

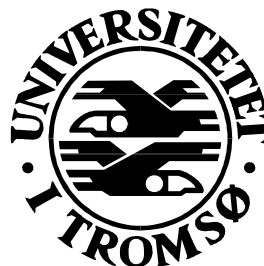
Clinical audit of pharmaceutical care recorded within a hospital pharmacy electronic prescribing system and the development of a structured pharmaceutical care plan

A clinical audit

A partial fulfilment of the Norwegian degree

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Abstract

Objective

This audit was conducted by reviewing two cohorts of patients in terms of pharmaceutical care delivered by examining free text electronic records and categorising care issues into a proposed reporting system. Qualitative research methods in an action research process were used to test the validity and the utility of the reporting system. A template for an electronic pharmaceutical care plan that meets defined criteria for service developments including non-medical prescribing was proposed by the investigators.

Methods

The investigator identified and gathered documented care plans from samples of patients receiving pharmaceutical care during February 2008 to April 2008 using the electronic care monitoring system. The context and outcomes of each care plan were identified by obtaining additional information from paper case records and through dialogue with the clinical pharmacist authors to overcome any gaps in the free text electronic records. An existing categorisation system used at the University of Strathclyde was modified to increase the robustness and clinical usefulness and a guideline for use of the system was developed. A contents analysis of the care plans was conducted in order to categorise the care issues. The inter-rater reliability in the categorisation of the care issues in the survey was demonstrated using Cohens kappa analysis. The proposed care plan template was evaluated in terms of validity and utility for reporting care plans using an action research approach and revised in response to the feedback obtained. The survey findings were also reported to the clinical pharmacy team.

Setting

The survey was sited at the orthopaedic ward at the Ayr Hospital where an electronic prescribing system is in use. A clinical pharmacist is at the orthopaedic ward every day from Monday to Friday.

Results

Ideas generated from group meeting with the clinical pharmacist at the Ayr Hospital were among others to implement databases and forms that already are used today. The care issue section should be more structured and include functions as review date and predefined texts.

The 90 patients that were included at orthopaedic ward had totally 270 care issues identified compared to the 71 patients at the cardiology ward where totally 377 care issues were identified ($p < 0.0001$). The number of care issues per patient categorised as a *Check* was significant higher at the cardiology ward than the orthopaedic ward (3.8 versus 1.1, $p < 0.0001$). The subcategory '*Change in clinical (shared) record of drug history*', which includes changes in the patients drug therapy based on errors or omissions in medicines prescribed on admission, was relative high on both wards (63 issues on orthopaedic and 37 on cardiology). For both wards most of the *Checks* were done during the treatment of the patient and therefore categorised as a '*monitoring*'. Similarly were the majority of care issues in both of the *Change* categories found at the '*verification*' stage in the delivery of the patient's treatment. Few '*reviews*' were identified among the '*Changes in drug therapy*' in both settings. The inter-rater reliability test for the categorisation found the agreement to be highest within the *Check* and the two *Change* categories and poorest in the part of the system with the Quality Assurance Descriptors '*Degree of change*'.

Conclusion

A care plan template will make the plan more structured and complete and the documentation process more effective and uniform between pharmacists. The categorisation system describes the contribution the clinical pharmacist to the patient's treatment but there is a need for a language within the pharmaceutical care.

Abbreviations

BD	twice a day (from Latin bis in die)
BMI	Body Mass Index
CI	confidence interval
CP	Community Pharmacy
DVT	deep vein thrombosis
ECS	Electronic Care Summary
eGFR	estimated glomerular filtration rate
EMPA	Electronic Prescribing and Medicines Administration
EPS	Electronic Prescribing System
EU	European Union
DTP	Drug Therapy Problem
GP	General Practitioner
IHD	ischemic heart disease
IQR	interquartile range
IV	intravenous
MR	modified release
N/A	not available
NHS	National Health Service
OA	osteoarthritis
OD	once daily (from the Latin, omni die)
OTC	over-the-counter
OSD	one-stop dispensing
PCI	percutaneous coronary intervention
PDO	Predefined orders
POD	Patient's Own Drugs
PRN	as necessary (from Latin, pro re nata)
QAD	Quality Assurance Descriptors
SOP	Standard Operating Procedures
STEMI	ST elevated myocardial infarction
TID	Three times a day (from Latin, ter in die)
TPN	Total parenteral nutrition
UK	United Kingdom
US	United States of America

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1 Introduction

1.1 Clinical pharmacy in the UK

Hospital pharmacy services have developed and expanded over the last 40 years to an extent where the clinical pharmacist has an important role and function in individual patients' care at the hospital ward. The United Kingdom (UK) has the largest population of hospital pharmacist in the European Union (EU). A survey from 2002 shows that around 20% of the pharmacists in the UK are connected to a hospital compared to 4-7% for most of the other countries in the EU⁽¹⁾. '*Clinical pharmacy*' has been defined in different ways but can be explained as a discipline concerned with making use of pharmaceutical expertise to help maximise drug efficacy and minimise drug toxicity in individual patients⁽²⁾. Surveys of the health of the Scottish population shows increasing average life expectancy, although low compared with most western European countries⁽³⁾. Like countries worldwide the patients with chronic conditions constitute the largest part of the patient population⁽⁴⁾. With several patients receiving more complex drugs and drug therapies a practitioner with focus on drug treatment monitoring and evaluation is absolutely needed.

The changes in the public health are reflected in the increasing number of spending on medicines despite a slightly fall in patients treated in hospitals⁽⁵⁾. This has led to a range of initiatives to support a safe, effective and economic use of medicines in hospitals; national strategy plans for handling the medicines in the National Health Service in the UK was published at the start of the twenty-first century. Central in both the NHS plan '*Pharmacy in the Future*' and the Audit Commission's report '*A Spoonful of Sugar*' is 'medicines management' which has been established as a term describing processes proposed to optimise the supply and use of medicines in the NHS^(6,7). In practice this mean changes of the systems around the patient delivering pharmaceutical services. Actions to make this a reality are for example the introduction of new schemes for use of the patient's medication, changes in the work areas and responsibilities among health care professions and improvement of the patient's journey through the health care system. The national strategy for pharmaceutical care in Scotland, '*The Right Medicine*', published in 2002, recommends the hospital service to focus on pharmacists working with patients in the wards and clinics⁽⁸⁾.

1.2 Pharmaceutical care

Pharmaceutical care is the pharmaceutical contribution to patient care and has been defined by Hepler and Strand⁽⁹⁾ as:

'The responsible provision of drug therapy for the purposes of achieving definite outcomes that improve a patient's quality of life'

The essential stages in pharmaceutical care as a model are the assessment of the patient's drug related needs, the development of the care plan and evaluation, succeeded by continuous follow-up evaluations to ensure that all drug therapies are effective and safe. Altogether this can be described as the patient care process which involves the identification of potential and actual drug therapy problems, the resolving of the actual drug therapy problems and prevention of potential drug therapy problems^(9,10).

Pharmaceutical care should be an integrated part in health care⁽¹⁰⁾. The fact that the definition of pharmaceutical care does not include any specific health care profession emphasise this; it is the care the patient receives that is brought into focus and not the type of staff who delivering it. Pharmaceutical care therefore includes every health team members contribution to the patient's medical treatment and not only the pharmacist's⁽¹¹⁾.

1.2.1 Assessment of the patient on admission

The assessment of the patient on admission includes taking medication history, checking what the patient is prescribed on admission, looking through clinical records and talking with the patient, carer or other members of the health care team. Establishing an accurate drug history for patients as early on admission to hospital is an important part to ensure safe treatment. The accurate drug history can uncover reasons for the patient's illness, for example adverse drug reaction or non-adherence to drug therapy. If the errors or omissions are not corrected on admission they will form the basis for the therapeutic decisions made for the patient while in hospital and

may increase the time spent on discharge correcting these. Drug history taking is a skill that needs to be learnt and practised. Pharmacists have shown advantages compared to doctors in taking drug history from patients on admission. In a study done on a medical admission ward these advantages included fewer errors in the history, fewer unintentional discrepancies in medicine prescribed on admission, better recording of patient's use of over the counter and complementary medicines, and a more complete recording of allergy status⁽¹²⁾. This also supports the recommendations from political authorities to have more pharmacists involved in the patients' care at admission and also the implementation of non-medical prescribing to reduce medication errors on admission^(6,7).

The completeness of the information obtained when assessing the patient is limited by the resources available, their reliability and also the skill of the person taking the medication history. It is shown that pharmacists are using more sources than doctors to obtain the drug history⁽¹²⁾. Talking with the patient, if at all possible, is a time consuming but important way to confirm the information gathered. It will also give the pharmacist an impression of the patient's relation to and comprehension of their medication regimen. In addition this meeting can reveal adverse reactions that the patient has due to the treatment. An evaluation of the patient and risk factors related to safety and effectiveness of the medicines, a need for closed monitoring or patient education is considered (Table 1). If some of the drug-related needs are not met with a pharmaceutical product or service as required an already existing or potentially developing drug therapy problems is revealed. Such problems are referred to as the patient's '*pharmaceutical need*' and elements of the pharmaceutical need, which are addressed by the pharmacist, can be described in terms of '*pharmaceutical care issue*'⁽²⁾.

Table 1 Drug related need categories⁽¹⁰⁾

Drug related need

The medication is appropriate

The medication is effective

The medication is safe

The patient is compliant

A desired output is identified for each pharmaceutical care issue. This states the goal the pharmacist aims to achieve of the therapy in order to meet the patient's pharmaceutical need. These outputs can be summarised as cure of a disease, reduction or elimination of symptoms, arresting or slowing of a disease process and preventing a disease or symptoms. Preferably, the goal should include desired changes of clinical parameters and/or values of laboratory results specified within a timeframe. Target outputs from evidence-based medicine act as treatment information and ideal therapeutic goals, but the consideration of the patient as an individual should always be kept in mind and the plan individualised accordingly ^(2,10).

1.2.2 The pharmaceutical care plan

The pharmaceutical care plan functions as a clinical tool to document and structure the pharmacist's contributions to the patient's care. This documentation has been guided in Scotland by a clinical practice guideline from 1996 which recommends the recording of actual and potential pharmaceutical care issues within the pharmaceutical care plan⁽²⁾. This includes recording of the pharmacist's actions with the patient, carer and other health team members to address those issues.

Clarity is important when stating or describing an identified pharmaceutical care issue. It is essential to describe the patient's condition, the drug therapy and emphasis the specific association between these. In a care plan the pharmaceutical care issue is structured into three parts; the desired output of the pharmaceutical need, the action(s) planned to achieve the outputs and the actual output. Both the action taken and the individuals involved in resolving the pharmaceutical care issue should be documented.

To deliver effective pharmaceutical care to patients it is required that the clinical pharmacist prioritising the care. The issues resulting highest risk to the patient should be resolved or prevented immediately. Subsequently problems that can be resolved by the pharmacist and patient directly is prioritised, followed by issues that require others, health care profession or relatives, to be included. Although this sounds like a matter of course it is important to have it prominently in mind. In a busy clinical

setting the prioritising of the care issues is essential to organise the workload to the pharmacist.

1.2.3 Follow up evaluation

The decision about when to review a patient again to determine the effectiveness and safety of the therapy is a clinical decision. Hepler and Strand observed that failure to monitor patients' drug therapy was the most important omission made by healthcare professionals⁽⁹⁾. All patients receiving drug therapy require some degree of monitoring. A monitoring strategy should be capable of measuring progress towards the desired outputs and typically are both qualitative (e.g. patients' reported pain) and quantitative (e.g. blood glucose) parameters used⁽²⁾. When the monitoring parameters are known the frequency for monitoring these has to be made. The check to see whether the treatment is effective will also ensure that the therapy is not creating other problems.

The processes around the patient to achieve the desired output in the pharmaceutical treatment can altogether be regarded as a quality assurance system. It is emphasised that to meet the desired goal all the parts of this system have to improve the level of pharmaceutical care. This demands a fully assessment of the patients pharmaceutical needs, clear goals and frequent monitoring. The pharmaceutical care plan has the function to document all this initiatives in this quality assurance system and it is therefore important to make it complete. An overriding objective for the patients' treatment is continuity in the pharmaceutical care he/she receives. The care plan can be used as a document that moves with the patient to accompany the patient's care⁽¹¹⁾.

1.3 Methods for categorisation of pharmaceutical care issues

As the focus on improving pharmaceutical care delivered to patients is increasing through several initiatives from the government, systems designed to describe and evaluate the established pharmaceutical services are in demand. To be able to make a descriptive tool a standardised language for the activities in pharmaceutical care are required and so far limited work with variable methodology in this field has been

published⁽¹³⁾. Development of structured presentations of the delivery process of pharmaceutical care can display in which way the pharmacists contributes to the treatment of the patient. It can also form the basis of a description of the pharmaceutical care needs within different patient groups or clinical settings and information as such can be valuable in strategy decisions in the further development of pharmaceutical services.

Through development projects in Scotland a categorisation method to document identified pharmaceutical care issues is commenced and tested to a certain degree⁽¹⁴⁾. This system consists of three parts which each care issue is assigned into:

- Drug therapy problems (Cipolle, Strand)
- Check or Change category (Strand, McAnaw)
- Quality Assurance Descriptors (McAnaw, Hudson)

1.3.1 Drug therapy problems

A drug therapy problem is defined by Cipolle and Strand⁽¹⁰⁾ as

‘any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy, and that interferes with achieving the desired goals of therapy’.

The drug therapy problem arises when a patient’s drug-related need has not been resolved. The identified categories of ‘actual’ and ‘potential’ drug therapy problems are associated with the patient’s drug-related needs in focus (Table 2), each referring to the undesired output of a drug therapy. The first six categories describe clinical problems that the patient experience resulting from the *actions of the drug therapy* while the last category, non-compliance, results from the *actions the patient makes* regarding the willingness or ability to use the medication as instructed.

Table 2 Drug therapy problems as unmet drug-related needs⁽¹⁰⁾

Drug-related needs	Categories of drug therapy problems
Medication needs	1. Unnecessary drug therapy 2. Needs additional drug therapy
Effectiveness	3. Ineffective drug 4. Dosage too low
Safety	5. Adverse drug reaction 6. Dosage too high
Compliance	7. Non-compliance

A paper from 2004 emphasis that although being a recognised classification system for drug therapy problems used in published studies, no validation of the usability of the system in practice is published⁽¹⁵⁾. In the same paper it is also pointed out that this categorisation system does not include *potential* drug therapy problems and therefore can only be employed when the event has already been experienced by the patient. As one of the main aims in pharmaceutical care is to prevent potential drug therapy problems, a system describing this activity should capture this part of the process to be complete.

1.3.2 Check and change

Each pharmaceutical care issue identified by the pharmacist can either be categorised as a check or a recommended change. The checks are made at the start, during or after a period of a medical treatment for the patient. The types of checks are found to closely match the drug therapy problems categories (Table 3). When a drug therapy problem is identified it must be clarified whether it is an actual or a potential problem. If it is a potential problem it will usually require some form of check activity by the pharmacist to confirm, exclude or prevent the problem. If the check identifies an actual this can lead to a change recommended or implemented by the pharmacist. The changes made are divided by patient behaviour, patient data handling and changes in the treatment plan addressed to drug therapy⁽¹¹⁾.

Table 3 The system for categorising pharmaceutical care issues and drug related problems^(11,16)

Action Check	Drug Therapy Problem	Action Change
	addressed by the care issue (actual or potential)	
Medication needs	1. Unnecessary drug therapy 2. Needs additional drug therapy	Patient behaviour: Patient expectations of treatment Comprehension Participation
Effectiveness	3. Ineffective drug 4. Dosage too low	Patient data handling: Patient characteristics History (indications, contra-indications) Continuity of care
Safety	5. Adverse drug reaction 6. Dosage too high	Treatment plan changes which address: Drug choice Dose Route, dose-form Dose interval/timing
Compliance	7. Non-compliance	Course duration With added precautions/interactions Stop drug pending review

1.3.3 Quality Assurance Descriptors

The use of medicines can be seen to form a treatment cycle (Figure 1). The categorisation system with the Quality Assurance Descriptors is based on the description of pharmaceutical care as of what the patient should receive and depicts the patients' medication treatment as a quality system feedback loop. The pharmacists' systematic role identifying care issues is seen as a process within this loop⁽¹¹⁾ and the system is designed to capture monitoring activity of the actual and potential drug therapy problems⁽¹⁴⁾.

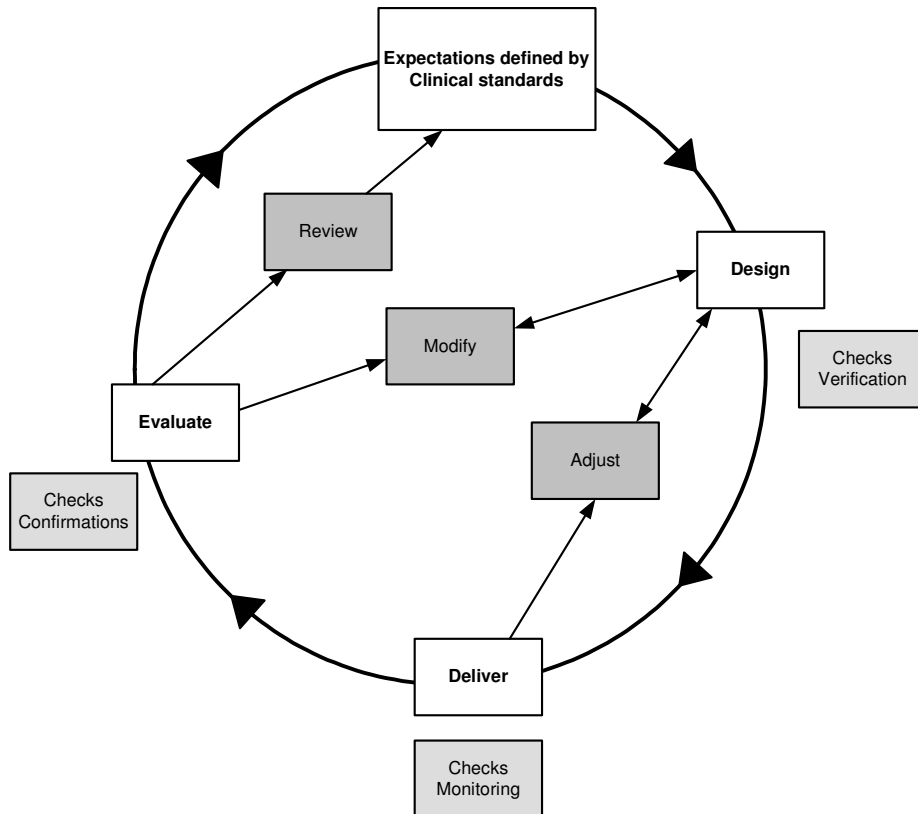


Figure 1 *Pharmaceutical care model*

The check and change categories mentioned above are a part of the processes in the quality assurance system the pharmacist contributes to. The checks are situated in the quality system feedback loop according to at what time in the patient's treatment course they are done. A check made at the design stage of a treatment to assure the appropriateness of the medication in the proposed treatment plan, is known as a 'verification'. A check for safety and effectiveness as the treatment is delivered is a 'monitoring', while a check to evaluate if the treatment produces a positive outcome is a 'confirmation' (Figure 1).

This system has also three quality assurance descriptors assigned the changes recommended in the patient medication loop. The starting point for these descriptors is the agreed treatment plan for the patient; a recommended change that individualises the pharmaceutical care within the agreed treatment plan is defined as an 'adjustment'. A change recommended as a result of a review by the health care team of the initial treatment plan is described as 'prompting a review' while the third

descriptor, *'modification'*, is defined as any other recommended change than an *'adjustment'* or *'prompting a review'* (Figure 1)⁽¹¹⁾. An *'adjustment'* and *modification'* can both be made at the start of and as the patient undergoes the treatment, while *'prompting a review'* is done after a period of treatment course.

1.4 Electronic prescribing in the UK

Electronic prescribing (known in the United States as computerised physician order entry) has been identified as a core service for all Trusts in the National Health Service through the national UK programme for information technology⁽¹⁷⁾. The strategy plan set out that all trusts to have installed electronic patient record systems including the reporting of results and prescribing within 2005. No recent surveys investigating the extent of implementation of electronic prescribing systems in UK hospitals have been found, but a survey from 2000 indicated that there were only 2% of hospitals with full electronic prescribing facilities⁽¹⁸⁾. Both issues related to change of working practice and the late evolution of software are factors that have been mentioned as possible explanations for the poor implementation of the electronic prescribing system⁽¹⁹⁾.

Most of the research within this field originates from US hospitals where electronic prescribing systems are more widely implemented. These results may not be applicable to UK settings because of the difference in systems of medication prescribing and supply. Studies from UK hospitals have observed benefits of using electronic prescribing including a reduction in rate of medication related errors, improvement in legibility and comprehensive audit trail of prescribing decisions made. These few studies have their limitations in that they are hard to generalise since their one-ward studies, they give little information about methods and definitions used and more quantitative data is demanded⁽²⁰⁾.

A study recently published showed that implementing an electronic prescribing system reduced both the number of prescribing errors and the number and types of pharmacists' clinical recommendation⁽²¹⁾. Despite a reduction in the number of recommendations made by the pharmacist the time spent on the ward did not decrease with electronic prescribing. This can be explained by both that not all

recommendations were documented but can also be due to better availability to the patient's medication charts⁽²²⁾. An important aspect of these systems is the identification of new error types that are specific to electronic prescribing. These errors are often involved in the selection of '*predefined orders*' (PDOs), a function which makes it more easily to capture complete data when prescribing by selecting a complete medication order in one process. This can nevertheless lead to errors because of incorrect or inappropriate selection of PDOs. Some of these errors can be solved by improving the software, but it is just as important that the staff using the systems is aware of these types of errors to be able to detect and minimise them⁽²¹⁾.

1.5 The new services introduced

As the hospital pharmaceutical services have evolved over the past decades to become an integrated and established part of hospital healthcare attention has been brought to the re-design of these services, with the primary objective to improve patient focus by making the systems more efficient, timely and safe⁽⁶⁻⁸⁾. The continuity of the patients' medication supply while moving between care settings is also highlighted as a problem intended to be solved by re-designing the pharmacy services⁽²³⁾. Three of the arrangements outlined for implementation in the National Health Service hospitals are *one-stop dispensing*, *use of patients' own drugs* and *self-administration schemes*. In a survey from 2002, including 82 dispensary managers from different trusts in the UK, 77% had programmes that used patients' own drugs, while 48% had implemented the self-administration scheme⁽²⁴⁾. Due to a small sample size a generalisation of these results referred to hospitals in the UK is uncertain and there is a need for newer information. A fieldwork done by Audit Scotland in 2003/04 shows limited implementation of these re-design schemes in most of the health boards in Scotland⁽⁵⁾. By introducing supplementary and independent prescribing by pharmacists national authorities also encourage to improve the co-operation between medical and pharmacist practitioners and to better utilise pharmacists' expertise for the benefit of patients⁽⁸⁾.

1.5.1 Re-use of patients' own drugs

Patients' own drugs (PODs) (also known as patients' own medications) is a term used for the medications that patients have obtained in the community setting and bring to the hospital when admitted. On admission the medicines are assessed, usually by pharmacy staff, and if the quality is deemed satisfactory, and the medicine is still required, the patients' own medicines are used during the inpatient stay and on discharge.

The criteria for deciding PODs suitability vary between hospitals but should ensure that the medicines show sufficient quality regarding: intact and clearly identifiable container, proper labelling according to patient name, strength, dose and frequency of the medicine, storage and expiry date. Not all hospitals consider controlled drugs and medicines in compliance aids justifiable to use while the patient is on the ward due to the potential problems of tablet identification and continuation of supply on discharge. Dependent on the strictness in criteria, the proportion of PODs found suitable to use in hospital varies from place to place and studies show a suitability of PODs brought in vary from 73-77%⁽²⁵⁾.

Another consequence introducing a re-use of the patients' own drugs scheme is that the medicines are stored in the patients' bed-side locker from which nursing staff administered them. Conflicting data on whether drug administration from individual patients' cabinets is associated with reduction in drug administration errors by nurses when compared with use of a drug trolley. In a study from two wards the introduction of administration of medication from bedside medicine cabinets did not affect the overall proportion of medication administration error defined as any dose omitted or deviated from the written medication order⁽²⁶⁾. Another study used the number of interruptions that nurses experienced during the administration process as a measure of safety. A reduction in interruptions by 64% after implementation of the PODs system was identified⁽²⁷⁾. Although these results can not be compared directly they show different aspects of the changes in drug delivery processes related to the use of PODs.

1.5.2 One-stop dispensing

One-stop dispensing, also referred to as '*dispensing for discharge*', refers to the practice of combining inpatient and discharge medicines into a single supply on admission, already labelled with administration instructions for the patient to take away on discharge. Such schemes generally involve the use of PODs, with supply of new medicines from the pharmacy stock as required, to complete the patients' discharge prescription. The patients are typically given a 28-days supply of their medicines on discharge, with exclusions where indicated e.g. controlled drugs, antibiotics, laxatives are typically supplied for a shorter time of period.

1.5.3 Self-administration of medication

A patient's ability to self-medicate while in hospital is preferably assessed by nurses, because they spend more time with the patient, but a pharmacist may also be involved where pharmaceutical advice is needed. A difficulty with this scheme is that the patients on an average do not stay in hospital long enough to be assessed properly. Therefore this is primarily implemented on long-stay wards or for patients that are not acutely unwell, e.g. rheumatology ward. The majority of patients have an unsatisfactory understanding of their medication, despite education and information from the health carer, to be able to self-administrate them in hospital. Still the independent administration of medicines can be an effective aid for improving adherence to medication regimens for selected patient populations, as those with chronic conditions⁽²⁸⁾.

1.5.4 Advantages and disadvantages of the medicines re-design services

The schemes with re-use of PODs and one-stop-dispensing ensure continuation of therapy during and after the patients' hospitalisation in several ways. In a systematic review, where 14 of the 19 primary studies included were from hospital settings in the UK, the accuracy in the patients' medication history taken on admission was improved when using PODs⁽²⁵⁾. One study shows that checking PODs is special useful in identifying errors and omissions when taking drug history on admission⁽²⁹⁾. Furthermore the risk to patients from having unsuitable medicines at home is reduced with the scheme as these will be destroyed and patients will not have

duplicate supplies of medicine dispensed by the pharmacy and their own medicines at home. Although not easily measured these schemes give health care providers additional opportunities for patient counselling and direct patient care.

The one-stop dispensing scheme should result in a quicker discharge, which is an advantage both for the patient and the hospital bed management, and the time spent on dispensing is reduced since this is only done once. There are still ward settings where this scheme may not be suitable. Because the patients' medication most likely is changed during the stay or the patients' stay is over a longer time of period and therefore the medication is likely to need re-dispensing before discharge, resulting in increased workload for pharmacy staff⁽³⁰⁾. Giving the supply of medicines on discharge ensures continuity of therapy after discharge in the way that the patients' general practitioner, through the discharge letter, is aware of changes in the patients' drug therapy during the stay in hospital before the patient attends the General Practitioner surgery in need for new prescriptions.

The main evidence for hospitals implementing this scheme is saving in drug costs by decreased wastage of PODs, either by preventing loss or avoiding destruction of the medicines. It is an effective way in saving costs for the National Health Service and also a necessity when it is estimated that medicines worth £15 million may be wasted each year in Scotland⁽⁸⁾. A disadvantage with the redesign of the service at the ward is the additional workload, as a result of the assessment of the PODs, which means increased training and staff costs. An initial cost of lockable bedside cabinets must also be taken into consideration when starting the implementing, but the financial support is eased with the inclusion of these schemes in government strategy documents. A comprehensive economic analysis which also includes associated costs for additional personnel involved in delivering the PODs is needed⁽²⁵⁾.

1.5.5 Non-medical prescribing in the UK

There are two models of pharmacist prescribing in the UK: pharmacist supplementary prescribing and pharmacist independent prescribing introduced in 2003 and 2006, respectively. These changes in roles and responsibility in the health care setting comes as a result of a government policy with the desire to make the prescribing, supply and administration of the medicines more efficient by making a

greater use of the clinical skills of health care professions as nurses and pharmacists⁽⁶⁾.

In supplementary prescribing a voluntary partnership between the responsible independent prescriber (a doctor or a dentist), the supplementary prescriber and the patient is established and a clinical management plan for the patients' disease agreed on. In practice the medical practitioner establishes the diagnoses and initiates the patients' treatment while the pharmacist monitors the patient and prescribes further supplies of medication only within the limitation of the clinical management plan and for the diagnosis included. An independent prescribing pharmacist will, unlike a supplementary prescribing pharmacist, be able to prescribe any medicine within all drug classes and for any condition, except for Controlled Drugs and unlicensed medicines. This increased degree of autonomy gives the pharmacist the opportunity to optimise the treatment by responding to the signs and symptoms of an additional clinical problem based on an overall assessment of the patient's treatment.

Pharmacists become licensed to be a supplementary prescriber after completing a training course given at both of the Schools of Pharmacy in Scotland. The first course for independent prescribing pharmacists is held in 2008. A survey from 2005 exploring the experience of supplementary prescribing in the UK found that 48.6% of 401 respondents (82% response rate) self-reported practising supplementary prescribing⁽³¹⁾. The pharmacists from the same survey brought up better patient management and job satisfaction as benefits of implementing supplementary prescribing. On the other hand barriers as restrictive clinical management plans and poor recognition of pharmacy role by other health professionals were mentioned. The former problem can be solved by the ongoing introduction of independent prescribing. Any changes in traditional roles in health care are difficult to introduce, but the new role with supplementary and gradually independently prescribing pharmacist is not intended to replace any other health care provider. Most of the already implemented supplementary prescribing pharmacists are found in special clinical areas as TPN/clinical nutrition, oncology-haematology and heart failure or cardiology⁽³²⁾ and a contribution of specialised management of patients with identified clinical conditions can be one of the main roles for the independently prescribing pharmacist.

1.6 Clinical audit

The concept clinical audit has evolved since it was first introduced in the National Health Service in the early nineties. Initially medical audit, it soon evolved to encompass all aspects of patient care, and with the involvement of other health care professionals it became clinical audit⁽³³⁾. 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’⁽³⁴⁾.

Clinical audit is a key clinical governance process which enables a healthcare organisation to identify, introduce and monitor best clinical practice⁽³³⁾. Clinical governance is a framework outset in 1998 and relates to all people who are involved in the treatment and care of patients within the National Health Service organisations to continuously improve and safeguard the quality of care being provided to patients.

NHS Quality Improvement Scotland is a special health board responsible for assuring that there is a clinical audit program within local trusts, and that this reflects national audit priorities. A programme of prioritised clinical audits within each health board is approved and followed up by the special health board. Over the last few years a substantial amount of clinical audit work has been undertaken within NHS Scotland on a wide variety of topics funded both centrally and through local clinical governance departments⁽³⁵⁾. A new strategy for future direction of National Clinical Audit in Scotland is currently developed.

1.6.1 The process of a clinical audit

A clinical audit can be described as a continuous cycle or spiral that involves observing practices, setting standards, comparing practice with standards, implementing improvements and observing new practice to ensure that the improvement is maintained. As this systematic process continues each cycle aspires to a higher level of quality ensuring that the best possible service to patients is

offered and the risk of errors minimised. A clinical audit should be viewed as an integral part of practice and as a part of quality assurance.

Each cycle in a clinical audit includes the following stages:

- preparing for audit
- selecting criteria
- measuring performance
- making improvements
- sustaining improvements

The process of audit involves multiple methods, such as document searching and analysis. It can also include collection of information by focus groups or by questionnaire. Both qualitative and quantitative methods for collecting descriptive data about process and structure can be used for a clinical audit⁽³⁶⁾.

1.7 Action research

Action research has the purpose to influence or change some aspect of whatever is the focus of the research. The roots of action research as a method lie in the first half of the twentieth century. Kurt Lewin (1890–1947), a social psychologist, is often credited with coining the term, connecting it to the way of learning about organisations through trying to change them⁽³⁷⁾. The method has since that been described and influenced by many authors but some fundamental criteria can be found which together distinguish the action research methods from other research methods.

A definition of action research, based on a review on the literature found, try to embrace the distinguishing features from previous definitions:

‘Action research is a period of inquiry, which describes, interprets and explains social situations while executing a change intervention aimed at improvement and involvement. It is problem focused, context-specific and future-oriented. Action research is a group activity with an explicit critical value basis and is founded on a partnership between action researchers and participants, all of

whom are involved in the change process. The participatory process is educative and empowering, involving a dynamic approach in which problem identification, planning, action and evaluation are interlinked. Knowledge may be advanced through reflection and research, and qualitative and quantitative research methods may be employed to collect data. Different types of knowledge may be produced by action research, including practical and propositional. Theory may be generated and refined, and its general application explored through the cycles of the action research process' ⁽³⁸⁾.

Two criteria found as key components of the framework in all action research are the research partnership and the cyclic process. In the theory about action research the process is widely adopted as a cycle or spiral containing stages of problem identification with reflection on practice, planning, action taken with a succeeding evaluation. The last phase may lead to identification of new problems and so the cycle repeat. In this way the research takes shape as it is being performed^(38,39). This stages aid to understand the process better although it is not always attained; if e.g. the project with action research is used to explore the acceptability and feasibility of an intervention and finds it is not acceptable to carry through; the change in practice is not implemented. By giving the term intervention a broader meaning in the action research process this can equally refer to changes in the participants understanding, beliefs, values and behaviour.

Action research, unlike other forms of research, includes those subjects who are being studied, whether they are practitioners or clients, as participant 'co-researchers'. This implies participation in both the development of ideas about what to study, the carrying-out and the interpreting of the results. The collaboration generates more easily interest and expands the ownership for the research to more than the researcher alone. As action research requires the participants to share experience, knowledge and ideas, with a view to researching and evaluating them, the research method also has an educative function. Including those who are being studied has the disadvantage that the phases of the research process are more time consuming than in other methods. To avoid conflicts arising among participants management of the group is an important factor to succeed using the action research method^(37,38).

In mainstream research, practice developments are secondary to the research. This scenario is reversed in action research, in which the emphasis is on practice or behaviour, with research being a tool to bring about and support change⁽³⁸⁾. Action research uses multiple research methods, most of which are qualitative, although some quantitative surveys may also form a part of the process. Other methods as focus group and in-depth interview are often used to give the participants an opportunity to be a part of the decision-making.

A scoping study from Scottish Government Health Directorates describes the theory practice gap in healthcare. It is emphasised that *“evidence about good practice is often failing to become good practice”*. Due to the lack of implementation of research based practice the attention on alternate methodologies such as action research has been focused on. Action research has been used to a limited extent as research method in health care studies in Scotland and the authors encourage the National Health Service organisations to collaborate with academics with interest for the action research method to develop models and framework using this as an improvement method⁽⁴⁰⁾.

1.8 Focus groups

A focus group is a type of group interview technique used for qualitative data collection. The method makes use of the interaction with the participants and the group leader to stimulate discussion, gain insights and generating ideas in order to pursue a topic in greater depth. Thus the focus group does not only examine what people think but how they think and why they think that way⁽⁴¹⁾.

The group typically contains between six and twelve participants with the investigator as a group leader, referred to as a moderator or a facilitator, who uses a list of topics or questions to stimulate and guide the discussion. The moderator needs to be skilled at creating a relaxed atmosphere, leading group discussion and handling conflicts, as well as drawing out passive participants. The discussion lasts about one hour and is generally audio-recorded. The advantages of having a second researcher involved in the running of the group are that he or she provides coverage of both the substantive area of interest and focus group experience. It is also a good practise to

have written observational notes made by this second person, even though the session is recorded.

Focus groups are particularly appropriate as qualitative research tools when the interviewer has a series of open ended questions and wishes to encourage research participants to explore the issues of importance to them, in their own vocabulary, generating their own questions and pursuing their own priorities. In unstructured approaches like this questions are typically divided into main questions which guide the interview, probes and follow-up questions⁽³⁶⁾. Since the method has the potential to raise consciousness and empower participants it is often used in action research where the investigator aspires to make the participants feel that they are an active part of the research process^(41,42).

1.8.1 Area of application of focus group

Although the focus group method can be used as the primary data collection method in a study, it has frequently been combined with other research methods where it generally employs as a research tool at different stages within larger exploratory and descriptive studies. Other uses include the focus group as a precursor to the development of a more structured instrument to ensure content validity, or the reverse sequence is also possible, for example using focus groups to amplify and understand the findings from a survey^(37,42). As the value of qualitative research has been more widely acknowledged, there has been increasing interest in the application of focus groups in pharmacy practice and health services research. In common with qualitative studies, focus groups are employed to research views and experiences, and identify their concerns and priorities which may explain behaviour patterns.

1.8.2 Disadvantages of focus groups

The analysis and interpretation of the data gathered in focus groups is a time-consuming and difficult stage of the method. Although the focus group in itself can be set up relatively quickly, they are not easy to conduct well and the skills and attributes of the moderator and the manner of data recording will exert a powerful influence on the quality of the data collected^(36,37). In a qualitative method like this the

results should only be found valid if data are an accurate reflection of the perspectives of the participants. The group dynamics or power hierarchies that affect who speaks and what they say can imply problematic methodological issues. Generation of only "surface" information on individual respondents is a disadvantage of the interview method since it is difficult or impossible to follow up views of individuals as in in-depth interviews. Generalisation from focus group data is problematic due to the sample size and to which extent the sample is representative of the population. Often the findings from focus groups are not intended to be generalised for a wider population, but rather designed as preliminary explorations to identify important issues.

Clinical setting

1.8.3 Electronic prescribing in the Ayr Hospital

An electronic prescribing system has been established in the Ayr Hospital since 1997 as one of the National Health Service UK pilot sites and as the only national pilot site in Scotland. The existing electronic prescribing system used at the Ayr Hospital, Electronic Prescribing and Medicines Administration (EPMA) system provided by JAC Computer Services Ltd, is linked to the pharmacy stock control system and the hospital patient administration system and provides online prescribing support and generates electronic discharge prescriptions. An electronic health record system is not yet implemented and so the patient medical notes are still paper based.

In the electronic prescribing system the prescriber can choose from a list of the medicines included in the local formulary of the hospital, all with predefined orders for dose frequency. The medicines prescribed for the patient are displayed in sections based on whether it is given as regular medication, as required medication, continuous or intermittent infusion (see example appendix 1). All items prescribed for the patient can be modified, discontinued, suspended and resumed during the treatment. The system also supports once-only orders and treatment courses where the time for stop can be automatic dependent on number of administrations or days. In addition orders can be prescribed with optional route of administration (e.g. cyclizine tablets and intra muscular injection), giving the nursing staff the opportunity to choose the clinically most appropriate product for the patient when administering the medicines. When medicines are administered the staff nurse moves from patient to patient with a computer attached to a trolley. The computer displays the required medication at each administration period and an electronic signature telling when the drug was given and by whom.

1.8.4 The clinical pharmacists actions on the electronic prescribing system

The electronic prescribing system can be accessed from anywhere in the trust that has a networked computer. The pharmacists at the Ayr Hospital have their own laptop personal computers which they can bring with them on the ward if necessary.

At Ayr delivery of hospital inpatient pharmaceutical care and transfer of care at discharge has been developed within the national framework for clinical pharmacy for hospital pharmacy that has been in place in Scotland since 1996⁽²⁾. On the electronic prescribing system in use the pharmacists make on line pharmaceutical care plans. 'Clinical notes' is a function that can be added to the patient or the drugs prescribed with the purpose to give messages to the health care personnel involved in the medication of the patient. This note file makes the basis for the care plan (Appendix 1).

Any prescription made by a doctor is treated as unverified. The clinical pharmacist verification is a function in the electronic prescribing system for pharmacists to clinically check a prescription. In the verification process the pharmacist also can add information such as whether the patient was admitted on the medicine or have their own supply to be recorded. A drawback with this version of the system is that if the verification of a prescription is done in error can not be changed back/'unverified'. An other function is used by the clinical pharmacists if an order prescribed is found inappropriate and he/she want to speak to the responsible doctor. The pharmacist awaits a verification of the drug, withheld the order and clarifies the problem with the prescriber. An order not verified or withheld by the pharmacist does clearly display the pharmacist's view of the order to all the users of the system, but the functions do not affect the possibility to administrate the drug. To ensure that the patient's are prescribed the correct drug treatment as required the pharmacist can also transcribe patient's medicines into the electronic prescribing system.

The Ayr Hospital provides an environment in which a documented, targeted, comprehensive, clinical pharmacy service has become established to a point at which the pharmacy team has the need to review its care planning documentation and report on pharmaceutical care activity within a peer review system. This survey intends to identify and categorise the pharmaceutical care activity at two wards at the Ayr Hospital. These quantitative results, along with qualitative investigations conducted during the study period, will make the basis for a proposed template for an electronic pharmaceutical care plan, which after discussion and revision in focus groups, gives an improved application in the electronic prescribing system.

1.8.5 The orthopaedic ward

The survey was sited at the orthopaedic ward (nurses station 10) at the Ayr Hospital. The ward has patients with arthritic conditions, patients with fractures or trauma admitted through accident and emergency departments and those booked in for routine orthopaedic surgery, such as hip and knee replacements. The station contains 36 beds divided into three nursing teams, A, B and post-op room, each comprising of two nurses. New patients on admission per week are estimated to be approximately 25 patients. One clinical pharmacist is at the orthopaedic ward every day from Monday to Friday. Every Wednesday morning and Thursday afternoon the clinical pharmacist meets patients for elective admissions at the pre operative assessment clinic and another clinical pharmacist then stays at the orthopaedic ward. In the morning (from 9 -13) one or two pharmacy technicians also stays on the orthopaedic ward to assess the patients' own drugs and to label patients medicine.

1.8.6 Taking medication history

When the clinical pharmacist first attends the ward in the morning all new patients admitted are identified. This is done using a print out from the patient administration system and also checking with the pharmacy technician which is keeping a diary of the patients admitted. When new patients are established the pharmacist makes a prioritisation of who to see first based on. If the patient has not been seen by a clinical pharmacist recently, which is the case for all patients for elective surgeries attending the pre-assessment clinic, the pharmacist first clarifies the patient's current drug regimen. A medicine reconciliation form is used to document the patient's medication history. This includes the regular medicines the patient was on before admission, included over-the-counter medicines, herbal medicines etc., and also what the plan to if any changes are made. The pharmacist speaks to the patient to clarify their current drug regimen. If the patient brought in their own medicines on admission the pharmacist often goes through these together with the patient. This meeting between the patient and the pharmacist makes it possible for the patient to ask questions he/she may have regarding the drug treatment, misunderstandings can be easily solved and it also makes it easier for the pharmacist to get an idea to which extent the patient is compliant or not to the drug regimen.

If the patient is unable to confirm their medication history or has not brought their medicines into the ward other sources for getting this information are used. This could be the patient's relatives, which also can contribute with other relevant information. Often there may be a discrepancy or uncertainty between the doses taken and the medicine label. The pharmacist may then need to contact the patient's General Practitioner to confirm the right medicine history. The patient's community pharmacy, repeating list or blister pack are also used, and more rarely an Electronic Care Summary (ECS) System and medical or nurses notes (Table 4).

Table 4 Sources used when taking medication history

Medication history sources

Patient
Patient's own drugs (PODs)
Patient's relatives
General Practitioner
General Practitioner's letter
Repeating list
Community pharmacist
Blister pack
Electronic Care Summary (ECS) System
Medical/nurses notes

The clinical pharmacist also asks each patient if he/she has any allergies or drug sensitivity known. If any drug allergy or sensitivity is identified the generic name of the constituents preparations and the nature of the reaction are documented both on the paper form and in the electronic prescribing system.

After clarifying the patient's current drug regimen the pharmacist checks if the medication prescribed on the electronic prescribing system on admission is in accordance with the confirmed history. Medicines that are already prescribed by the doctor on admission are verified by the pharmacist. Any medicines omitted on admission can be transcribed by the clinical pharmacist and documented in the medical notes. For any other discrepancies in the drugs already prescribed, such as

dose, dose timing, formularity etc., the pharmacist withholds the verification of the drug on the system, speaks to the doctor to make him/her aware of the actual regimen on admission and changes accordingly if there is no reason/intention for the alteration. As all patients for elective surgeries have already got their regular medication transcribed to the electronic prescribing system by the pharmacist at the pre assessment clinic, only a check is needed to see if any changes to the medication have occurred in the period of time before admission to hospital.




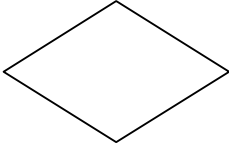
1.8.7 Pharmaceutical care delivered by the clinical pharmacist at the orthopaedic ward

For every patient on the ward that the pharmacist is seeing a pharmaceutical care plan is started. Based on a blank clinical note the pharmacist writes in a standard setup of information about the patient including present complaints, previous medical history, drug history, bloods, drug allergies or sensitivities, over-the-counter (OTC) and non-drug treatment (e.g. herbals) the patient is taking and identified care issues. All patients admitted are assessed and their new medication orders are checked by the pharmacist if they are clinically appropriate. An order not found to be appropriate is withheld by the pharmacist in the electronic prescribing system while the issue is addressed to the prescriber (Figure 2).

The clinical pharmacist on the orthopaedic ward get into different drug therapy areas but as a surgical ward the pharmacist mainly manage issues regarding prophylaxis treatment of deep vein thrombosis (DVT), antibiotic cover and pain relief. An example can be the check the pharmacist performs to clarify if the patient has indication for DVT prophylaxis as per post operation sheet, evaluate the clinical appropriateness and monitor for possible side effects. After a major surgery, as a hip- or knee replacement, the patient is started on antibiotic prophylaxis. This treatment is followed up by the pharmacist by monitoring the patient's levels of inflammatory markers and also ensuring that intravenous treatment with antibiotics is switched to oral administration when appropriate. The results from the blood tests taken are found in an electronic database. Ensuring effective treatment of the patient's pain after surgery is also essential. The pharmacist checks that the patient is prescribed an optimal combination of analgesics while inpatient and also at discharge. The

nurse staff is an important collaborator in the assessment of the patient's effect, side-effect and need of medication.

Table 5 Shapes of boxes used in process mapping

	This figure is used to describe a process being started or terminated
	The square is used to describe processes undertaken. If the square has to lines on the sides the boxes it is referring to is a predefined process.
	This figure is used to describe the part of the process that includes some form of documentation
	The diamond is used to describe a decision being made. The decision is often answered with yes or no.

Pharmaceutical care delivered by the pharmacist on the orthopaedic ward

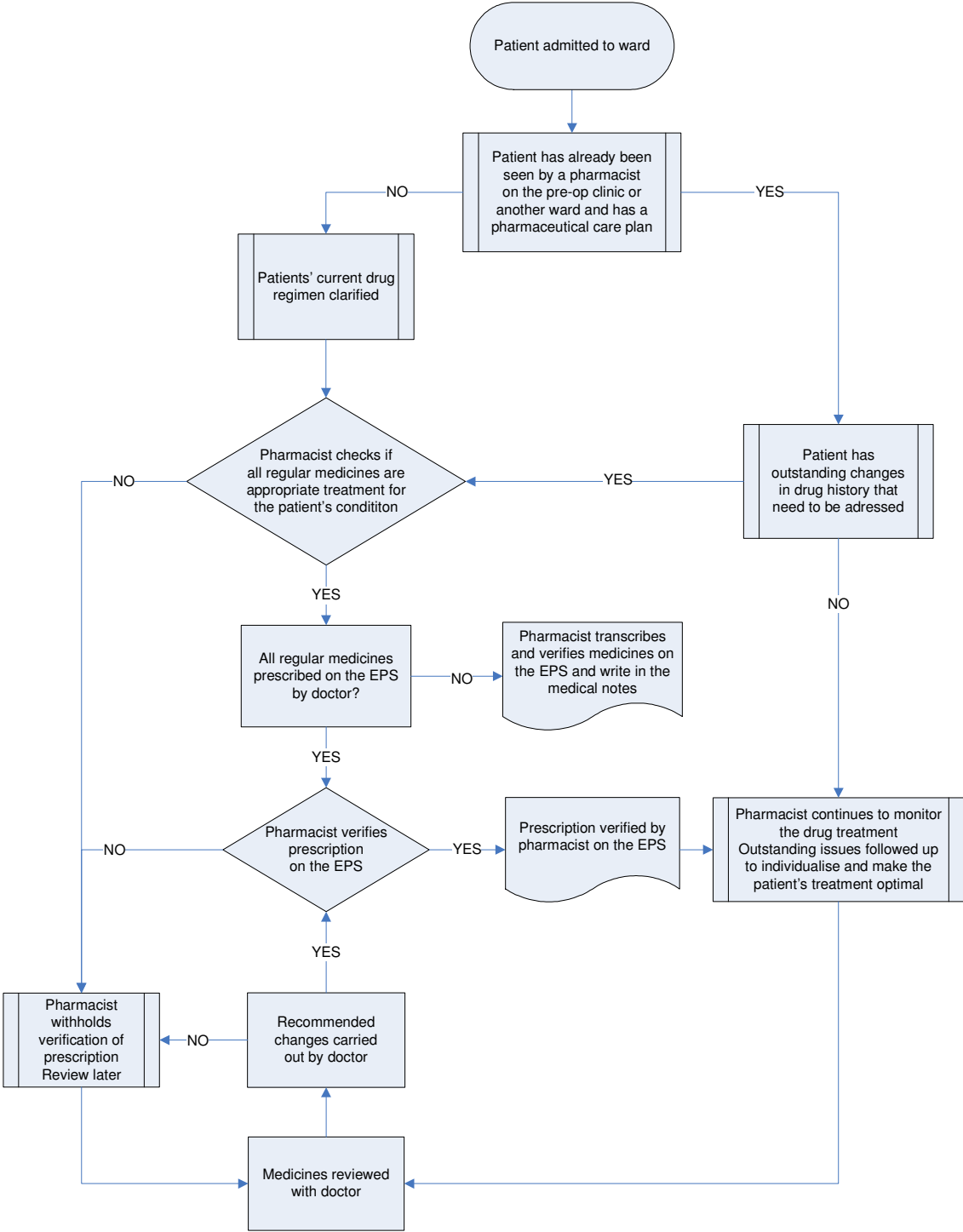


Figure 2 Process map of pharmaceutical care delivered by the pharmacist on the orthopaedic ward

1.8.8 The orthopaedic ward as a medicines re-design ward

At Ayr Hospital the patients' own medicines and one-stop dispensing schemes are implemented in the two medicines re-designed wards which include the orthopaedic ward. The self-administration of medication scheme is not yet introduced. Patients for elective admissions bring in their medication to be registered by the pharmacist or admitting nurse at the pre-assessment clinic. The pharmacist gives these patients information about the scheme, including a leaflet, and a consent form is completed if the patient accepts that their own medicines are used during the stay in hospital. The patient also gets a bag to bring in the medicines on admission.

When admitted to the ward the medicines brought in are stored in a locked cupboard at the patient's bedside (Figure 3). If the patient has not brought the medicines into hospital, which primarily is the case for emergency admissions, the patient relatives is asked to bring them in and consent is taken from the patient to use them in hospital. This is generally a task for the pharmacy technician, but for admissions in the weekend, when no pharmacy staff is on ward, the nurse staff ensures that this is done. The consent to use the patients' own medication encompasses also the possibility to destroy the medicines. If this consent is refused, which is very rarely the case at the orthopaedic ward, all the patients' own medicines, discontinued medicines included, is stored in the bag in the patients' bed-side locker and all medicines used while in-patient are ordered from the pharmacy.

The medicines brought into hospital by a patient are assessed by a pharmacy technician using a form considering all the criteria the patients' own drugs must meet to be suitable for use while the patient is admitted. At the Ayr Hospital medicines in compliance aids that is a blister pack can be used provided that it is clearly marked with the name of the medicine, strength and expire date, while medicines in other compliance aids as refillable boxes are not used. Controlled drugs brought in on admission that are found suitable are registered in a PODs controlled drugs protocol, stored in the wards controlled drugs cabinet and administered to the patient as long as indicated. PODs brought in on new admissions during weekends, when no pharmacy staff is on ward, should be assessed by a trained nurse before they are administered. This is however a part of the scheme where the practice is not as intended. The medicines for these admissions out of pharmacy opening hours are

administered to the patient without any assessment of their suitability. The assessment is not done until the next working day for the pharmacy technician. This shows the importance of establishing an efficient co-operation between nursing and pharmacy teams, and it is recommended from other wards where such schemes are implemented to appoint a change management nurse to facilitate this process^(43,44).

For each patient the clinical pharmacist checks if the medicine the patient brought in is to be continued while in hospital or if the dose has been changed on admission. When the clinical pharmacist is verifying the medicine on the electronic prescribing system a box for "Patients' own medicine" is ticked off to display for discharge what medicines was brought in to hospital and not. The clinical pharmacist informs the technician on ward that the patient's medicines are verified and about any changes made. The medicines are then labelled accordingly to changes made and those found not suitable for use while in-patient are labelled as such and returned, together with medicines stopped, to the pharmacy for destruction.

As a part of the medicines re-design service the one-stop dispensing scheme is implemented at the orthopaedic ward. After the assessment of the suitability of the patient's own drug the pharmacy technician checks if the amount is sufficient to take away on discharge. Additional medicines needed, as well as substitution for the medicines found not suitable for use and medicines commenced on admission, are supplied from either the ward medicine stock or in most cases ordered and sent via pneumatic postal tube which dispatches from the pharmacy to the orthopaedic ward. If the patient has enough of a medicine at home, and therefore does not need further supply on discharge, or if the patient wants a medicine returned although it was found unsuitable for use in hospital the technician makes a note in the electronic prescribing system to provide this information to the staff doing the discharge.

The handling of patients' own drugs (PODs) at the orthopaedic ward

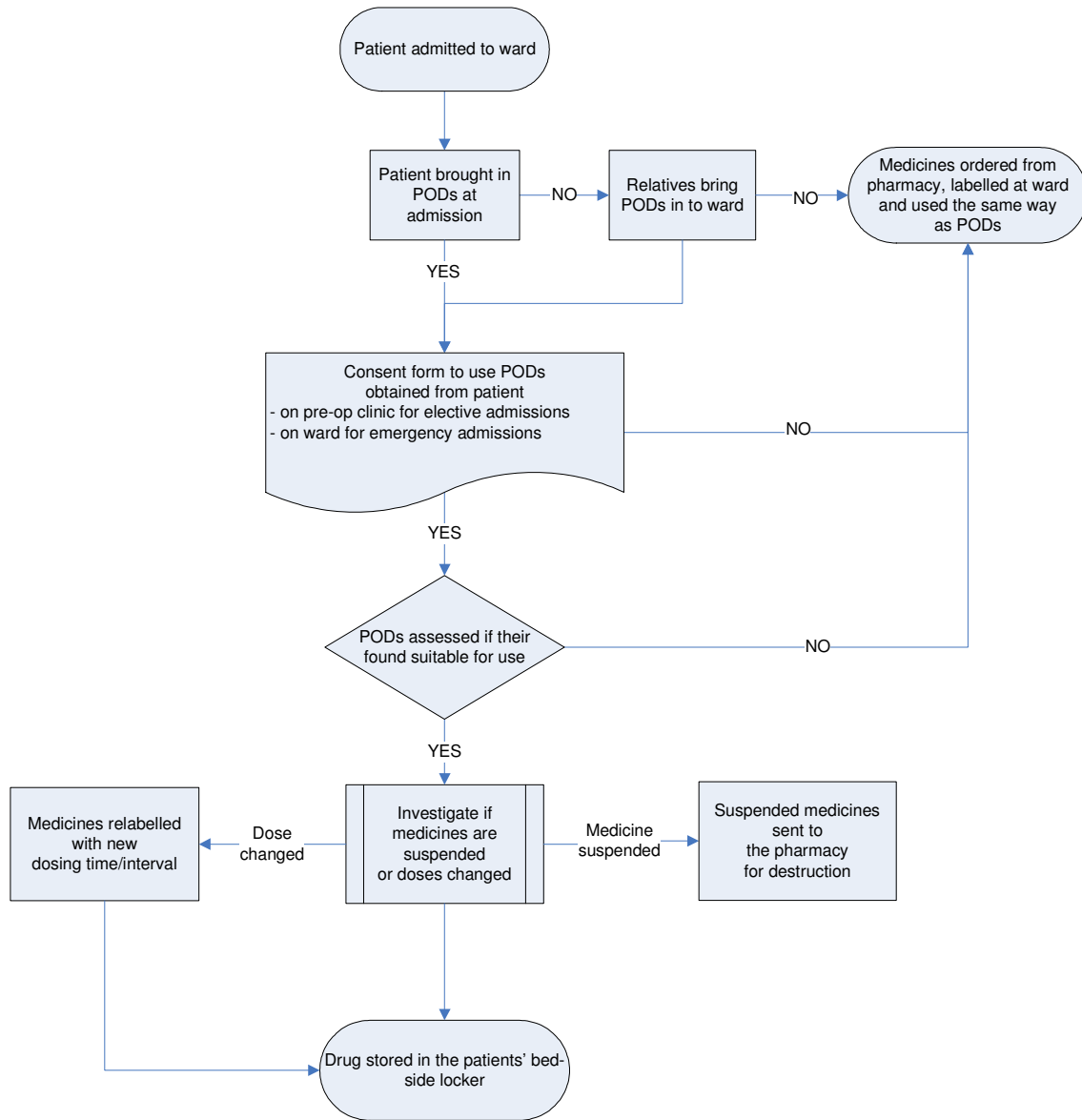


Figure 3 Process map of handling of patients' own drugs (PODs) on the orthopaedic ward

1.8.9 Discharge planning

When a patient is ready for discharge the doctor fills the electronic discharge prescriptions for medicines to take away for the patient (Figure 4). A printout of this is given to the clinical pharmacist who clinically checks and verifies each of the patient's prescriptions both electronic and on paper if no changes has to be made. Any medicines that are missed out on the discharge letter are added by the pharmacist if it is confirmed to still be required. For prescriptions on laxatives and analgesics, the patients' administration details during the stay is often checked and staff nurses' are asked to ensure the supply is needed on discharge. If there still are any outstanding care issues in the care plan these are also dealt with. Information to the patient's General Practitioner regarding any medicines started, changed or discontinued during the stay is written in the discharge letter.

When the prescription is verified the clinical pharmacist informs the technician who gets the patient's medicines from the bedside locker and checks if any additional medicines need to be supplied and ordered from the pharmacy. At the Ayr Hospital they ensure that patients have a minimum of 14 days supply on discharge. The technician on the ward labels the medicines before a checking technician or the clinical pharmacist is doing a second check of the medicines.

Finally the medicines are given to the patient with information from either a technician or the pharmacist. If poor compliance is identified during the stay the pharmacist often makes a medication chart including a list of each of the patient's medicines name, what they do and at what time they should be taken. Before the patient is discharged the pharmacist or a technician goes through the list and possible misconceptions can be solved. The patient counselling and education are unique and important contributions from the pharmacy staff to the patient's pharmaceutical care.

Discharge planning at the orthopaedic ward

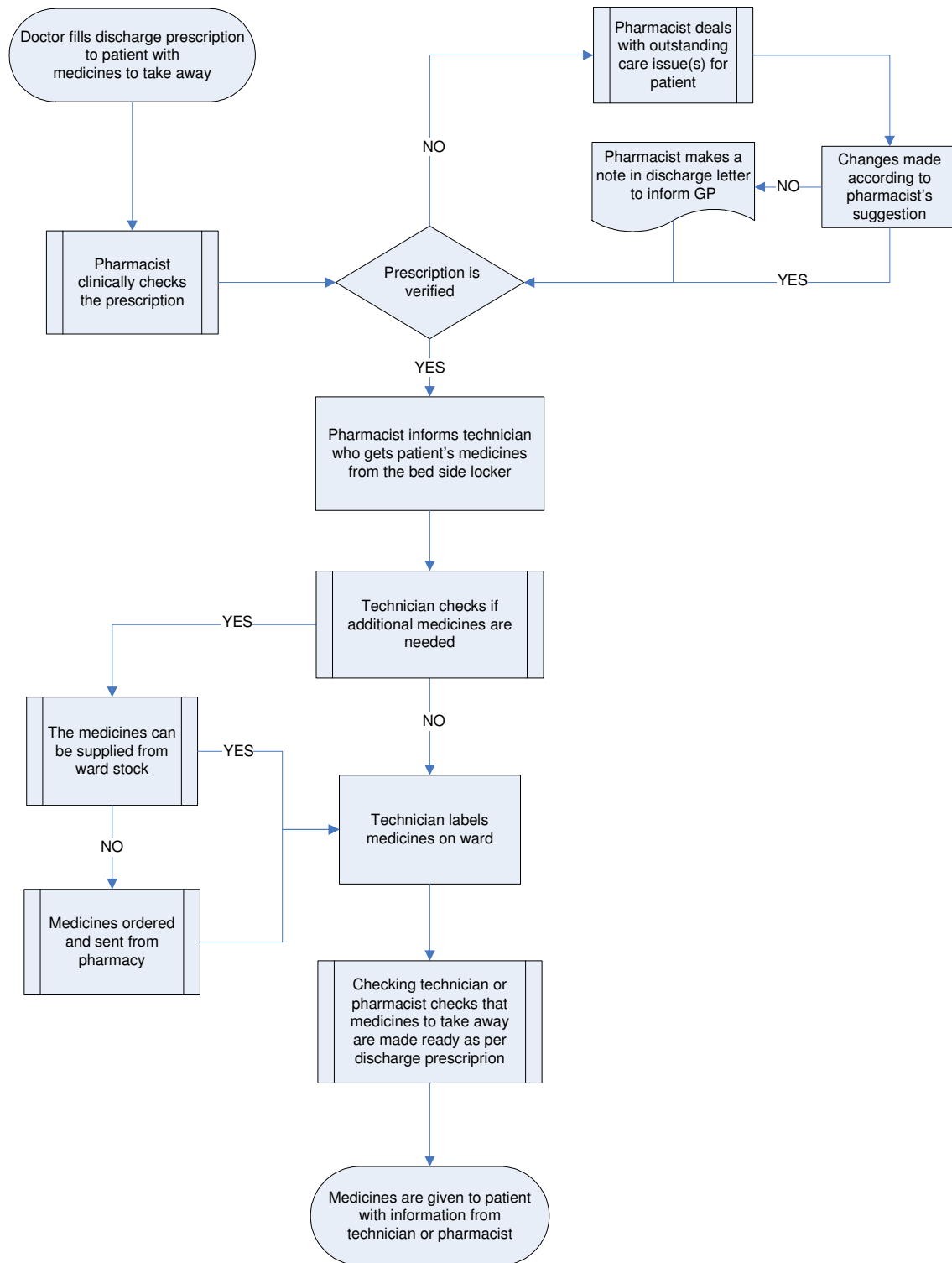


Figure 4 Process map of discharge planning at the orthopaedic ward

2 Aims and objectives

2.1 Aims

- To review two cohorts of patients in terms of pharmaceutical care delivered by examining free text electronic records and categorising care issues into a proposed reporting system.
- To test the validity and the utility of the reporting system, by using qualitative research methods in an action research process.
- To propose a template for an electronic pharmaceutical care plan that meets defined criteria for service developments including non-medical prescribing.

2.2 Objectives

1. Review the literature on orthopaedic, the application of electronic health records; and the documentation of clinical pharmacy activities to inpatients and at the point of discharge from hospital. The usage of a pharmaceutical care issue categorisation system will also be a focus in the review as will be the introduction in the UK of non-medical prescribing.
2. To describe the operational delivery of the clinical service using a process map that is validated by pharmacists and technicians involved in care delivery.
3. Identify documented care plans from samples of patients receiving pharmaceutical care during January 2008 to March 2008 using the electronic care monitoring system. Identify context and outcomes of each care plan by obtaining additional information from paper case records and through dialogue with clinical pharmacist authors to overcome any gaps in the free text electronic records.
4. Modify existing categorisation system used at the 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.

5. Conduct a contents analysis in a formal survey of the care plans in order to categorise the care issues.
6. Demonstrate inter-rater reliability in the categorisation of the care issues in the survey.
7. Conduct a survey of prescribing activity to measure prescription turnover and to quantify exposure of each patient to medication during their stay.
8. Evaluate proposed templates in terms of validity and utility for reporting care plans using an action research approach. Survey findings will be reported to the clinical pharmacy team over a series of meetings, in order to revise the template in response to the feedback obtained.
9. Draw conclusions on the role of the audit findings in defining future application of non-medical (including pharmacist) prescribing.

Study design

2.3 Ethical approval

Approval to undertake the survey was granted from the Ayrshire and Arran Health Board Ethics committee. This was made late in January and due to this the data gathering did not start before the first days of February.

2.4 Inclusion criteria

For inclusion in the survey, patients had to meet the following criteria;

- New patients identified at the orthopaedic ward during the recruitment period between the 4th of February and the 17th of March 2008.
- Patients seen by a clinical pharmacist at the orthopaedic ward with a pharmaceutical care plan started.
- Patients able and willing to sign a consent form.

The patient inclusion at the cardiology ward had the same criteria and recruitment period as the orthopaedic ward.

2.5 Data collection period

The recruitment period was between the 4th of February and the 17th of March 2008. Data from the pharmaceutical care plans was collected until the last patient included was discharged in the middle of April 2008.

2.6 Investigators

The investigator is in her 5th and final year of her degree as Master of Pharmacy at the University of Tromsø in Norway, and this project was conducted in partial fulfilment of this degree.

Additional researchers involved at the time this work was undertaken include Stephen Hudson, Professor of Pharmaceutical Care at the University of Strathclyde (Academic Supervisors), Carl Fenelon, Lecturer in Clinical Practice, Pharmaceutical

Care Health Service Unit at the University of Strathclyde (Co-Supervisor), Gillian Jardine, Clinical Pharmacy Manager at the Ayr Hospital (Clinical Co-Supervisor). The part of the project at the Ayr Hospital was conducted in partnership with co investigator Reidun Os Husteli. The development of guideline for use of the modified system was done through co-operation with Reidun Os Husteli, Marit Bergheim Christensen and Kari Jansdotter Husabø.

3 Methods

3.1 Literature review

The literature on the clinical specialities was obtained from research in electronic databases as PubMed, from referred articles in previous work done by others^(45,46) and relevant references from the clinical pharmacist at the Ayr Hospital. National strategy plans and programmes, internal guidelines for the NHS Board and the hospital (e.g. Joint Formularies) also formed the basis literature for the survey.

3.2 Produce process maps of the delivery of pharmaceutical care, use of patient's own drugs and discharge

The investigator observed the clinical pharmacists at the medical receiving ward, the cardiology ward, the pre-assessment clinic and the orthopaedic ward at the Ayr Hospital over two weeks during October 2007. Most of this time with observations was spent on the ward where the survey was done to better understand how the pharmaceutical care is given to inpatients there. The investigator also spent in all a one day period in the dispensary at the pharmacy and also at the medicines re-design ward together with one of the pharmacy technicians to better understand how medicines are supplied and delivered at the hospital cardiology ward, where patients own drugs (PODs) not are used and at the orthopaedic ward, where PODs are used.

Process maps were made as graphical presentations of the processes including pharmaceutical care delivered, the supply and administration of drugs and the discharge. The investigators was co-operating on making a process map of how the patient's own drugs was used of in practice. Process maps showing the pharmaceutical care delivered by pharmacists was made by the investigator in the setting where the survey was carried out. These descriptions were made based on both the major objectives in the processes identified during the observation period, and information gathered from the pharmacists and technicians involved in the provision of pharmaceutical care and the supply and administration of drugs.

There were standard operating procedures (SOPs) in place for the different processes that is a part of the pharmaceutical care delivered at the wards and these

were also used in the making of the process maps. The investigator made sketches of the processes including exceptions, errors and risk factors and asked the pharmacist involved in the process to comment on these. In total the process maps were corrected and commented on three occasions to ensure validated process maps. The mapping was done by using specialised software, Microsoft Visio 2003.

3.3 Collect patient data to describe prescription activity and pharmaceutical care profile of the acute receiving ward

Measurements of the prescription turnover and quantification of exposure of each patient to medication during their stay was to be studied and analysed separately using methods developed by CF and SH. These numbers will be gathered retrospectively for the cohort entering the audit survey, based on statistics generated from the electronic prescribing system.

3.4 Propose a pharmaceutical care plan template

3.4.1 Training period

The investigator was trained by SH and CF on making paper profiles of patients in the period from November to December 2007. A patient paper profile, based on care plan templates used in the training of pharmaceutical care at the University of Strathclyde, was developed to capture the information found relevant for the survey. The investigator did this training together with co investigator ROH based on the cardiology ward. In this period previous to the survey the investigators gained experience in patient data gathering from the electronic prescribing system, medical notes etc. and a total of 30 patient paper records from the orthopaedic ward and the cardiology ward were made. During this training period the investigator worked alongside the pharmacist SMCK at the orthopaedic ward.

3.4.2 Data gathering

Data to identify patients in the recruitment period was gathered from both the electronic prescribing system and the patient administration system census and also the daily bed state form at the ward, since patients transferred or discharged during

the weekend no longer will be in the prescriber database for the ward on Monday. The investigator quantified the number of patients admitted, the number of patients seen by the pharmacist on ward, the number of patients missed out in the weekend and the number of patients where consent was not received including the reason for that.

The investigator went to every patient that was identified suitable to consent with an information sheet about the survey and asked the patient to sign a consent form (appendix 3). The patients included in the survey were followed until they were discharged, transferred to another ward or died, and so the survey lasted until the last patient had left the ward. Patients that were readmitted to the ward in the recruitment period were counted as one patient if the same pharmaceutical care plan was continued on. The daily bed state form on the ward was used to confirm both where the patient was admitted from and discharged to. Patient data was anonymised and the investigator kept personal data for the patients included in the survey in a book with an identification number belonging to each patient. This made it possible for the investigator to identify the patients in order to gather clinical relevant information and at the same time maintain confidentiality.

All patients included in the survey had an electronic paper profile written by the investigators with information drawn from:

- a: Pharmacist authors' free text notes within the electronic prescribing system
- b: Patients' medical records
- c: Patient profile notes
- d: Discharge letter
- e: Interviews with the pharmacist authors with reviews of the paper profiles to verify the accuracy of the description of care delivered.

The above approach overcome gaps in the free text electronic records, and document the care delivered. The investigator kept a copy of the free text notes written by the pharmacist and the medicines prescribed for each patient that was reviewed continuously for any updates during the hospital stay. The investigator used the patients' medical records to get data about previous medical history, drug history and social history. The discharge letter was available from the dispensary and used if relevant for the patient. Patients' clinical characteristics and care issues was clarified

according to an action research approach where the investigator regularly talked with the pharmacists involved to identify the actions that actual had been taken in the situation.

3.4.3 Critically review and feedback on the care plan template

The patient paper profile was intended to serve as a basis for making a care plan template within the electronic prescribing system. The investigator used action research as a method, through a group meeting, for giving feedback on the template. The meeting was held at the pharmacy department at the Ayr Hospital the 21st of April 2008 with six of the clinical pharmacists participating. The investigator presented, together with co investigator ROH, the categorisation system used for categorising the care issues, key figures of the results from the survey and ideas for a care plan template. The feedback obtained from this meeting made the basis for the care plan template draft presented on the focus group held at the University of Strathclyde in Glasgow the 28th of April 2008. The views generated during the first group meeting were documented by notes taken of the investigators while the comments on the focus group were tape recorded.

3.5 Practical application and evaluation of the existing categorisation system

3.5.1 The modification of the categorisation system

An existing categorisation system to describe pharmaceutical care developed and used at the University of Strathclyde was evaluated and modified through cooperation with co investigators ROH, MBC and KJH, all doing projects on similar surveys in four different hospital settings. The system was based on analysing documented care issues and assigning them into the categories;

- a: Drug therapy problems (Cipolle, Strand)⁽¹⁰⁾
- b: Check or Change category (Strand, McAnaw)⁽¹¹⁾
- c: Quality Assurance Descriptors (McAnaw, Hudson)⁽¹¹⁾

Literature on drug therapy problems, categorisation and categorisation systems was reviewed to better comprehend all aspects of pharmaceutical care or clinical

pharmacy^(10,11). Modifications of the existing categorisation system were made with the purpose to make it more applicable in a clinical setting and ensure that it covered all aspects of pharmaceutical care. Ideas generated from the literature review, paper records from the orthopaedic ward and the cardiology ward and through several research meetings with SH, CF, ROH, MBC and KJH were incorporated. This modified system was presented in a guideline describing the categorisation system (Appendix 6)

The categories of Drug Therapy Problems (DTP) used was those defined in the book *Pharmaceutical Care Practice – The Clinician’s Guide* ⁽¹⁰⁾ by Cipolle et al. The examples given within each category was modified in the guideline to enhance the correlation between the heading of the DTP subcategories and the type of care issues included in them (See appendix 5). 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 6).

Table 6 *Modified categories of Drug Therapy Problems*
(from ‘Guideline for categorisation of pharmaceutical care issues’, Appendix 6)

Categories of Drug Therapy Problems	
1	Unnecessary drug therapy
2	Need for additional drug therapy
3	Ineffective drug
4	Dosage too low
5	Adverse drug reaction
6	Dosage too high
7	Inappropriate compliance
8	Unclassified i.e. Non-DTP

The four *Check* categories were kept as they were originally while the existing category *Change* was divided into two types of subcategories; *Change in Drug Therapy Process* and *Change in Drug Therapy* (Table 7). This division was made on whether the care issue was associated with a change in the care process around the patients' drug treatment or directly to the drug therapy. The subcategories that related to the care process in the existing change system under the headings '*Patient behaviour*' and '*Patient data handling*' (see table 3) were included in *Change in Drug Therapy Process*, while the existing subcategories under the existing heading '*Treatment plan changes*' were included in the *Change in Drug Therapy* category. The number and designation of the subcategories were further changed to be comprehended more easily. The background for the division was that the investigators found that while a *Change in the Drug Therapy* could be assigned a recognisable *Drug Therapy Problem* category the impact of the outcome of care issues in the care process was hard to determine and too speculative to lead to a *Drug Therapy Problem* category.

Table 7 *Modified categories of Change*
(from '*Guideline for categorisation of pharmaceutical care issues*', Appendix 6)

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

The existing definitions of the Quality Assurance Descriptors were modified to be more comprehensive for practical use. To emphasise what the subcategories for the Quality Assurance Descriptors was describing in the patients treatment loop they were designated *Time Perspective* and *Degree of Change* (Table 8). The modified definitions in *Time Perspective* specifies to a greater extent at which stage in the quality assurance loop the check is done. The investigators also modified the definitions in *Degree of Change* to make it easier to differentiate between the extent of changes and the categories assigned to them. The new definitions are found in the guideline (Appendix 6)

Table 8 Quality Assurance Descriptors categories with designated names
(from 'Guideline for categorisation of pharmaceutical care issues', Appendix 6)

Categorisation of checks according to <i>where</i> they are done in the quality system feedback loop	Categorisation of changes according to the <i>extent</i> of the change in the quality system feedback loop
Time perspective	Degree of Change
Verification	Adjustments
Monitoring	Modification
Confirmation	Reviews (prompting a review)

This pilot phase included an initial assessment of researcher care issue categorisation by conducting a peer-review inter-rater reliability testing with ROH, MBC and KJH to get an idea of whether the categorisation coincides among the different researchers.

3.5.2 The development of a guideline describing the categorisation system

The guideline for use of the modified system was developed through cooperation with ROH, MBC and KJH. There was an existing set of guidelines devised by the Pharmaceutical Care Health Service Unit at the University of Strathclyde (see appendix 5). This was extended by the investigators to fully describe the categorisation of a care issue into the triangularised system. As a result of the modifications of the existing guideline the investigators came to that each care issue should be categorised in three such dimensions (see table 9);

1. As either a *Check* or a *Change*; 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 Descriptors*; which indicate a care issue's position in the process of delivering pharmaceutical care (*Time Perspective*).
If the care issue is a *Change in Drug Therapy* this category also describes the extent of the change made (*Degree of Change*).

The third dimension in the system is

3. *Drug Therapy Problem* and only a care issue identified as a *Change in Drug Therapy* was categorised as such.

Table 9 Categorisation system of pharmaceutical care issues

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

If the outcome of the care issue is unknown, the care issue is incomplete and can not be categorised in the categorisation system. Care issues regarded as part of the standard procedure, as for example general checks for dose and indication at admission, during the stay and at discharge, is not included.

Characterisations of the subcategories within each section were made in the guideline to clarify which of the care issues that would be assigned to it. The guideline also includes a description of the way the pharmaceutical care delivered can be thought of as a quality assurance system. To make the definition of 'verification' in the '*Time Perspective*' applicable for different clinical settings the pharmacist can meet the patient, the 'verification' was more precisely described to occur when a patient is either admitted, when the pharmacist first see the patient or a new treatment is started. A selection of issues from the patient profiles made in the

training period from November to December 2007 was gathered to exemplify how different care issues are categorised according to the guideline.

3.5.3 Evaluation of the categorisation system

The investigators used a focus group as a method in order to get feedback on the completeness and usability of the modified categorisation system. The focus group was held at the University of Strathclyde in Glasgow on the 28th of April 2008. The invited participants were clinical pharmacists connected to different clinical settings at the Ayr Hospital and the Glasgow Royal Infirmary where the surveys had been conducted. In addition the supervisor of the group was participating.

The invited participants received the guideline and the examples of categorisation of care issues in advance of the focus group. The investigators were the moderators of the focus group. The categorisation system and the results from the surveys at the four different clinical settings were presented for the participants. The presentation was structured in to the results from the surveys compared between the four wards belonging to the different categories. A set of pre defined questions were asked during the presentation to encourage discussion and to get feedback from the participants on the categorisation system. The focus group was audio recorded and transcribed by the investigators afterwards.

3.6 Categorisation of care issues

3.6.1 Training in the practical application of the categorisation system

The investigator was together with co investigator ROH categorising the care issues found in the 30 patient paper records from the care plan training period from November to December 2007. The training on categorising the care issues was done both by Steve Hudson and Carl Fenelon and through the development of the guideline for the categorisation system.

Care issues generated from the survey populations care plans was characterised by using the triangulated system described above. In addition the investigator and the co investigators quantified care issues related to drug interactions and care issues

where the pharmacist made a recommendation to the prescriber regarding changes in the patient's drug therapy. If the recommended change is carried out the care issue is categorised as a *Change in Drug Therapy Process* or a *Change in Drug Therapy*. On the other hand, if the change of different possible reasons is not followed up the care issue will be categorised as a *Check*. None of these data were captured in the categorisation system but were included in the database.

3.6.2 Database

A database was used to key in all the care issues identified from the survey population and further categorise each of them according to the modified categorisation system. The database allowed the investigator to more easily do statistical analysis on the data, do queries and transfer data to other program for further analysis. The database is made in Microsoft Access®

3.6.3 Inter-rater reliability testing

An inter-rater reliability test to demonstrate the inter-rater reliability in the categorisation process between the investigator and co researcher ROH was done. The investigator and co researcher picked a randomly sample of 50 care issues from each of the two survey populations. These 100 care issues were categorized by both the investigator and ROH. The inter-rater reliability of the categorisation of care issues generated from the survey was demonstrated for the categories *Checks*, *Changes in Drug Therapy Process* and *Changes in Drug Therapy* and the categories within the Quality assurance system (See Table 10). These system sections were therefore analysed separately to demonstrate the validity within each of them.

Table 10 Parts of the system tested for inter-rater reliability for categorisation of care issues

Checks, Changes in Drug Therapy Process, Changes in Drug Therapy

Subcategories within *Checks, Changes in Drug Therapy Process, Changes in Drug Therapy*

Verification, Monitoring, Confirmation

Adjustment, Modification, Review

3.6.4 Cohen's Kappa

The inter-rater reliability was analysed using Cohen's kappa statistic. Cohen's kappa (κ) is a measure of the agreement between two raters which also takes into account the agreement occurring by chance. The data is arranged in a matrix with one rater vertically and the other horizontally⁽⁴⁷⁾. Different parts of the system with different numbers of categories were tested and the size of the matrix therefore varied from a 3x3 matrix to a 16x16 matrix. The calculation of the value of kappa is shown for a 3x3 table (Table 11)

Table 11 Example of a matrix used to calculate the value of Cohen's kappa

Investigator A	Investigator B			Total
	Checks	Changes in Drug Therapy Process	Changes in Drug Therapy	
Checks	1.1	1.2	1.3	Y1
Changes in Drug Therapy Process	2.1	2.2	2.3	Y2
Changes in Drug Therapy	3.1	3.2	3.3	Y3
Total	X1	X2	X3	N

The number of issues where exact agreement is observed among the raters is the sum of the values in 1.1, 2.2 and 3.3. This can be expressed as the relative observed agreement (p_o) which is:

$$p_o = \frac{\text{number of exact agreement observed}}{\text{total number observations}} = \frac{1.1 + 2.2 + 3.3}{N}$$

The next step is to calculate the number of agreements that would be expected by chance. For each square this is the product of the total of the relevant column (X) and the total of the relevant row (Y) divided the total number of observations (N). The

total amount of expected observation by chance is expressed as the relative expected agreement (p_e) which is:

$$p_e = \frac{\text{number of exact agreements expected by chance}}{\text{total number observations}} = \frac{\frac{(Y1 \cdot X1)}{N} + \frac{(Y2 \cdot X2)}{N} + \frac{(Y3 \cdot X3)}{N}}{N}$$

The raters agreement and the value of kappa (κ) is then calculated as the equation:

$$\text{Kappa } (\kappa) = \frac{p_o - p_e}{1 - p_e}$$

If the raters are in complete agreement then $\kappa = 1$. If there is no agreement among the raters, other than what would be expected by chance, then $\kappa \leq 0$.

4 Results

4.1 Pharmaceutical care plan template

4.1.1 Group meeting with critically review and feedback on the care plan template

The group meeting with the clinical pharmacists was held at the Ayr Hospital on the 21st of April 2008. The investigator and co investigator ROH presented the care issue categorisation system, results from the survey and ideas for how a care plan template within an electronic prescribing system could look like. Different suggestions for how each section of the care plan template could be presented were introduced for the clinical pharmacists and they gave the investigators feedback on which solution that would possibly be the best in their work. The group suggested that the 'Medicine Reconciliation Form', now used on paper by the pharmacist when taking the medication history for a new patient, could be implemented in the care plan template. The meeting led to different ideas that are presented in table 12. It was commented that the free text document used by the pharmacist in the electronic prescribing system today is called a 'note' instead of what it actually is; a care plan. The participants pointed out that their greatest demand within the care plan documentation is an improved section for the care issues.

Table 12 Ideas generated from the group meeting for discussing the care plan template

-
- Each pharmacist have an individual profile within the electronic prescribing system
 - Relevant parts from the 'Medicine Reconciliation Form' used today should be implemented into the template
 - Information as 'Presenting complaints', 'Past medical history' and 'Relevant drug history' can be presented as free text boxes
 - Tick boxes for often used sources and free text space for other sources are wanted. Only sources ticked of will later appear in the care plan
 - Relevant information already found in the electronic prescribing system, as allergies and patient demographics should be implemented in the care plan
 - Other functions that calculates eGFR, digoxin level etc. should be available
-

Ideas related to the care issues:

- Actions made in the electronic prescribing system, e.g. when the pharmacist withholds a verification of a drug should be automatically linked to the care plan
- 'Shortcuts' where the pharmacist can choose predefined texts for making care issues
- Each issue's review date outlines the priority of these. The care issues can be sorted in the care plan after this review date
- Issues relevant for discharge can be marked by ticking the discharge box and be placed between the active and inactive care issues.
- The sections in the '*Medicine Reconciliation Form*', e.g. notes about the patient's compliance, need for compliance aid, number to community pharmacy, if the patient can self administer drugs etc. are information that should be presented as care issues

4.1.2 The care plan template draft

The investigator and co investigator ROH made a care plan template draft based on the ideas generated at the group meeting at the Ayr Hospital (Figure 5). This draft was presented on the focus group held at the University of Strathclyde in Glasgow on the 28th of April 2008 with clinical pharmacists participating. It was emphasised from one of the participants that the pharmaceutical care planning does not have the same focus in other parts in UK as it has in Scotland and that this is a hindrance to the evolvement of systems demanded by some pharmacists.

PHARMACEUTICAL CARE PLAN					Review [review date]
[Patient identification]					
Presenting Complaints [free text box]					[sign/ date]
Past Medical History [free text box]					[sign/ date]
Relevant Drug History [free text box]					[sign/date]
Admission Medicines					
Name, Form	Route specify if not oral	Dose	Frequency	Sign	
				[sign/ date]	

OTC / Herbal / Homeopathic / Illicit substances				
Name, Form	Route specify if not oral	Dose	Frequency	Sign
				[sign/ date]

Allergies		
Medicine/Substance	Reaction	Sign
		[sign/ date]

Drug History		Sign
<input type="checkbox"/> GP surgery <input type="checkbox"/> GP letter <input type="checkbox"/> Discharge letter <input type="checkbox"/> Patient <input type="checkbox"/> Patient's family <input type="checkbox"/> Community pharmacy	<input type="checkbox"/> PODs <input type="checkbox"/> Nursing home <input type="checkbox"/> Medical notes <input type="checkbox"/> Electronic Care Summary System <input type="text" value="[freetext box]"/> <input type="text" value="[freetext box]"/>	[sign/ date]

Investigations								
	Date	Date	Date	Date	Date	Date	Date	Date
Weight				BP				
Height				HR				
BMI								
Laboratory Results								
		Date	Date	Date	Date	Date	Date	Date
Test	Range	Units						
K	3.5-5.0	mmol/l						
Na	135-145	mmol/l						
Free text								
[freetext box]								

Pharmaceutical Care Issues						
<input type="checkbox"/> Active <input type="checkbox"/> Inactive	Care issue/ Desired Outcome	[sign/ date]	[free text space for care issue/desired outcome]	Outcome		Review date
	Action	[sign/ date]	[free text space for planning/documenting action]	[sign/ date]	[free text]	[# days] <input type="checkbox"/> Discharge
		[sign/ date]	[free text space for planning/documenting action]	[sign/ date]	[free text]	[# days] <input type="checkbox"/> Discharge

Figure 5 Pharmaceutical care plan template draft

4.2 Pharmaceutical care data from the survey

4.2.1 Ward characteristics

There were 90 patients included to the survey during the recruitment period on the orthopaedic ward from 04.02.08 to 17.03.08. This formed a part of 68.7% of the totally 131 patients that were seen by a ward pharmacist and got a care plan started in the same time period. The 41 patients excluded although they were seen by a pharmacist were so because the patient was not willing (n=6) or unable to consent (n=24), or that the investigator did not see the patient, due to a short stay on the ward, and therefore did not get consent from the patient before he/she was discharged home or to another ward (n=11). The count of patients that were admitted and discharged during the same weekend was found to be one. The orthopaedic ward had totally 184 admissions during the recruitment period.

4.2.2 Comparison of the orthopaedic ward and the cardiology ward

In table 13 the number of drugs on admission per patient is presented from both the orthopaedic and cardiology ward. The sources of information used to obtain drug history are those documented in the care plan. The different sources gathered in 'Other' include nursing home, medication record, box filled by dispensing doctor, Electronic Care Summary and repeating list.

Table 13 Drug history on admission and sources used to obtain it at the orthopaedic and cardiology ward

	Orthopaedic	Cardiology	p value (t test)
Total drugs on admission	468	398	
Mean (CI)	5.2 (4.4-5.9)	5.6 (4.4-6.8)	0.53
Median (IQR)	5.0 (2.3-7.0)	4.0 (1.5-9.0)	
Range	0-14	0-23	
Frequency distribution (%)			
Sources of information used to obtain patient drug history	(n=90 patients)	(n=71 patients)	
Number of sources used			
0	9 (10.0)	0 (0)	
1	23 (25.6)	26 (36.6)	
2	52 (57.8)	40 (56.3)	
3	5 (5.56)	5 (7.0)	
4	1 (1.1)	0 (0)	

(Table 13 cont.)

Actual sources used	(n=146 sources)	(n=123 sources)
Patient	56 (38.4)	39 (31.7)
Patient's own drugs (PODs)	40 (27.4)	14 (11.4)
Patient's relatives	2 (1.4)	5 (4.1)
General Practitioner	19 (13.0)	16 (13.0)
General Practitioner letter	8 (5.5)	8 (6.5)
Community Pharmacy	2 (1.4)	5 (4.1)
Discharge letter	4 (2.7)	12 (9.8)
Notes	0 (0.0)	7 (5.7)
Other	15 (10.3)	15 (12.2)

4.2.3 Categorisation of care issues

The survey was done at the orthopaedic ward with 36 beds and the cardiology ward with 30 beds. The inclusion criteria and period for the survey at the two settings was the same. The patient characteristics were similar between the two settings. There were 90 (40% males) patients included at the orthopaedic ward and 71 (63% males) patients included at the cardiology ward to the survey. The mean length of stay was longer at the orthopaedic ward than the cardiology ward. None of these differences between the two groups were statistically significant (Table 14).

The total number care issues per patient (CI) identified was 3.0 (2.6,3.4) on the orthopaedic and 5.3 (4.2,6.5) at the cardiology ward. This result was found to be statistically significant with a $p < 0.001$. The distribution of the care issues into the categories *Check*, *Change in Drug therapy process* and *Change in Drug Therapy* is also presented in table 14.

Table 14 Comparison of patient characteristics and pharmaceutical care activity at the orthopaedic ward and the cardiology ward

Parameter (per patient)	Orthopaedic			Cardiology			p value (t-test)
	Mean (CI)	Median (IQR)	Range	Mean (CI)	Median (IQR)	Range	
Age	64.5 (61.2,67.8)	68.0 (59.0,74.8)	23-92	67.2 (64.0,70.4)	66.0 (59.0,79.0)	27-89	0.25
Length of Stay	9.0 (7.5,10.5)	8.0 (4.0,11.8)	1-35	7.2 (5.5,8.9)	5.0 (4.0,9.0)	1-45	0.16
Number of diagnoses	4.0 (3.5,4.5)	4.0 (2.3,5.0)	0-11	3.8 (3.3,4.2)	3.0 (2.0,5.0)	0-9	0.28
Total care issues	3.0 (2.6,3.4)	2.0 (1.0,4.0)	0-15	5.3 (4.2,6.5)	5.0 (2.0,7.5)	0-29	<0.001
Care issues not categorised	0.7 (0.4,0.9)	0.0 (0.0,1.0)	0-5	0.9 (0.6,1.1)	1.0 (0.0,1.0)	0-4	0.23
Check	1.1 (0.8,1.4)	1.0 (0.0,2.0)	0-7	3.8 (3.0,4.5)	3.0 (2.0,6.0)	0-16	<0.0001
Change in Drug Therapy Processes	0.9 (0.5,1.2)	0.0 (0.0,1.0)	0-9	1.0 (0.6,1.4)	0.0 (0.0,1.0)	0-9	0.67
Change in Drug Therapy	1.0 (0.8,1.3)	1.0 (0.0,2.75)	0-7	0.6 (0.3,0.8)	0.0 (0.0,1.0)	0-5	0.019

$\alpha=0.05$ have been used for 95% confidence interval (CI). $p>0.05$ means that the null hypothesis remains, and that there is no demonstrable difference between the two populations, while a $p<0.05$ means that there is a 95% likelihood of a real difference between the two populations based on the comparison of the two samples. The closer the p-value approaches zero respectively, the greater the likelihood of a real difference. Interquartile range (IQR) specifies the variability around the median.

Table 15 Pharmaceutical care issues within the quality assurance descriptor categories Time Perspective and Degree of Change: Comparison of orthopaedic and cardiology ward

	Orthopaedic		Cardiology		p value (chi square)
	n	% (95% CI)	n	% (95% CI)	
Check					
Verification	27	30.7 (22.0, 41.0)	68	25.5 (20.6, 31.0)	0.7885
Monitoring	50	56.8 (46.4, 66.7)	199	74.5 (69.0, 79.4)	< 0.0001
Confirmation	22	25.0 (17.1, 35.0)	0	0.0 (0.0, 1.7)	< 0.0001
Total	88		267		
Change in Drug Therapy Process					
Verification	69	89.6 (80.6, 94.9)	49	71.0 (59.4, 80.4)	0.0058
Monitoring	8	10.4 (5.1, 19.4)	20	29.0 (19.6, 40.6)	0.0058
Confirmation	0	0.0 (0.0, 5.7)	0	0.0 (0.0, 6.3)	< 0.0001
Total	77		69		
Change in Drug Therapy					
Verification	55	58.5 (48.4, 68.0)	22	52.4 (37.7, 66.6)	0.5756
Monitoring	30	31.9 (23.3, 41.9)	15	35.7 (22.9, 50.9)	0.6961
Confirmation	9	9.6 (4.9, 17.4)	5	11.9 (47.3, 25.5)	0.7619
Total	94		42		
Adjustment	81	86.2 (77.6, 91.9)	31	73.8 (58.8, 84.8)	0.0924
Modification	13	13.8 (8.1, 22.4)	9	21.4 (11.5, 36.2)	0.3153
Review	0	0.0 (0.0, 4.7)	2	4.8 (0.5, 16.7)	0.0938
Total	94		42		

Only care issues categorised into the *Change in Drug Therapy* will be assigned one of the quality assurance descriptors 'adjustment', 'modification' or 'review' (Table 15).

Table 16 Pharmaceutical care issues within Check, Change in Drug Therapy Process and Change in Drug Therapy : Comparison of orthopaedic and cardiology ward

	Orthopaedic		Cardiology		P value (chi square)
	n	% (95 % CI)	n	% (95 % CI)	
Check					
Medication need inquiry	59	59.6 (49.7, 68.7)	27	10.1 (7.0, 14.4)	< 0.0001
Effectiveness inquiry	15	15.1 (9.3, 23.6)	83	31.1 (25.8, 36.9)	0.0021
Safety inquiry	23	23.2 (16.0, 32.5)	142	53.2 (47.2, 59.1)	< 0.0001
Compliance inquiry	2	2.0 (0.1, 7.5)	15	5.6 (3.4, 9.1)	0.1734
Change in Drug Therapy Process					
Clinical (shared) record of patient characteristics	0	0.0 (0.0, 5.7)	11	15.9 (9.0, 26.5)	0.0002
Clinical (shared) record of drug history	63	81.8 (71.6, 89.0)	37	53.6 (42.0, 64.9)	0.0003
Continuity of information / care between clinical settings	5	6.5 (2.5, 14.7)	11	15.9 (9.0, 26.5)	0.1093
Level of patient monitoring	3	3.9 (0.9, 11.3)	2	2.9 (0.2, 10.6)	1.0
Health care team member(s) information/education	6	7.8 (3.3, 16.3)	8	11.6 (5.7, 21.5)	0.5755
Change in Drug Therapy					
Drug selection (starting new or changing drug)	35	37.2 (28.1, 47.3)	6	14.3 (6.3, 28.2)	0.0082
Dose	6	6.4 (2.7, 13.5)	6	14.3 (6.3, 28.2)	0.1884
Route/dose-form	13	13.8 (8.1, 22.4)	0	0.0 (0.0, 10.0)	0.0095
Dose interval/timing	5	5.3 (2.0, 12.2)	0	0.0 (0.0, 10.0)	0.3235
Duration	0	0.0 (0.0, 4.7)	0	0.0 (0.0, 10.0)	1.0
Stop drug temporarily/permanently	30	31.9 (23.3, 41.9)	23	54.7 (40.0, 68.8)	0.0139
Patient or carer level of education (Understanding/compliance)	5	5.3 (2.0, 12.2)	7	16.7 (8.0, 30.9)	0.0470

The distribution of the care issues within each of the subcategories in *Check, Change in Drug Therapy Process* and *Change in Drug Therapy* is included in table 16. The care issues found in *Change in Drug Therapy* are categorised as a Drug Therapy Problem. The results from the orthopaedic ward and cardiology ward are found in table 17.

Table 17 Drug Therapy Problems: Comparison of orthopaedic and cardiology ward

	Orthopaedic n (%)	Cardiology n (%)
Unnecessary drug therapy	27 (28.7)	16 (38.1)
Need for additional drug therapy	28(29.8)	3 (7.1)
Ineffective drug	9 (9.6)	1 (2.4)
Dosage too low	7 (7.4)	5 (11.9)
Adverse drug reaction	11 (11.7)	5 (11.9)
Dosage too high	4 (4.3)	4 (9.5)
Inappropriate compliance	7 (7.4)	8 (19.0)
Unclassified	1 (1.1)	0 (0)

The total number of recommendations related to a change that the pharmacist made to the prescriber is presented in table 18. The distribution of the outcome of the recommendation is also found in the table.

Table 18 Pharmacist's drug therapy recommendations

	Orthopaedic n (% of total care issues)	Cardiology n (% of total care issues)
Total recommendations	171 (63.3)	80 (21.2)
	n (% of total recommendations)	
Recommendations which remained a check	15 (8.8)	9 (11.3)
Recommendations which lead to a change in Drug Therapy Process	67 (39.2)	37 (46.2)
Recommendations which lead to a change in Drug Therapy	89 (52.0)	34 (42.5)

4.3 Focus group

The focus group was held at the University of Strathclyde in Glasgow on the 28th of April 2008. All the persons invited attended, except for one (Table 19). The moderators gave a short introduction of the background for the project. Subsequently each section of the categorisation system were presented with the relevant results from the surveys that had been done in four different settings. During the presentation and for each part of the system the moderators asked questions that were made to identify the participants' impression of the categorisation system regarding to comprehension and practical usability. New and changed parts of the system were especially in focus.

The questions the moderators asked and the discussion among the participants that followed regarding these are presented in Table 20. One participant, GJ, arrived the about 40 minutes out in the focus group, when the part regarding recommendations and interactions.

Table 19 *Participants at the focus group*

Title	Initials
Clinical pharmacist, Ayr Hospital	GJ
Clinical pharmacist, Ayr Hospital	KW
Clinical pharmacist, Glasgow Royal Infirmary	CF
Clinical pharmacist, Glasgow Royal Infirmary	LS
Supervisor, Professor of Pharmaceutical Care, Strathclyde Institute of Pharmacy and Biomedical Sciences	SH
Investigator	MRR
Investigator	ROH
Investigator	MBC
Investigator	KJH

Table 20 Questions and themes with discussion at the focus group

Question /discussed parts	Discussion / opinions
<p>Any questions to the guideline?</p> <p>What your first impression of the guideline is?</p> <p>Is it readable?</p> <p>Is it possible to use the system by reading the guideline?</p>	<ul style="list-style-type: none"> - <i>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 (SH).</i> - <i>I find it a bit complex, reading it. (LS)</i> <p>Two of the participants (LS and KW) commented that the parts of the system with checks and changes were easy understandable but that the Quality Assurance Descriptors were not system you could start using intuitively.</p> <p>The language used in the Quality Assurance System with classifications as 'modifying' and 'adjusting', or 'confirming' and 'verifying' was mentioned to be difficult to differentiate and that this could affect the inter-rater reliability between the users of the system.</p>
<p>Division of change</p> <p>We've tried to divide the changes category in two, and we would like to have your thoughts about a division like that.</p>	<ul style="list-style-type: none"> - <i>In some ways I see the 'health team member information/education' as something outside the drug therapy process, rather than individual (...) patient related changes.(CF)</i> <p>The investigators explained that this category includes care issues related to 'patient specific information on using medicines'.</p> <p>The participants would not necessarily refer to this type of issue as a <i>change</i> in drug therapy process, but that it rather is the drug therapy process and you more are <i>assuming</i> that it is a change. This part of the pharmacist's work is not even always documented as a care issue in the care plan. The participants did agree on the following suggestion:</p> <ul style="list-style-type: none"> - <i>Under the general heading of changes you've got 'Contribution to drug therapy process' and 'Change in drug therapy' (SH).</i>
<p>Check</p> <p>Do you think the varying distribution of the subcategories between the wards can be explained or are they expected?</p>	<p>The participants did agree on that the variations in 'checks' between the wards was as expected.</p> <ul style="list-style-type: none"> - <i>The expected compliance is quite high in care of the elderly, it is not really that surprising in all because... It depends on the type of ward(...) (LS)</i> <p>The high proportion of 'medication need inquiry' checks done at the orthopaedic ward was also mentioned to be explained by patient's need for anticoagulation and proper analgesia.</p>
<p>Change in Drug Therapy Process</p> <p>Can the differences and similarities you see here be explained and are they expected?</p>	<ul style="list-style-type: none"> - <i>I think the clinical, sort of shared record, drug history, it probably so high on the Ayr side because the medical staff very much leaves that up the pharmacist, whether that's right or wrong, to sort out the drug history and to transcribe everything on admission so that probably makes the number pretty much as predicted(KW).</i> <p>A comment was made that the relatively low frequency of issues in 'continuity of care' at the cardiology ward could be due to under documenting in since these issues are done at the pharmacy and not at the ward. But it was cleared up that the data gathering method would ensure that outcome of these issues captured by the investigators.</p>

<p>Change in drug therapy The number of 'Change in drug therapy' was small for all wards and no care issues were put in the 'Duration' category at all. Do you think there is a need for this subcategory?</p>	<p>Some of the participants were surprised of that this category was not used since you usually talk about 'duration of therapy'. KJH explained how we had categorised everything about duration as stop drug or start drug. The duration was mentioned to either relate to switch to oral formulations or to change the duration as well, and that both of these would be a stop drug category.</p> <ul style="list-style-type: none"> - <i>I think there is an overlap here, and the definition potentially needs tidying up</i> (CF). - <i>So, duration is a change of the length of the course, that is more a subtle</i> (SH) <p>A suggestion was to split the 'stop drug' category into two, so that the duration is qualified within stop drug, as length of course necessarily can go on but no further comments were made on this.</p>
<p>Drug therapy problems We wanted to discuss the need for the new eight category, 'Unclassified i.e. Non-DTP'. Do you think it would be interesting to categorise care issues regarding cost savings for instance that will be unclassified other ways, because they aren't clinical?</p>	<p>Some of the participants reacted on that an additional category had been added to a standard categorisation system as the Drug therapy problems is. The issues should be tried to put in some of the existing categories.</p> <p>The participants agreed upon that the work pharmacists are doing regarding choice of non-formulary drug is an important part of their work and issues as such should therefore still be included in the categorisation system. However, there were some disagreement in whether these issues related to cost should be included to the category 'ineffective drug' or if it should be kept as an own category to be able to separate them out.</p> <ul style="list-style-type: none"> - <i>So if you are gonna have an extra category, call it something a little bit more specific</i> (LS). <p>Participants agree on this.</p>
<p>Interactions This is not a part of the system today and is information we have gathered beside the system. Do you think interactions should be integrated into the system?</p>	<p>General agreement among the participants that interactions in general are a just one among other checks that the pharmacist does to reveal if there is a need for changes in the patients drug therapy and that all these checks done not necessarily is written down routinely.</p> <ul style="list-style-type: none"> - <i>I think it's the outcome, you're saying dosage too high, dosage too low, it's the outcome of the interaction.</i>(GJ) - <i>This is how we used to have categorisation systems. Based on what pharmacists do, rather than what was delivered to patients</i> (SH).
<p>Recommendation As the interactions this part is not implemented in the system today. Do you think this information is interesting and that it should be implemented into the categorisation system?</p>	<p>There were some confusion about what these results really showed and a comment was made on that the term recommendation was ill-defined.</p> <p>Some of the participants disagreed that these numbers should be characterised as 'recommendations from pharmacist not acted upon'. This was one of the comments:</p> <ul style="list-style-type: none"> - <i>Usually when you may have identified something, a potential issue that you want to discuss with the prescriber, and you may think that a change is indicated, but on further discussion maybe further clinical issues have come out in the discussion and overall hopefully you get consensus</i> (CF) <p>One of the participants (LS) expressed that this data could be useful (...).</p>

<p>Sum up check and change part Just in general, do these categories describe the pharmaceutical care delivered? Are there any categories you would like to see or that are missing so far?</p>	<p>The participants agreed on the comment that: - <i>Obvious you would get documented problem, individual practice is various at the moment</i> (SH). The participants did not come up with any concrete missing parts. Some opinions about this part of the system was mentioned: - <i>I think you got the basis of a degree of describing a lot of the (...) pharmacist contributions to care. And I think it's probably some room for some tweaking</i> (CF) It was pointed out that these results revealed a problem caused by the electronic prescribing system in Ayr. A participant mentioned that the proportions of the workload could give ideas if it is a reasonable distribution.</p>
<p>Time Perspective The results from the surveys about distribution within the 'verification', 'monitoring' and 'confirmation' were presented. What does the 'Time Perspective' add to the description of the pharmaceutical care? How do you comprehend this category and the subcategories?</p>	<p>There was obviously confusion among the participants while this part was presented and it was stated that categorising both checks and changes into the Time Perspective could make it even more complex and difficult for the participants to understand. - <i>This is very, very far from the original system (...)</i>(SH). A problem was that the terms used in this category seemed to mean the same thing for the participants. A redescription of the categories used was suggested: - <i>(...) if you say it happen at the design stage or the delivery stage or the evaluation stage. (...) Then you avoid the duplication of using the same word...you still got the time perspective (...)</i> (LS)</p>
<p>Quality Assurance Degree of change The results in this category were presented. What does the Degree of Change add to the description of the pharmaceutical care? How do you comprehend this category and the subcategories?</p>	<p>- <i>I'm surprised there were not many reviews, generally.</i>(SH) A explanation to that was suggested could be due to the short stays for the patients Clearly the terms used also here are more difficult to relate to for the participants. Many examples of changes in practice were referred to and suggestions of their placing in the category were discussed. One main problem mentioned was that the pharmacist usually don't set treatment goals and that this can explain the low frequency of 'reviews'.</p>
<p>Summing up Which potential uses you can think of for this system all the categories we've presented today included? Can you mention anything positive and negative sides about the system?</p>	<p>- <i>You can prepare pharmacists, and pharmacist can benchmark their practice and see what they need to be working on. (...) It makes you thinking: it makes you thinking about process, it's make you thinking about the patient actually going home and evaluating the outcome in another term. The negative is that's quite complex.</i>(LS) Participants did agree on the comment that: <i>The more intuitive you can make it, the better</i> (LS)</p>

4.4 Inter-rater reliability testing of the categorisation system

The inter-rater reliability for categorising care issues found after the training period was analysed by using Cohen's kappa statistic. The higher value of kappa the higher is the agreement between the two raters. There is no absolute definition for the interpretation of the kappa value but a scale for the different kappa values is shown in Table 21 as a guideline. The value of kappa from the tests done is given with a 95 % confidence interval in the tables 22-25. The relative observed agreement (p_o) and the relative observed agreement (P_e) in each test are also included in the results.

Table 21 Scale value of Cohen's kappa⁽⁴⁷⁾

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

Table 22 Result of inter-rater agreement in the categories Check, Changes in Drug Therapy Process and Changes in Drug Therapy

Investigator A	Investigator B				Total	κ Strength of agreement P_o P_e	0.93 (0.87-1.00) Highly good 0.96 0.41
	Check	Change in Drug Therapy Process	Change in Drug Therapy				
Check	55	0	0	55			
Change in Drug Therapy Process	0	17	0	17			
Change in Drug Therapy	2	2	24	28			
Total	57	19	24	100			

Table 23 Result of inter-rater agreement within the subcategories of the Checks, Changes in Drug Therapy Process and Changes in Drug Therapy

Investigator A		Investigator B																
		Checks			Changes in Drug Therapy Process					Changes in Drug Therapy								Total
		MED	EFF	SAFE	COMP	CHAR	DH	CONT	MON	INF	SEL	DOSE	FORM	INT	DUR	STOP	EDU	
Checks	MED	11	1		1												13	
	EFF	4	12														16	
	SAFE			24													24	
	COMP				2												2	
Changes in Drug Therapy Process	CHAR					1											1	
	DH						15										15	
	CONT							1									1	
	MON								0								0	
Changes in Drug Therapy	INF									0							0	
	SEL	1					1				8						10	
	DOSE			1			1				4						6	
	FORM											0					0	
	INT												1				1	
	DUR													0			0	
	STOP										1					9	10	
EDU																1	1	
Total		16	13	25	3	1	17	1	0	0	9	4	0	1	0	9	1	100

κ 0.87 (0.46, 1.28)
Strength of agreement Highly good
P_o 0.89
P_e 0.85

Table 24 Result of inter-rater agreement in the categories verification, monitoring and confirmation

Quality Assurance Descriptors: Time perspective					
Investigator A	Investigator B			Total	κ 0.76 (0.64,0.88) Strength of agreement Good P_o 0.87 P_e 0.46
	Verification	Monitoring	Confirmation		
Verification	44	1	0	45	
Monitoring	7	42	4	53	
Confirmation	0	1	1	2	
Total	51	44	5	100	

The results from the inter-rater agreement test of the quality assurance descriptors in 'Time perspective'; verification, monitoring and confirmation are presented in table 24. A similar test done for the issues that were assigned a quality assurance descriptor within the 'Degree of change' (Table 25)

Table 25 Result of inter-rater agreement in the categories adjustment, modification and review

Quality Assurance Descriptors: Degree of change					
Investigator A	Investigator B			Total	κ 0.44 (0.18,0.69) Strength of agreement Moderate P_o 0,79 P_e 0,63
	Adjustment	Modification	Review		
Adjustment	16	2	0	18	
Modification	3	2	0	5	
Review	0	0	1	1	
Total	19	4	1	24	

5 Discussion

5.1 Known differences in the delivery of the service to the orthopaedic ward compared to the cardiology ward

The main difference between the orthopaedic and the cardiology ward is found in the way the discharge process is organised. As the orthopaedic ward is a medicines re-design ward including re-use of patient's own drugs and one-stop dispensing schemes, the verification of the prescribed medicines to take away on discharge is done by the pharmacist on the ward. By doing this process on the ward the nurse and medical staff are easily available to clarify the patient's need for the prescribed medicine and any other outstanding care issues. At the cardiology ward on the other hand, the discharge letter including prescribed medicines to take away is sent electronically from the doctor on the ward to the dispensary. There a pharmacist checks the prescription and consults with the doctor on the ward if needed before it is verified and the medicines given to the patient.

This difference in the way the discharge process is organised obviously results in differences in what the pharmacist spends his/her time doing on the ward. At both wards most of the time spent is on the clarification of the drug history to the patient and follow-ups of active care issues. To reduce the work load for the pharmacist in relation to the discharge process in the medicines re-design ward the technicians are attending the ward every day. In addition to assessing the patient's own drugs and preparing the medicines to take away on discharge they are giving the pharmacist assistance in the pharmaceutical care given. An example is when the pharmacy technician gives the patient their medicines on discharge with the information that is necessary.

5.2 The care plan template draft

The care plan template draft made by the investigator and co investigator ROH is supposed to optimise the pharmacist's documentation of their contributions to the patient's care (Figure 5). There are several reasons for having a care plan template.

Compared to a free text electronic record that is used at the Ayr Hospital at today, a care plan template will make the plan more structured and complete. A care plan template has also the advantages of making the pharmacists' documentation process more effective and uniform between pharmacists. The care plan template is drafted by using care plan drafts from different settings as a starting point and including ideas generated during the survey and through a group meeting with the clinical pharmacists at the Ayr Hospital. An example from the survey of a patient free text electronic care plan is found in appendix 1 and is also made in the proposed patient template care plan found in appendix 2.

The patient's care plan is a document that is used by several people within the hospital during the hospital stay. For this reason a good care plan template should make it easy to get an overview of how the pharmaceutical care is intended to be provided and to document which actions that have been undertaken in this process. The aim by using the care plan template should be to capture as much as possible of the work done. By implementing the information from different forms and databases the pharmacists use, and often duplicates into the free text record today, the care plan will end up as a more complete document of the contribution in the pharmaceutical care. An example of the forms that should be implemented is the '*Medicine Reconciliation Form*' that is used in paper form today when taking the patients medication history. But also other parts of the system as laboratory results and information from the patient's demographics, in the electronic prescribing system could be a part of the care plan template. This can reduce the time the pharmacist spend on duplicating information and also reduce the risk of error when transcribing into the care plan.

One of the main advantages with an electronic documentation system is the possibility to audit trail all the actions made on it. The idea for this care plan template is to give each clinical pharmacist an individual profile within the electronic prescribing system and in that way all the contributions the pharmacist makes to the care plan is automatically signed with the name and date for the pharmacist. In this way no new information is added without knowing who did it. The pharmacist profile can also contain different help functions that the pharmacist can use during the work on the ward. This is thought to include calculations for example for eGFR, digoxin

levels, BMI from the weight and height etc. and the pharmacist can choose to switch these functions on or off according to what he/she wants. The pharmacist can ideally choose lab results that are relevant, and have these implemented into the investigations section in a similar manner as the weight is updated from the electronic prescribing system. These results could also then update themselves when a new sample is drawn and present values out of range. The care plan template is not meant to be a complex system of technical functions but a tool to help the pharmacist making their documentation easier.

In the care plan template draft information as presenting complaints, past medical history and relevant drug history can be written in free text boxes in the care plan. When the pharmacist verifies the medicines in the electronic prescribing system and ticks the “Medicines on admission” box these will appear in this section of the care plan. The care plan template contains most of the already existing ‘*Medicine Reconciliation Form*’ used at the Ayr Hospital where among others drugs on admittance, OTC, herbals and etc. can be documented. All information on this form that should be presented as care issues is intentionally omitted. E.g. notes about the patient’s compliance, need for compliance aid, number to community pharmacy, if the patient is able to self administer drugs etc. The sources used for obtaining information for drug history can be ticked off in boxes for often used sources or be written in free text space for other sources. Only sources ticked of will later appear in the care plan.

The care issue section is structured into three parts; the desired output of the pharmaceutical need, the action(s) planned to achieve the outputs and the actual output. Each issue’s review date outlines the priority of these. A function that sorts issues after review date could therefore make it easier for the pharmacist to get an overview of the care plan. The first coming review date would automatically be chosen as the care plan’s review date and will also appear on the top of the care plan. If the patient is not seen on the review date, the date will automatically be updated. Issues relevant for discharge can be marked by ticking the discharge box and be placed between the active and inactive care issues. The pharmacist writes in the number of days till review in the review date box, which converts it to the date for

review. The pharmacist is able to get an overview of each patient's review date and the patients' with no care plan started.

Other technical functions the investigators has thought of as usable in the care plan template are for example a link from the prescribed orders in the electronic prescribing system to the care plan. When the pharmacist withholds verification of a drug this can be automatically linked as an care issue in the care plan and so the pharmacist can go back there later and write the reason why. Each pharmacist can also make their own 'shortcuts' for making care issues. E.g. if a pharmacist has a patient with ST elevated myocardial infarction and writes the keyword **STEMI* in the care issue field, there would be possible to choose a predefined text that the same pharmacist has added in as a function. In this way care issues that are typed several times a day can be pasted in automatically.

A care plan template structured like this should not only facilitate the pharmacists daily work on the ward, but also make it possible to gather data and do research on the contribution the clinical pharmacist makes to the patient's pharmaceutical care. With a more structured way of presenting the care issues these can be analysed, categorised and used to describe the activity that is being done on the ward.

5.3 Comparison of the pharmaceutical care data from the survey at the orthopaedic ward and the cardiology ward

5.3.1 Drug history on admission and sources used to obtain it at the orthopaedic and cardiology ward

Looking at the number of drugs per patient on admission there were found to be no statistically difference for the orthopaedic ward and the cardiology ward (Table 13). This number includes medicines the patient was prescribed before admission to hospital. This includes not OTC, herbal medicine etc. The number of sources used to obtain the patients drug history is those that the pharmacist documents used in the care plan. At both the orthopaedic ward and the cardiology ward this information is most often obtained by using two different sources. Among 10% of the care plans at

the orthopaedic ward the information source used is not documented. The pharmacist documents the patient's medicines on admission on the '*Medicine Reconciliation Form*' which is filed in the patient's notes. This documentation should also be duplicated in the free text care plan but is potentially forgotten. This documentation procedure in both the written medical notes and care plan is a time consuming activity for the pharmacist.

In both settings the patient is the source of information most often used when the drug history to the patient is obtained (Table 13). The percentage use of the patient's own drugs as a source of information is higher on the orthopaedic ward (27.4% of all sources) compared to the cardiology ward (11.4% of all sources) and can be explained by the difference in the use of the PODs while inpatient at the orthopaedic ward and not at the cardiology ward.

5.3.2 Patient characteristics

The statistical analysis of the patient characteristics shows that there is no demonstrable difference between the two wards in terms of age and number of diagnosis (Table 14). The number of diagnosis is obtained by the investigators through those noted in the patient's care plan and also additional findings in medical notes. This can be incomplete since more often only relevant diagnosis is documented in the notes on admission. The length of stay has a mean (CI) of 9.0 (7.5,10.5) days at the orthopaedic ward and 7.2 (5.5,8.9) days at the cardiology. The mean values are outside the 95% confidence interval which means that it is a difference between the length of stay to the patients at the two wards. The t-test gives a p-value of 0.16 and no statistically difference is therefore found. This difference in the statistical analysis can be due to that the patient population does not show normal distribution.

5.3.3 Pharmaceutical care activity at the orthopaedic ward and the cardiology ward

The difference in the number of pharmaceutical care issues identified per patient in the two settings is statistically significant with a higher mean (CI) at the cardiology ward than at the orthopaedic ward (5.3 (4.2,6.5) versus 3.0 (2.6,3.4)) (Table 14). This can possibly be explained by the difference in the group of drugs the patients at the two wards use. The medicines on the cardiology ward can possibly generate more issues related to closely monitoring than the medicines that are found among the patients at the orthopaedic ward. Looking at the distribution of the care issue within the *Check*, *Change in Drug Therapy Process* and *Change in Drug Therapy* this difference is revealed through the number of *Check* done per patient. The number of *Checks* at the cardiology ward is found to give a mean of 3.8 for *Check* per patient while the value for the same category at the orthopaedic ward is 1.1, $p < 0.0001$

The *Check* category includes all the care issues related to when the pharmacist is doing a check to ensure that the patient's treatment is safe and effective. The data in table 16 confirms that the *Check* for '*Safety inquiry*' is higher on the cardiology ward compared to the orthopaedic. When adding the '*Time perspective*' categories in Quality Assurance Descriptors to the checks, information is revealed about if the check was performed at the start of the treatment, during treatment or as a check for that the treatment was stopped. As seen in table 15 most of the checks for both wards are done during the patient treatment; as a *monitoring check*.

The care issues that were not categorised were so because the outcome of the care issue was unknown. The data from the survey does not show any differences between the numbers of care issues not categorised per patient (table 14). The method used for the data gathering with an action research approach where the investigator regularly talks with the pharmacist should ensure that all actions taken, also those not documented in the care plan, have been captured. There are various reasons for why the care issue has not got any outcome. It can be due to that the patient is not seen by a pharmacist on discharge. This happens when the patient is discharged to another hospital ward. On this type of discharge no discharge letter with prescription is made and of this reason the patient does not necessarily get a

review by the pharmacist before discharge. Prescriptions for patients discharged on Sundays are not verified if not the day of discharge is planned in advance and therefore reviewed by a pharmacist before the weekend. All care issues where the treatment is to be reviewed by the pharmacist on discharge are therefore without an outcome and is not categorised. Other examples are situations where the drug in the care issue is discontinued before monitoring was done by the pharmacist and it does therefore not get any outcome.

The occurrence of '*Medication need inquiry*' within the category *Checks* (Table 16) is higher at the orthopaedic ward compared to the cardiology ward. Care issues found in this group are typically checks performed by the pharmacist to ensure that short term treatments as antibiotic courses, anti-emetics after operation and analgesics are either started or stopped during the hospital stay. A check done to ensure that the patient is started on DVT-prophylaxis after a major operation is also found in this category. This check will in the '*Time perspective*' categories be related to as a *verification check* for the new treatment started. The data in table 15 for '*Time perspective*' reveals that while the orthopaedic ward has a relative high number of checks that are confirmations, while no *confirmation checks* were found in the care issues from the cardiology. These confirmation checks are typically checks to assure that expected effect of treatment are achieved. For example that an effective antibiotic treatment is stopped or that the patient does not suffer from pain any more and therefore have no need for analgesics. These results can possibly be related to that antibiotic prophylaxis courses are more common among the patients at the orthopaedic.

From the results in subcategories within the '*Change in drug therapy process*' the differences in '*Clinical (shared) record of patient characteristic*' and '*Clinical (shared) record of drug history*' are commented below (Table 16). The cardiology has a higher prevalence of changes in '*Clinical (shared) record of patient characteristic*' compared to the orthopaedic ward where no such changes were found among the care issues identified (15.9% vs. 0%, $p=0.0002$). These changes are typically an up-date of the patient's allergy status. It is interesting that it was not found any care issues in this category among the care issues generated from the orthopaedic ward. One possible reason for this can be that for all of the elective admissions to the orthopaedic ward

the assessment of the patient including allergy updates is done at the pre-assessment clinic. Any up-dates done there will not be included as a care issue in this survey since all of it is performed outside the orthopaedic ward.

The finding of changes categorised into the subcategory '*Clinical (shared) record of drug history*' is relatively high in both wards but statistically significant higher at the orthopaedic ward compared to the cardiology ward (Table 16). The care issues in this category are related to changes made to drugs prescribed in error or missed out on admission. This result indicates that the pharmacist spend much of their time on the ward ensuring that the patients are prescribed all of their regular medicines with dosages and frequencies similar to what they usually are prescribed outside the hospital setting. It is worthy of note that for all the patients for elective admissions at the orthopaedic ward the drug history is taken by the pharmacist on the pre-assessment clinic. This means that the total number of changes in the '*Clinical (shared) record of drug history*' mainly relates to errors in the drug history taken for the emergency admissions and point out the need for a pharmacist taking drug history at the ward.

Changes in both of the above mentioned subcategories in '*Change in drug therapy process*' will be assigned a check for '*verification*' in the 'Time perspective'. Put together they can therefore explain the high portion at both wards of verifications in the '*Change in drug therapy process*' category (Table 15).

The results for the subcategories in '*Change in Drug Therapy*' are presented in table 16. For the cardiology ward the total number of care issues within this category is relatively small (n=42). The subcategory '*Stop drug temporarily/permanently*' constitutes more than half of the changes in drug therapy at this ward. The high prevalence of stop of treatment seen here can partly be explained by a problem caused by the electronic prescribing system; when a drug is intended to be stopped it is often only '*suspended*' by the doctors on the ward. This brings about many care issues where the pharmacist must ask the doctor to change the order from stop drug temporarily to stop drug permanently.

All the care issues categorised in '*Change in drug therapy*' will also be categorised into a '*Drug Therapy Problem*' (Table 17). The '*Drug Therapy Problem*' category reveals more of the reason for the change in the patient's therapy. Together these two categories fully describe what in the drug therapy that was changed and why it was changed. At the cardiology ward most of the '*Drug Therapy Problems*' are found to be '*Unnecessary drug therapy*' and most of the changes in drug therapy are therefore done due to this. For the orthopaedic ward most '*Drug Therapy Problems*' are found to be '*Need for additional drug therapy*'. The numbers of care issues related to not patient specific changes due to non-adherence with local formularies was very low, only one care issue found at the orthopaedic ward and no such issues at the cardiology. One explanation to these small numbers can be that the prescribers can choose medicines only included in the local formulary of the hospital when adding an order in the electronic prescribing system.

For all the subcategories within '*Change in drug therapy*', except for '*Patient or Carer Level of Education (Understanding/Compliance)*', the pharmacist must make a recommendation to the patient's prescriber, which must be carried out to make a change in the drug therapy. The distribution of these care issues within the '*Time perspective*' category is found in table 15 and gives information about at which stage in the patient's treatment cycle these recommendations were made. The '*Changes in drug therapy*' from the two wards show a similar distribution within the '*Time perspective*' category with most changes in '*verification*' followed by '*monitoring*' and '*confirmation*'. This can give a description of how the pharmacist works at the ward; most of the recommendations the pharmacist makes is done at the start of the treatment when he/she checks if the drug, dose, frequency, route of administration etc. and find that they are not appropriate or optimal for the patient. Further some changes are recommended during the treatment (for example if the patient's condition changes) and some changes are recommended because the expected effect of the treatment are achieved.

Only the care issues categorised as a '*Change in Drug Therapy*' (and '*Drug Therapy Problem*') are also given a quality assurance descriptor within the '*Degree of change*' (table 15). From the results most of the changes in the patients' drug therapy were described as '*adjustments*'. These changes are made within the treatment plan to

individualise the treatment to the patient and can for example be a change of dose according to the patient's weight or that aspirin prescribed to a patient with a history of gastrointestinal upset must be stopped. The results from the survey show that 'reviews' are seldom found among the changes (table 15). This can be explained by the relative short stays the patients have on the hospital where the patients presenting complaints are prioritised before a total re-assessment the patient's treatment.

Sometimes the change in the patient's treatment is made by the prescriber after a recommendation from the pharmacist. Of the total number of care issues 63% of those identified at the orthopaedic (ward and 21% of those identified at the cardiology ward included a recommendation from the pharmacist (table 18). The cases where the pharmacist makes a recommendation to a change that the prescriber does not carry out is categorised as a check. This data is not a part of the system as it is today and was gathered beside the other part of the categorisation system. These numbers can be a measurement of the degree the pharmacist has an influence on the patient's treatment.

5.4 Focus group

At the focus group consisting of clinical pharmacists, the projects academic supervisor and the investigators the modified version of the categorisation system for care issues was discussed. Results from the surveys the investigators had done were presented to give a better idea of how the system works in practice and to give a discussion around the modified parts of the categorisation system.

The participants of the focus group agreed that the categorisation system is partly difficult to comprehend. The intention for a categorisation system is that it should be easy to understand and use by pharmacists, who are the target group for the system. A language which describes the different activities the pharmacist performs within the pharmaceutical care must therefore be developed and used in practice. Some of the terms as '*verification*' and '*confirmation*' used in the system today can be difficult to differentiate and because they are terms that already exist to describe activities on the ward it makes the categorisation harder to understand. One of the participants

suggested that instead of using these terms for the subcategories within the '*Time perspective*' the related stage; design, delivery or evaluation to each check should be underlined.

The division of the change category was one of the major changes that were done by the investigators during the modification process. Some of the participants of the focus group stated that actions found in the subcategory '*Health team member information/education*' within the *Change in Drug Therapy Process* actually would be hard to characterise as a *change* in the process and that it rather *was* the drug therapy process. This comment emphasised the statement for the division of the change category that the investigators had from the start of, where the actions taken related to the process around the patient and the patient's treatment results in outcomes that are hard to determine. Care issues related to patient specific information on using medicines that the pharmacist gives to other health team members are an important contribution to the pharmaceutical care for the patient. Since using the word *change* to describe these subcategories can be confusing the suggestion from the participants to exchange it with *contribution* and end up with '*Contribution to drug therapy process*' and '*Change in drug therapy*', could make it clearer.

During the focus group especially two subcategories in '*Change in drug therapy*' and '*Drug therapy problem*' were discussed. In the results from the categorisation of the care issues generated from the survey the subcategory 'Duration' within 'Change in drug therapy' was not used once among any of the investigators. The need for this subcategory was therefore discussed on the focus group. No clear outcome of the question was obtained although it was suggested to include the duration as a part of the '*Stop drug temporarily/permanently*' category. The subcategory which the investigators had added to the Cipolle and Strands classification of *Drug Therapy Problem* was also discussed. This eighth category captures the issues related to cost effectiveness questions in the pharmaceutical care. It can be discussed whether this is a part of the drug therapy problems and it can be viewed in different ways related to it is a part of the '*Ineffective drug*'. However, it is a fact that cost related factors are important in the system and the pharmacist must take into consideration while

assessing the treatment of the patient. Therefore an own category for this type of care issues could be of valuable.

During the survey the investigators gathered data regarding two aspects of the pharmaceutical activity that were not captured in the modified categorisation system. This was information about care issues related to drug interactions and notification of the cases where a pharmacist makes a recommendation to the prescriber which is either acted upon or not. The numbers found on drug interaction related care issues were very small. The participants' comments to this part were that they saw this as one of other type of checks the pharmacist does all the time. The data regarding the pharmacist's recommendation on care issues were presented and some reactions on the use of the term recommendation were mistaken. Some of the participants didn't like the term '*recommendations from pharmacist not acted upon*' that was used. When a potential issue is discovered in a clinical setting the pharmacist always starts a dialog with the prescriber and in the discussion which follows the two parts agree on something that may not were the pharmacist's suggestion in the first part.

Another part of the system that the moderators wanted to get feedback on was the Quality Assurance Descriptors. In the section with the 'Time perspective' it was commented that the way the categorisation system was changed to describe both *Check* and *Change* in the *Time perspective* it was very far from the original system. This was thought to make it even more complicated for the other users of the system. For the part of the system with the '*Degree of change*' comments were made on that the number of reviews found were few. But the short stay for the patients was suggested as one reason for that another one could be that the pharmacists not usually have treatment plans and that the difficulties in knowing the goal for the treatment can lead to few reviews. The participants expressed difficulties in understanding the terms for this category as well.

In the end of the focus group all the parts of the categorisation system were summed up and in which way the system can be useful in practice. It was mentioned that pharmacists can use it to benchmark their practice and see what they have to work more on. Other opinions about the system were that the check and change part make a basis where he pharmaceutical care can be described.

5.5 Inter-rater reliability testing of the categorisation system

5.5.1 Inter-rater agreement within the Check, Change in Drug Therapy Process and Change in Drug Therapy

The strength of the agreement between the investigators in categorising care issues in either the 'Check', 'Change in Drug Therapy Process' or 'Change in Drug Therapy' categories is found to be 'highly good' on the scale of kappa values (table 22). In the test presented in table 23, where the subcategories for the same three groups were included, the strength of the agreement between the investigators was reduced to some degree due to that more differences in the choice of subcategory were revealed.

The investigator found this part of the categorisation system relative easy to use, but to get the same outcome between the raters it is necessarily important that the involved raters have understood the situation the care issue describes in the same way. If the situation described is quite complex or if the issue is not described specific enough it can lead to different assumptions of what actually happened in the situation. A care issue where the raters do not agree in whether it was a check or a change can for example appear when the pharmacist's action in this issue is understood different between the raters. If the change is understood as a result of a recommendation from the pharmacist it is categorised as a change, but if the investigator that the pharmacist only checked for that the change had been done it would fall into one of the check categories. In a same manner a care issue describing a change can be categorised differently into change in process and therapy due to if the situation described was got as a drug history clarification or not. Is the situation understood as it describes an error prescribed on admission this will be categorised as a change in '*Clinical (shared) record of drug history*' while if this is understood as a change made in the patients treatment during the stay this care issue will fall into one of the subcategories in Change in drug therapy.

The inter-rater reliability test revealed that the investigators had some unclearness around if a care issue classifies as a check for medication need or effect. These issues were often related to monitoring of duration of supplements, where one of

the investigators regarded the check for duration of the treatment in different ways. While one understood it as the pharmacist were checking for if the supplements were to be given any longer the other investigator understood the situation as if the pharmacist wanted to confirm that the supplements had given effect.

5.5.2 Inter-rater agreement in the categories verification, monitoring and confirmation

The inter-rater reliability between the two investigators was tested for the '*Time perspective*' of the *Quality Assurance Descriptors* (table 24). The overall agreement between the investigators for this group gave a kappa value $\kappa = 0.76$. The distribution of the disagreements among the raters shows that the difficulties in this part of the system lies in whether the care issue is a '*verification*' or '*monitoring*' and if it is a '*monitoring*' or '*confirmation*'. To be able to differentiate a verification from a monitoring the care issue must give the rater sufficient information whether this is the first time the pharmacist comes across the patient's treatment or not. It is obvious that the care issue is a verification if the it tells that the check for example is done on admission. The monitoring is happening if the pharmacist's action is done further out in the patient's treatment course.

5.5.3 Inter-rater agreement in the categories adjustment, modification and review

The result of the inter-rater reliability test of the part of the system '*Degree of Change*' resulted in the weakest agreement between the investigators (Table 25). The kappa value was estimated to be 0.44 which interprets as a 'moderate' agreement on the scale in table 21. The disagreements among the raters were found in the subcategories of 'modification' and 'adjustment'.

The subcategories in this part of the categorisation system shall describe the degree of change made in the patient's treatment. To be able to evaluate how big the change is you have to know something about the expectations for the treatment of the patient. This set a focus on the need for a treatment plan for the patient's condition. Since a treatment plan for the patient that includes a goal or desired

outcome in most cases is not known, it is more difficult to know how far the change differs from the expected course of the treatment. This was therefore the part of the system the investigator had to put most effort in to understand.

Only care issues categorised as a *Change in drug therapy* is further categorised in the *Quality Assurance Descriptors* 'adjustment', 'modification' and 'review'. Therefore, if the care issue is to be assigned to one of the categories within the *Degree of Change* it depends on where it is found in the check and change part of the system. This means that for all situations where one investigator categorise the care issue within the *Change in drug therapy* while the other investigator assign it to one of the categories *Check or Change in drug therapy process*, only the former care issue will be assigned a *Degree of Change* category. As a consequence of this disagreement these care issues can not be included in the inter-rater test of this last part of the system. Four of the care issues in the random sample for the inter-rater reliability test were categorised different between the raters as explained above and were therefore excluded from this test.

5.6 The future of a categorisation system for care issues

There is need for a categorisation system that can be used to describe the pharmaceutical work that is performed around in different care settings. To make it useful it is important that it describes all parts of the contributions a pharmacist make to the pharmaceutical care but that it at the same time not get too complex and difficult to understand.

The most difficult part with the categorisation system as it is today is the description of where the pharmacist is involved in the patient's treatment and to what extent this changes the patient's treatment. The section with the *Degree of Change* in the *Quality Assurance Descriptors* is a way of describing the changes in the patient's drug regimen that is not easy applicable in practice because of the lack of the same language. Both the comments from the focus group participants and the result from the inter-rater reliability test confirm this. However, it is a good starting point to use to characterise parts of the health care system. In the further development of the

system one of the most important actions that must be started on is to develop a language that clearly defines the activities that it is desirable to include in a system. These descriptions must be transferable to all clinical settings. Secondly, the pharmacists must learn the way of thinking of the patient's drug treatment as a cyclical process and the language describing it. If this is done the focus on having defined goals included in a treatment plan for the patients' disease may be increased.

6 Conclusion

Pharmaceutical care planning is well developed and has become a standard part of the pharmacist work in clinical settings in Scotland. The electronic recorded care plans that are made at the Ayr Hospital has the advantage compared to paper based care plans that they are more easily accessible and therefore facilitates the continuity between the pharmaceutical services within the hospital. However, there is a need to make the care issue documentation more complete and a care plan template where the pharmacist writes the care issues in a more structured way can make this possible.

The development of a care plan template within an electronic system can open up for implementation of other databases or document with relevant information for the pharmacists. Together with other functions this can make the care plan template to a complete documentation of the pharmaceutical care provided. Potentially this can act as a pharmaceutical care profile for the patient that follows the patient when he or she is transferred between different clinical settings. The challenge is to make these ideas become a reality.

The categorisation system as it is today is able to give data that describes which parts of the pharmaceutical care the clinical pharmacist makes a contribution to the patient's treatment. The results from the survey found differences between the two clinical settings evaluated in where the pharmacist spends their time delivering pharmaceutical care. The differences can among other things be explained by the diagnosis and treatment within the patient population. The survey results also visualised a problem caused by the electronic prescribing system.

The evaluation of the categorisation system found the system useful for pharmacists to benchmark their practice and in describing the activity of the pharmacist. It is a need for improving the language which describes all of the activities the pharmacist performs within the pharmaceutical care. By evolving the terms used in the *Quality Assurance Descriptors* these together with the check and changes can act as a useful descriptive tool for the activities in pharmaceutical care.

7 Appendices

- Appendix 1. Example of a patient free text electronic care plan and prescribed medicines in the electronic prescribing system**
- Appendix 2. Example of a patient template care plan**
- Appendix 3. Consent form used in the data gathering**
- Appendix 4. Patient paper profile used in the data gathering**
- Appendix 5. The existing guideline used at the University of Strathclyde**

Appendix 1. Example of a patient free text electronic care plan and prescribed medicines in the electronic prescribing system

Care plan

PC: Red, hot, swollen R ring finger (Excision boney swelling 4/52 ago) Had flucloxacillin from GP

PMH: Prev excision boney swelling R thumb Aug 07, IHD, PCI, OA

Meds: From PODs and confirmed with patient

Allergy: Morphine - breathlessness, sweats, shivery (pt described 100 patch changed every 3 days - sounds more like fentanyl)

Augmentin - D&V (OK with penicillin)

Bloods:

16/2 CRP 14, Hb 12.6, WCC 9.4, Pl 282, ESR 19 Pharm1 18/2

17/2 Ur 5.4, Cr 76, K 3.7 Pharm1 18/2

Issues:

*1. IV antibiotics - monitor route, duration and inflam markers Pharm1 18/2

*2. Analgesia. Admitted on DHC Continus 120mg bd and 60mg lunch. GP is aware above max daily dose. For OA hip. Advised to discuss with GP regular paracetamol and could perhaps cut out lunch dose DHC Cont. Annotate Discharge please. Pharm1 18/2

Print of the electronic prescribing system

The screenshot shows the 'Allergy Details' window in the dataPT 10.35 - M system. It displays a table of allergies and a detailed medication list for the period 16-Feb-2008 to 20-Feb-2008.

Allergy	Reaction	Recorded By	Date/Time
fentanyl	Breathing Difficulties	MISS MARION YOUNG	18-FEB-2008 11:05
clavulanic acid	GI Upset	MISS MARION YOUNG	18-FEB-2008 11:05

Status	Drug Name	Dose	Frequency	Route	Start Date/Time	Stop Date/Time	BNF
	PREMIQUE Tablets	1 Tablet	1x07 - ON...	Oral	18-Feb-2008 07:00		Endocri...
	FYBOGEL ORANGE Sachets	1 x Sachet	1x22 - ON...	Oral	18-Feb-2008 22:00		Gastro...
	MEBEVERINE 135 mg Tablets	135 mg	3x7/12/1...	Oral	17-Feb-2008 18:00		Gastro...
	RANITIDINE 150 mg Tablets	150 mg	2x - TWIC...	Oral	17-Feb-2008 07:00		Gastro...
	FLUCLOXACILLIN 500 mg Capsules	500 mg	4x - FOUR...	Oral	20-Feb-2008 13:00		Infections
	PENICILLIN V 250 mg Tablets	500 mg	4x - FOUR...	Oral	20-Feb-2008 13:00		Infections
As required (PRN) Medications							
	GLYCERYL TRINITRATE 400mcg pe...	1 Spray(s)	PRN	Subling...	18-Feb-2008 12:26		Cardiov...
	DIHYDROCODEINE 30 mg Tablets	30 mg	4x - FOUR...	Oral	16-Feb-2008 22:49	18-Feb-2008 12:24	Central...
Intermittent Infusions							
	BENZYLPENICILLIN 1200 mg Injection	1200 mg	STAT	Intrave...	16-Feb-2008 22:49	16-Feb-2008 22:49	Infections
		1200 mg	4x - FOUR...	Intrave...	17-Feb-2008 07:00	20-Feb-2008 11:03	Infections
		1000 mg	STAT	Intrave...	16-Feb-2008 22:50	16-Feb-2008 22:50	Infections
	FLUCLOXACILLIN 1 g Injection	1000 mg	4x - FOUR...	Intrave...	17-Feb-2008 07:00	20-Feb-2008 11:03	Infections
TTA Medications							

Appendix 2. Example of a patient template care plan

PHARMACEUTICAL CARE PLAN on day 4, discharge day

Review 20/2

Female, 65

Presenting Complaints

Red, hot, swollen R ring finger (Excision boney swelling 4 weeks ago)

P1, 18/2

Past Medical History

Prev excision boney swelling R thumb Aug 07, IHD, PCI, OA

P1, 18/2

Relevant Drug History

Had flucloxacillin from GP 4 weeks ago
--

P1, 18/2

Admission Medicines

Name, Form	Route specify if not oral	Dose	Frequency	Sign
Isosorbide mononitrate	MR tablet	60mg	od	P1, 18/2
Nicorandil		10mg	bd	
Propranolol		40mg	tid	
Ramipril		5mg	od	
Simvastatin		20mg	od	
Clopidogrel		75mg	od	
Glyceryl trinitrate	Sublingual spray	400mcg	prn	
Dihydrocodeine	MR	60 mg	od	
Dihydrocodeine	MR	120 mg	bd	
Mirtazapine	Orodispersible tablets	45mg	od	
Mebeverine		135mg	tid	
Lormetazepam		500mcg	od	
Fybogel orange	Granules in sachets		od	
Ranitidine		150mg	bd	
Premique			od	

OTC / Herbal / Homeopathic / Illicit substances

Add data <input type="checkbox"/>

Allergies

Medicine/Substance	Reaction	Sign
Augmentin	D&V (OK with penicillin)	P1,18/2
Morphine	Breathlessness, sweats, shivery (pt described 100 patch changed every 3 days - sounds more like fentanyl)	

Drug History

<input checked="" type="checkbox"/> Patient

<input checked="" type="checkbox"/> PODs
--

Sign

P1,18/2

Investigations							
Add data <input type="checkbox"/>							
Laboratory Results							
			Date	Date	Date	Date	Date
Test	Range	Units	16/2	17/2			
CRP	< 5	mg/L	14				
Hb	11.5-16.5	g/dl	12.6				
WCC	4 -11.5 x109	l-1	9.4				
PI	150-400 x 109	l-1	282				
ESR	1-9	mm/hr	19				
Ur	2.5-7.5	mmol/l		5.4			
Cr	50-80	mmol/l		76			
K	3.5-5.0	mmol/l		3.7			

Pharmaceutical Care Issues							
<input checked="" type="checkbox"/> Active <input type="checkbox"/> Inactive	Care issue/ Desired Outcome		Analgesia. Admitted on dihydrocodeine 120mg bd and 60mg lunch Ensure optimal analgesic treatment for OA hip.				Review date
	Action	P1,18/2	Dihydrocodeine 30mg tablets qid prn Verificarion withhold by pharmacist [data from the EPS]	P1,18/2	Doses and formulary changed		
		P1,18/2	Advised pt to take regular paracetamol and could perhaps cut out lunch dose dihydrocodeine	P1,18/2	Pt will discuss with GP		
		P1,18/2	Annotate discharge please				<input checked="" type="checkbox"/> Discharge
<input checked="" type="checkbox"/> Active <input type="checkbox"/> Inactive	Care issue/ Desired Outcome		IV antibiotics Monitor route, duration and inflammatory markers				Review date
	Action	P1,18/2	Monitor inflammatory markers	P1,18/2	CRP and ESR out of range		
<input type="checkbox"/> Active <input checked="" type="checkbox"/> Inactive	Care issue/ Desired Outcome		Citalopram prescribed in error on admission				Review date
	Action	P1,18/2	Citalopram 10mg od Verification withhold by pharmacist [data from the EPS]	P1,18/2	Citalopram stopped		

Comments:

- Laboratory tests is automatically updated and will be marked if out of range
- Review dates are not always given in the free text record. In the template the pharmacist will be reminded to choose number of days till a review should be done.
- The drug, dose and frequency will appear automatically in the action box when the pharmacist withholds the verifications of the drug in the electronic prescribing system

Appendix 4. Patient paper profile used in the data gathering

PATIENT PAPER PROFILE

PATIENT DETAILS			
Number		Sex	Age
Height N/A	Weight N/A	BMI N/A	Ability to self medicate
Allergies/Sensitivities		Type of reaction	
NKDA			
Social History			

PATIENT STAY		Presenting Complaints	Notes
Admitted/Transferred from			
Date of admission to ward			
Discharge Date(Planned)			
Discharge Date (actual)			
Discharged to			

RELEVANT MEDICAL HISTORY		RELEVANT DRUG HISTORY		
Date	Problem Description	Date	Medication	Comments

Drugs on admittance verified with	
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OTCs:

RELEVANT NON DRUG TREATMENT	
Treatment Description	Comments

CLINICAL MANAGEMENT	
Diagnosis	Pharmaceutical Need

#	Date and sign	Care Issue/ Desired Output	Date and sign	Action	Date and sign	Output

REVIEWS									
Review Dates (Planned)									
Review Dates (Actual)									

Appendix 5. The existing guideline used at the University of Strathclyde

PHARMACEUTICAL CARE ISSUE DEFINITIONS

Definitions of categories for recommended or implemented changes

Adjust - *Adjustment* is a change to the implementation of the treatment plan to individualise or optimise prescribing/administration/concordance. Adjustments occur as a result of monitoring actions.

Review - a prompted *review* leads to a medical review of the patient's treatment and their needs (due to inadequate response/unwanted drug effect/ change in a patient's needs).

Modify A *modification* is any change to the implementation of the treatment plan which is not an adjustment or review (including response to errors in prescribing/administration, non-compliance with local formulary /protocol/procedures).

Definitions of categories for recommended or implemented checks

Verify - a *verification* is a check to exclude an initial error in prescribing/conditions of administration.

Confirm - a *confirmation* is a written record of a patient/laboratory check that confirms medication has met expectations (in terms of defined goals for a given stage of treatment).

Monitor - *monitoring* is a periodic patient/laboratory check to ensure satisfactory implementation of the treatment plan and that further adjustment is not required.

Normally a single care issue would address a single drug therapy problem (DTP). In the case of a care issue seeming to address more than one DTP, then the care issue may best be resolved into multiple care issues. There are two exceptions to this that we are prepared to recognise as common examples

1. **Checks of Dosage (Verification or Monitoring)** to exclude both too high and too low a dose will need to have three DTP categories (DTP4, DTP5 and therefore DTP6). This can only be avoided by recognising such checks as TWO care issues; a check for safety of the dose (and therefore DTP 5 + DTP 6) and a check for effectiveness of the dose (DTP 4)
2. **Checks for dose-related unwanted drug effects (Monitoring)** will need to have two DTP categories (DTP5 and DTP6). This dual designation will carry an advantage in allowing the number of dose related ADRS (classed as DTP5 + DTP6) to be differentiated from non dose-related (DTP5 only).

3. **Drug history checks** are classified as addressing the prevention of Non-Compliance (DTP7) to acknowledge the fundamental purpose and so avoid many and various other inconsistent interpretations. The DTP code DTP7 is also used when a change is made that communicates the discontinuation of a drug during transfer of care.
4. **Where checks of dosage involve initial check (verification) of dose and further check (monitoring)**, for instance of plasma concentration or clinical effect, then the separation of the designation of the actions requires the recognition of two care issues.

Appendix 6. Guideline for categorisation of pharmaceutical care issues

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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 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.

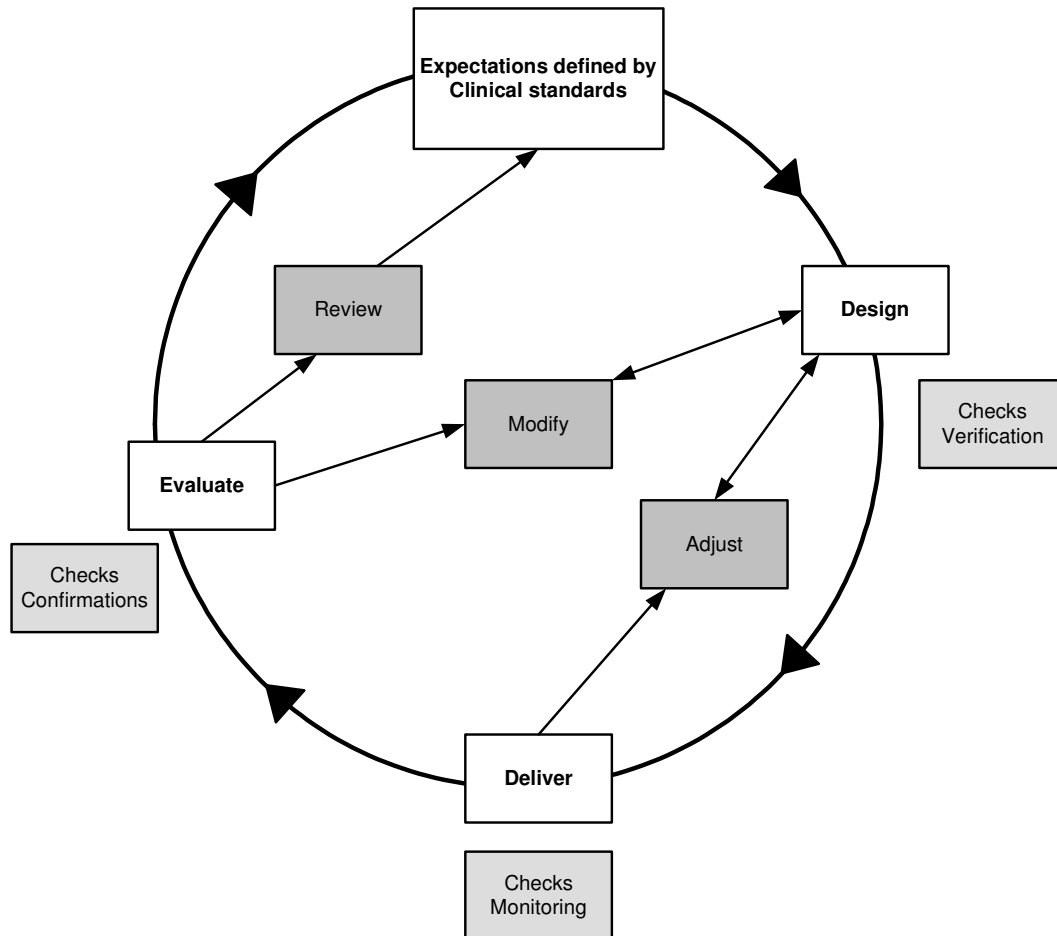


Figure 1 Pharmaceutical care model

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	VER	Checks at the start of the treatment to make sure that, for each medicine, the patient:
Verification of appropriateness of medications in the proposed treatment plan		<ul style="list-style-type: none"> - 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

<p>Monitoring</p> <p>Implementation of treatment is appropriate and checking for safety and effectiveness</p>	<p>MON</p>	<p>Checks as treatment continues which should ensure that, for each medicine, the patient:</p> <ul style="list-style-type: none"> - 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
<p>Confirmation</p> <p>Checking that medication is producing positive outcomes</p>	<p>CON</p>	<p>Confirmation and documentation to identify that medication is:</p> <ul style="list-style-type: none"> - 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 **Adjustment**. 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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