidence of nephropathy is called microalbuminuria and this is the appearance of low levels of albumin in the urine (30 mg/day). The overt nephropathy is urinary albumin excretion

of more than 300 mg per day. About 20-30% of patient with both types of diabetes develop evidence of nephropathy.

The typical time frame for nephropathy to develop is 10 to 20 years after onset of diabetes mellitus. Elderly patients with diabetes are therefore at higher risk than younger patients at developing nephropathy, which progresses from microalbuminuria to overt proteinuria. Independent risk factors for proteinuria and renal insufficiency include poor glycaemic control over many years, hypertension, high serum total cholesterol levels, and smoking. [30] In addition to it being the earliest manifestation of nephropathy, albuminuria is a marker of greatly increased cardiovascular morbidity and mortality for patients with either type 1 or type 2 diabetes. [25]

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) have shown that intensive diabetes therapy can significantly reduce the risk of the development of microalbuminuria and overt nephropathy in people with diabetes.[25] As the kidney is one of the major excretion pathways for drugs in the body it is essential to have the knowledge of which drugs are affected when the patient suffer from renal impairment. To spot the need for dose reductions or contraindications leading to a change in drug therapy are of very high importance in order to prevent serious adverse drug reaction and toxicity.

The DCCT and the UKPDS studies further stated that prevention is the keyword in the management of microvascular diseases in general. Tight blood pressure control (average 140/88 mmHg) gave a reduction of 37% in microvascular disease, and an intensive blood glucose control (between 4 and 6 mmol/l before meals, and less than 10 mmol/l two hours after a meal) decreased the risk of microvascular disease by 25%. [25, 30, 33]

1.14.4 Macrovascular disease and diabetes mellitus

Macrovascular disease refers to illnesses in the large blood vessels including the coronary arteries, the aorta, and the biggest arteries in the brain and in the limbs. A common term for the diseases which affect these arteries are cardiovascular diseases (CVD) and these include; ischemic heart disease (angina and heart attack), heart failure, stroke and all other diseases of the heart and circulation, such as

hardening and narrowing of the arteries supplying blood to the legs - peripheral vascular disease (PVD). This latter also account for much of the morbidity associated with foot problems among people with diabetes. Heart diseases and stroke are however the two most common forms of CVD. [22, 23, 27]

The risk of CVD is increased up to a fivefold in people with diabetes compared to those without diabetes. [23, 34, 35] Cardiovascular disease is also the major cause of both morbidity and mortality in people with diabetes, with coronary heart disease as the most common cause of death among people with diabetes type 2. [34, 36] The United Kingdom Prospective Diabetes Study (UKPDS) showed that an increase in HbA_{1c} levels from 6% to 11% doubled the risk of myocardial infarction. [35] The reason for this is believed to be prolonged, poorly controlled blood glucose levels, which affect the lining of the body's arterial walls. As people with Type 2 diabetes often also have low level of HDL cholesterol and raised levels of triglycerides this further increases the likelihood of plaque and formation of atherosclerosis. In general raised blood lipid levels are known to be a risk factor for coronary heart disease and management of the lipid levels can contribute to the reduction in cardiovascular risk in people with type 2 diabetes [23,36]

Hypertension is another risk factor associated with many complications of diabetes, especially cardiovascular disease. General recommendations state that blood pressure in diabetic patients should be < 140/90 mm Hg or <130/85 mmHg.[26, 33, 37] Findings from the United Kingdom Prospective Diabetes Study (UKPDS) indicated that tight blood pressure control (average 144/82 mm Hg) reduced the risk significantly by 24 % for any end points related to diabetes. Heart failure and stroke achieved a reduction in risk of 56 % and 44 % respectively.[33, 36]

At the Diabetes UK's Annual Professional Conference in Glasgow in March 2008 numbers from a ten years study was presented. It revealed that between April 2005 and March 2006 people with diabetes accounted for 13.9 per cent of all hospital admissions for heart attacks compared to 7.2 per cent between April 1996 and March 1997. Further the researchers studied hospital records for more than 2.8 million major cardiovascular events and over 600 000 cardiovascular procedures in England. From these findings there were shown that in the same two periods angina admissions more than doubled from 6.7 per cent to 15.3 per cent in people with type

2 diabetes. Stroke admissions increased from 6.1 per cent to 11.3 per cent as well. These results give rise to concerns, as 80 percent of people with diabetes die of CVD related complications each year. However it has been shown that good diabetes management can reduce the risk of heart disease by 56 per cent, [38] and it is of great importance that people with diabetes have good access to high-quality care to enable them to control their disease. This would include monitoring of blood lipid levels and blood pressure regularly. [36]

There is a range of other complications that can occur in diabetic patients. These include hypoglycaemia, diabetic ketoacidosis, non-ketotic hyperglycaemic coma, musculoskeletal problems and dermatological conditions. In addition it seems that many infections (e.g urinary tract infection) are seen more frequently in diabetes patient due to poor diabetic control [22, 26].

General information and education around these diseases are important. Polypharmacy enhances the risk of adverse side effects, interactions, and nonadherence to taking drugs. These problems are increased in patients with comorbidity of diabetes and cardiovascular disease, in which several medications are necessary to manage hyperglycemia, hyperlipidemia, hypertension etc.[30] Assessment and follow-up need to be performed and undertaken both in primary - and secondary care, wherever the patients are. Continuity of care is thus essential in this setting.

1.15 Non-medical prescribing

The Health and Social Care Act 2001 gave permission for the introduction of independent and supplementary prescribing status for health care professionals, and this included community and hospital pharmacists.[13]
Hence there are two types of prescribers to be recognised;
The independent prescriber (doctor/ dentist) is responsible for the assessment and diagnosing of patients and decision about their clinical management, including prescribing.

The supplementary prescriber (pharmacist or nurse) will be responsible for the continuing care of a patient who has been assessed by the independent prescriber.

This might include prescribing within clinical guidelines, repeating prescriptions and adjustment of dose or dosage form according to the patient's needs. [39]

The definition of supplementary prescribing is "a voluntary partnership between an independent prescriber and a supplementary prescriber to implement an agreed patient–specific Clinical Management Plan with the patient's agreement." [40] This means that before supplementary prescribing can take place, it is mandatory for an agreed Clinical Management Plan CMP to be established (written or electronic). The plan will be developed to include the diagnosis of the patient by the doctor/dentist and followed by a consultation and an agreement between the independent and supplementary prescriber.[40] The principle emphasised in the concept of supplementary prescribing is partnership. This include the patient, so in order to carry out this action it is required that an explanation of what supplementary prescribing entails is given to the patient and then the patient's approval must be obtained. The CMP may include local or national clinical guidelines, as an alternative to listing medicines individually. It should though be emphasized that supplementary prescribing only will be undertaken as long as the pharmacist has the skills to perform this task. In order to become a supplementary prescriber the pharmacists must undertake a specific programme of preparation which standards are set by the Royal Pharmaceutical Society of great Britain (RPSGB) and approved by NHS Education for Scotland (NES) [39]

The supplementary prescribers responsibilities lies within monitoring and assessing the patient in accordance with the patient's condition and medicines prescribed. The supplementary prescriber has influence on the choice of dosage, frequency, product and other variables in relation to medicines within the limits specified by the CMP. In order for the supplementary prescribing to be safe and effective it is essential that the relationship between the independent prescriber and the supplementary prescriber is based upon good communication where they agree and share a common understanding of the written CMP. They must share the same local or national guidelines or protocols if these are referred to in the CMP and consult each other when needed in the review of the patient. [39]

Supplementary prescribing is primarily intended for use in managing specific chronic diseases or health needs affecting the patient. Still, there are no legal restrictions on the clinical conditions that supplementary prescribers may treat, provided that they

are included in the CMP. Supplementary prescribers are able to prescribe all medicines with the current exceptions of Controlled Drugs and unlicensed drugs.[39]

1.15.1 Aims of supplementary prescribing

The Scottish Executive's strategy document "The Right Medicine: A Strategy for Pharmaceutical Care in Scotland", calls for joint working between medical and pharmacist practitioners. "Supplementary prescribing by pharmacists facilitates joint working, particularly between community pharmacists and GPs and hospital doctors and pharmacists by allowing registered medical and dental practitioners to better utilise pharmacists' expertise for the benefit of patients." [39]

The Department of Health defined that; "Supplementary prescribing is intended to provide patients with quicker and more efficient access to medicines, and to make the best use of the clinical skills of eligible professionals." [41] The intention is further to improve the ongoing process of optimising the patient's drug treatment. The supplementary prescribing is based upon the foregoing development of pharmaceutical care as a system for identifying, resolving and preventing drug therapy problems. The pharmacist is already taking part in the team process of pharmaceutical care by assessing the effectiveness and safety of drugs, monitoring and giving patient education etc. Fulfilling the care by being able to prescribe new medicines or altered doses, which the pharmacist himself recommends in the first place, ensures the follow-up by one health care member. It is however important to emphasise that there should be a dialogue and discussion between the pharmacist and the physician, or other health care members, when it comes to ensuring the best drug treatment for the patient, as pharmaceutical care is a health care team responsibility. The effectiveness of supplementary prescribing is in this regard to avoid unnecessary time spent by the physician on clerical which the pharmacist can do him/herself when the prescription is the result of an agreement between the two health professionals. The intention forward is that with time, supplementary prescribing is likely to reduce the doctor's workloads, freeing up their time to concentrate on patients with more complicated conditions and treatments. [6, 13, 42] "Time spent initially developing a simple Clinical Management Plan, is intended to be time saved when the patient returns for review to the supplementary prescriber rather than the doctor." [41]

1.16 Clinical Audit

Audit is a system widely used in the UK. It is generally a term involving an evaluation/review of a product, process or system in order to spot areas which need to be improved or changed.

Clinical audit was introduced to the NHS in the late 1990s. A Clinical Audit is defined as " 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." Clinical audit is used in a wide variety of topics and differs from clinical research in that clinical audit "…*aims to establish the extent to which actual clinical practice compares with best clinical practice…" ,* whereas *"…clinical research aims to establish what is the best clinical practice...*" [43]

The primary function of clinical audit, which involves several professionals, is to improve patient care by evaluating healthcare professionals understanding of how they practice. A performance is reviewed to make sure that what should be done is being done. The outcome would either be that the process is satisfying or that improvements need to be commenced. A clinical audit is collaboratively and systematically and can be describe as a cycle where there are stages to be followed; First the problem or issue that needs to be reviewed is identified. Secondly, criteria and standards relevant for the audit are defined. Thereafter the data collection is initiated and performance observed. Based on the data collection the performance/processes are compared with the standards and criteria. If the results are deviating from the criteria in a way that can not be approved, implementation of suggested changes is the final stage. The audit should be repeated a time after implementing the changes to see if improvements has succeeded, hence the process can be seen as an audit –loop. The purpose is to review the quality of care with an approach that is supportive and developmental to reach the goal of best services provided for the patients. [43, 44]

1.17 Project focus

The focus of this project has been to analyse the documentation within the care plans written by the pharmacist at the General Medical ward at Glasgow Royal Infirmary. In order to do this analysis an existing categorisation system used at University of Strathclyde has been modified. A guideline for this modified system has also been developed, with the purpose of making future documentation easier and more standardised. This project is concentrating on secondary care delivery of pharmaceutical care but has been researching a tool, in form of a categorisation system that will have a goal of maintaining continuity of care with primary care services after a patient's discharge.

2 Methods

2.1 Aims and objectives

2.1.1 Aim

To compare two clinical settings in terms of the profile of pharmaceutical care delivered and the profile of medication use.

To report the findings in ways that allow quantitative comparison of pharmaceutical care issues addressed by the clinical pharmacy service in a proposed reporting system.

2.1.2 Objectives

1) Review the literature on major common diseases in acute general medicine/cardiology and diabetes 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 service 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.

2.2 Subjects and setting

The clinical setting for this project was the General Medical ward at Glasgow Royal Infirmary, Glasgow. This ward has one permanent clinical pharmacist, Mr. Carl Fenelon, who works 8.30 am to 12.30 pm Monday to Friday which may vary according to clinical need. The ward does not have any technicians as member of the staff. Being a ward for male, it has 22 beds which all where mostly occupied during the collection period. There are two rooms for isolated patients.

There were two incidents were the ward was closed, eight days all together due to an outbreak of vomiting and diarrhoea. During these periods there were no new patients admitted. The pharmacist did also go away for some days in February and patient during these days were not included in the survey either.

Patient turnover during the period survey period of 13 weeks was 122. Being a general medical ward the patients coming here have a diversity of conditions and diseases they need treatment for. Cardiovascular disease, diabetes, cancer, alcohol problems/liver diseases and infections, were among those that were seen most frequently. Comorbidity is quite common for most of the patients.

2.3 Investigators

This project was conducted in parallel with investigator KH and collaborator Chan Sue Li. The investigator and KH had the same aims and objectives but were collecting their data from different wards. MPharm student Chan Sue Li studied prescription turnover and quantification of exposure of each patient to medication during their stay at the General Medical ward.

2.4 Ethical Approval.

The study was considered to be audit in nature. This was forwarded to the chair of the local Glasgow Royal Infirmary Ethics committee who agreed that it was audit and further ethical approval was unnecessary. The investigator maintained confidentiality by anonymising all the patient included at the hospital, before bringing the data out.

2.5 Literature review

The investigator started the information search by reading through government document on pharmaceutical care and medicines management in the UK. The book *Pharmaceutical Care Practice – the Clinician's Guide* by Cipolle et.al has also been one of the main sources to both clinical pharmacy and drug therapy problems.

A literature search was performed in order to review the documentation on pharmaceutical care, medicines management, diabetic mellitus and cardiovascular disease, chronic disease management and non-medical prescribing etc.

Searches were performed in medical databases such as Medline and Embase for articles related to the different subjects by using predefined searching terms. (MesH terms) SIGN or NICE guidelines were also used. Reference list to published articles on relevant issues etc. was also examined and those references of interest searched for. Different web pages of pharmaceutical information such as the Pharmaceutical Journal, Royal Pharmaceutical Society of Great Britain etc. and Google were used to supplement the search for literature when necessary. The search was limited to publication between 1990- 2007/2008.

2.6 Collecting data from the ward.

The investigator started to collect care plans from patient admitted to the ward from the 12th of January 2007. A 100 patients were included in the survey by the 8th of March. Care delivery was recorded from admission date to patient discharged / transferred/died. For the purpose of this project the pharmaceutical care plans were collected and copied retrospectively at the hospital in the period January to April on the average of twice weekly. Attending ward rounds and discussing with the clinical pharmacist validated the clinical interpretation of the care issues. The investigator and the pharmacist subsequently went through the care plans in order to clear up things that were ambiguous and illegible.

The discharge prescriptions data were also collected and together with the medicines listed in the care plans these latter data were given to the MPharm student, Chan Sue Li, to be used in her report of prescription turnover.

2.7 Process Mapping

In order to describe the operational delivery of the clinical service by the pharmacist at the hospital ward, process maps were produced by using the software program Microsoft Visio 2003.

Process mapping is diagrammatic form that describes and presents processes. It displays geometrically the various tasks a certain process contains using different boxes. To obtain a process map it is essential to talk to and involve the people who perform the tasks [45] By observing and conducting a dialogue with the people responsible for the task in focus, one can get a detailed overview over the actions performed and a good description of the different processes. Hence this is a way to identify areas where processes can be improved. This is also a good way to get a clearly set out summary over different processes made in a clinical setting.

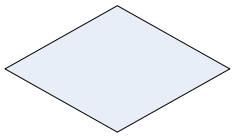
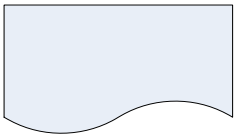
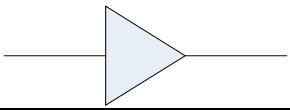
The investigator spent several days, from November and during the data collection period (January to March) at the ward. Two process maps were produced by a combination of observing, when attending ward rounds, and talking to/interviewing the pharmacist. There was no Standard Operational Procedure (SOP) in use for this ward.

One process map was made to describe the action and steps taken by the pharmacist from the admission of the patient and during his stay, and one process

map was made to describe the actions taken place when the patient is going to be discharged. Suggested process maps were made and thereafter validated by the pharmacist at the ward in order to get them correct.

Shaped used in making the process maps are described below:

Table 3. Shapes of boxes used in process maps [46]

	**Terminator**, is used to describe the first and last step in a process.
	**Process**, describes a process undertaken and represents a step in the process.
	**Predefined process**, is a step where a sub-process is defined, the main process is defined elsewhere in the process map or in a new process map
	**Decision**, this shape indicates a point where the outcome of a decision dictates the next step. The decision is often answered with yes or no.
	**Document**, a step that describes a document being produced
	**Connector**, this show the flow of the processes and the feedback loop

2.8 Review and modification of the existing Categorisation system

At the beginning of this project, in November 2007, the investigator in cooperation with collaborator KH started to test out the existing categorisation system, used at the University of Strathclyde, by analysing some previous care plans given by LS. This system was developed to describe pharmaceutical care. This system categorises a care issue into a Check or Change category (Strand, McAnaw)[7], a Drug Therapy Problem (Cipolle, Strand)[5] and a Quality Assurance Descriptors (McAnaw, Hudson)[17]. The advantages of combining different categorisation systems into one triangularised system is that the

categories supplement and support each other, and therefore they capture different dimensions of the pharmaceutical care issues.

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.

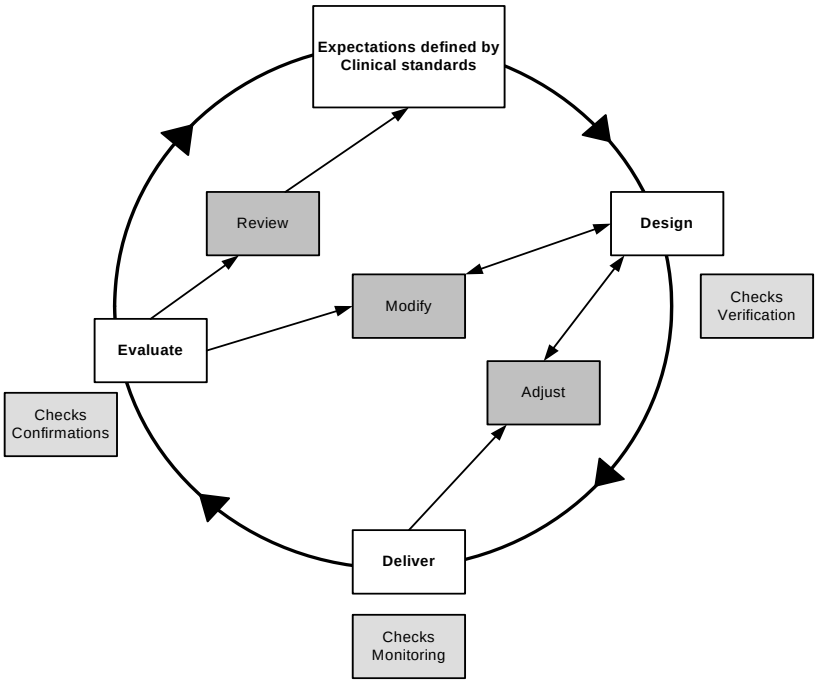


Figure 1 Pharmaceutical care model

The sources for the existing categorisation system, used at the University of Strathclyde were Pharmaceutical care class notes from the University of Strathclyde"[14] the article "The Changing Roles of Pharmacist In Society" [7] and a "Data collection form for MSC project" (Appendix 1). As a result of assessing this system and testing out the categorisation by using care plans, it was revealed that there were difficulties and inconsistencies in the interpretation of the different

categories. The investigators in Ayr were also using the same categorisation system to evaluate the documentation of the pharmacist's work, and had the same opinions. All four investigators (MRR, ROH, KH and MBC) came then together over several meetings during the period January – April 2008 to evaluate and improve the categorisation system. The system was scrutinised and those categories which the researcher thought needed a modification were explained and exemplified. The purpose was to optimise the categorisation as a triangularised system. By increasing the robustness and clinical usefulness of the categorisation system the aim was to develop a documentation-tool to be applied in future clinical practice.

During this period literature on drug therapy problems, categorisation and categorisation systems were also reviewed. In addition it was arranged research meetings were the investigators ideas were discussed with the supervisors SH and CF, and PhD student TD. As a result of this, modification and new ideas were incorporated and implemented in the categorisation system. As the investigators realised how different they all comprehended the existing system and that part of the system was difficult to interpret when categorising care issues in practice, it was decided that a guideline needed to be developed so that the categorisation could be perform on the same basis, and the system could be easy to use. The results/outcomes of the modifications, specifications and exemplifications made were all presented in the guideline developed. Fellow investigator IL used the system to categorise care issues in her project. She gave feedback on the use and understanding of the guideline. Also supervisor SH gave feedback during this process.

Using the developed guideline to analyse care issues from the collected care plans, tested the utility and validity of the modified categorisation system.

2.9 Database tool

The data from the handwritten care plans were analysed and keyed in a database made to fit this project. The database was modified in cooperation with researcher assistant Susan McKellar using Microsoft Access®. Since recommendation made by the pharmacist was not taken into account in the categorisation system, the investigators made a tick box in the database to capture all care issue where the

pharmacist had made a recommendation in the modified system. The recommendations could be related to both checks and changes. The primary reason for this was to intercept the recommendations that were not taken into account and thus only categorised as a check in the categorisation system. The changes resulting from the pharmacist making a contribution to the clinical assessment were also marked.

It was made a tick box to mark interaction as well. The investigators thought it would be interesting to see how many care issues were concerning interactions; either as checked for, or changes made in drug therapy due to. As pharmacists have the specific knowledge to discover interaction there was a interest to see if there was an attach importance to this type of drug therapy problem in particular.
The categorisation of the care issues was done within the database and hence eased the systematic approach to the categorisation. By using the database, combination of different categories was possible and the investigator could extract statistical analysis of the data easily by making the necessary queries to the database. Data from the database was transcribed to Excel for further statistical processing

2.10 Inter-rater reliability and Cohen's Kappa

In order to test out the practical application of the modified categorisation system, Cohen's Kappa statistic was used to analyse the inter-rater reliability.
The investigators wanted to test out the consistency in categorisation and the hence the comprehension of the categorisation system by using the guideline developed.
The inter-rater reliability was performed between the investigator and co-investigator KH. Fifty care issues were randomly picked from each ward and categorised by both investigators. A comparison was made using the method of inter-rater agreement and Cohen's Kappa.

The inter-rater agreement was tested in four part of the system, and therefore four Kappa were estimated. The first part was whether the care issue had been assigned the same main category, which is a 'Check', a 'Change in Drug therapy Process' or a 'Change in Drug Therapy'. The division to two types of different changes had modified the category of changes. The measurement of inter-rater agreement in these categories were therefore of particular interest, to see if this division was

applicable and used similarly. The next part was the agreement into the subcategories of the former main categories.

The last two parts were the Quality Assurance Descriptors (QAD). All care issues in the modified system are assigned into the QAD 'Time Perspective', but only 'Changes in drug therapy' are categorised into the QAD 'Degree of Change'. The understanding of this part of the system and the consistency in categorising care issues into these subcategories were of specially interest. The subcategories of 'Drug Therapy Problems' were not tested since these were regarded well known and not modified. (Appendix 3)

2.10.1 The Inter-rater reliability test

The data were arranged in a matrix with one rater vertically and one rater horizontally.(ref) The investigators tested four different parts of the system. Both 3x3 matrix and 16x16 matrix were produced. (Appendix 3)

Table 4. Example of matrix used to calculate Cohen's Kappa

		Investigator B			
		Checks	**Changes in Drug Therapy Process**	**Changes in Drug Therapy**	**Total**
Investigator A	**Checks**	1.1	1.2	1.3	X_1
	Changes in Drug Therapy Process	2.1	2.2	2.3	X_2
	Changes in Drug Therapy	3.1	3.2	3.3	X_3
	Total	Y_1	Y_2	Y_3	N

The observed agreement between the raters is the sum of the cells where the raters agree; 1.1, 2.2, 3.3.

$\Sigma_O = 1.1+2.2+3.3$

The total proportion of observed agreement P_O was calculated as; Σ_O / N

Since it will be expected some agreement in each square between the raters by chance, this is also calculated.

Expected agreement in cell 1.1 by chance would be:

$\Sigma_{1.1\ ec} = (Y_1 * X_1) / N$, and so on for cell 2.2 and 3.3. The sum of all these expected values would be the number of agreements expected by chance, $\Sigma_{e\ c.}$ The proportion expected by chance, P_{ec} for every category was calculated as;

$P_{ec} = \Sigma_{ec} / N$

The measure of overall agreement is Kappa κ, a value ranging between 0 and 1. A larger value indicates better reliability. Kappa is calculated from the proportions of observed agreement and expected agreement by chance frequencies as follows;

$$\kappa = \frac{(Po - Pec)}{1 - Pec}$$

κ =degree of agreement between the rater
Po = proportion of relative observed agreement
Pec= proportion of relative agreement expected by chance
1 = maximum agreement among raters (ref)

The standard error (SE) and confidence interval (CI) were also estimated.

$$SE\ (\kappa) = \sqrt{\frac{Po(1 - Pec)}{N(1 - Pec)^2}}$$

κ = degree of agreement between the rater
Po = proportion of relative observed agreement
Pec= proportion of relative agreement expected by chance
1 = maximum agreement among raters
N = total trials (ref)

The 95 % confidence interval for the percentage of agreement was calculated as;

$95\%\ CI = \kappa \pm 1.96 * SE\ (\kappa)$

2.11 Comparison of Patient Characteristics and Pharmaceutical care activity between two wards.

The categorisation of care issues lead to comparison of pharmaceutical care activity, as well as patient characteristics, between the General Medical ward and the Care of the Elderly ward at Glasgow Royal Infirmary. Statistical comparison of the distribution of care issues across the care issue categories was undertaken by using Fischer's exact test, two-tailed. Statistical significance was defined as $p<0.05$ and so a 95% confidence interval (CI) was calculated. The CI was calculated from standard errors and value of t (in this case 1.984 for n= 99; t tables). The calculations were prepared by using both Microsoft Exel® and GraphPad Software - QuickCals.[47]

The two wards were also compared after applying data from the findings of the parallel survey of prescribing activity. This part of the project turned out to be smaller than first anticipated, due to other priorities, so the results and comments will only be briefly commented.

2.12 Focus group

A focus group could be defined as "a group of interacting individuals having some common interest or characteristics, brought together by a moderator, who uses the group and its interaction as a way to gain information about a specific or focused issue." [48]

Focus group is an interview technique and provides an alternative method to collect data, from individual face-to-face interviews. The focus group typically consist of 6-10 participants who are selected because they have certain common characteristics in common that relate to the topic of the focus group (e.g. clinical pharmacists working at hospital wards). The focus group give an insight to how a group of people think about a specific topic and is a way of evaluating an issue and promote solutions. An important feature of focus group is the interaction between several participations and the results of a discussion where opinions arise on a chosen issue. Hence the data obtained from a focus group, in terms of issues raised and views expressed, are natural interactive processes. By having a group discussion where several opinions are express and views given on a topic, information on different participants' attitudes are obtained. This group interaction can stimulate participants' ideas that might not

have been revealed in individual interviews. The identification of solutions for both old and new problems brings a wider perspective on the issues discussed. Focus group is viewed as a qualitative research tool and the use of this application has increased in pharmacy practice and health service research the recent years. [48-50]

The four investigators ROH, MRR, KH and MBC worked together with the arranging of the focus group and were also the moderators. Invitations to participations were sent out and a power point presentation was made. The intention with this focus group was to get a feedback on the understanding and usefulness of both the categorisation system and the guidelines. The main focus was to evaluate the modified system with attached importance to the changes made within the Change category and the Quality Assurance Descriptors. Also opinions on the importance of marking checks and changes related to recommendations made by the pharmacist and interaction were desirable. Questions were made to each part of the system to clearly set out what feedback was necessary. The participants had been given the guidelines with examples of categorisation of care issues and the power point presentation on beforehand.

The focus group was held at the Strathclyde Institute for Biomedical Science on the 28th of April 2008. The four investigators KH, ROH, MRR and MBC presenting the categorisation system via the guidelines and the results from categorising care issues documented at different wards. The participants were pharmacists from Glasgow Royal Infirmary and Ayr Hospital, in addition to Professor and supervisor Steve Hudson. The focus group was recorded and retrospectively transcribed by the four investigators.

3 Results

3.1 Literature review

The literature search resulted in articles and studies about pharmaceutical care, medicines management, documentation, chronic disease management, diabetes mellitus and cardiovascular disease. As all these fields have expanded in recent years there was not a problem to find sources on these subjects. On the contrary the challenge was to find reliable sources and those most relevant. The medical databases Pubmed and Embase where mostly used, but also the National Health Service's web pages. These latter were sources in particular for non-medical prescribing and clinical audit. The book "Pharmaceutical Care Practice – the clinician's guide" by Cipolle et al. was one main source on drug therapy problems and clinical pharmacy. These subjects were however supplemented by relevant articles. The book "Practical statistics for medical research " by Altman was an aid for the statistical analysis.

3.2 Producing Process Maps

The investigator spent several days during the survey period shadowing the pharmacist at the General Medical ward at Glasgow Royal Infirmary. By observing and interviewing the pharmacist the understanding of tasks and processes performed during ward rounds were described by the investigator in process maps. One map was made for the admission and patient's stay, and one process map was made for processes taking place at discharge.

3.2.1 Process map Admission

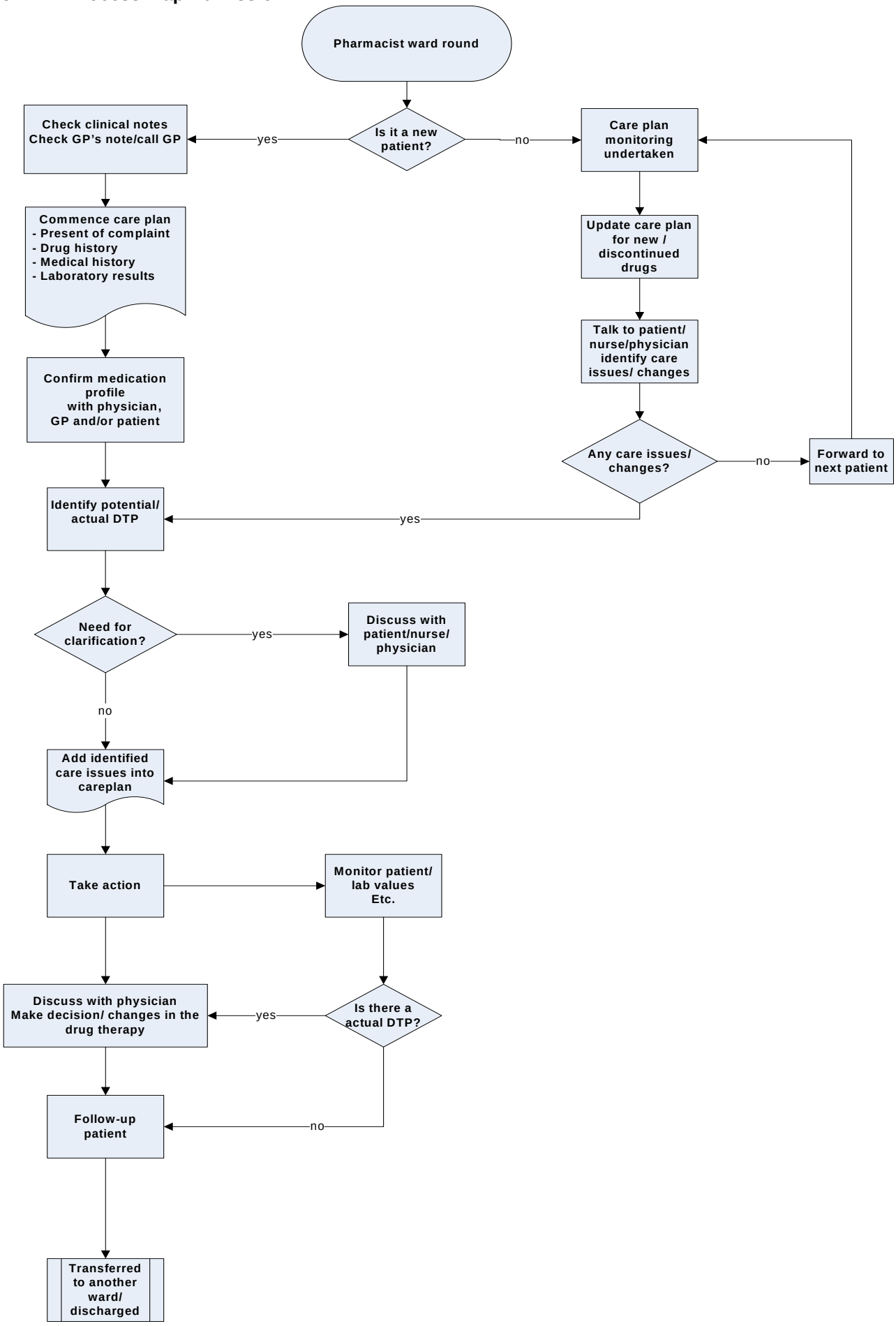


Table 5.Descriptions in the Process Map – Admission and hospital stay

Processes	Descriptions
Check clinical notes/GP notes	In general the pharmacist starts with checking the clinical notes written by the nurses and/or physicians. The first task is to take the patient's drug history. If any information is missing the pharmacist have to make sure that the important information about the patient is gained and added in the notes. This could be done by talking to either the nurses/physicians or calling the GP. Also talking to the patient can be clarifying enough.
Commence care plan	Information from the clinical notes /GP are written down in the pharmaceutical care plan in order to have an overview to identify the patient and do the assessment.
Confirm medication profile with physician, GP and or /patient	The information gained is confirmed and any discrepancies cleared with the staff members or the patient.
Identify care issues and reveal potential/actual Drug Therapy Problems	This is an ongoing process, which is undertaken both for new patients and inpatients. By checking the kardex, monitoring every stage of drug therapy and talk to the patients / staff, the pharmacist is able to identify care issues and reveal and prevent any potential or actual drug therapy problems. Having the responsibilities of optimise the patients drug therapy, giving the patients education or instruction on how to use their medicines (e.g. an inhaler) and explaining why there are on different drugs, (e.g. warfarin) are also part of identifying potential problems.
Take action	The care issues identified are added into the care plan along with the following action taken and the final outcome. The pharmacist happens to document check and changes that he confirms is performed by other health care team members. The action taken depends on the care issues identified, but often involves monitoring lab values etc. and the patient's reactions to the treatment in general.
Discuss with physician. Make a decision/change in the drug therapy	If the care issues lead to actual or potential drug therapy problems, which require a change in the drug therapy the pharmacist discuss this with the physician in order for a change to be made in the drug record.
Follow –up patient	The care plan works as a quality assurance document and should follow the patient as long as he is at the ward and when transferred to another ward. The follow-up comprises monitoring the commenced treatment and continuing to identify care issues and subsequently potential and actual drug therapy problems. In other words ensuring safe end effective treatment.

3.2.2 Process map – Discharge

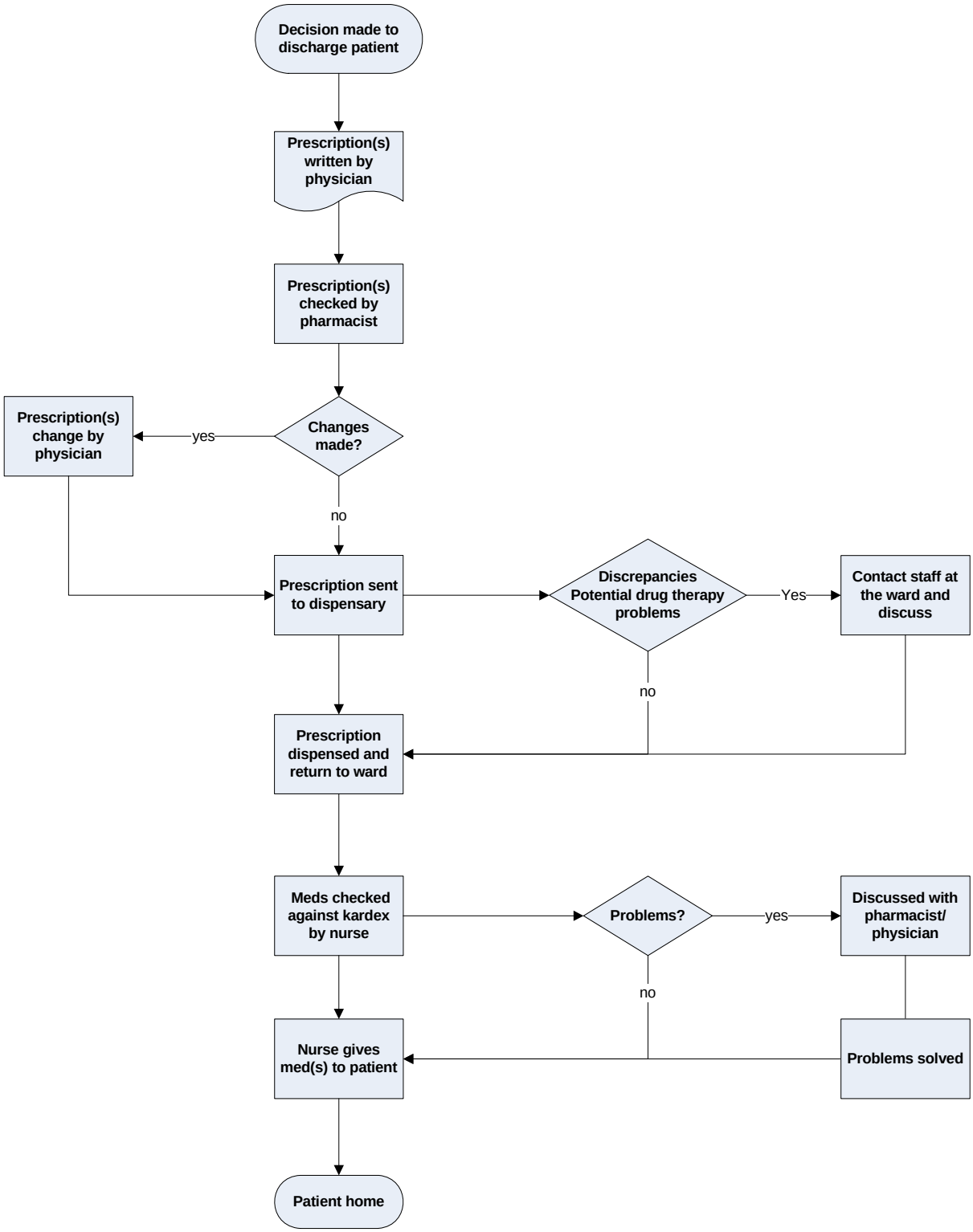


Table 6. Descriptions in the Process Map – Discharge

Processes	Descriptions
Decision made to discharge patient	Many of the patients are transferred to another ward for continuing of care so this concerns those who are discharge home from this ward. Occasionally as part of discharge planning the community pharmacist is contacted, particularly if there are issues surrounding compliance packs in order to ensurechanges are made promptly.
Prescription written and checked	The physician prescribes the patient's new medication(s) and the pharmacist subsequently checks doses and indications. Additional information is occasionally added such as medicines stopped and reasons for this. Also recommendations are occasionally made also such as additional monitoring etc. Also here will identification of care issues and potential and actual drug therapy problems be screened fore. Any changes made are discussed with the physician before the discharge prescription is sent to the dispensary.
Discrepancies /Potential drug therapy problems	The dispensary is calling the ward if discrepancies and hence potential drug therapy problems are revealed. A clarification is made and then the prescription is dispensed and returned to the ward.

3.3 Modifying the categorisation system

Following are the results of the each step of modifications and adjustments made to the categorisation system. The complete results presented as a Guideline are to be found in Appendix 2

Checks

The ‘Check’ category and its subcategories were kept in the same way as presented in the ”Pharmaceutical care class notes from the University of Strathclyde” [14] and the article “The Changing Roles of Pharmacist In Society”.[7] Thus compared to the sheets of description used at the University of Strathclyde (Appendix 1) the subcategory “Formulary adherence” was removed.

Table 7.The categories of Checks

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

The Change category

In the existing system all changes made in the care plan, whether they were related to the actions taken to prevent drug therapy problem indirectly (patient data handling, patient behaviour) or action affecting drug therapy directly (treatment plan changes) were combined in one category.(see Table 8) This lead however to difficulties when categorising. The actions made to patient behaviour and patient data handling were often not necessarily changes, more often just action taken in order to prevent future changes from happening. E.g. up-dates of the patient’s drug record if patient got NSAID allergy in order to prevent a drug therapy problem from arising if patient were given NSAID. (which would lead to a change in drug therapy). The outcome of these types of actions were therefore difficult to predict and so a subsequent assignment of a drug therapy problem.

Table 8.The original Change category [7]

Action Change
Patient behaviour
▪ Patient expectations of treatment ▪ Comprehension ▪ Participation
Patient data handling
▪ Patient characteristics ▪ History (indications, contraindications) ▪ Continuity of care
Treatment plan changes which address
▪ Drug choice ▪ Dose ▪ Route, dose form ▪ Dose interval / timing ▪ Course duration ▪ With added precautions/interactions ▪ Stop drug pending review

The pharmacist takes different actions to improve the pharmaceutical care of the patient. Not all of these actions result in a change in the patient's drug therapy or have an outcome known to the pharmacist. Still it is important that these actions are quantified, as they are an important part of the pharmacist's delivery of pharmaceutical care.

The Change category was modified by dividing it into two categories of changes – 'Change in Drug Therapy Process' and 'Change in Drug Therapy'. It was considered necessary to distinguish between actions concerning the patient's drug therapy and action regarded other pharmaceutical care needs of the patient.

Table 9. Division of the Change category into two;

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

Change in Drug Therapy Process

The category 'Change in Drug Therapy Process' are changes in care process where the outcome is hard to determine or is too speculative to lead to a drug therapy problem. This category describes the actions the pharmacist performs to prevent potential drug therapy problems and to identify actual drug therapy problems.

The wording of the subcategories were modified to enhance the comprehension of what they were concerning.

Patient data handling

- *Patient characteristics*
- *History (indications, contraindications)*
- *Continuity of care*

This former subcategory was modified by transforming the wording into three new subcategories;

- Clinical (shared) record of patient characteristics
- Clinical (shared) record of drug history
- Continuity of information/care between clinical settings

The description of each of these are described in the guideline (in the Appendix 2)

There was also added some new subcategories to the 'Change in Drug therapy Process';

- Health care team member(s) information/education.

The investigators regarded recommendation in form of information/ education provided by the pharmacist to other health care members as an important action to be documented. This was not captured in the existing system. Neither this subcategory can be assigned a drug therapy problem and is therefore rather a change in the care process given.

- Level of patient monitoring was also added.

The addition of this subcategory was a result of care issues identified in the care plans regarding a need to increase/improve monitoring. This monitoring had been initiated or advised by the pharmacist as an action made to prevent drug therapy problem and spot those care issues which could lead to actually drug therapy problems.

All these actions were regarded as important parts of the provision of pharmaceutical care, although they are neither checks or a changes.

Change in Drug Therapy

The ‘Change in Drug Therapy’ category includes changes related to drug therapy and prescription, where the outcome can be assigned a recognisable ‘Drug Therapy Problem category’.

Patient behaviour

- *Patient expectations of treatment*
- *Comprehension*
- *Participation*

This former category was also one which were difficult to measure the outcome as having resulted in some kind of change. Although the pharmacist intention is to provide information and education so that a patient’s comprehension and participation enhances, it is difficult to confirm that this has happened. It was decided, however, that these subcategories should be transformed and renamed into ;

- Patient or Carer Level of Education (Understanding/Compliance)

This subcategory was now modified to more clearly defining the pharmacist action to attempt to enhance the patient’s comprehension and participation. Although not measurable in a definite outcome this category now concerns compliance and the pharmacist intention and effort in improving compliance .The subcategory can further be categorised into a ‘Drug Therapy Problem’ (Inappropriate compliance) and was therefore regarded as a ‘Change in Drug Therapy’ due to this.

Except from the addition of this latter modified category in to the category of ‘Change in Drug Therapy Problem’ the subcategory ;

Treatment plan changes which address

- *Drug choice*
- *Dose*
- *Route, dose form*
- *Dose interval / timing*
- *Course duration*
- *With added precautions/interactions*
- *Stop drug pending review*

was only modified to a lesser extent by changing the name to ‘Change in Drug Therapy Problem’ and specifying some of the terms. (table 10)

Table 10. Adjustment made to the subcategory ‘Treatment plan changes which address’

Treatment plan changes which address	Changes in Drug Therapy
▪ *Drug choice*	▪ *Drug selection (starting new or changing drug)*
▪ Dose	▪ Dose
▪ Route, dose form	▪ Route/dose form
▪ Dose interval / timing	▪ Dose interval/timing
▪ *Course duration*	▪ *Duration*
▪ *With added precautions/interactions*	▪ *excluded*
▪ *Stop drug pending review*	▪ *Stop drug temporarily/ permanently*

Key: Italics = adjustments made

Drug Therapy Problem

The subcategories of 'Drug Therapy Problems' were those defined in the book "Pharmaceutical Care Practice – The Clinician's guide" by Cipolle et. al (ref)

These were basically kept in their original way. Still, some adjustments were made by giving more examples to the subcategories to include a broader range of care issues. In addition the common causes for each subcategory were 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' was 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.

Table 11. Adjustments to the categories of Drug Therapy Problems

	Drug therapy problem	Common causes of DTP
1	**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 *single drug therapy*→ **fewer drug therapies** ▪ The medical condition is more appropriately treated with nondrug 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**
2	**Need for additional drug therapy**	▪ 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**
3	**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 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**

Table 12. (cont.) Adjustments to the categories of Drug Therapy Problems		
4	**Dosage too low**	▪ The dose is too low to produce the desired *effect* response ▪ The dosage interval is too infrequent to produce the desired response ▪ A drug **A drug-drug/food/lab/disease** interaction reduce the amount of active drug available ▪ *The duration of drug therapy is too short too produce the desired response* → Need for additional drug Therapy
5	**Adverse drug reaction**	▪ The drug product causes an undesirable reaction that is not dose-related ▪ A safer drug product is required due to risk factors ▪ *A drug interaction* →**A pharmacodynamic drug-drug/food/lab/disease interaction** causes an undesirable reaction that is not dose-related ▪ The dosage regimen was *administered or* 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**
6	**Dosage too high**	▪ Dose is too high ▪ The dosing frequency is too long ▪ *A drug interaction* **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
7	***Non-compliance*** **Inappropriate compliance**	▪ The patient does not understand the instructions ▪ The patient prefers not to take the medication ▪ The patient forget to take the medication ▪ The drug product is too expensive for the patient ▪ The patient cannot swallow or self-administer the drug product *available* appropriately ▪ The drug product is not available for the patient ▪ **The time of dosing or the dosing interval is decreasing compliance**
8	**Unclassified ie. Non-DTP**	▪ **Formulary adherence, e.g. generic switch**

Comment:

The italics are those terms which were changed or deleted and the bold are those terms which were added. The modified version of 'Drug Therapy Problems' will be presented in the Guidelines (Appendix 2)

Quality Assurance Descriptors (QAD)

This third category was the one which the investigators found challenging to categorise a care issue into since the meaning of the different terms were confusing and also the time aspects according to where they were applicable. There were a continuously modification of this part of the system in order to make it work in all aspects for both checks and changes. According to the existing system only checks were assigned the subcategories of *verification, monitoring* and *confirmation*. These terms were related to the *Start of treatment*, *as treatment continues* and *after a period of a course of treatment*, respectively.

What was contemplated was the subcategories of *Changes*; *adjustment, modification* and *review*. According to the existing system both adjustment and modification could be done at the *Start of treatment*, and *as treatment continues.* By just signing a change the QAD of either adjustment or modification it was not specified where in the treatment cycle this change took place. In order to make this happen it was decided that each change also would be categorised into the QAD for its preceding check in order to give it a time aspect as well.

Since now both Checks and Changes, that is “Change in Drug therapy Process” and “Change in Drug Therapy” all were categorised into the QAD for Check, to add a time perspective in the treatment cycle to the triangularised system, the QAD for Checks was renamed *QAD Time perspective*. The QAD for Change was renamed Degree of Change since this subcategory now only described what extent of change in the category *Change in Drug Therapy* is made.

Short summary of assigning a care issue into the modified categorisation system.

The care issue identified is either a Check or a Change (the latter, a check leading to a Change). The care issue is assign a subcategory of either the Check or Changes depending on its concerning. If the care issue is a change it is either a “Change in Drug Therapy Process” or a “Change in Drug Therapy”. All care issues are categorised into the Quality Assurance descriptor “Time Perspective”. Only “Change in Drug Therapy” is further categorised into the Drug Therapy Problem category and the Quality Assurance Descriptor “Degree of change”. The following table will give an overview over the system and how far the care issues are categorised.

Table 13. Combination of different categories to a care issue

Care issue	QAD – Time Perspective	QAD – Degree of Change	Drug Therapy Problem
Check	√		
Change in Drug Therapy Process	√		
Change in Drug Therapy	√	√	√

The Guideline describes each step of the categorisation process. (Appendix2)

3.4 Ward characteristics and Pharmaceutical care profile of the General Medical Ward

The total number of patients admitted to the General Medical Ward during this survey period was 122. The pharmacist only saw 100 patients (82.0%) and these were provided a care plan and included in the survey. These 100 patients were admitted between the 12th of January and the 8th of March and all were discharged by the 10th of April. The reasons why the pharmacist didn't see all the 122 patients admitted during this period were that some were admitted and discharged at the weekends and that the pharmacist was absent for 8 days during the survey period without cover.

Table 14. Characteristics of patients on the General Medical ward (n= 100)

Parameter (per patient)	Mean (SD)	95 % Confidence Interval	Median (IQR)	Range
Age (years)	64.1 (14.2)	(61.2, 66.9)	66.0 (54.0, 74.0)	26-98
Length of Stay (days)	11.8 (10.6)	(9.7, 13.9)	8.0 (5.0, 14.0)	1-53
Number of diagnoses	2.0 (1.2)	(1.8, 2.3)	2.0 (1.0, 3.0)	0-6
Total care issues	3.6 (3.2)	(3.0, 4.2)	3.0 (1.0, 5.0)	0-17
Care issues not categorised	0.5 (0.7)	(0.4, 0.7)	0.0 (0.0, 1.0)	0-3
Checks	1.8 (1.9)	(1.4, 2.1)	1.0 (0.8, 2.0)	0-11
Changes in Drug Therapy Processes	0.3 (0.6)	(0.1, 0.4)	0.0 (0.0, 0.0)	0-3
Changes in Drug Therapy	1.6 (1.7)	(1.2, 1.9)	1.0 (0.0, 2.0)	0-9

Key SD = Standard Deviation, IQR= Inter Quartile Range

The table shows that the average age (SD) for the patients was 64.1 (14.2) years and that the range was quite broad, the youngest patient being 26 years and the oldest 98 years. The range of length of stay is also broad ranging from 1- 53 days. This

gives a relative high mean (SD) of 11.8 (10.6) days and is caused mainly by three long-term patients. The median (IQR) of 8.0 (5.0,14.0) would be the most correct description of average length of stay. These numbers are explain by the fact that this is a General Medical ward were patients in all age groups and with different conditions are admitted.

The total number of care issues documented for all 100 patients during the survey period was 359 with an average (SD) of 3.59 (3.2) care issues per patient. As seen from the table the range of care issues was between 0-17, which is a broad range and thus making the SD high. It needs to be emphasised that these number are not representative for the delivery of pharmaceutical care by the pharmacist. These numbers only represent what the pharmacist is actually documenting. Also the fact that only care issues with an outcome have been categorised and taken into this analysis needs to be considered. 51 care issues documented were not included due to unknown outcome.

Care issues regarded as part of the standard procedure were neither included. In general this would for instance be taking or checking drug history, general checks for dose and indication at admission, during the stay and at discharge.

Table 15. Patient characteristics of different parameters

		Prevalence, %
Chronic Diseases		
	CVD	59
	AF	22
	DM	17
Discharge		
	Another ward	28
	Home	67
	Deceased	5
Most common drug history sources (n=154)		
	Notes	61.7
	GP	4.5
	Patient	1.9
	Nursing home	0.6
	Patient's family	0.6
Number of drug history sources		
	0	5
	1	83
	2	12

Key CVD: cardiovascular disease, patient with one or more CVD diagnosis, counted as one
DM: diabetes mellitus, type 1 or type 2: AF= Atrial fibrillation

Table 16.Diagnosis included in the term CVD [51]

Cardiovascular disease (CVD)
Cardiovascular accident
Congestive cardiac failure
Coronary artery disease
Deep venous thrombosis
Hypertension
Ischemic heart disease (Myocardial Infarction, Angina Acute Coronary Syndrome)
Paroxionous atrial fibrillation
Peripheral vascular disease
Pulmonary thrombosis

Table 17. Prevalence of diagnosis (top 6)

Diagnosis	**Percent (%)**
Ischemic heart disease (Myocardial Infarction, Angina, Acute Coronary Syndrome)	33
Atrial fibrillation	22
Diabetes Mellitus	17
Chronic Obstructive Pulmonary Disease	15
Hypertension	10
Cancer	10

Key Percent of total patients

There was a total of 65 different diagnosis documented. The patients could represent with more than one diagnosis, that is one patient could have Ischemic heart disease, Atrial fibrillation and Diabetes Mellitus. They are however counted here as one diagnosis for each patient. 4 of the 100 patients had none diagnosis documented.
The primary drug history source documented is clinical notes. This would be a clinical note written by nurses and /or physicians. The pharmacist has used notes for 95 of the 100 patients. In most instances the pharmacist has only documented the use of one drug history source. Five of the patient had no sources of drug history.

3.5 Categories and distribution of Care Issues

Table 18. Distributions of care issues into main categories

Main categories	Count	Percent %
Checks	177	49.3
Change in Drug Therapy Process	27	7.5
Change in Drug Therapy	155	43.2
Total	359	100

This table shows the distribution of the total of 359 care issues documented. There were an almost even distribution between the ‘Checks’ 177(49.3%) and ‘Changes in Drug Therapy’155 (43.2%) while care issues categorised into the ‘Change in Drug Therapy Process’ 27(7.5) only was documented to a lesser extent.

Quality Assurance Perspective

Table 19. Subcategories of the QAD Time Perspective according to type of care issue.

QAD Time Perspective	Checks(%)	Change in DT Process (%)	Change in Drug Therapy (%)	Total(%)
Verification	59 (16.4)	10(2.8)	47 (13.1)	116(32.3)
Monitoring	113(31.5)	17(4.7)	92(25.6)	222(61.8)
Confirmation	5(1.4)	0(0.0)	16 (4.5)	21(5.9)
Total	177(49.3)	27(7.5)	155(43.2)	359(100.0)

Key Percent of total care issues

All care issues are categorised into this QAD category so this reflects the distribution of the main categories of all care issues. As seen from this table, most of the care issues are monitoring (222(61.8%) and hence care issues documented during the patient's treatment (during the delivery of the treatment plan). 'Checks' and 'Change in Drug therapy' are types of care issues which are documented most frequently during monitoring.

Table 20.Distribution of subcategories of Checks into subcategories of Time Perspective.

	TIME PERSPECTIVE			
CHECKS	**Verification (%)**	**Monitoring (%)**	**Confirmation (%)**	**Total**
Medication needs inquiry	39(22.0)	18(10.2)	3(1.7)	60 (33.9.)
Effectiveness inquiry	6(3.4)	35(19.8)	0(0.0)	41 (23.2)
Safety inquiry	8(4.5)	60(33.9)	2(1.1)	70 (39.5)
Compliance inquiry	6(3.4)	0(0.0)	0(0.0)	6 (3.4)
Total	59(33.3)	113(63.9)	5 (2.8)	177(100.0)

Key Percent of total Checks

This table shows that those ‘Checks’ most frequently documented are monitoring of ‘Safety inquiry’ (during the patient’s treatment) and verification of ‘Medication needs’, (at the start of treatment) respectively. Of the total of 59 (33.3%) checks being verification it can be seen that 39(66%) of these were ‘Medication Need’ inquiries. Most of the checks performed during the patient’s treatment (monitoring) were; ‘Safety inquiry’, 60(33.9) and ‘Effectiveness inquiry’, 35(19.8).

Few of the checks documented were ‘Compliance’ check 6 (3.4). There are also few documented checks categorised as ‘Confirmation’ 5(2.8%)

Table 21. Distribution of subcategories of Change in Drug Therapy Process into subcategories of Time Perspective

CHANGE IN DRUG THERAPY PROCESS	TIME PERSPECTIVE			
	Verification (%)	**Monitoring (%)**	**Confirmation (%)**	**Total**
Clinical record of patient characteristic	1(3.7)	1(3.7)	0(0.0)	2 (7.4)
Clinical record of drug history	6(22.2)	1(3.7)	0(0.0)	7 (25.9)
Continuity of information/care between clinical settings	2(7.4)	2(7.4)	0(0.0)	4 (14.8)
Level of patient monitoring	1(3.7)	5(18.5)	0(0.0)	6 (22.2)
Health care team member(s) info/education	0(0.0)	8(29.6)	0(0.0)	8 (29.6)
Total	10 (37)	17 (62.9)	0(0.0)	27 (100.0)

Key Percent of total Change in Drug Therapy Process

There is a relative even distribution among the different subcategories of the ‘Change in Drug therapy’ process but most process are regarding ‘Health care team information’ and ‘Level of patient monitoring’ (the pharmacist informing the staff to increase the frequency of monitoring). It is shown that most of these happen during the delivery of care, as monitoring. The pharmacist is also documenting action taken

in verifying clinical record of drug history. This could be a drug missing in kardex or drugs not prescribed on admission, which the patient is suppose to be on etc.

Table 22.Distribution of subcategories of Change in Drug Therapy into subcategories of Time Perspective

CHANGE IN DRUG THERAPY	TIME PERSPECTIVE			
	Verification (%)	**Monitoring (%)**	**Confirmation (%)**	**Total (%)**
Drug selection (new or changing drug)	26 (16.8)	10 (6.5)	0 (0.0)	36 (23.2)
Dose	1 (0.6)	25 (16.1)	0 (0.0)	26 (16.8)
Route/dose form	1 (0.6)	4 (2.6)	0 (0.0)	5 (3.2)
Dose interval/timing	1 (0.6)	10 (6.5)	0 (0.0)	11 (7.1)
Duration	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stop drug temporarily/permanently	7 (4.5)	32 (20.6)	16 (10.3)	55 (35.5)
Patient or Carer level of education (understanding/ compliance)	11 (7.1)	11 (7.1)	0 (0.0)	22 (14.2)
Total	47 (30.3)	92 (59.4)	16 (10.3)	155 (100)

Key: Percent of total Change in Drug Therapy

It can be seen from this table that the different subcategories of ‘Changes in drug Therapy’ mainly are distributed throughout the ‘verification’ and ‘monitoring’ subcategories.

Most of the changes documented were made during the delivery of care (monitoring) in form of drugs ‘Stopped temporarily or permanently’. An example would be; a drug stopped temporarily due to a surgery, or permanently as no need for drug. The second most frequent change documented is ‘Drug selection (new or changing

drug)'at the start of treatment (verification), that is when the pharmacist first sees the patient or new treatment is started. Thus, Drug selection (new or changing drug) could be commenced during treatment, but being a new drug started this would be assign a verification since the pharmacist is verifying the need, and the dose and indication for this new treatment. Drugs recommence would be regarded as monitoring.

'Stop drug temporarily/ permanently ' is also the only type of 'Changes in drug Therapy' that is categorised as a 'Confirmation'. This would be those stop regarding antibiotic courses and other short term treatment (enoxaparin stopped when patient is mobile etc.) Also drugs stopped due to no indications, contraindications, interactions etc.

The subcategory 'Dose' is also a quite frequently 'Change in Drug Therapy' and are typically a change related to monitoring of the patient's treatment.
A typically example of the subcategory, 'Patient or Carer level of education (understanding/compliance)' is education/ instructions given on warfarin, which typically are done twice at the start (verification) and during treatment (monitoring), to ensure that the patient have understood the information given

Table 23. Distribution of care issues as counts (%) - in 'Change in Drug Therapy' into 'Drug Therapy Problem categories

	DRUG THERAPY PROBLEM							
CHANGE IN DRUG THERAPY ↓	**Unnecessary drug therapy**	**Need for additional drug therapy**	**Ineffective drug**	**Dosage too low**	**ADR**	**Dosage too high**	**Inappropriate compliance**	**Unclassified**
Drug selection (starting new or changing drug)	0(0.0)	35 (22.6)	1 (0.6)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Dose	0(0.0)	0(0.0)	0(0.0)	16 (10.3)	0(0.0)	10 (6.5)	0(0.0)	0(0.0)
Route/dose form	0(0.0)	0(0.0)	2 (1.3)	0(0.0)	1 (0.6)	0(0.0)	2 (1.3)	0(0.0)
Dose interval/timing	0(0.0)	0(0.0)	6(3.9)	2 (1.3)	0(0.0)	3 (1.9)	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 (11.6)	0(0.0)	4 (2.6)	0(0.0)	28 (18.1)	4 (2.6)	1 (0.6)	0(0.0)
Patient or Carer Level of Education (Understanding/Compliance)	0(0.0)	0(0.0)	0(0.0)	0(0.0)	2 (1.3)	0(0.0)	20(12.9)	0(0.0)
Total	18 (11.6)	35 (22.6)	13 (8.4)	18 (11.6)	31(20.0)	17 (11.0)	23 (14.8)	0(0.0)

Key ADR : Adverse drug reaction

This table shows the relating ‘Drug Therapy Problem’ causing the most frequent ‘Change in Drug Therapy’ (’Stop drug temporarily/permanently’ and ‘Drug selection (starting new or changing drug)’) . Within these subcategories most of the ‘Stop drug temporarily/permanently’ were due to the ‘Drug Therapy Problem’ ‘Adverse drug reaction 28 (18.1%) and ‘Unnecessary drug therapy’ 18 (11.6%).

‘Need for additional drug therapy’ was the subcategory of ‘Drug Therapy Problems’ which were the primary reason for ‘Drug selection (starting new or changing drug)’.
‘Dose’ was also among the most frequent care issues documented as a ‘Change in Drug Therapy’. The underlying ‘Drug Therapy Problem’s were ‘Dosage too low’ and ‘Dosage’ too high respectively.

‘Duration’ was a subcategory in ‘Change in Drug therapy’’ that no care issues were categorised into. There was neither no care issues categorised into the added ‘Drug Therapy Problem’ category ‘Unclassified’

Table 24. Distribution of subcategories of Change in Drug Therapy into subcategories of Degree of Change

CHANGE IN DRUG THERAPY	DEGREE OF CHANGE			
	Adjustment (%)	Modification(%)	Review(%)	Total
Drug selection (new or changing drug)	31 (20.0)	5 (3.2)	0(0.0)	36
Dose	26 (16.8)	0 (0.0)	0(0.0)	26
Route/dose form	4 (2.6)	1(0.6)	0(0.0)	5
Dose interval/timing	11 (7.1)	0 (0.0)	0(0.0)	11
Duration	0 (0.0)	0 (0.0)	0(0.0)	0
Stop drug temporarily/permanently	38 (24.5)	17 (11.0)	0(0.0)	55
Patient or Carer level of education (understanding/compliance)	22 (14.2)	0 (0.0)	0(0.0)	22
Total	132 (85.2)	23(14.8)	0(0.0)	155(100)

Key Percent of total Change in Drug Therapy

Only the main category ‘Change in Drug Therapy’ is categorised into the QAD ‘Degree of Change’. Most of the ‘Changes in Drug therapy’ are seen to be ‘Adjustments’ related to drugs being stopped temporarily or permanently. Second is ‘Adjustment’ made to changes concerning a new drug being commenced. Most are hence changes anticipated within the treatment plan and only 17(11)% of the ‘Changes in Drug Therapy’ were modifications (meaning drug selection not anticipated and leading to a change in the patient’s treatment plan)

None of the care issues were categorised as being a ‘Review’ of treatment, meaning reassessment of the patient’s treatment leading to a change in the expectations defined by clinical standards.

Table 25. Time perspective linked to Degree of Change

	DEGREE OF CHANGE			
TIME PERSPECTIVE	**Adjustment(%)**	**Modification (%)**	**Review (%)**	**Total**
Verification	40(25.8)	7(4.5)	N/A[b]	47
Monitoring	92(59.4)	N/A[b]	N/A[b]	92
Confirmation	N/A[b]	16(10.3)	0(0.0)	16
Total	132(85.2)	23(14.8)	0(0.0)	155(100)

Key Percent of total Change in Drug Therapy; N/A = not applicable according to the Guideline

As only ‘Change in Drug Therapy’ are categorised into the ‘QAD Degree of Change’ this table shows how extensive the ‘Change in Drug Therapy’ documented have been, and when in the patient’s treatment process the changes have been made.

This numbers substantiate the findings in the previous tables and sum up that for ‘Change in Drug Therapy’ most are adjustments made during the patient’s treatment (monitoring).

Recommendation

Table 26. Recommendations made in main care issue categories

Care issue category	Count (%)
Checks	19 (12.7 %)
Change in Drug Therapy Process	9 (6.0 %)
Change in Drug Therapy	122 (81.3 %)
Total	150 (100.0 %)

These numbers show that of all care issues documented (359) recommendation made by the pharmacist were involved in 150 (41.8%) of them.

Of the total 150 recommendations, 122 (81.3%) were related to 'Change in Drug therapy'. Recommendations made by the pharmacist but not taken into account by the physician ('Check') comprised 19 (12.7 %) of the total recommendations documented.

Interaction.

The investigators did also make a tick box in the database to track those care issues that dealt with interaction. Only 9 (2.5%)of the total 359 care issues were concerning interaction.

3.6 Inter rater reliability test

The investigators wanted to test out the consistency in categorising care issues and hence the comprehension and practical application of the modified categorisation system, by using the guideline developed. Cohen's Kappa statistic was used to analyse the inter-rater reliability.

There was an uneven distribution between some of the cells as there were no care issues in the subcategory 'Review' ('QAD Degree of Change'). There were also quite few care issues in the subcategories 'Confirmation' and 'Modification'. (Appendix 3)

There are no absolute definitions of the kappa values. The interpretation of the Kappa (κ) and with that, strength of agreement between the two investigators, was done by means of the literature [52] :

Value of Kappa	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

Table 27.Inter rater reliability results between investigators; KH and MBC

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_{ec}	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

Key Main Categories with subcategories.

The matrix for the different categories and subcategories are found in Appendix 3.
The kappa for all categories ranged from 0.72 – 1.00 and this was interpreted as strength of agreement 'Good' to 'Very good' for all categories.
In the main categories the investigators only disagreed in one of the total of 100 care issues giving a κ (95 % CI) of 0.96 (0.94,1.00.) and strength of agreement 'Very good'.

When testing the inter rater reliability in the subcategories of all the main categories, the kappa within subcategories of 'Change in Drug Therapy Process' and 'Change in Drug Therapy' were both found to be 1. The agreement in the subcategories of 'Check' was also within the range 'Very good', but here the investigators disagreed

on 3 of the 100 care issues. This gave a κ (95 % CI) of 0.93 (0.85,1.00) within the subcategories of 'Checks' and a total κ (95 % CI) of 0.95 (0.90,1.00) for all the subcategories.

The QAD 'Time Perspective' was the subcategory which had the poorest kappa, κ (CI) = 0.72 (0.59 – 0.85). Although the strength of agreement was 'Good' the lower value of the confidence interval for this kappa, *0.59,* would be interpreted as 'Moderate'. The investigators disagreed in 15 of the 100 care issues in this subcategory.

The strength of agreement in the last QAD subcategory 'Degree of Change' was 'Very Good' and here the investigators did agree on all 26 care issues categorised into this subcategory.

As all part of the modified system had a κ (CI) >0.60 (0.59, 1.00) this means that the strength of agreement between the two investigators in categorising care issues according to the guideline was satisfactory. Further comparison between the wards; General Medical and Care of the Elderly, of pharmaceutical care activity documented, could therefore be carried out.

3.7 Comparison of Patient Characteristics and Pharmaceutical care activity between two wards.

Two ward, namely the General Medical ward (Ward A) and the Care of the Elderly Ward (Ward B), were compared in terms of the profile of pharmaceutical care delivered. The Care of the Elderly ward has one clinical pharmacist as member of the staff and the working hours are quite similar to that of the pharmacist at the General Medical ward.

Table 28.Comparison of Patient Characteristics and Pharmaceutical care activity

	Ward A			Ward B			
Parameter (per patient)	**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 Process	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

Comments to the table;

The mean and median for almost all parameters compared are similar within both wards and this indicates a normal distribution and a suitable t-test was applied. Statistical significance was defined as $p<0.05$ and so a 95% confidence interval (CI) was calculated. The CI was calculated from standard errors and value of t (in this case 1.984 for n= 99; t tables).

There is a statistic significant difference in age between the two wards, where ward A has a mean age (CI) of 64.1 (61.2, 66.9) years and ward B has a mean (CI) age of 80.9 (79.5, 82.3) years. This can be explain by the fact that ward B be is a Care of the Elderly Ward with age ranging from 82-98 years and ward A is a General Medical ward, with age ranging from 26-98 years.

There is no statistical significant difference between the two wards in 'Length of stay'. Both wards have a broad range in the length of stay and this is in both wards due to a few long-term patients.

Number of diagnosis differs between ward A and ward B with the means (CI) 2.0 (1.8, 2.3) and 4.2 (3.7, 4.6), respectively. The total care issues documented per patient differs significantly between the two wards; ward A has a mean (CI) of 3.6 (3.0, 4.2) care issues and ward B has almost three time as many with its mean (CI) of 9.7 (8.6, 10.8). This is further reflected in the category of 'Checks' where there also is a statistically significant difference between the wards; ward A has a mean (CI) of 1.8 (1.4, 2.1) care issues and ward B has a mean (CI) of 6.4 (5.7, 7.1) care issues, which is more than three time as many as ward A.

There is also a statistical difference in the mean (CI) of 'Change in Drug therapy Process' between ward A and ward B. The mean and median in this category differs substantially, and the data are probably not normal distributed.

There was no statistical significant difference in the category of 'Change in Drug Therapy' between the two wards.

Table 29. Comparison of distribution of Pharmaceutical Care Issues into different subcategories

	WARD A		WARD B		
	n	**% (95 % CI)**	**n**	**% (95 % CI)**	**p-value (Fischer's exact)**
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

Only significant differences between ward A and ward B will be commented.

Main categories:

Ward B had a higher proportion of both ‘Checks’ with a mean (95% CI) of 65.8% (62.8, 68.8) and ‘Changes in Drug Therapy Process’ with a mean (95% CI) of 19.3% (17.0, 22.0) compared to ward A (49.3% (44.2, 54.5) and 7.5% (5.2, 10.8), respectively. Ward A had on the contrary a higher proportion of ‘Changes in Drug Therapy’ compared to ward B the mean (CI) being 43.2% (38.2, 48.4) vs. 14.8% (12.7, 17.2) respectively.

Subcategories Checks:

The proportion of ‘Compliance inquiry’ was four times higher in Ward B compared to Ward A.

Subcategories Changes in Drug Therapy Processes:

Ward A had a considerably higher proportion of ‘Health care team member information/education’ than ward B, with a mean (CI) of 29.6 % (15.7, 48.7) and 1.6% (0.3, 4.8) respectively. Ward B on the other hand had a higher proportion of ‘Clinical (shared) record of drug history’ than ward A. The means (CI) were 63.8% (56.7, 70.4) and 25.9% (12.9, 44.9) respectively.

Changes in Drug Therapy:

No statistical significant differences between the two wards.

Table 30.Comparison of distribution of Pharmaceutical Care Issues into QAD

	Ward A		Ward B		
	n	% (95% CI)	n	% (95% CI)	p value (Fischer's exact)
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

Only significant differences between ward A and ward B will be commented.

Time Perspective

Checks

The proportion of ‘verification’ is seen to be higher in ward B compared to ward A with a mean (CI) of 45.9% (42.1, 49.8) and 28.8% (26.8, 40.6), respectively. The proportion of the subcategory ‘confirmation’ is seen to be more than three times higher in ward B compared to ward A.
Ward A has though a higher proportion of ‘monitoring’ with a mean (CI) of 63.8% (56.5, 70.6) compared to ward B with a mean (CI) of 44.2% (40.4, 48.1).

Changes in Drug Therapy Processes

Higher proportion of verification are seen in ward B and compared to ward A, means (CI) of 68.6% (61.7, 74.8) and 37.0% (21.5, 55.8), respectively
As the proportion of verification almost differs by a twofold, so does the monitoring.
Ward A has a higher proportion of monitoring in this subcategory compared to ward B, the mean (CI) being 63.0% (42.2, 78.5) and 31.4% (25.2, 38.3), respectively.

Changes in Drug Therapy

Ward B had a considerably higher proportion of ‘verification’ with a mean (CI) of 75.7% (68.1, 82.0), compared to ward A with its mean (CI) 30.3% (23.6, 38.0).

Ward A had a substantially higher proportions of both ‘monitoring’ and ‘confirmation’ with means (CI) of 59.4% (51.5, 66.8), and 10.3% (6.4, 16.2) respectively, The values for ward B being 20.1% (14.4, 27.5) and 4.2% (1.7, 9.0) respectively.

Degree of Change.

No statistically significant differences in the proportion of different subcategories.

3.8 Comparison of ward A and ward B after applying data from the findings of a parallel survey of prescribing activity.

MPharm students Chan Sue Li and Amiruddin Bin Ahmad Ramly studied prescription turnover and quantification of exposure of each patient to medication during their stay as a separate project. The prescribing activity and pharmaceutical care activity of the two wards; the General Medical ward (Ward A) and Care of the Elderly ward (Ward B) was compared. This part of the project turned out to be a smaller than first anticipated, due to other priorities, so the results will only be briefly commented

Table 31.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 per patient (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 (courses/change)	6.6		4.6	

Key: *Significantly different ($p<0.05$)

Table 32. Explanation of prescription parameter

Prescription parameters	Definition
Total medicines courses per patient	Number of medicines exposed to the patient during stay at the ward
Total Course-days	The total exposure of medicines to the patients during their inpatient stay. The sum of all course-days, where one is the number of medicines prescribed on a given day.
Mean duration of prescription (days)	Sum off all prescriptions divided by the total number of prescriptions
Medicines courses at discharge	Medicines courses at discharge are the sum of medicines on admission and new medicines commenced substracting the medicines discontiuated.
Internal prescription turnover	Internal prescription turnover describes the changes in prescription actions during the patient's stay at the ward and is obtained by dividing the total courses of medicines commenced and discontinued during ward stay by the total course-days.
Total prescription turnover	Total prescription turnover is obtained by totaling up the courses of medicines on admission and medicines commenced and discontinued during stay, as well as courses on discharge and dividing the sum with the total course-days.
Number of courses needed to monitor (courses/change)	Number of changes per course monitored can be expressed as number of courses needed to monitor to affect one change. (Total medicines courses per patient**/** Changes per patient)

Note that not all parameter presented in Table 32. will be used in this comparison. Statistical significance was defined as $p<0.05$ with a 95% confidence interval (CI) The two wards were regarded statistical different if the mean of one ward where outside the range of the CI of the other ward. The table shows that only three of the prescribing parameter were significantly different between the two wards. These are the 'Total medicines courses per patient', 'Total course-days' and 'Medicines courses at discharge'. The mean numbers of 'Total medicines courses per patient' was 11.9 in ward A and 15.3 in ward B, while the mean numbers of 'Total course-days' were 99.4 at ward A and 119.5 at ward B. 'Medicines courses at discharge' were 7.4 and 9.0 in Ward A and ward B respectively. Ward B had thus higher values than ward A on all these parameters.

The ‘Total Prescription turnover’ on the two wards was non-significantly different, and this indicates that the number of changes in drug therapy per course-day per patient is similar in ward A and ward B.

‘Mean duration of prescription’ was almost the same in the two wards; 7.0 days in ward A and 7.4 days in ward B.

3.9 Results focus group

The focus group was held at the Strathclyde Institute for Biomedical Science on the 28th of April 2008. The participants were pharmacists from Glasgow Royal Infirmary and Ayr Hospital in addition to Professor Steve Hudson (see the table below).

Table 33. Participants attending the Focus group

Title	Initial
Pharmacist Ayr Hospital	KW
Pharmacist and Clinical Supervisor Ayr Hospital	GJ
Pharmacist and Clinical Supervisor Glasgow Royal Infirmary	LS
Pharmacist and Project Supervisor Glasgow Royal Infirmary	CF
Professor of pharmaceutical care and Project Supervisor	SH
Investigator	ROH
Investigator	MRR
Investigator	KH
Investigator	MBC

The participants had been given the guidelines with examples of categorisation of care issues and the power point presentation on beforehand.
Questions had been made to get feedback on the changes made to the categorisation system and the results from the categorisation of care issues at the four investigators’ respective wards.

Following are a general description on the outcome and feedback gain from the focus group. There were mostly a discussion around each of the main questions asked during the presentations, where the participants gave comments on each question to a lesser or greater extent.

The focus group had been recorded and retrospectively transcribed by the four investigators. The results will be presented around the main questions asked.

3.9.1 The Guideline

What your first impression of the guideline?
Is it readable?
Is it possible to use the system by reading the guideline?

The general feedbacks from the pharmacists were that the guideline needed to be read several times in order to comprehend the *whole* system. The categories of 'Checks' and 'Changes' were comprehended easy but the Quality Assurance Descriptors were thought to be a bit complex. Comments on this part of the system were ;

- " I think the concept of time perspective is a little bit (…) unfocused. And I think the intention is that this has to do with a role in quality assurance and that the time perspective becomes a little bit secondary. Certainly when talking about changes it becomes even more vague.."
- " Some of the language you use, there are lots of words that could mean the same thing, but are taken to mean different things……. But if you are actually modifying or adjusting things, or confirming and verifying things, that means two different things(?) you would need to know what language to use in this context."

Care issue not categorised

Comments from the participants after an explanation from the moderator of which care issues were not categorised;

- .."quite usually the pharmacist would write down things and not have the time to follow that up"

Division of the change category into two

Is it a logical division of the change category into two; 'Change in Drug Therapy Process' and ''Change in Drug Therapy?

There was a discussion on whether some of the subcategories of the 'Change in Drug therapy Process' could be described as a change in 'Change in Drug Therapy Process'. The subcategory discussed was the 'Health team member information/education', which was thought to be something outside the process and more of an action the pharmacist is involved in continuously. However it was emphasised by the moderators that in this system 'Health team member

information/education' information was linked to a patient related problem, and hence had to be patient specific to be categorised. The participants gave examples of different action taken among the pharmacist and type of information/ education provided. (e.g. notes to nurses on how to give I.V. infusions) The pharmacist at the Ayr hospital used an electronic prescribing system and would document this type of information in the care plans. Another pharmacist would only make a mark in the kardex, and therefore not document this type of action in the care plan.

Comments that were made to the statement that giving information/ education to other health care members not were *changes* in process;

- "it's not a change in the drug therapy process, it *is* the drug therapy process……. It's an activity, and a useful activity. So I'm just wondering if we should actually call these changes? "
- "If we say changes in the environment of delivering drug therapy. Then that will satisfy the problem with it and it would also adequately describe the rest of them. "
- "A way of thinking about it as contribution to the drug therapy process. "
- "So would that work then? Under the general heading of changes you've got contributions to drug therapy processes and changes in drug therapy**.**

They all agreement was that this will still be classified under the overall changes. And that it should be regarded as a part of the processes the pharmacist is *contributing* to.

Checks

The results from the categorisation were presented. First the four wards were presented with their distribution of 'Checks' into its subcategories. The distribution between the wards varied.

Can similarities and differences be explained?

The participants came with examples and explanations of what they thought were the reasons for the distribution of different types of checks at their respective ward. The agreement was that the different types of checks were cause by the nature of the ward; high proportions of 'Compliance Inquiry' at the geriatric ward was explained by patients here having a lot of polypharmacy. There was also comments on the number of checks; that these were probably not concurrent with the check actually performed. This was explained by the care plan not being a check list and that the pharmacists rather went through the checks mentally and performed them without spending the time writing them all down. Not all checks were routinely written down.

There was agreed that documenting should be more consistence in future.

Change in Drug Therapy Process

There were differences in the distribution into subcategories between the wards

Can similarities and differences be explained?

Some pharmacists explained that the reason for the difference in the 'Clinical record of Drug history' could be that at some of the wards the pharmacist were responsible for taking the drug history, but on other wards the pharmacists only used the clinical notes written by nurses/physicians.

Comment to this;

- "It's actually medical, legally one of the things that you would want to make sure was documented. It shows that you have all the information passed on."

Change in Drug therapy

None of the four investigators had used the category 'Duration' when categorising the care issues into the subcategories of 'Change in Drug therapy'.

Is there a need for the subcategory 'Duration' to be a part of this category?

Some of the participants were surprised that none care issues were categorised into this subcategory as they thought of duration of drug therapy as a common term.
The investigators explained that they had categorised care issues concerning duration as stop drug temporarily/ permanently or start drug.
There was agreed that the terms were overlapping as to whether the drug was stopped or the duration changed. It was suggested that the 'Stop drug temporarily/ permanently' would be the simplest and that the reasons for why a drug is stopped would be explained by the relating 'Drug Therapy Problem' category.

Drug Therapy Problem

In the modified system the investigators had added a category and named it 'Unclassified' (i.e. Non-DTP - care issues regarding cost savings etc) However, very few of the documented care issues had been categorised into this category.

Should the category 'Unclassified' be a part of the system?
Are these types of issues, regarded as pharmaceutical care issues?

Comments:

- " I would say if someone is on a non-formulary drug that would be a care issue, and it's something that we do spend time doing. So if you just loose it, you will be loosing parts of what the pharmacist does."

- "If you've got a category called 'unclassified' it would just be a bin, people would just put anything in it. So you are not sure what is put into there, and you would loose information. So if you are going to have an extra category, call it something a little bit more specific."

There was an agreement on these comments, and as the numbers were small for all the wards it was commented that this category did not give so much information in this aspect. The investigators explained that care issues regarding switch of dose form etc in most instances were classified as ineffective / not safest drug. This could however be due to an ambiguity by the way the care issues were documented. If they were not clearly documented as non-formulary drugs, the investigators might have just assumed that the reason for the switch was ineffective / not safest and the like.

Interaction

Should interaction be part of the system?

There was a an unanimity among the pharmacist that there was no point in having a own tick box for those care issues concerning an interaction. The argument was in general that interaction was just one of many reason for why the pharmacist take action in changing drug therapy. The interaction is just an outcome of a care issue in the same way as ‘dose to high’, ‘dose too low’. The assumption was that interaction is not a bigger concern than making sure that the dose is correct, blood levels ok etc. Some of the pharmacist also state that they often went through a care issue regarding a interaction mentally and the only wrote down the result of the check or change made due to this, and not that it was an interaction originally.

Recommendation

Should recommendation be part of the system?

The pharmacist did not see the importance of marking the changes and checks that were influenced by a recommendation made by the pharmacist. They argued that the recommendations in most instances lead to an discussion where the physician and the pharmacist most of the times came to consensus and this would be the succeeded check or change. One pharmacist did see that it could be useful depending of what you were using this numbers fore.

Summary question;

Do these categories in general describe the pharmaceutical care delivered?

There was a unanimity that the individual practice is various at the moment and that this system would contribute to documentation of problems. The guideline was though to be a basis for describing pharmaceutical activity, the pharmacists' contribution to care. So far a potential tool for looking at different part of assessment.
It was also commented that this categorisation system also would be useful for the pharmacist him/herself, to see where they put most of their effort, and by this be able to evaluate the reason for different distribution of the care issues documented (due to workload, or something not done often enough) and reconsider their prioritises.

Quality Assurance Descriptors – Time perspective

This part of the system were a bit confusing for all participants as they had different understanding of the terms; verification, monitoring and confirmation. In the guideline the terms are description of where in the patient's treatment cycle a check or a change is performed. But the meaning of the words as individually descriptions of type of checks lead to a confusion since some of the pharmacists not familiar with using this system in their documentation, would say that a confirmation for instance could happen when the pharmacist first spoke to the patient. (this would be a verification according to the guideline)

As the investigators in the modified system had categorised the changes according to their preceding check as well, in order to give the changes a time aspect in the treatment cycle, this lead to confusion about the terms. The participants had problems with assigning a change into categories which describes checks; verification, monitoring and confirmation. The pharmacists came with a suggestion to change the terms in order to capture the time aspect for both checks and changes.
Comment;

- " (...) if you say it happen at the design stage or the delivery stage or the evaluation stage. Could you do that? Then you avoid the duplication of using the same word (….) you still got the time perspective, you're still following that…you just say design stages instead…"

This was discussed thought of as a good solution to simplify a complex linking.

Quality Assurance Descriptors – Degree of Change

Also in this category there were different opinions about the meanings of the subcategories adjustment, modification and review. The results from the categorisations showed that there were few 'Review' overall, and this surprised some of the participations. There were however revealed that the meaning of review in this context would be a re-assessment of the patient's treatment and that it therefore did not happen too often at the wards where the patients often had a treatment plan.
There were also discussions on what type of changes would be an adjustment and what would be a modification. The pharmacists did not all have a clear definition of this.

The overall suggestion was to separate the changes into adjustment and modification made at the design stage, adjustment made at the delivery stage and modification and review made at the evaluation stage. This would then describe at which delivery stage the pharmacist is affecting a change.

The discussion lead to the sum up that; The explanation for not using the 'Review' is that this type of change have to be prompted by the pharmacist and the doctor set the treatment goal. The pharmacist would probably have more influence on this type of change if he/her were attaining ward rounds with the physician, which few of the participants were doing in practice.

Summary question

Which potential uses you can think of for this system?
Can you mention some positive and negative sides of the system?

- "….pharmacist can benchmark their practice and see what they need to be working on. (..) it makes you thinking about processes, 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"
- "So that's positive. The negative is that's quit complex (…)I think that could potentially lead to inter-rater problems ?(…) The more intuitive you can make it, the better."

4 Discussion

4.1 Evaluating processes described in the Process Maps

After evaluating the process maps, the observations made after shadowing the pharmacist and analysing care plans were also taken into consideration. It was obvious that the process maps are describing some of the general services the pharmacist ideally should provide for all the patients. The individual patients will however require different needs, extent of assessments and action to be taken. Thus, the pharmacist encounters diverse situations, and often needs to prioritise the time he spends at the ward.

By assessing the patients' medical needs and making an effort in identifying, resolving and preventing drug therapy problems, both the process maps have substantiated that the pharmacist is a contributor to the provision of pharmaceutical care.

The investigator did not attend every ward round for all patients included in the survey and had therefore not seen every process taken for each patient. Nevertheless, the time spent shadowing the pharmacist did clearly show that documentation on the care plans did not coincide fully with actions actually performed. During this survey period of 13 weeks, 359 care issues had been documented .Based on this documentation it can be anticipated that the pharmacist has provided much lesser pharmaceutical care activity than the actuality. There are reasonable explanations for the pharmacist not being able not document every step taken. It needs to be emphasised here that the intention is not that the pharmacist should document every step taken in provision of patient care, cause that would lead to the pharmacist spending time on writing down action instead of performing them. Still, it is important that patient specific action taken in the treatment plan is documented to ensure safety and effectiveness for the patient, and also to improve continuity of care.

4.2 The modified categorisation system

The complete result of modifying the categorisation system is presented as the Guideline in Appendix 2. The reasons for the modifications of the different parts of the existing system have been presented in the results and are also justified to some degree in the Guideline. Following are a discussion on the modifications made in each part of the system and the experiences gained after testing the practical application of the categorisation system.

4.2.1 Categorising care issues

Different kinds of challenges occurred when applying the care issues from the care plans to the modified system. First of all, as the documentation on the care plans often were in the form of key-words and not systematised into the standardised lay-out of a care issue; *care issue – action – outcome,* it was sometimes hard to capturing and interpret what all the care issue really concerned, and further categorising them. The documentation on the care plan was supposed to be cleared up by going through them with the pharmacist, but this was not completely fulfilled for all care plans. The care plans were discussed with the pharmacist to some degree and did clarify several aspects, but still there had to be made assumption by the investigator on some of the care issues. Secondly, the fact that the investigator was a student and due to that did not have enough clinical experience must also be taken into account when considering the clinical judgement needed to fully comprehend some of the situation. (This would typically be to assess whether a change would be an adjustment or a modification) A pharmacist documenting his/her own care issues by categorising would know the circumstances for the care issues, and what the investigators have had obstacles with would probably speak for it self and be more intuitively to the pharmacist.

After scrutinising the system, making modifications and developing a guideline, the system was still thought to be a bit complex at some parts. All four investigators had to used the guideline to decide how to categorise many of the care issues.

Check

The ‘Check’ category and its subcategories were not modified, as the applicability was thought to be good enough. There were no particular problems with the understanding and use of this category.

Change in Drug Therapy Process

The argumentations for dividing the existing change category into two have been explained in the results and guideline. The experience with this division when categorising, was that this was an applicable way of differentiate between changes related to drug therapy and prescription, and hence drug therapy problems, and those actions made to processes such as information to health care personnel, drug history and continuity of care. Common for the whole categorisation process were that some care issues did not fit perfectly to the alternatively subcategories of all categories and therefore had to be put into the one most obvious. An example here is the pharmacist offering smoking cessation to the patient. In those cases where the patient agreed to get help with smoking cessation this was considered a ‘Change in Drug Therapy Process’ as ‘Continuity of care between clinical settings’. But in those cases where the patient turned down the offer this care issue did not fit into any proper category. As no kind of change had been made this was categorised as a Compliance check, since this was considered as the closest one.

When the existing system first was scrutinise the idea to separate some of the subcategories underneath the Change category was that the investigators though it was important to document the actions the pharmacist contributed with that where neither a check nor a change, which where the only options in the former system. As just ‘Action’ was assumed to be a diffuse description, the suggestion of describing these processes as ‘Change in Drug Therapy Processes’ came up. The purpose was to describe actions not regarded as drug therapy and drug therapy problem, but still important part of the pharmacist contributions in the patient care process.

However, the term ‘Change in process’ was after categorising care issues and evaluating the system thought *not* to be the best description after all, as *change* is not the right description for all subcategories within this category. Many of the processes representing the subcategories cannot really be described as a change made. Like for instance ‘Health care members information’ and ‘Patient monitoring’.

These terms were among those discussed at the focus group. It was reach an general agreement that, for instance educating a nurse in how to give I.V is not a change in drug therapy process but rather a *contribution* to the drug therapy process. A reasonable suggestion to change the name of this category to ‘Contribution to Drug Therapy Process’ was made.

Change in Drug Therapy and Drug Therapy problems

These two categories had not been modified to the same extent as the former category and the following categories of Quality Assurance Descriptors. In general assigning a care issue into a ‘Change in Drug Therapy’ and a subsequent category of ‘Drug Therapy Problem’ category, were thought to be logically and quite intuitively.

The subcategory ‘Duration’ as a ‘Change in Drug Therapy’ had not been used by any of the four investigators when categorising care issues, and after a discussion with the focus group it was suggested that this subcategory was unnecessary as one could use ‘Stop drug temporarily / permanently ’ or ‘Drug selection – start new or change’ instead.

In the category ‘Drug Therapy Problem’ the investigators had added one category and named it ‘Unclassified’. The purpose with this was to handle those ‘Changes in drug Therapy’ that where not patient specific. (i.e. formulary adherence like generic switch due to cost control implications). After analysing the outcome of the categorisation it was shown that only a few care issue had been assigned into this category. Because many of the care issue only were written in the care plans as a switch of drug, most of them they were interpret to be due to ‘ineffective/not safest drug’. The investigators did not know the whole background for all the changes of drug, and therefore this category did not benefit. This ‘Unclassified’ category was also discussed at the focus group, and some of the pharmacist said that they spent a lot of time making sure that the patient where on the proper drug according to local formularies. Not regarding this a care issue and categorising it, would lead to information lost on what the pharmacist were doing. Still, renaming the category was called upon, to specify what to include within it.

Quality Assurance Descriptors

Categorising care issues into the ‘Quality Assurance Descriptors’ categories lead to most of the speculations. First of all, although the different terms of these subcategories (*verification, monitoring, confirmation* and *adjustment, modification*) had been defined in the guideline they were not always intuitive when practical care issues were to be assigned into these subcategories. Since one not knew the whole aspect of all care issues this lead to problems in general with giving the care issues the right ‘Time Perspective’ as well as the ‘Degree of change’. Despite that a ‘Change in Drug Therapy’ had been made, one did not always know the extent of the change just by analysing the care plan.

It was revealed at the focus group that the pharmacist working at different wards had different experience and understanding of the terms within the QAD subcategories as well. For some of them the terms ‘adjustment’ and ‘modification’ (‘Degree of Change’) had the same meaning and where difficult to differentiate between, although the care issue and its outcome were fully understood. This underline that these terms in general are difficult to use in this aspects as they are interchangeable and that a guideline with the explanation probably would be needed to perform the categorisation using these terms. Other had a clearer comprehension of adjustment and modification and used them to describe what changes they made. The same was the case with the ‘Time Perspective’ terms. There was an inconsistency between the pharmacists as what verification, monitoring and confirmation would be. The problem was that in this categorisation system these terms are a description of the time aspect in the treatment cycle, because they originally where QAD for checks. But as the meaning of the terms individually describe different types of checks there were confusion among some of the pharmacist since they argued that a ‘verification’ could happen during the treatment of the patient and not only necessarily at the start of treatment. This would apply to ‘confirmation’ as well. Some would say that they are ‘confirming’ checks when they first see the patient and not only as an evaluation. The investigator had also experienced these inconsistencies when categorising, but had still followed the guideline and the definition made there.

To be repeated; the investigators made a change in the existing categorisation system by renaming the QAD for ‘Checks’ to QAD –‘Time perspective’. All care

issues have been categorised into this category in order to capture the time aspect of *when* in the patient's treatment the care issue was identified and acted upon.
In the modified system this was practically carried out in the way that each 'Change in Drug Therapy' also was categorised into the QAD for its preceding check, as the QAD for 'Check' had a time perspective related to each of its subcategories (verification – beginning, monitoring- during treatment, confirmation - as treatment continues) But relating 'Change in Drug Therapy' to these term only to capture the time aspects has been realised to be too complex and confusing both by the investigators and the pharmacists at focus groups as well.

4.3 Further improvements

A solution for making the QAD more applicable has been discussed among the investigators and was also with the participants at the focus group. It has been realised that there is a need to make the terms in the QAD more specific by using a simpler and more neutral wording. The purpose with the QAD is to describe *when* in the treatment process the pharmacist is taking action and making his contribution to patient care (checks or changes), and also to capture the *degree* of changes made.
Instead of talking about at the start-, during-, and as treatment continues, other more general descriptions of the treatment cycle can help the improvement.

If this latter terms to describe the time aspect were renamed to stages in the treatment cycle; like *design stage, delivery stage* and *evaluation stage*, these could be applied neutrally to both checks and changes. It would be more reasonable to talk about an adjustment made in the delivery stage instead of "in monitoring" which one needs to know means during treatment in this aspect. These terms would more likely fit better to all care issues as they are not a description of a type of check but neutral descriptions of stages in the treatment cycle; when in the cycle care issues are identified and acted upon.

The delivery of pharmaceutical care to could then be described as follows;

Changes in Drug Therapy

1. **Adjust an initial design**
2. **Modify an initial design**
3. **Adjust during delivery**
4. **Modify after evaluation**
5. **Review after evaluation**

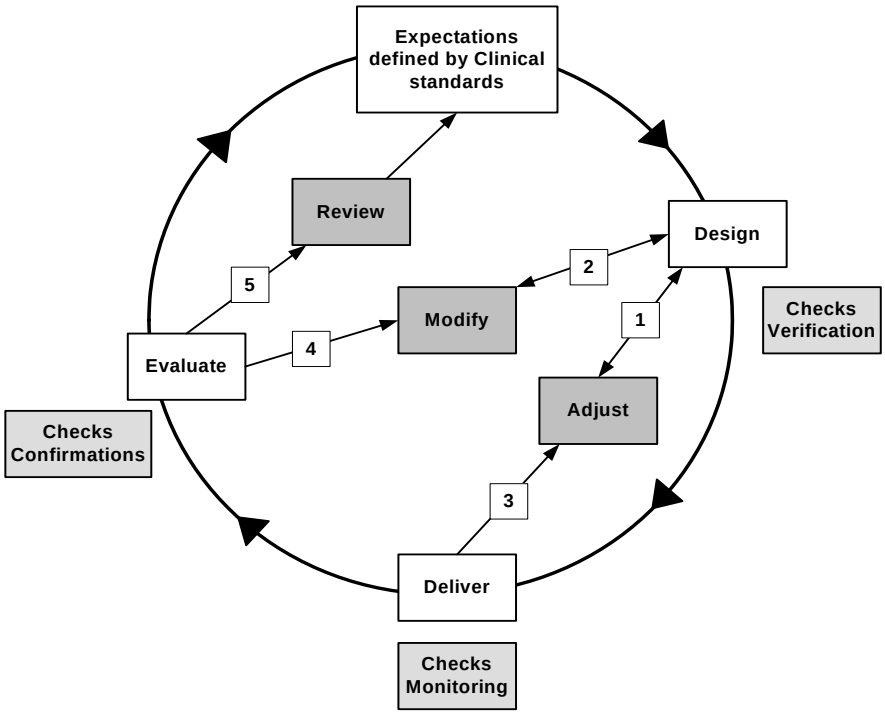


Figure 2. Modified Pharmaceutical Care model

The QAD categories would be better linked within the treatment circle and these categories would be less complex as both check and changes would fit into the general description of design stage, delivery stage and evaluation stage.
Then the different 'Degree of Change would be described as in the in the table; that is attached to each of the different stages and by describing a time aspect as well. The meaning of the different type of changes still needs to be interpreted and comprehended. But this circle indicates that an adjustment is a type of change made either at the initial design or during the delivery stage and is hence less comprehensive than a modifications, which also could be made at the initial design but often is a result of a change made after an evaluation.

When it comes to the 'Check' category, it can be argued that its subcategories can be used interchangeable in the different stages of the treatment cycle. However as a pattern these subcategories in most instances fit with the time aspects they had. Getting familiar with these different definitions in the settings of categorising care issues, by using the guideline, are regarded as acceptable and applicable. The investigator has had the experience that these terms mostly are appropriate to use by the way they are defined in the guideline.

4.4 Amendment ahead and applicability of the categorisation system

The intention with this system is good and the system has been shown to be applicable for practical use. It is however regarded to bee too complex to be used in everyday practice, as it is today, especially the QAD as they are not intuitively enough. In general both the categories for ‘Check’ and ‘Changes’ were regarded as easy and intuitive to categorise a defined care issue into. But the guideline has to be used to capture and use the whole triangularised system. The Quality Assurance Descriptors needs to be modified further, by changing the wording and specifying the link with time aspect. This would make this part of the system more comprehensive and usable.

In general it is thought that the different terms describing the documentation made, by categorising care issues, is an unfamiliar and new way of thinking for many pharmacist working clinically. To just present them this guideline and assume that they will start to document their care issues by categorising them would probably be to expect too much. Nevertheless, there is a potential of this system as a tool to aid future pharmacist in their documentation. Documenting problem solving is essential for the purpose of evaluating the work the pharmacists do as part of a hospital team on the wards. And by having a common system for documentation, it will be easier for the pharmacists to work within the same standards and for researcher to review and do research with their work. If further improvements are made to enhance the applicability and understanding of this categorisation system, it is believed that the system has the potential and could be implemented and presented in the curriculum for pharmacy students. In order to improve the lack of documentation by pharmacist today, it is essential that pharmacists learn and comprehend how to document early on, so that when starting to work clinically this is a naturally part the work at the ward.

4.5 Inter rater reliability test

The inter rater reliability test had been performed by picking 50 care issues from the two wards randomly. This gave an uneven distribution between the different categories as there were some categories not represented or too few of (e.g. ‘Review’). The problem with this is that the value of kappa depends upon the proportions of prevalence in each category. Uneven proportions in the different

categories could be one reason why the Cohen's kappa overall is so high, due to different 'chance expected frequencies'. [52]

The investigators still thought that picking the care issues randomly was the best way to test the agreement in categorising care issues, instead of ensuring that all categories were represented. The testing of the comprehension and utility of the modified categorisation system would best be shown if the raters did not know that a certain number of care issues were supposed to be in a specific category. Despite the uneven distribution, Cohen's Kappa is the best approach to indicate agreement between categorical interpretations.

The results from the inter rater reliability test showed that the strength of agreement between the investigators was 'Very good' in all levels except from the 'Time Perspective' where the strength of agreement was 'Good'. This could in addition to the facts explained above be due to close cooperation between the investigators during the survey period and development of the guideline. In general when categorising their own care issues the investigators discussed a lot how to interpret different care issue and which category a type of care issue should be assigned into. This former cooperation could have lead to a common interpretation, which could have resulted in a common categorisation pattern and also can explain the overall high kappa.

It was however not surprisingly that the agreement was 'Very Good' in the main category because assigning a care issue into a 'Check', 'Change in Drug Therapy Process' or 'Change in Drug Therapy' does not require as much assessment and background information of the care issue as long as you have the action and outcome.

The subcategories of the different main categories did also have a 'very good ' strength of agreement. The investigators had given each other relevant information on the care issues on beforehand, the type of info that would have been given by talking to the pharmacist who documented the care issues. Knowing the background for the care issues could be the reason why there were few disagreements in the subcategories. Within the subcategories there was only a disagreement in the subcategories of Checks (kappa (CI) =0.93 (0.85,1.00)). The subcategories of

‘Change in Drug Therapy Process’ and ‘Change in Drug Therapy’ had Cohen’s Kappa of 1. (Appendix 3). The strong kappa could indicate that between the investigators the comprehension and intuitive application of these two change categories were good. This is however biased by the fact that both the investigators have taken part in the modification and development of the guideline and discussed many of the care issues in general.

The Quality Assurance Descriptors had been a part of the system which where thought to be complex and a bit confusing. In the QAD ‘Time Perspective’ the kappa and hence strength of agreement were lowest (κ (CI) = 0.72 (0.59 – 0.85)). The raters had disagreed on 15 of the 100 care issue categorised into this category. The reasons for these disagreements were showed to be that the raters had made assumptions or misunderstood the setting of the those care issue which were unfamiliar, the background for the care issue had not been clear enough. An analysis showed that eight of the disagreements concerning ‘Time Perspective’ were ‘Checks’ and seven ‘Change in Drug Therapy’.

The kappa of 1 in the QAD ‘Degree of Change’ was quite surprisingly as this had been one category causing difficulties to the investigators during the categorisation in general. One explanation could be the uneven distribution of care issues as explained above. In this category none of the care issues were ‘Review’ and 23 of the total of 26 care issues in this category were categorised as ‘Adjustment’ and only 3 were ‘Modification’. Also knowing that this would be a difficult category could have led to giving too much information about the care issues to each other unintentionally.

The inter rater test in this regard has shown that the two investigators had a common understanding of the categorisation system and due to this a comparison of distribution of care issues between the wards could be performed. To further test the comprehension and utility of the system in practice, an inter rater test between two raters who are neutral to the modification of the system would be the best way to get unbiased results.

4.6 Pharmaceutical care profile of the General Medical Ward

The total number of care issues documented for all 100 patients during the survey period was 359 with an average (SD) of 3.59 (3.2) care issues per patient. This is as mention in the review of the process maps thought to be a misrepresentation of the care provided. A broad range 0-17 underline the impression that the pharmacist has had to prioritise his time spent on patients.

Care issues considered as part of the standard procedure were not regarded as a care issue to be categorised. This would for instance be where the pharmacist have checked drug history and made a note about it, or sees that the patient got all medicines needed for an indication and this is fine. Only if these checks lead to a change or were out of the ordinary these would be identified as a care issues and categorised. The reason for this is that there would have been a lot of similar checks recurring, and this information would better be presented in the process maps and not as a part of the documentation system.

4.7 Categories and distribution of Care Issues

The ‘Checks’ were accounting for 177 (49.3%) of the care issues documented. These numbers are not surprisingly as checks are of great importance and comprises much of the tasks the pharmacist performs in order to ensure optimal drug therapy. These numbers might however be misleading according to the total checks actually made by the pharmacists, because as already explained, many of the checks are in general standard procedures and not regarded as care issues. The pharmacist may also perform routinely checks, which he does not write down although they might have concerned a care issue. This was the assumption the investigator had after shadowing the discussing with the pharmacist.

The category “Change in Drug Therapy ” was the second most frequent type of care issues documented. This is reasonable since many of the checks (preceding) lead to a change in drug therapy. As opposed to the ‘Checks’ these numbers are more consistent with the changes the pharmacist actually has influenced (investigator observed when shadowing and confirmed by the pharmacist). There is however a

lack of totally changes documented (changes to enhance compliance is one example.)

The category ‘Change in Drug Therapy Process’ was the smallest one as just 27(7.5%) of the total number of 359 care issues documented was categorised into this category. This could be explained both by the fact the priorities of the pharmacist not are within this category or that these processes taken are not documented to the same extent as changes concerning drug therapy.

4.7.1 Subcategories of the QAD Time Perspective according to type of care issue

The distribution of care issues into the subcategories of the QAD 'Time Perspective' showed that for all the main categories 'monitoring' were the major subcategory. This mean that common for all types of care issues is; they are mainly performed and documented during the patient's treatment and delivery of the treatment plan. This is actually logical as these monitoring would typically with the purpose of ensuring safe and effective treatment. Examples would be checking that treatment is optimal by monitoring levels of digoxin and the like, blood pressure, liver function and kidney test (K^+, Na^+), estimating creatinine clearance, etc.

Verification encompasses one third of the care issues. These are typical action taking place when the pharmacist first sees the patients and verification of the patient drug treatment is done, or when a new treatment/drug is started during the patient's stay. This latter explains the high prevalence in verification regarding 'Change in Drug therapy'.

'Confirmation' only involved 21 (5.9%) of all care issue and were mainly related to Change in 'Drug therapy'. As the patients at the General Medical ward often are admitted due to an acute exacerbation of a chronic disease or an acute episode of disease, 'Confirmation' in this aspects would in general be an evaluation of the patient's treatment to assure that expected effects are achieved (antibiotic course) adverse effects avoided (contraindication, interactions) etc. 'Confirmations' is a category that 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. The continuing evaluation of a chronic disease would in most instances be done in the outpatient clinics.

Distribution of subcategories of Checks into subcategories of Time Perspective

Those 'Checks' most frequently documented were 'Safety inquiry' taking place during the patient's treatment (monitoring) and verification of 'Medication needs', respectively. This is not surprising as continually monitoring of the patients drug treatment are of high importance and essential. Also checking need for medication

is a task the pharmacist often does when he first sees the patients and during the patient's treatment, to ensure that the patient is one the drugs needed and not on drugs unnecessary.

Few of the checks documented were 'Compliance inquiry', 6 (3.4%). Those checks concerning compliance have thus been done in the start of treatment (verification) and would typically in this ward setting be the pharmacist offering the patient smoking cessation, checking inhaler technique, etc. If the pharmacist provided some kind of education or instruction this would be categorised as a 'Change in Drug Therapy' because it is related to the 'Drug Therapy Problem' 'Inappropriate compliance' There were also few documented 'Checks' categorised as 'Confirmation' 5(2.8%) and this can be explain by the fact that most checks are done at the beginning of the treatment (verification) or during treatment (monitoring) and most confirmation would be related to changes made during treatment.

Distribution of subcategories of Change in Drug Therapy Process into subcategories of Time Perspective.

There was a quite even distribution between the care issues in this category. Those 'Changes in Drug Therapy Process' documented were however mostly done during the patient's treatment, (monitoring) and encompasses mainly 'Health care team information' and 'Level of patient monitoring'. Also verifying a drug history resulting in a correction, in the start of the patient's treatment were among the frequently documented care issues in this category. These numbers could be explained both by the fact the priorities of the pharmacist are within these subcategories or that the changes in the other subcategories are just not documented to the same extent.

Distribution of subcategories of Change in Drug Therapy into subcategories of Time Perspective

The changes in 'Change in Drug Therapy' were mainly distributed throughout the 'monitoring' and 'verification' subcategories, as 'Stop drug temporarily/permanently' and 'Drug selection (new or changing drug)', respectively.

These most frequent 'Changes in drug Therapy' are related to the preceding checks, 'Medication Need inquiry and Safety checks'. These latter are one of the most frequently 'Checks', and the changes shows that many of these checks lead to either

a new drug being commenced or a drug stopped temporarily/ permanently due to no need for medication or stop due to safety concerns.

Distribution of care issues in 'Change in Drug Therapy' into 'Drug Therapy Problem categories.

Those 'Drug Therapy Problem' causing the most frequent 'Change in Drug Therapy' ('Stop drug temporarily/permanently') were 'Adverse drug reaction 28 (18.1%), 'Unnecessary drug therapy' 18 (11.6%). These numbers are substantiated by the literature facts implying that these are one of the most frequently drug therapy problems in general. [12]

All care issues in the changes regarding 'Drug selection (starting new or changing drug)' were caused by the 'Drug Therapy Problems'; 'Need for additional drug therapy' except for one which was due to 'Ineffective drug'. These numbers are not so surprisingly although the distribution is skewed. As there are clinical guidelines to be used for treatment in most instances, ineffective drug is in general not so frequent compared to patients actually being sub optimally treated.

'Duration' was a subcategory in 'Change in Drug therapy'' that no care issues were categorised into. The reason could be the interpretation of the care issues by the investigator, since potential care issues for this subcategory was assumed to be 'starting new or changing drug' or 'stop drug'. There were neither no care issues categorised into the added 'Drug Therapy Problem' category 'Unclassified'. The investigator did not find any documented care issue regarding this category (i.e. non-adherence with local formularies.)

Distribution of subcategories of Change in Drug Therapy into subcategories of Degree of Change.

Only the main category 'Change in Drug Therapy' is categorised into the QAD 'Degree of Change'.

'Adjustments' constituted 132(85.2%) of all care issues categorises as a 'Change in Drug Therapy' and only 24 (14.8%) were categorised as 'Modifications'. There were none care issues categorised as a 'Review'. This means that most of the 'Stop drug temporarily/ permanently' and 'Drug selection – new or changes' which were caused

by ‘Adverse Drug Reaction’ and ‘Need for additional drug therapy’, respectively all mainly were adjustments. (an anticipated change within the treatment plan).
As the QAD category was the one that the investigator have had most trouble with assigning the cares issues into, this could have affected the distribution. The guideline was followed to aid the interpretation of the care issues. Still, not having the whole background for all the care issues and not comprehend the fully assessment for all situation could have biased this outcome.

The way the care issues were documented and the way that the investigator have interpret them could be the reason why none of the care issues were regarded as a review. This category would involve a re-assessment of the patient’s treatment and lead to a change in the expectations defined by clinical standards.

4.7.2 Time perspective linked to Degree of Change

The way of assigning the ’Change in Drug Therapy’ into the QAD ‘Time perspective’ (originally the QAD for ‘Checks’) was to add a time aspect to the changes. The numbers from (table 25) show that most of the ‘Changes’ are adjustment made during the delivery of the treatment plan to the patient (monitoring). These numbers are quite reasonable as it was seen that these types of actions were among those that the pharmacist priorities to spend his time on.

4.7.3 Recommendation

Of the 359 care issues documented 150 were marked as resulting from a recommendation made by the pharmacist. Most of these recommendations were regarding ‘Changes in Drug Therapy ’ 122 (81.3%). However the investigators had also marked the ‘Checks’ that could be considered to have involved a recommendation from he pharmacist. This latter would in most cases be the pharmacist and the physician having a discussion and coming to an agreement.

The investigator thinks that marking these care issues and thereby underlining the contribution to drug therapy is useful and interesting. The intention was to have a way to differentiate between the changes made due to the pharmacist input and those contributions made to check and changes in general. However marking these

recommendations would depend on the purpose with the documentation. If there is an interest to underpin how the pharmacist makes a value to the health care team, in one particular way, this could be useful. On the other hand, in every-day basis this could be argued to be unnecessary. These markings have just been a part of the database tool and have not been included in the guideline.

4.7.4 Interaction

The investigators did also make a tick box in the database to track those care issues that dealt with interaction. Only 9 (2.5%)of the total 359 care issues were concerning interaction. The same would apply here as for the recommendation. In this project there was an interest to see whether the pharmacist were paying particular interest in this type of drug therapy problem and therefore interactions were tracked. The pharmacist at the general medical ward did not document these in particular. And the number might be smaller than what actually is encounter as an interaction often is underlying to the care issue, but only the result of the care issue/change is documented.

4.8 Comparison of Patient Characteristics and Pharmaceutical care activity between two wards.

There was a difference in age between the two wards, ward A had a mean age (CI) of 64.1 (61.2, 66.9) years and ward B had a mean (CI) age of 80.9 (79.5, 82.3) years. This can be explained by the differences of the wards in general. Ward B is a Care of the Elderly Ward with an expecting high mean age, ranging from 82-98 years and ward A is a General Medical ward, with an diversity age –range, from 26-98 years.

Care issues not categorised were different between the wards. These care issues would be care issues with unknown outcome. It was discovered that the pharmacist at ward B often wrote all care issues he was concerned about on beforehand and due to limit time did not cover them all. The difference can also be speculated to be differences in documentation, that is that either the outcome was not documented although it had an outcome, or that the care issues with no outcome was documented to a lesser extent between the two wards (that is when the pharmacist

documents care issues retrospectively he leaves out those care issues that did not result in an outcome).

The relative big differences in number of care issues per patient are thought to be due to difference in documentation and not necessarily in the provision of pharmaceutical care activity. In general more checks are performed at ward B, being a Care of the Elderly ward, where poly-pharmacy has a higher prevalence compared to the General Medical ward. The difference in documentation of 'Change in Drug Therapy Process' with a higher mean at ward B can be explained by different degree of documentation in general, but also that more drug history inquiries are made at ward B. As the numbers of 'Change in Drug Therapy' were statistically non significantly different these did not affect the difference in the total number of care issues per patient.

4.8.1 Comparison of distribution of Pharmaceutical Care Issues into different subcategories.

Main categories:

Ward B had a higher proportion of both 'Checks' and 'Changes in Drug Therapy Process compared to ward A . Ward A on the contrary had more 'Changes in Drug Therapy' compared to ward B. These differences might be due difference in degree of documentation rather than differences in actual work performed as both Checks and Changes in Drug Therapy Processes are categories the pharmacists admitted to omit to document (according to Focus Group). The fact that ward B had 972 care issues documented and ward A 359 care issues could also underpin this. The higher proportion of checks would be expected at ward B, as this is a Care of the Elderly ward and due to higher risk of adverse drug reactions and problems with compliance more checks to reveal these have a high priority.

Subcategories

Checks

The proportion of 'Compliance inquiry' was higher in Ward B compared to Ward A. This is also reasonable as ward B is a Care of the Elderly ward. Compliance is known to be a greater problem with ageing, both due to reduced mental and physical function and to poly-pharmacy.

Drug Therapy Processes.

Ward A had in general very few care issues in this category, a total of 27 care issues compared to 188 care issue being a process change in ward B.

Ward A had thus a higher proportion of processes regarding 'Health care team member information/education' than ward B. This difference can be explained by the different wards layout. Ward B is a long corridor where the patients are staying in different rooms. Ward A, the General Medical ward, is arranged as one big room with all patients together, and the kardex' are to be found on each patient's bed. This means that the pharmacist and other health care team members are in the same area at the same time and more interaction can take place without the pharmacist having to spend time looking for physician/nurses and vice verca.

Ward B had a higher proportion of 'Clinical (shared) record of drug history' compared to ward A. The difference could be due to the overall higher number of 'Change in Drug Therapy Process'. But the investigators had also the impression, after shadowing the different pharmacists, that this difference could result from the clinical pharmacists' time priorities.

Drug Therapy.

There were no statistical differences between the wards in these subcategories. This could imply that these changes are of priority to document for both pharmacists and The respective numbers were quite similar for ward A and ward B; 155 vs. 144.

Comparison of distribution of Pharmaceutical Care Issues into QAD Time Perspective

Checks

The proportion of 'verification' and 'confirmation' were higher in ward B than A.
Ward A had thus a higher proportion of 'monitoring'. These results were expected after shadowing the pharmacists at both wards and can be explained mainly by different prioritising of documentation. More checks at ward B in general is what's causing a higher proportion of both the verification and confirmation. While verification of 'Checks' would typically be made at the start of treatment, the proportion of confirmation on this ward would typically be confirming that drugs such as antibiotic and heparin had been stopped.

Changes in Drug Therapy Processes

In this category there was a higher proportion of verification in ward B compared to ward A. This could be explained by more changes needed due to lack of drug history at site B. Ward A had a higher proportion of monitoring in this subcategory compared to ward B. The contributing parameter here is most likely the higher number of care issues concerning 'Health care team member information' and 'Level of patient monitoring.

Ward B had a higher proportion of 'verification' compared to ward A, whereas ward A had higher proportions of both 'monitoring' and 'confirmation'.
'Verification' and 'monitoring' show here the same trends as under the checks. This is probably a result of the fact that when a high proportion of checks being made at different times this would lead to a corresponding high proportion of changes in drug therapy at the same time.

Changes in Drug Therapy

'Changes in Drug Therapy' being categorised as a 'confirmation' differs from the pattern of 'Checks'. These could be du to the pharmacist at ward A having a more proactive role when it comes to stopping drug therapy and this could further be explained by the ward layout where the pharmacist more often run into the physician and can influence these changes faster. The pharmacist at ward A is also in more contact with the patient as the kardex' are by the bedside and not in the corridor as in

Ward B. By dialoguing with the patients the pharmacist is able to reveal more the need of the patients and hence suggest stopping unnecessary drug therapy (pain, constipation, nausea etc.)

4.9 Comparison of ward A and ward B after applying data from the findings of a parallel survey of prescribing activity.

Since this part of the project turned out to be given lesser prioriy than first expected, the findings here will only be commented briefly.

The data from this comparison showed that only three of the prescribing parameter were significantly different between the two wards. 'Total medicines courses per patient', 'Total course-days' and 'Medicines courses at discharge' were all higher at ward B compared to ward A. The fact that ward B is a care of the Elderly Ward could explain these facts as there is a higher prevalence of poly-pharmacy in the elderly in general**.** The two settings were hence statistically different on all parameters regarding pharmaceutical care activity except changes in drug therapy. This can be explained by the differences in mean number of medicines courses prescribed during the stay, where more courses would require more checks by the pharmacist.

4.10 Non- medical prescribing

The analysis of the documented care issues on the care plans collected from the General Medical ward has revealed that the pharmacist is contributing to pharmaceutical care in several aspects. A total of 359 care issues had been documented. As 155 (43.2%) of these concerned 'Change in drug Therapy' this shows that the pharmacist is actively taking part in assessing and making changes in the patient's drug therapy. This contribution is underpinned by the fact that 122 (81.3%) of the total 150 recommendations were categorised as 'Change in Drug Therapy'.

The results from the categorisations of care issues showed that many of the changes in 'Change in drug Therapy' were regarding the choice of dosage, route form, frequencies, product and the like. These would be typically prescription changes,

which the pharmacist could have perform himself as he did the assessment that lead to the change made. The effectiveness of the pharmacist being a supplementary prescriber on this ward can be that unnecessary time spent by the physician on clerical which the pharmacist can do himself, can bee avoided. This would reduce the physicians' workloads, freeing up their time to concentrate on patients with more complicated conditions and treatments.

Although the findings from this audit cannot be generalised, they underpin some goals of supplementary prescribing already realised by the NHS. The hospital pharmacists have access to the patient's clinical notes and are also in direct contact with the patient's on daily basis. These are hence good reasons, in addition to those already mentioned, to encourage the further introduction of supplementary prescribing.

5 Conclusion

For the time being pharmacists have not to a considerable extent undertaken the responsibility to document their provision to patient care and drug treatment. There has been a demand both from the NHS and others, that actions performed by pharmacists need to be recorded in order to develop and ensure the improvements in pharmaceutical care in Scotland.

The focus of this project has been to analyse the documentation within the care plans written by the pharmacist at the General Medical ward at Glasgow Royal Infirmary.
In order to do this analysis an existing categorisation system used at University of Strathclyde has been modified. A guideline for this modified system has also been developed and used in the categorisation process. A further evaluation of the system after testing the practical applicability and comprehension, and presenting it at a focus group, lead to proposals for additional improvements to enhance the usefulness and robustness. The intention with this categorisation tool is to make future documentation easier and more standardised. This could hence be an aid in maintaining continuity of care with primary care services after a patient's discharge.

The categorisation of care issues lead to a description of the pharmaceutical care activity provided by the pharmacist. Process maps were also produced to describe the operational delivery of the clinical pharmacy service at the ward. The overall evaluation of the processes taken by the pharmacist and analysis of the care plans lead to the assumption that care issues documented did not reflect the total care provided.

A comparison of patient characteristics and provision of pharmaceutical care activity was also done. These results showed that both the type of care issues and documentations on care plans between the pharmacists of two wards were statistically different. Nevertheless, by assessing the patients' medical needs and making an effort in identifying, resolving and preventing drug therapy problems, it has been substantiated that the pharmacist is a contributor to the provision of pharmaceutical care.

6 Appendices

6.1 Appendix 1

DATA COLLECTION SHEETS FOR MSC PROJECT

CATEGORIES OF PHARMACEUTICAL CARE ISSUES

Checks (CK)
Changes (CG)

CHECKS

Check	Code
Medication need inquiry	1
Effectiveness inquiry	2
Safety inquiry	3
Compliance inquiry	4
Formulary adherence inquiry	5

CATEGORISATION OF CHECKS

Type of check	Code
Verification	VER
Monitoring	MON
Confirmations	CON

CHANGES

Changes	Code
Patient comprehension	
Patient agreement and participation	
Patient characteristics	
Drug history	
Continuity of information/ care between clinical settings	
Drug selection	
Daily (total) dose increase	
Daily (total) dose decrease	
Route/dose form	
Dose interval/timing/duration	
Drug use precautions e.g. potential interactions	
Stop drug pending review	

CATEGORISATION OF CHANGES

Type of change	Code
Modification	MOD
Adjustments	ADJ
Reviews (promt a review)	REV

CATEGORISATION OF DRUG THERAPY PROBLEMS (DTP)

DTP	Code
Unnecessary drug therapy	DTP1
Additional drug therapy needed	DTP2
Inappropriate drug	DTP3
Dosage too low	DTP4
Adverse drug reaction	DTP5
Dosage too high	DTP6
Non-compliance	DTP7

Pt behavior
Starting new drug
Change of drug
Daily dose increased
Daily dose decreased
Route/dose form
Dose interval/timing
Duration
Drug use precaution
Stop drug

6.2 Appendix 2

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.

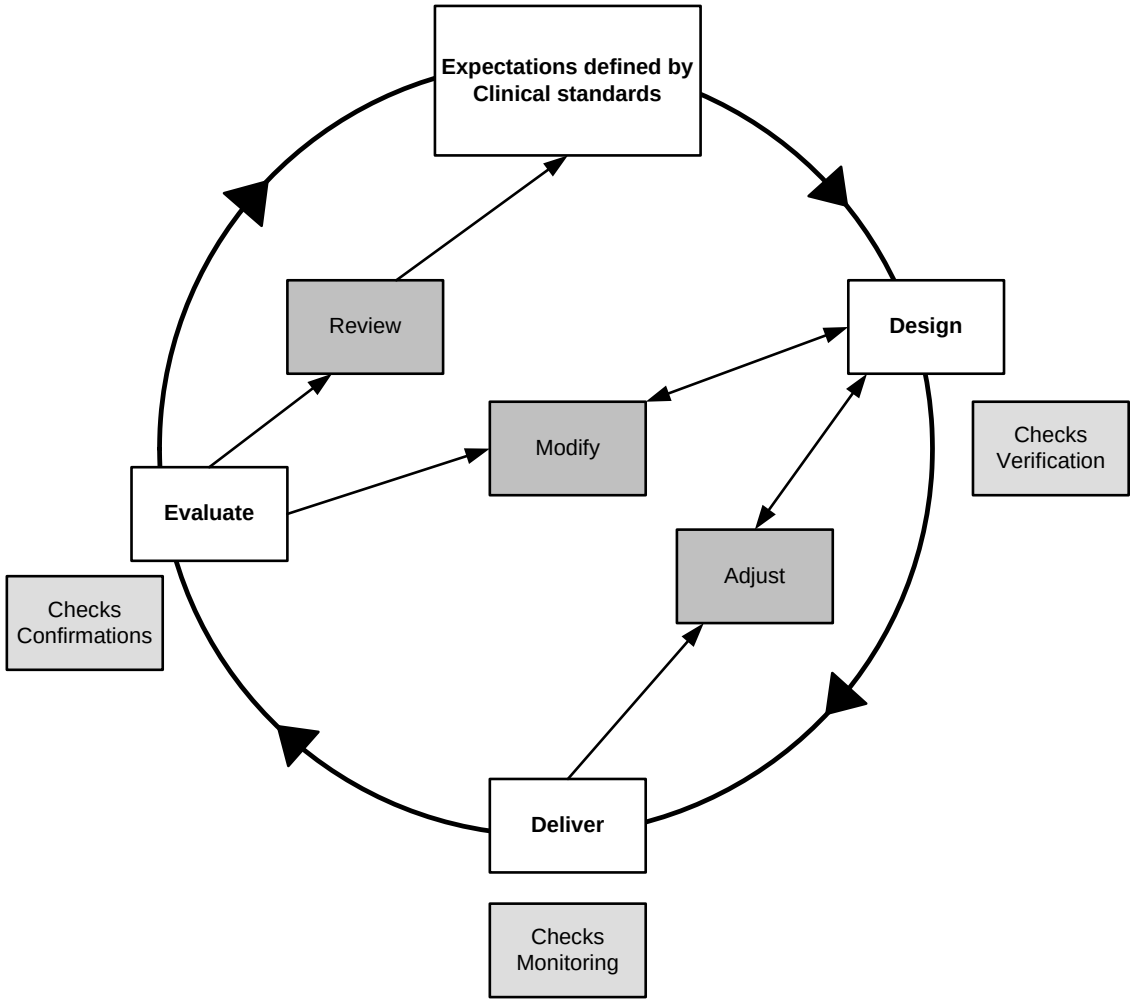


Figure 1 Pharmaceutical care model

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: - resulting in expected effects on the patient's condition - not failing to control condition - 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.

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6.3 Appendix 3

Matrix' - Inter rater reliability test

Table 34.Distribution of care issues used for inter-rater agreement

		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	**39**	**55**	**6**	**100**

Table 35.Main categories

		Investigator B			
		Checks	**Changes in Drug Therapy Process**	**Changes in Drug Therapy**	**Total**
Investigator A	**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 36. QAD Time Perspective

		Investigator B			
		Verification	**Monitoring**	**Conformation**	**Total**
Investigator A	**Verification**	33	9	0	42
	Monitoring	3	49	0	52
	Confirmation	0	3	3	6
	Total	36	61	3	100

Table 37.QAD Degree of Change

		Investigator B			
		Adjustment	**Modification**	**Review**	**Total**
Investigator A	**Adjustment**	23	0	0	23
	Modification	0	3	0	3
	Review	0	0	0	0
	Total	23	3	0	26

Table 38.Distribution of agreement within the subcategories of Checks

		Checks				
		MED	**EFF**	**SAFE**	**COMP**	**TOTAL**
Checks	**MED**	18		2		20
	EFF	1	7			8
	SAFE			28		28
	COMP				7	7
	TOTAL	19	7	30	7	63

Table 39.Distribution of observed agreement in all subcategories of the main categories

		Investigator B																
		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
Investigator A — 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

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