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

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Abstract

Background

There is a need for a common way of documenting and planning pharmaceutical care within the electronic prescribing system used at Ayr hospital.

Aims and objectives

Conduct a contents analysis of care issues in a formal survey of the care plans in order to categorise the issues, and propose a starting point for an electronic care plan template.

Methods

Documentation of pharmaceutical care and the distribution of care issues in two different settings were investigated in a prospective, clinical audit. A categorisation system was modified and guideline for this categorisation system was made, and documented care issues were subsequently subject to content analysis in the system. All results were evaluated in a focus group. A proposal for an electronic care plan template was made

Results

It was confirmed in a focus group meeting that the electronic care plan template had captured the needs set by the pharmacists at Ayr Hospital. The validity and usability of the different parts of the categorisation system differed. The content analysis of care issues between two wards at Ayr Hospital showed differences in the mean value of care issues per patient and also the type of care issues most commonly seen at the wards.

Conclusion

An electronic care plan template have great potentials. The categorisation system as a whole needs further development, since certain parts of it were ambiguous.

Abbreviations:

ACE inhibitor	Angiotensin Converting Enzyme inhibitor
ACS	Acute Coronary Syndrome
A/E	Accidents and emergencies unit
AF	Atrial Fibrillation
aPTT	Activated Partial Thromboplastin Time
BMI	Body Mass Index
BP	Blood Pressure
CI	Confidence interval
COPD	Chronic Obstructive Pulmonary Disease
CP	Chest Pain
DRP	Drug-Related Problem
DTP	Drug Therapy Problem
ECS	Electronic Care Summary
EPA	Electronic Prescribing and Administration
EPMA	Electronic Prescribing and Medicine Administration
EPS	Electronic Prescribing System
IDDM	Insulin Dependant Diabetes Mellitus
IQR	Inter Quartile Range
INR	International Normalised Ratio
LRTI	Lower respiratory tract infection
MM	Medicines Management
NKDA	No Known Drug Allergies
NSTEMI	Non-ST Elevated Myocardial Infarction
OTC	Over the counter medicines, non-prescription medicines
PCP	Pharmaceutical care plan
PIP	Pharmacist Independent Prescriber
PODs	Patient's own drugs
POE	Prescription Order Entry, an EPS/EPA system
PRN	Pro Re Nata = as required
PSP	Pharmacist Supplementary Prescriber
RF	Renal function

R/v	Review
SD	Standard Deviation
STEMI	ST Elevated Myocardial Infarction
TAH	The Ayr Hospital
TFTs	Thyroid Function Tests
TTA	To Take Away, Medicines prescribed for discharge
TID	Three times a day
U&E’s	Urea and electrolytes

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1 Introduction

1.1 Pharmaceutical care

Pharmaceutical care is defined by Hepler and Strand as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life”[1].

Pharmaceutical care is what the patient receives in terms of better drug therapy, and this is a result of what the whole medical team provides to the patient. The pharmacist is the health care worker who leads the pharmaceutical care provision, but i.e. doctors and nurses are involved in the delivery of this care.

1.1.1 Pharmaceutical care provided by the clinical pharmacist

Clinical pharmacy emerged in the US in mid 1960s[2] , and both hospital pharmacy and community pharmacy have changed a lot since then, along with the educational establishments. To day there are clinical study programmes in i.e. USA, Canada, Japan, Australia, Netherlands, Spain and the UK [2, 3]. In Europe the UK is well advanced with several universities offering masters degrees in clinical pharmacy and courses in pharmacist prescribing.

The pharmacist is a drug expert with broad knowledge on several aspects regarding medicines; like pharmacology, drug manufacturing, pharmacy practice, pharmaceutics, biochemistry, pharmacokinetics and medical microbiology. The pharmacists thus have unique competences and skills, and can contribute with new aspects regarding patient specific drug therapy, in addition to supporting already existing services. In the pharmaceutical care team the pharmacist is the only health professional that is an expert on medicaments. The education and experiences of pharmacists give them another perspective regarding drug use compared with doctors or nurses. Pharmaceutical care is a care practice on the same level as for instance nursing care and mental health care, and is therefore something more than a support service.

The pharmacy profession has altered with the emergence of clinical pharmacy, and "clinical pharmacy is a move away from the re-active quality control towards pro-active involvement in direct patient care and the anticipation of errors"[4]. The clinical pharmacist have a greater opportunity to anticipate potential drug therapy problems compared with the dispensing pharmacists, due to access to the patient's medical notes and the closer co-operation with the patient's care team. The pharmacist's expertise is therefore well utilised in a clinical setting. The clinical pharmacist's provision of pharmaceutical care can be described as a cyclic process where the patient's needs and treatment is reviewed continuously.

1.2 The pharmaceutical care plan

The pharmaceutical care plan is a tool the pharmacist uses when providing pharmaceutical care. The plan has two main functions; to facilitate that the patient is provided pharmaceutical care as needed, and to document what actions the pharmacist has undertaken to ensure the delivery of pharmaceutical care. A good care plan helps to deliver pharmaceutical care in a structured manner by giving the pharmacist an overview of which care issues that needs to be reviewed and which ones that already are sorted. A care plan should ideally include 3 main parts[5]:

1. A statement of the goals of the therapy/therapies
2. The actions the practitioner has identified as necessary to be undertaken to resolve any drug therapy problems, to meet the goals of therapy, and prevent drug therapy problems
3. A schedule for follow-up evaluation or a review of the care plan

More precisely the pharmaceutical care plan should contain the following information:

1) Patient characteristics
    a) Patient demographics
    b) Presenting complaints
    c) Past medical history
    d) Allergy status
    e) Relevant drug history

2) Current drug regimen
3) Relevant investigations
4) Care issues presented in an orderly manner which clearly states and documents:
    a) Desired outcome
    b) Actions needed to be undertaken or that already are undertaken
    c) Outcomes
    d) Review dates
5) The care issues should include plans for pharmaceutical care in the present setting and also for continuity of care between settings where this is relevant.
    a) Verification of present drug regime
    b) Monitoring of drug use and effects and side effects, need for further medication, general lab values
    c) A plan for discharge

A care plan made by a pharmacist that sees the patient over a longer time period, for instance in a primary care setting, will differ from a care plan made by a pharmacist that sees the patient in a interim setting, for instance at a hospital ward. The following section describes what an ideal care plan for use in a hospital setting should contain.

1.2.1 Use of patient demographics

The risk of acquiring different diseases changes with age, gender, lifestyle, body weight, social drug use, smoking, occupation and living situation. Recommended drug therapies also varies with these demographic parameters, and these patient specific information should therefore be noted in the pharmaceutical care plan, among others as this information is relevant when evaluating the patients drug therapy. Usually recommended dosing regimes are made based on the average patient who is male, 55 years old, weighs 70 kg and has a body surface area of 1.73 m^2.

Age: Absorption, metabolism and elimination changes with age. Factors that are important to bear in mind when assessing doses for elderly patients, are that renal

function decline with 1 percent after 20 years of age, and that it is estimated that liver function declines at a similar rate.

Gender: The body composition differs between men and women, with women having a higher percentage of adipose tissue than men, women also have a lower average height and thereby also a lower a body weight.

Height and weight: For lipophilic substances such as for instance benzodiazepines and theophylline, weight is generally a good measure for dosing, but for hydrophilic drugs which often are excreted unchanged by the kidneys, such as atenolol, doses should be estimated based on ideal weight and creatinine clearance. High dose cytostatics and certain drugs when they are used to treat children, needs to be dosed according to body surface area. Even though there are exceptions, a high BMI may indicate overweight or obesity, and should therefore be noted by the pharmacist. The pharmacist can give the patient advices regarding diet and exercise, or identify a need for the patient to be referred to a dietician.

Occupation: Some drugs should be used with caution in relation to some occupations; for instance shouldn't drugs that cause drowsiness be used when driving or operating heavy machinery, and a person that travels a lot should be aware of the regulations that applies to bringing prescribed medicines classified as narcotics out of the UK.

Living situation and compliance: It is relevant to know if a patient that needs help with administering their medicines within primary care, already has someone helping them with this, or if it should be arranged for continuity of care. Notes should also be made about the use of compliance aids such as blister packs and etc.

1.2.2 Presenting complaints and past medical history

This section should contain a short presentation of the reason for the hospitalisation. Sometimes a diagnosis is yet to be set when the pharmacist first sees the patient, and symptoms should then be presented in stead.

The patient's relevant medical history gives a broader understanding of the patient's clinical condition, and it is therefore important that the clinical pharmacist acquire this information. If the ward pharmacist only has limited time to spend on a patient, the focus for the pharmaceutical care provision will often be the presenting complaints, but nevertheless past medical history should always be reviewed as co-morbidities inevitably may affect the condition currently presented. These co-morbidities and the medications used to treat them may reveal pharmaceutical care issues of high clinical relevance, either seen separately or in connection to the presenting complaints.

1.2.3 Drug history

The complete current drug regimen is an essential section of the pharmaceutical care plan, and should either be incorporated in it or attached as an appendix. An important part of the pharmacists provision of pharmaceutical care is to clarify a correct drug history. A detailed and accurate drug history helps to prevent both that the patient is receiving inappropriate drugs, as well as it reduces the number of omitted drugs, both which may deteriorate the patient's condition. By taking an accurate drug history the pharmacist therefore helps to lower the number of errors in prescribing.

A prospective audit that compared junior doctor and pharmacists accuracy in taking drug history, found that junior doctors transcribed errors to 65% of their patients drug chart, while pharmacists transcribed errors to 5% of their patients charts.[6] The higher error rate for doctors was partly explained by an over reliance on the GP letters. A weakness with the survey design were that the pharmacists knew about the survey, while the doctors did not.

Table 1 Checks conducted when drugs on admittance and newly prescribed drugs are verified

- Discrepancies between patients drug regimen on admittance and transcribed drug regime
- Indication for drug therapy
- Right medicine
- Right dose of medicine
- Right dosing interval for the medicine
- Right dosing time
- Need for additional medicine due to transcription discrepancies/missed regularly used OTCs
- Unnecessary medicines
- Interactions with other prescribed drugs, OTCs and herbal medicine
- Contraindications

Table 2 Sources to confirm a patient's current drug regimen

- Patient
- Patient's relatives
- GP referral letter
- GP surgery
- Community pharmacy
- Previous discharge letter
- PODs brought in
- Medical notes
- Nursing home
- ECS (Electronic Care Summary) System

Speaking with the patient or the patient's relatives/closest care takers is of great value, since this will clarify which drugs the patient really used on admission. The patient's actual drug regimen may differ from the prescribed regimen, since the patient may be taking the drugs in another way than prescribed; either intentionally or

unconsciously. The pharmacist should therefore ideally interview every patient about their drug therapy by using open-ended questions, as this allows the patient to explain how and why each drug is used. If the patient have their own drugs (PODs) brought in with them, the patient can show the pharmacist how each of these are being used. As the patient may forget to mention inhalers, eye drops and injections and only list medicines in tablet form, the pharmacist should specifically ask if any such preparations are used. The patient may also omit to tell the pharmacist about herbal medicine or non-prescription medicines out of forgetfulness or because the patient don't think this information is relevant to the pharmacist.

If the pharmacist thinks it is helpful, an interview scheme can be used for taking drug history, as this may help the pharmacist remember to ask the patient all the relevant routine questions.

Table 3 Questions to clarify the patient's actual drug regimen

Do you use:

- All of the prescribed drugs?
- Any herbal/alternative medication?
- Any other drugs than those the doctor have prescribed for you?
- Any vitamins?
- Any inhalers, injections, topical ointments or eye drops?

The pharmacist should respect and understand the patients need for privacy, and ask their questions in a discreet way. In an outpatient clinic discretion may be ensured by interviewing the patient in a private room, but if the patient meeting is situated in a hospital environment, discretion may be harder to ensure as most inpatients share rooms. Obviously some patients may think that questions about i.e. illicit drug use, laxatives and contraceptives is taboo and therefore hesitate answering them, but a patient may as well feel that the treatment of their diabetes treatment or use of painkillers is a private matter as well, and the level of discretion should therefore always be as high as possible.

Questions about the patients compliance should be asked in a non-judgemental way, as it is important that the patients feel that they can be honest with the pharmacist. A question like “You do take all your medicines, right?”, is more leading than the question “Some patients think it is hard to remember to take all their medicine, do you sometimes feel this way?”. While the first questions tells the patients that the pharmacist expects them to answer that they always take all their medicines, the latter one opens up for the patient to feel more comfortable about telling the pharmacist about possible compliance problems.

Table 4 Questions to clarify compliance

- How do you take your medication?
- When do you take your medication?
- How often do you take your medication?
- How much of the drug do you take?
- Some patients think it is hard to remember to take all their medicine, do you sometimes feel this way?
- Have you experienced any adverse events?

By asking the patient these questions the pharmacist clarifies relevant drug history at the same time as the patient may reveal care issues regarding compliance, interactions between prescribed and herbal medicine or drug transcription discrepancies. Once the drugs on admission have been clarified, the pharmacist can begin to verify the drugs prescribed at the hospital.

A complete medication history will also contain information about social drug use; e.g. weekly alcohol consume and smoking status (never, ex-smoker or number of cigarettes per day). Excess alcohol can greatly affect the liver metabolism for a number of drugs, in addition to affecting the patient’s health in a number of ways.

Allergy status should always be determined when a patient is transferred between care settings, as the patient may have been exposed to new drugs and reacted to

these in between settings. The pharmacist should ask the patient to describe the adverse events experienced, as it is important to differentiate between allergies, sensitivities and pseudo allergies. If a patient is sensitive to a drug, this is important information because the drug can potentially be used again if necessary, while a drug the patient have experienced a severe allergic reaction to never can be administered again. If a condition later should appear where a drug is indicated that the patient is sensitive to, they should be included in an evaluation of the benefits of taking the drug compared to the risks. Where it is relevant notes can be made about drugs that have been used earlier and which effect they had. For patients treated for e.g. manic depressive disorder several medication regimens may have been used to treat the patient previously, and details about the patients experiences with these would therefore be relevant for the clinical pharmacist when evaluating the present medication regime.

1.2.4 Presenting care issues

The most important part of the pharmaceutical care plan is the section where the pharmaceutical care issues are presented. The issues should be presented in a concrete and concise manner, since this will make it clear what the patients care needs are.

A care issue expressed as a desired outcome should be defined as precisely as possible, together with one or more identified actions. When the pharmacist describes an action to be undertaken, notes should also be made to explain if the pharmacist will take responsibility for solving the issue their self, or if it needs to be referred to another member of the pharmaceutical care team, e.g. the medical practitioner. It is also natural in most cases to state when a possible outcome may be expected/checked for, and this makes the basis for setting the review date for the issue. On the next review date the outcomes should be documented for all those care issues where actions have been undertaken.

Table 5 Presentation of care issue in a care plan

Care issue/ Desired outcome	Action	Outcome	Review date

A scheme like this is used as a tool with the aid of helping the pharmacist to organise the care planning in a structured way. The idea behind splitting the issues into several parts is that this will make it easier for the pharmacist to see what the problem is and how it is planned to be addressed. The care plan has two functions, in addition to functioning as a tool for planning pharmaceutical care, it is the pharmacists primary documentation paper. The pharmacists should document their care giving to the same extent as doctors and nurses do, and the separate outcome box underlines the importance of this fact.

1.2.5 Investigations and monitoring

Monitoring is a cyclical process where the results from the monitoring determine the next step in the process of giving pharmaceutical care. An initial plan for management of the care issue is first made, where relevant indicators for monitoring should be specified. A good plan will include suggestions for management of probable scenarios and outcomes, and so the initial plan simply can be adjusted or modified according to changes in the patient's condition. If something unexpected happens the plan might need to be revised in order to meet the patient's new needs.

Table 6 Relevant indicators to check when monitoring

Indicators	Examples
Lab values	Renal function, K^+, FBC
Effect	CRP, fever, analgesic effect
Side effects	Platelets and dalteparin
Drug titrated up	ACE inhibitors, beta blockers
Drug titrated down	Steroids, opioids
Drug stopped	Antibiotics, steroid courses
Change of administration form	IV antibiotics to oral antibiotics

Table 6 (Cont) Relevant indicators to check when monitoring

Suspended drug started again	Furosemid and renal function
Suspended drug stopped	Bendroflumetiazide
Interactions	Theophylline and Erythromycine
Contraindications	ACEi and renal function

1.2.6 Transitional care planning

Continuity of care is how individual patients experience coordination and integration of services. Discharge and transfer between wards can be viewed as gaps in the continuity of the patient's care, that needs to be detected and bridged[7]. Transitional care is a term used to describe the efforts undertaken to bridge this gap, and has been defined as "a set of actions designed to ensure the co-ordination and continuity of health care as patients transfer between different locations or different levels of care in the same location"[8] . When transferring a patient between hospital wards or discharging the patient, this implies that there must be established good routines that ensure collaboration between health care workers, and that all relevant information is transferred along with the patient.

An early arrangement of continuity of care for discharge is important since the time for this can be difficult to plan. A discharge of an inpatient to primary care can be hastened by unexpected events; i.e. an other patients may have a greater need for the bed that the patient occupies, the patient may wish to leave on their own initiative and etc. Transfer of a patient between clinical settings may also be difficult to plan as a patient's conditions may deteriorate or improve in another rate then expected. Some discharges are planned to take place at times where practical arrangements may be more difficult to organize, for instance during weekends.

Before the patient leaves the hospital the patient should have been educated and have an understanding of how all the drugs works and how to take them. The National Prescribing Centre suggests in the guide "Modernising Medicines Management" that "services that enable patients to remain safe and independent in

their normal environment for as long as possible, may include improving patient education and awareness about medicines and/or support to carers"[9]. When the patient is discharged there may be a lot of things happening around the patient that can be distractive, in addition to that the fact that the patient gets to go home may be distractive in it self. Earlier during the hospital stay the patient will have more time to reflect on the information he/she gets, and if there are problems with understanding how to take the medication, the patient will have an opportunity to ask the ward staff about their medication use one more time.

In a randomised controlled trial investigating the effects of providing patient education combined with an adherence aid, the results showed substantial and sustained improvements in adherence as a long as this service was provided[10]. All the patients in the study were 65 years or older, lived independently and was taking at least four chronic medications daily. Some 91.5% of the patients had drug treated hypertension and 80.6% had drug treated hyperlipidaemia. There were 200 patients that entered the study and these were randomised into two groups; "usual care" or "intervention", consisting of pharmacist provided education and follow-up every 2 months, in addition to the supply of custom blister-packed medication. After a two month run-in phase baseline adherence, systolic blood pressure and LDL-cholesterol was measured. The measurements was repeated 6 month after intervention to both groups, and then again 6 months after the patients was randomised into "intervention" and "usual care" groups.

Table 7 Patient education study results [11]

	2 month run-in phase	**6 month intervention phase, both groups**	**6 month randomisation phase**	
			Intervention	**Usual care**
Medication adherence (%)	61.2 (SD 13.5)	96.9 (SD 5.2)	95,5 (SD 7.7)	69,1 (SD 16,4)
Systolic blood pressure (mmHg)	133.2 (SD 14.9)	129 (SD 16.0)	-6.9 (CI -10.7 to -3.1)	–1.0 (CI -5.9 to +3.9)
LDL-Cholesterol (mg/dl)	91.7 (SD 26.1)	86,8 (SD 23,4)	No differences	No differences

This study does not say what effect the patient counselling or the adherence aid alone would have had, but makes it clear that the two of them together both increases adherence and thereby increases therapy outcome. This illustrates that there is a clear connection between poor adherence and low health benefits of pharmacotherapy.

Another randomised study's conclusion confirmed these findings, stating that "A pharmacist intervention for outpatients with heart failure can improve adherence to cardiovascular medications and decrease health care use and costs, but the benefit probably requires constant intervention because the effect dissipates when the intervention ceases"[12]. In this study 314 low-income patients aged 50 or older was randomised into 9 months of multilevel intervention followed by a 3 months post-study phase, or "usual care" for 12 months. The patients in the intervention group were provided verbal and written instructions and were followed up every 2nd month. During the study period the pharmacists monitored medication use, health care encounters and body weight, and adherence was measured to be 78,8% in the intervention group versus 67,9% in the usual care group, but that this effect dissipated to respectively 70.6% and 66.7% after the intervention period. The researchers also found that emergency department visits and hospital admissions where 19.4% lower in the intervention group.

These two studies shows the importance of preparing the patients for discharge from hospital by giving them proper education about their drugs, but also highlights the great health benefits the patient can experience when it is arranged for continuity of their care within primary health care services.

The clinical pharmacist also has an important role in ensuring that the patient is prescribed the correct TTAs. A prospective cohort study published in 2003 reported that nearly 1/5 of patients experienced an adverse drug event (ADE) during transition from the hospital to home[13]. One third of these ADEs where evaluated to be preventable and another 1/3 to be ameliorable. The severities of these ADEs ranged from serious laboratory abnormalities to permanent disabilities, and were in part explained by ineffective communication between the ward staff and the GP as well as between ward staff and the patient. As a way of communicating better with the GP, it

was suggested that the discharge letter should contain specific information about what the follow-up physician needs to do, when they should do it, and what they should watch for.

A UK survey of discharge prescriptions reported in 2002 that junior medical staff members where responsible for preparing virtually all discharge prescriptions, and that these where checked against the ward prescription charts by pharmacists in 75% of UK Trusts[14]. Junior doctors are the least experienced of the medical practitioners when it comes to pharmacotherapy, and this may be one of the reasons why pharmacists write more accurate discharge prescriptions than doctors.

1.3 Medicines management

While pharmaceutical care is patient specific, medicines management (MM) applies to populations of patients as well as individuals. “Medicines Management encompasses all the activities that contribute to safe and rational medicines use, including strategic functions such as purchasing, formulary policy, risk management and many other roles of pharmacists and pharmacy technicians”[15].

“Medicines Management in hospitals encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed by to optimize the contribution that medicines makes to producing informed and desired outcomes of patient care”[4]. This means that the term medicines management includes a range of activities, from an individual medical review to a health promotion program. The superior emphasis for medicines management will anyhow be to optimise drug treatment for the individual patients, regardless of what the actions undertaken are.

The NHS groups Medicines Management services into 5 broad types[9, 16];

- *Clinical* MM is patient-centred and includes assessments, medicines monitoring and reviews of prescribing for individual patients.
- MM *systems and processes* are used to, for instance, implement clinical governance and national guidance and policies. The aim is to make the best out of available resources, and an example of this is improving repeat prescribing. An audit is a tool, which the NHS the recent years has encouraged the NHS boards and organisations to undertake with the aim of implementing new guidelines. Special boards such as the National Prescribing Centre and the National Institute for Clinical Excellence (NICE) and also the Royal Pharmaceutical Society of Great Britain have published a lot of material describing how different NHS organisations and services can undertake audits.
- *Health of the public* MM Services are aimed at improving the health of the population as a whole. Examples of such services are disease prevention strategies like low dose aspirin for secondary prevention of heart attack, and services that target specific groups like smoking cessation.
- *Continuity of care*. The NHS' supplying of medicines for 28 days after discharge from hospital and the use formularies and guidelines across different care settings are examples of efforts undertaken to ensure continuity of care.
- *Patients and their medicines*. Services may include improving patient education and awareness about medicines, provision of support for carers and repeat dispensing of prescriptions, which is convenient for both the patient and the GP.

1.4 Categorisation

In this project a triangularised categorisation system was used to quantify care issues. The categorisation system was based on theory on:

1. Drug Therapy Problems
2. Check and Changes
3. Quality Assurance Descriptors

1.4.1 Drug Therapy Problems

Drug Therapy Problems are defined as “any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy, and that interferes with achieving the desired goals of therapy.”[5]

Theory about Drug *Related* Problems (DRPs) were first presented by Strand et al. in 1990[17], but this terminology where later changed by Strand, Morley and Cipolle to Drug *Therapy* Problems (DTPs), as presented in the book “Pharmaceutical Care Practice – the Clinician’s Guide”[5]. The terminology and theory behind DTPs is well known in clinical pharmacy research environments, and the categorisation system is well tried out in practical use.

Drug Therapy Problems consists of 7 categories, and all of these are further divided into subcategories.

Table 8 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 single drug therapy
		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
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

Table 9 (Cont.) Categories and common causes of drug therapy problems

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
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 interaction reduces the amount of active drug available
		d	The duration of drug therapy is too short to produce the desired response
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 drug interaction causes an undesirable reaction that is not dose-related
		d	The dosage regimen was administered or changed too rapidly
		e	The drug product causes an allergic reaction
		f	The drug product is contraindicated due to risk factors
6	**Dosage too high**	a	Dose is too high
		b	The dosing frequency is too short
		c	The duration of drug therapy is too long
		d	A drug interaction occurs resulting in a toxic reaction to the drug product
		e	The dose of the drug was administered too rapidly
7	**Non-compliance**	a	The patient does not understand the instructions
		b	The patient prefers not to take the medication
		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

DTP categories describe both potential risks for the patient to develop medical conditions and actual events that the patient has experienced. A potential risk may be non-compliance, even though non-compliance is defined as a actual DTP, this DTP per se does not always lead to an event that deteriorate the patients health. For

instance if the patient have hypercholesterolemia but have problems remembering to take their daily simvastatin, this may or may not contribute to a subsequent development of a cardiovascular event. However, the repeated omission of doses inflicts a risk to the patient, and can therefore be identified as a DTP. In another scenarios the patient may present with urinary tract for which Nitrofurantion 50 mg x 3 for a week is started, but at the end of the week the patient's condition has not improved. The DTP in this scenario may for instance be non-compliance due to the drug product's emetic effect or that the medical condition is refractory to the drug product. Anyhow the DTP will describe the reason for an actual event that the patient is experiencing, namely that the medical condition that hasn't improved.

1.4.2 Check and Change

The theory on *Check* and *Change* is developed by Strand and McAnaw, and build on the Drug Therapy Problems. The *Check* category describes the checks the pharmacist undertakes in order to identify the DTPs, while the *changes* describes actions undertaken aiming to resolve the DTPs. The following table is presented in McAnaw's doctor thesis[18]:

Table 9 Pharmaceutical Care Issues and Drug Therapy Problems

Checks: ***Single inquiry, or Ongoing monitoring schedule***	**DTP:** ***Confirm or Exclude a DTP***	**Changes:** ***Modify inappropriateness***
		Patient behaviour:
Modification need inquiry	Additional medication needs Unnecessary medication use	Patient comprehension Patient agreement and participation
		Documentation (Patient Data Set):
Effectiveness inquiry	Ineffective drug prescribed Dose too low (sub-optimum)	History Continuity of care/information
		Treatment plan:
Safety inquiry	Adverse drug reaction Dose too high	Drug selection Daily (total) dose Route/dose form Dose interval/timing/duration
Compliance inquiry	Inappropriate compliance	Drug use precautions e.g. potential interactions

All drug therapy problems are identified through checks and investigations undertaken/initiated by the pharmacist or other members of the pharmaceutical care team, except for those issues that the patient without being asked present themselves.

The four categories of checks are directly linked to DTP categories[5], implying that a check of for instance safety, more precisely is a check for adverse drug reactions and/or too high dosage.

When a DTP is identified, one or more changes may be necessary to carry out in order to resolve it. For instance, if the patient experiences a severe adverse drug reaction, the drug needs to be stopped and the patients characteristics updated. If the patient have a compliance problem, education may be an suitable action in addition to changing the dose interval or route.

The check and the change categories have been used for categorisation previously. In a study on pharmaceutical care documentation at a cancer centre, 430 care issues was found in a sample of 171 patients[19]. Out of these 55% were checks and 44% were changes.

1.4.3 Quality Assurance Descriptors

Quality Assurance Descriptors (QA Descriptors) build on the “Check and Change” system, and describe the ongoing process of providing pharmaceutical care. The theory on QA Descriptors is developed at the University of Strathclyde by McAnaw and Hudson[3, 18].

This model explains how pharmaceutical care can be provided according to a therapeutic plan; “the provision of quality assurance relies on the documentation of in-process monitoring activity and checks in the assessment of the quality of the product (therapeutic plan)”[18].

Pharmaceutical care planning is here regarded as a cyclical process which can be described in a quality system feedback loop. The following figure[3] illustrates this quality system feedback loop.

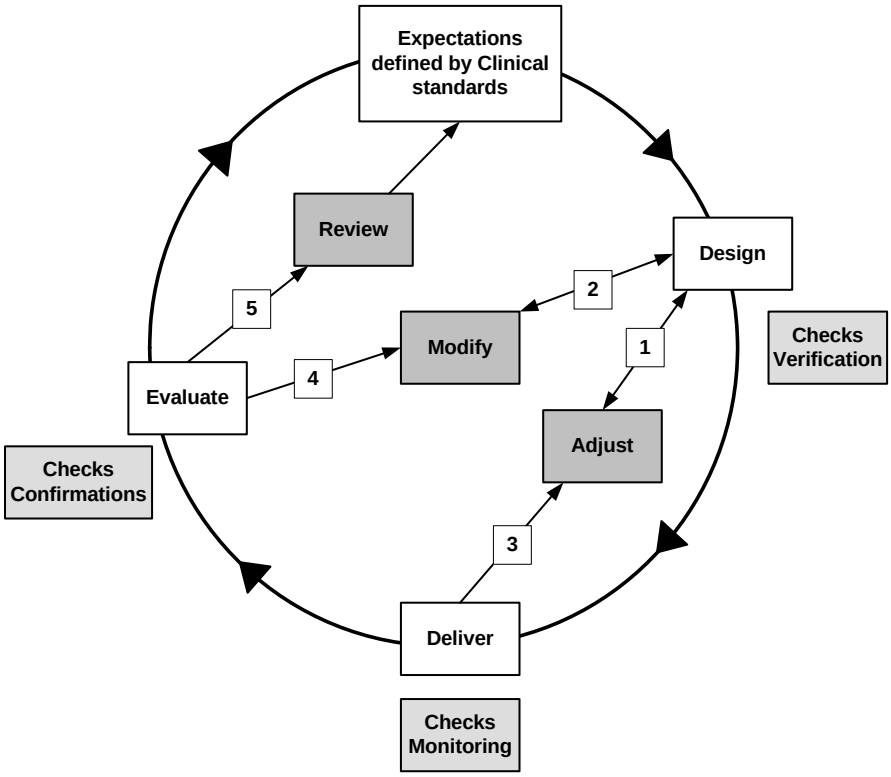

Figure 1 The Quality Assurance Feedback loop

Table 10 Explenations of the numbers in figure 1

Pharmaceutical Care Profile Distribution of Changes	
1	Modify an initial design
2	Adjust an initial design
3	Adjust during monitoring
4	Modify after evaluation
5	Review after evaluation

There are three degrees of changes that can be undertaken in the feedback loop[3]:

1. **Adjustment** is defined as a recommended change to the patients behaviour, treatment regimen or continuity of care that individualises pharmaceutical care within the agreed treatment plan
2. **Prompting a review** which is defined as a complete review of the initial treatment plan
3. **Modification** which is any recommended change other than adjustments and reviews.

When drug therapy is initiated and a treatment plan started, the pharmacist will undertake a number of checks in order to verify the prescribed drug regime. At the point of verification a need to adjust or modify the treatment plan may be identified. As the treatment continues, the delivery of the treatment plan will be monitored, and the plan may once again be subject to adjustments or modifications. An evaluation is done at the end of the treatment to confirm either that the predefined expectation have been met, or that the treatment have failed to meet them. A confirmation may result in a review or modification of the treatment. A pharmacist will be able to suggest changes that are adjustments and modifications alone, but will not be able to perform a review on their own; it can only be prompted by the pharmacist, and that is the reason why this category is called prompting review.

Table 11 Categorisation of checks according to quality system feedback loop[3]

Checks at the *Start* of Treatment	
Verification of appropriateness of medications in the proposed treatment plan	*Checks to make sure that for each medicine, the patient*: Is on the right medicine Is on the right dose Is not on unnecessary medication Doesn't have any new needs for additional medication Is not receiving a combination of interacting medicines Understands how to take their medication and what it will do to them

Table 14 (Cont.) Categorisation of checks according to quality system feedback loop[3]

Checks as treatment *continues*	
Monitoring implementation of treatment is appropriate and checking for safety and effectiveness	*Checks should ensure that, for each medicine, the patient*: Is on receiving medication as intended Continues to be on the most suitable dose Has no symptoms of unwanted (adverse) effects Understands how to take their medication
Checks after a period of a *Course* of Treatment	
Confirmation Checking that medication is producing positive outcomes	*Confirmation and documentation to identify that medication is*: Resulting in expected effects on the patient's condition Not failing to control condition Not producing unwanted effects requiring clinical review.

The checks in the QA Descriptor system are the same as those presented in section 1.4.2; Medication need, Effectiveness, Safety and Compliance.

Table 12 Categorisation of changes according to quality system feedback loop[3]

Changes recommended at the *Start* of Treatment	
Modification/ Adjustment of the proposed treatment plan	*Changes recommended to address initial inappropriateness to ensure the patient:* Is on appropriate medication Is on appropriate medication regimen Has all needs for medication addressed Has the necessary understanding of how to take their medication and what it will do to them

Table 13 Categorisation of changes according to quality system feedback loop[3]

As treatment *Continues*	
Modification/ Adjustment of the initial treatment plan	*Changes recommended should ensure that any necessary individualisation is implemented so that the patient have their*: Dose adjusted according to the treatment plan Medicine choice changed if it is a part of the initial treatment plan Education reinforced about their medication and their condition Continuity of care maintained
After a period of a *Course* of Treatment	
Prompting a review of the initial treatment plan	*Changes recommended as a result of a review of the treatment plan by the health care team:* Dose changes outside the initial treatment plan Choice of medication outside the initial treatment plan New requirements for patient monitoring outside the initial treatment plan to ensure safety/effectiveness

1.5 Electronic prescribing

The use of computer technology could significantly reduce the number of prescription errors, which cost the NHS £1/2 billion each year in longer stays in hospital[4]. From 2003-2006 the NHS prioritised £ 6.2 billions on the IT programme "Connecting for Health", and are with that encouraging hospitals to implement electronic prescribing and medicines administration systems (EPMA)[20]. The original deadline for implementing electronic prescribing and electronic patient records was 2005[21], but this process has halted.

1.5.1 Electronic prescribing at The Ayr Hospital

An electronic prescribing system has been established at the Ayr Hospital (TAH) since 1997. The electronic prescribing system used at TAH is called Prescription Order Entry (POE) and is a part of the hospitals electronic filing system delivered by JAC Computer Services Ltd (previously delivered by Pharmakon UK, both companies now owned by Mediware).

TAH is the only hospital in Scotland and one of few in the UK, which have a fully computerised electronic prescribing and medicines administration system (EPMA). A survey conducted in 188 UK hospitals in 2000 found that only 2% of the hospitals have full electronic prescribing facilities[22]. Today 5 hospitals in the UK use JAC's software for electronic prescribing and medication administering[23].

A study evaluating of the EPMA system used at TAH has shown that it is at least as safe or safer than the previous paper-based system [22, 24]. The study was conducted at TAH between February 1998 and July 1999, and evaluated the implementation of an EPA system at an orthopaedic ward with 36 beds. The study compared rates of prescribing errors for inpatient prescriptions and discharge prescriptions, and also rates for medication administration errors. Rates were measured when the existing paper-based prescribing system was used, one month after the implementation of the EPMA system, and 12 months after implementation.

Table 14 Frequency of prescribing and medication administration errors

	Prescribing errors								
	Inpatient prescriptions			Discharge prescriptions			Medication administration errors		
System	Numbers	%	95% CI	Numbers	%	95% CI	Numbers	%	95% CI
Existing paper-based system	166/2238	7.4	6.3,8.5	62/286	7.5	5.7,9.3	303/3364	9.0	8.0,10.0
1 month after implementation of EPMA	151/2153	7.0	5.9,8.1	49/634	7.7	5.6,9.8	198/3334	6.0	5.2,6.8
12 months after implementation of EPMA	95/2030	4.7	3.8,5.6	98/1658	5.9	4.8,7.0	153/2805	5.4	4.6,6.2

After the implementation of the EPA system, the inpatient prescribing error rate fell from 7.4% to 4.7% over 12 months ($p<0.001$). The discharge prescription error rate initially increased from 7.5% to 7.7% and then dropped to 5.9%, but these numbers were not significant. There was a reduction in administration errors, with a decrease from 9.0% to 5.4% over 12 months ($p<0.001$), but these numbers were biased since IV drugs and controlled drugs was not included.

TAH has been one of the pilot sites for use of electronic prescribing, and the system is now well established. Throughout the hospital wards laptops are connected to the EPMA system via a wireless internet connection. The laptops are attached to trolleys and are moved around by the medical team on the ward rounds, and this makes the EPMA system an electronic, portable drug chart. Even though the doctors can prescribe drugs through EPMA system from any location at the hospital, they tend not to. Most of the prescribing is still done during the ward rounds, based on decisions undertaken there. The medical records at TAH are paper based and located outside the patient rooms, and it is therefore convenient for the doctors to prescribe drugs at this site, also at other times than during the ward round.

Laptops are also attached to the drug trolleys, and the nurses therefore have access to EPMA at the bed site which facilitates that administration can be documented at the same time as it is done. It is important that drug administration is documented accurately with moment times, especially when blood samples for through and peak concentration are drawn, and when IV antibiotics are given. Easy access to EPMA ensures that prescribing and administering of drugs can be done and documented the same way as with paper based drug charts.

Laboratory results and X-rays are also available electronically within the filing system, while all other patient records and notes are paper based. Due to convenience, INR results and prescribed warfarin dosages, as well as monitoring of blood glucose levels and prescribed insulin dosages, dosing regimens for infusions and etc. are kept together with the nurses' paper notes.

1.5.2 Advantages and disadvantages with electronic prescribing systems

The main advantages with Electronic prescribing systems (EPS) are that they reduce medication and transcription error rate[25] due to elimination of illegible hand written prescriptions and interpretations of these. The EPS facilitates a more structured way of writing drug prescriptions, ensuring that dosing regimens and administration routes are clearly stated in addition to the drug name it self. However, when the prescriber writes the drug name into the EPS, available formularies and doses gets available for selection, which can lead to juxtaposition errors. For the prescriber it generally also takes longer time to write separate prescriptions in an EPS than on a paper chart, while functions like ordered prescribing sets saves time for the prescriber. Electronic prescribing and administration (EPA) systems also provide a full and accurate medication history for the patient in the clinical setting. With the introduction of electronic prescribing and medicines administration documentation it is also easier to identify doctors, nurses and pharmacists within the system. A pharmacist verification function within the prescription system helps to streamline the pharmacist's work in terms of the prescription verification process.

The new screen interface can lead to a loss of overview in the prescribing process, since the prescriber can't see the other drugs the patient is on when the prescribing window is open. At a paper chart it is possible to view the whole chart simultaneously, while the EPS can fragment information for drug regimens consisting of several drugs, due to a fixed interface size. The users of such systems therefore have to adapt to a new way of writing and reading information.

Electronic prescribing opens for the possibility of connecting a range of support services directly to the prescribing process, which further can reduce the error rates. A decision support system is pro-active and alerts the prescriber with pop-up boxes when drugs are prescribed. Like there are several EPA systems on the marked, there are several support systems, and these may include:

- drug-drug interactions checks
- drug class duplication checks

- allergy checks
- Information about cautions/contraindications
- Dose checking against patient parameters such as age and weight
- Formulary/prescribing status
- Monitoring warnings

A support system will also give access to updated monographs

Even though the alerts are intended to attain the prescriber's attention, their effect will be limited by the prescribers acceptance and willingness to use the system, alerts can be ignored. A survey of the clinical relevance of automated drug alerts among primary care providers, demonstrated a wide variance in the perceived usefulness of decision support systems. Generally the prescribers had the opinion that duplication alerts had low utility, while drug interaction alerts were perceived to have a high utility[26].
With electronic prescribing data are immediately available and the job of gathering prescription data for analysis and audits takes is simplified. Data gathered electronically will be reliable and of easy access, as long as ethical approval for their use is obtained.

Medication ordering errors are the largest identified source of preventable hospital medication errors[27]. While electronic prescribing reduces the rates of some errors, it also creates new types of errors; a study published in 2005 reported 22 new types of medication error risks[27]. There were two main types of errors:

1. Information errors generated by fragmentation of data and failure to integrate computer and information.
2. Flaws in the interface between human-machine, reflecting that a machine operates by rules that not can be manipulated.

The prescribing system used in this study is not the same as that used at TAH, and some of the faults found with the system in this study will not relate to POE which is used at TAH. Generally type 1 faults involved that hospital staff lacked adequate

information about the use of the EPS, or that the system was not practical for to use under all circumstances. Examples of type 2 faults are:

- Wrong patient selection
- Wrong medication selection
- Loss of data, time and focus when the prescribing system were non-functional due to computer crash or maintenance work

1.6 Clinical Setting

1.6.1 The medical cardiology ward

The medical cardiology ward at TAH has a capacity of maximum 24 patients and usually all bed sites are occupied, with 3-4 new patients entering the ward every day. The patients generally are admitted from primary care on planned admissions, or they are transferred from the coronary care unit or the medical receiving ward after emergency admissions to the hospital. This means that many of the patients at the medical cardiology ward already have a pharmaceutical care plan started for them when they transfer to the ward, and that the GPs prescriptions already are transcribed over to the EPMA system and verified by a pharmacist together with some of the drugs prescribed at the hospital.

There are one shared female and two shared male bed rooms with 6 beds each, and six single bed rooms at the ward, and this is reflecting that more men than women is admitted to the ward, and that more men than women suffers from cardiovascular diseases. The patients on the ward primarily have cardiac/cardiovascular disorders, however they will inevitably have other co-morbidities. If the pressure to accept patients at TAH is high, some of the patients at the ward may present with a wide range of other non-cardiovascular medical problems. Two pharmacists, MC and KW, work every other week at the cardiology ward. No pharmacists work at the ward on Saturdays or Sundays, but there is a clinical pharmacist on call on Saturday mornings that can be called by the ward if needed. Since the patients with the worst conditions

are admitted elsewhere, to the Coronary Care Unit, it rarely happens that there is a need for a pharmacist at the cardiology ward in the weekends.

1.6.3 The Coronary Care Unit

The Coronary Care Unit is a high care unit for patients with severe cardiac conditions. Patients are generally transferred to this unit from the accident and emergency unit after acute incidents, or from the medical cardiology ward after complications to their condition. One pharmacist, GJ, usually covers the ward during the weekdays and in addition an “on call pharmacist” can be contacted Saturday mornings. The unit has four single rooms and one double room, and the number of admitted patients varies from as low as two to six patients. As this is a high care unit patients will be transferred to another ward when their condition is improving, since this will make their bed site ready for another emergency patient.

1.7 Delivering pharmaceutical care at the medical cardiology ward and the Coronary Care Unit

A table over how much time the pharmacists at the medical cardiology ward spends on the pharmaceutical care processes can be found in appendix 1. Process maps showing the provision of pharmaceutical care can be found in section 1.8 *Process maps.*

For the pharmacist working at the Coronary Care Unit it is not a problem to have an overview of the patients admitted and their pharmaceutical needs, but at the medical cardiology ward where the patient number is higher the pharmacists need to plan how they best can spend their time. While all patients at the Coronary Care Unit generally needs to have their pharmaceutical care plans reviewed daily, some patients at the medical cardiology ward may need to be followed up less frequently. The pharmacists therefore have a system they use for identifying who patients they will see that day.

Every morning the pharmacist identifies patients newly admitted to the ward by looking at the daily bed state located at the ward, or by printing a list from the electronically available HIS System (Hospital Information Support System). The pharmacist will subsequently start the day by seeing all new patients and initiate a pharmaceutical care plan where this is needed.

From the electronic prescribing system another list that shows which patients' care plans that are to be reviewed can be printed, and the pharmacist will see through these patients clinical notes and provide them with pharmaceutical care during the day.

An issue generator program called "Crystal Reports" can be asked to find unverified orders, drugs that needs to be monitored like amino glycosides and digoxin and etc. The pharmacists will routinely check for unverified drugs, but rarely use the issue generator for other tasks at these wards. The pharmacist will by checking for unverified orders capture changes made to all patients drug treatment, and not only those that have a review date on that particular day.

The pharmacists at the medical cardiology ward don't attend the morning ward rounds, but still have good communication with the medical staff since they spend most of their available time at the ward. If the pharmacist wants to discuss a care issue with a member of the medical staff, a junior doctor will be first be contacted. If the issue doesn't get sorted by this and the pharmacist disagrees with the junior doctor, a senior doctor or the consultant at the ward will be contacted.

1.7.1 Taking drug history and medical history

A considerable part of the pharmacists' time are spent on ensuring a correct drug history. The pharmacists at the cardiology ward use 15 – 20 minutes per newly admitted patient on reviewing medical records, taking medication history, clarifying current drug regime and allergies and initiating the pharmaceutical care plan.

When a new patient is admitted or transferred to the medical cardiology ward or the Coronary Care Unit, the pharmacist first checks if a care plan already have been started for him/her. If a care plan is started this means that the patient already has been seen by another pharmacist, and that relevant drug- and medical history have been taken and that drugs on admittance have been verified.

If the patient hasn't been seen by a pharmacist yet, the pharmacist at the ward will first read the patient's medical notes to clarify relevant medical history. This gives the pharmacist an overview of the patient's medical condition and the indications for drug treatment. Once this is done the pharmacist begins to clarify the patient's current drug regime (drugs on admittance) and if the patient has any allergies. The pharmacist tries to get the drug history confirmed with more than one source if possible, but this isn't regarded as necessary if the pharmacist thinks that the patient has good knowledge about his/her drug regime. Patient's own drugs (PODs) are not used at the medical cardiology ward or the coronary care unit.

Since the patients' drug regimens are available together with the pharmaceutical care plan in the electronic prescribing system; POE, there is no need for the pharmacist to list dosing regimes for any drugs except insulin and warfarin and some drugs for infusion in the care plan. Even though dosing regimes generally not are listed in the pharmaceutical care plan, the pharmacist will list deviations of drugs on admittance, as a part of the documentation process when verifying drugs.

1.7.2 Transcription and verification

Clinical pharmacists that have their approval from the chief clinical pharmacist, are allowed to transcribe drugs prescribed by the patient's GP/doctors outside TAH. Both pharmacists and nurses are allowed to transcribe drugs in addition to doctors. To transcribe a drug means to make an exact copy of a prescription made by a doctor, and the transcribed prescription is therefore regarded as equally valid as a prescription issued at the hospital by one of the doctors there. By transcribing and verifying prescriptions such as these, unnecessary brakes in the patients medicinal treatment can be avoided, which ensures that the patient's pharmaceutical care is

continued at the hospital. Pharmacists are also allowed to transcribe prescriptions made in the patients medical notes on to the EPMA system, or transcribe changes in doses and etc according to the patients treatment plan. This means that the pharmacist can both start and stop drugs as long as it is documented in the patients medical notes that this should be done.

As a part of the prescribing quality and control system at TAH, the pharmacists are routinely verifying most drugs that are transcribed and newly prescribed, and the pharmacists spend 10–15 minutes per patient on doing this. The pharmacists will check the appropriateness of each drug regimens and evaluate if the drugs should be verified and/or transcribed to the hospitals electronic prescribing system (EPS).

If the pharmacist thinks that any prescriptions are inappropriate they will withhold the verification for it, or in severe cases suspend the drug. Since the pharmacists at the TAH aren't authorised to prescribe drugs, they principally can't suspend them either, but on rare occasions they nevertheless will do so if they think the drug can harm the patient and are unable to get a doctor to stop or suspend the drug. When a drug verification is withheld the reason for this will be documented in the pharmaceutical care plan by the clinical pharmacists, and the pharmacist will also discuss the reason for the withholding with a ward doctor to get it sorted.

While verifying the prescriptions, the pharmacist also evaluates the drug regime as a whole, and checks if any additional drugs should be transcribed/prescribed or if any drugs needs to be monitored and etc.

1.7.3 The pharmaceutical care plan in use at the present

The prescribing system in use at TAH, POE, have one big weakness, it does not contain a template for an electronic pharmaceutical care plan to be saved together with the prescribing data. The pharmacists in stead writes care plans in free text in an interface intentionally made for writing notes to the clinical pharmacist. The pharmacists could have used a paper based care plan with a structured template, but the pharmacy department have evaluated that the advantages with saving the care

plan electronically in POE, is greater than the disadvantages with working without a care plan template. An electronic care plan will never be lost and it will follow the patient between wards which helps to maintain the pharmaceutical care process.

When a new PCP is initiated the pharmacist presents the patient and his/hers medical condition by listing presenting complaints (PC), past medical history (PMH), drug history (DH), drug allergies and laboratory results. The pharmacists writes these same headlines every time a care plan is started, as a way of structuring and unifying the documentation process between them selves. They further systemise the care plan by marking outstanding care issues with a star, and then remove it when the issue have been sorted out. Examples of pharmaceutical care plans are attached in the appendix part.

1.7.4 Monitoring

The pharmacists at the medical cardiology ward uses 1-1 ½ hours per day on reviewing patients care plans and identifying new care issues where a care plan already have been started.

1.7.5 Discharge planning and continuity of care

The pharmacists at the medical cardiology ward uses 5 minutes per patient or 30 – 40 minutes per day on providing patient education, and 5 minutes per patient or 15 – 30 minutes per day on arranging for continuity of care.

1.7.6 The discharge process

When a patient is ready for discharge the doctor (usually a junior doctor) writes a discharge letter within the electronic prescribing system POE. The discharge letter includes a short résumé of the patient's presenting complaints and results from patient examinations, a list of changes to the drug regime with information to the GP

about dose titration, why drugs are stopped and etc. If the patient needs any drugs for discharge the doctor prescribes TTA drugs (To Take Away) together with the discharge letter in the EPMA system, and sends the letter electronically down to the dispensary. If the patient doesn't need any TTAs the discharge letter is faxed directly to the GP/primary care setting. When the doctor prescribes TTA drugs, a list with all the patient's active prescriptions will appear as a pop up for the doctor to make a selection from. The doctor can easily make changes to the patient's drug regime, and prescribe additional drugs or discontinue drugs that no longer are indicated. The list over active prescriptions will include PRN medication, suspended and withheld drugs, and this may be a source for errors since a tick at a suspended drug is all it takes to prescribe it in error for discharge. An advantage with this system is that it ensures that a specific drug is continued in the same formulation, dose and dosing interval as last prescribed at the hospital, which will give fewer errors as long as it is desired that the patient continues to use the drug the same way as it was last prescribed.

The pharmacists at the medical cardiology ward and the coronary care unit rarely verify TTAs or review the discharge letter, and the discharge process today is therefore not optimal. However, at the moment there is a project at the medical cardiology ward where the pharmacist writes the discharge letter and prescribes the TTA prescriptions. Since the clinical pharmacist at the ward knows the patient better than the pharmacists at the dispensary, the clinical pharmacist should ideally verify the drugs for discharge. The clinical pharmacist should also ideally review the discharge letter and check that all relevant information regarding changes in drug therapy and drug management is included in the letter. The clinical pharmacists in stead writes in the care plan what the pharmacist at the dispensary should check for regarding discharge. Since not all patients get TTAs, the discharge letter is not reviewed by a pharmacist for all patients. The clinical pharmacist writes information regarding discharge in the medical records if it is not feasible to speak with the doctor in person.

1.7.7 The dispensing pharmacists

When the patient needs drugs for discharge and the discharge letter containing TTA prescriptions is sent to the dispensary, the pharmacist here will verify this if it haven't

been done already. The pharmacist at the dispensary will then read both the discharge letter and the pharmaceutical care plan for the patient, and if the pharmacist doesn't think any changes needs to be made, the TTA drugs are dispensed according to the prescription. If minor interventions have to be made the pharmacist will simply document that the necessary changes are done on the paper print of the discharge letter, and dispense the drugs with interventions. For instance, according to a local policy no patients will ordinarily get PRN (as required) drugs like hypnotics to take home, and the dispensary will therefore not supply this for discharge. Since patients can get up to 28 days supply of TTA drugs at the hospitals charge, the POE will suggest that all drugs are prescribed for 28 days. The pharmacist therefore often changes antibiotics, steroids and other short term courses according to information from the discharge letter or the pharmaceutical care plan. If the patient uses a blister pack at home, one week of medication will be supplied. Minor changes like these will not be documented in the care plan.

If anything regarding the TTA prescriptions is unclear or if the pharmacist thinks that greater changes needs to be made to the prescription, the discharge doctor will be called and the issue discussed. If the issue is complex the clinical pharmacist may be called and asked to contact the discharge doctor, since the clinical pharmacist have greater knowledge of the patient's case and also more time to sort out care issues. If the doctor is contacted, this usually will be noted in the pharmaceutical care plan as well as on the paper print of the discharge letter. With today's discharge process the pharmacists at the dispensary do most of the quality assurance of the TTA and the discharge letter from the coronary care unit and the medical cardiology ward.

1.8 Process Maps

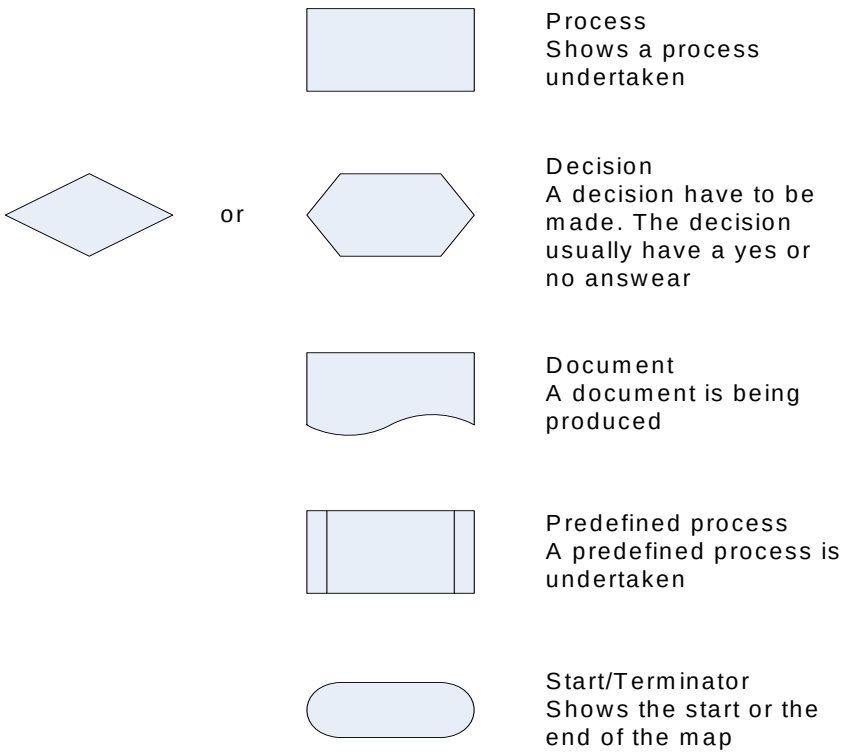

Figure 2 Symbols used in process maps

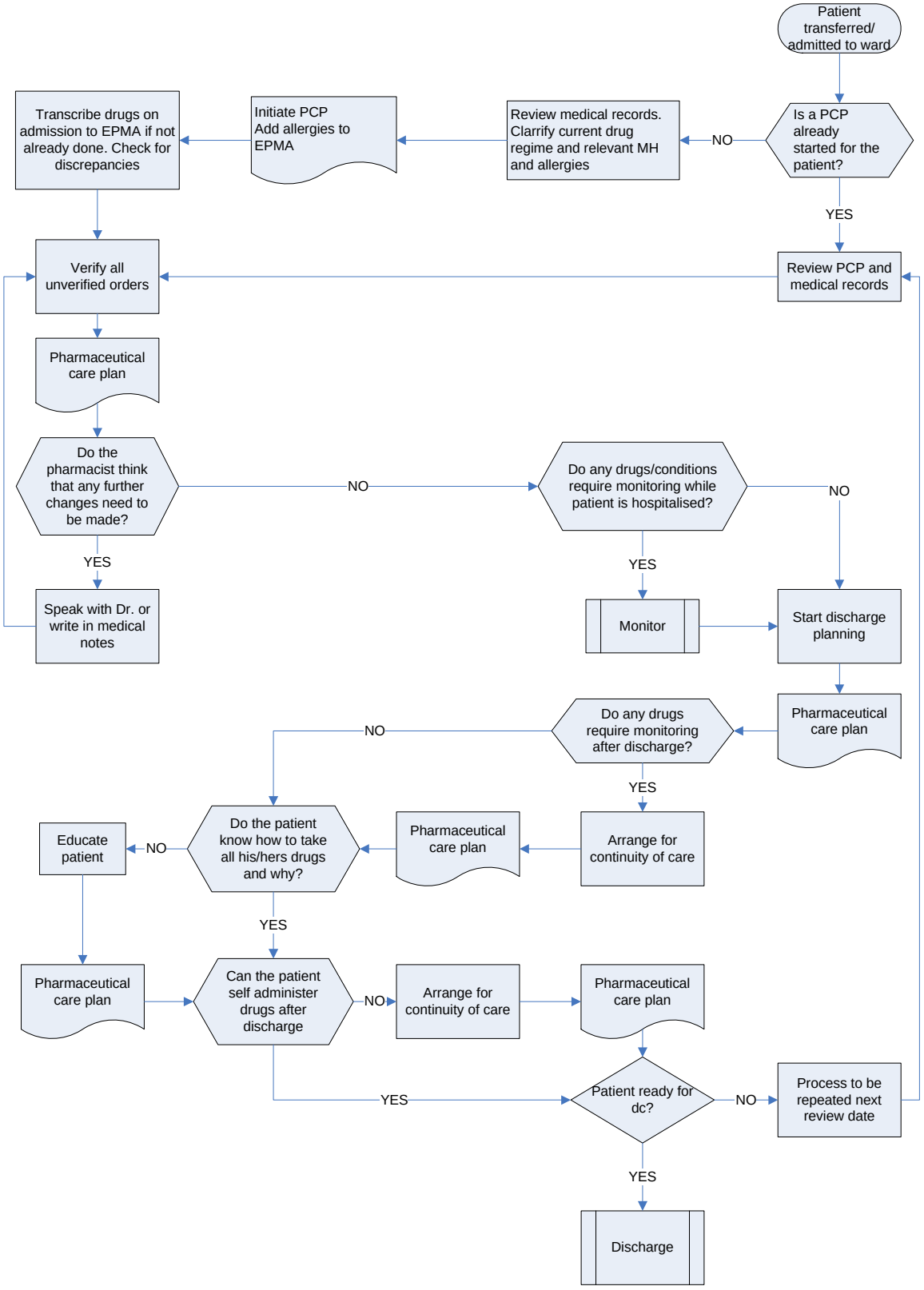

Figure 3 Process map over pharmaceutical care at the medical cardiology ward and coronary care unit

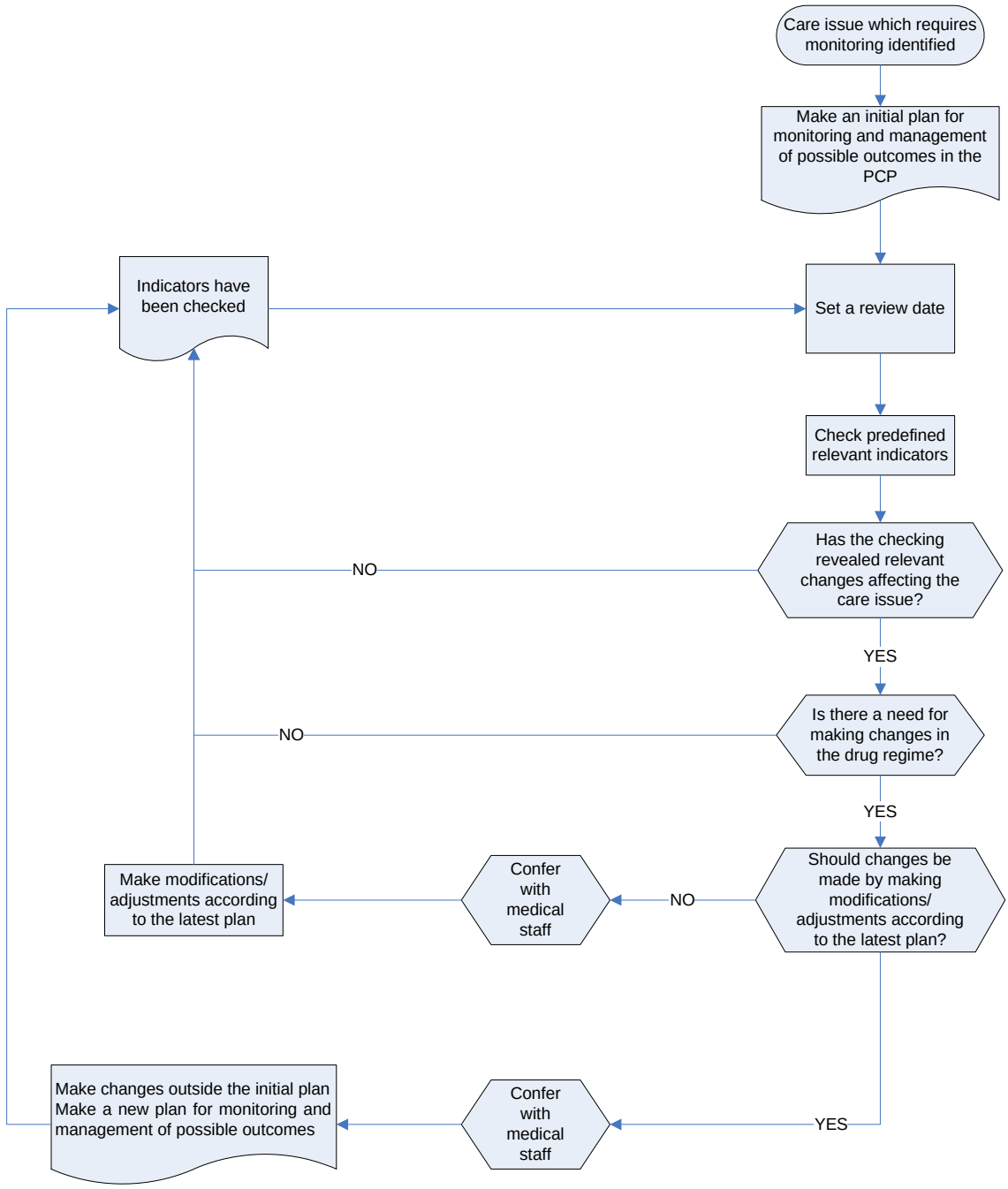

Figure 4 Monitoring as a part of pharmaceutical care at the medical cardiology ward and coronary care unit

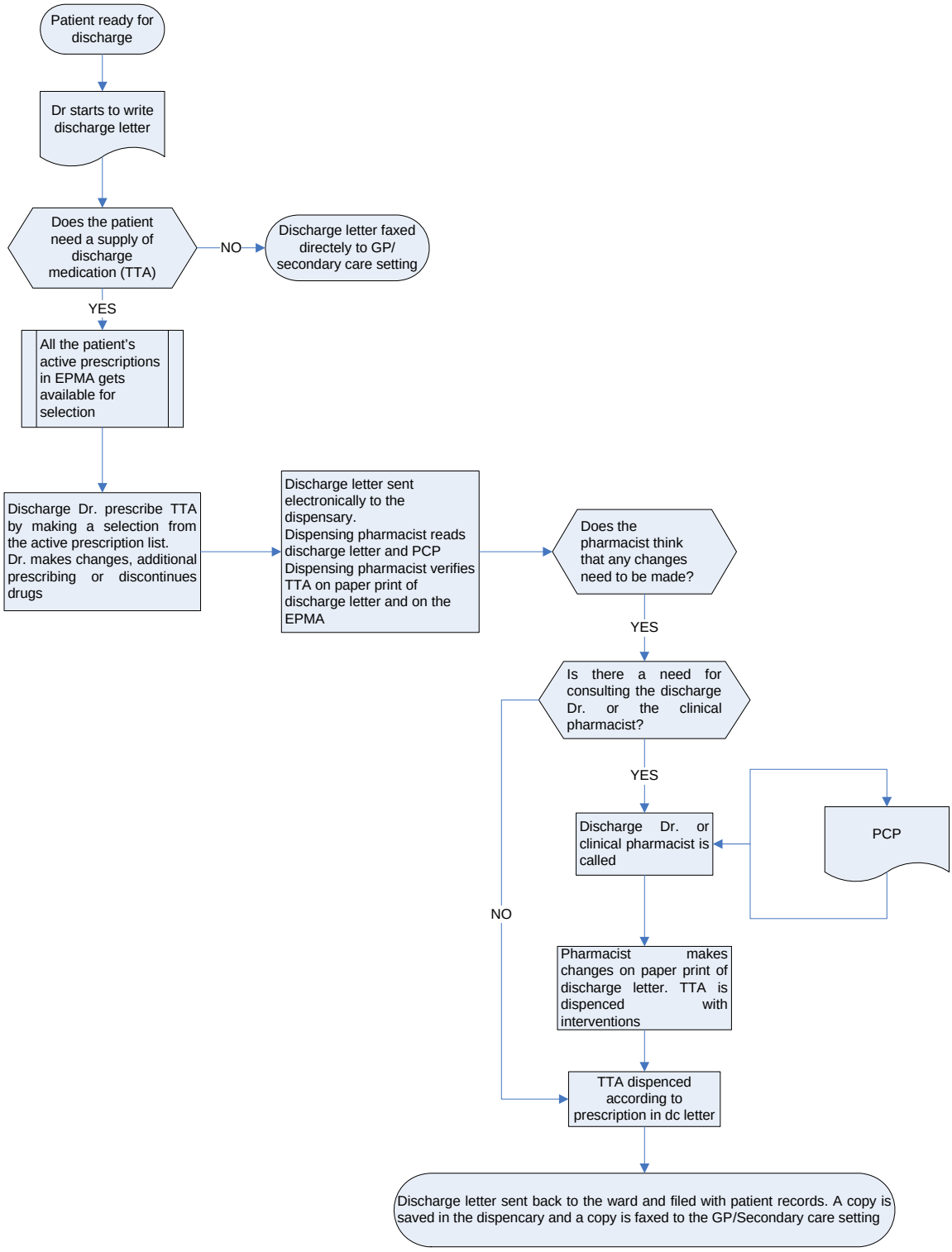

Figure 5 Process discharge map at the medical cardiology ward and coronary care unit

1.9 Non-medical prescribing

Many of the clinical pharmacists that work at the Ayr Hospital today are trained and registered with the Royal Pharmaceutical Society of Great Britain (RPSGB) as supplementary prescribers. However, the local policy at TAH says that the pharmacists only can practice their supplementary prescribing at the hospital's clinics, and not at the wards. There are no plans to change this policy in the near future, but if or when the policy opens for pharmacist supplementary prescribing at the wards, it is essential to have a good routines for documenting this practice.

It was the Health and Social Care Act of 2001 that opened for pharmacist prescribing[28], and the first pharmacist supplementary prescriber (PSP) in the UK started prescribing in March 2004[29], while the first pharmacist independent prescriber (PIP) started in 2007[30]. In May 2007 there were 34 supplementary training programmes accredited by the society in the UK, whereby two of these where in Scotland[31]. It is a local decision to train pharmacist prescribers, and where this is considered it is recommended by the RPSGB that in advance there is established a prescribing partnership with a medical practitioner, and that the pharmacist have at least two years of appropriate patient oriented experience. To become a pharmacist independent prescriber the pharmacist can take either a conversion course that takes the supplementary course a step further, or an independent prescriber programme, which last the equivalent of 28 days over three to six months.

A pharmacist supplementary prescriber can prescribe licensed, unlicensed and controlled drugs after a written treatment plan agreed upon by the medical prescriber, the pharmacist and the patient. A PIP can only prescribe licensed drugs independently, but since PIP also can prescribe supplementary through an established prescribing partnership, unlicensed and controlled drugs can be prescribed where there is a written treatment plan regarding these drugs.

Together with Patient Group Directions and Over the counter sales there are now 4 major routes by which the pharmacist and other medical and non-medical prescribers

can supply a patient with drugs. For each of these routes it applies that they should only be used where the benefit to the patients are clear[32]:

- Improved patient convenience
- Increased equality
- Maximised use of scarce resources and flexibility of workforce
- Increased quality of care
- Value for money
- Reduced waste

1.10 Qualitative research

Qualitative research describes how and/or why something is done. In descriptive surveys the aim is to communicate to outsiders an accurate and detailed process or action, but also why a process is done in the observed manner. Later on observations from the survey can be used to evaluate how things can be done in another way. The researcher will take different approaches in a quantitative survey and a qualitative one. Once the survey instruments have been developed in a quantitative survey, the data collection, processing and analysis will become to some extent administrative tasks. In qualitative surveys however, the researcher must remain sensitive to the responders' viewpoints and be prepared to consider new issues and ask questions throughout data collection and analysis [33].

1.10.1 Clinical audit

An audit is defined by the Royal Pharmaceutical Society as "Improving the care of patients by looking at what you are doing, learning from it and, if necessary, changing practice" [34].

Hence an audit is a part of health care workers quality assurance. A clinical audit is a systematic approach aiming to optimise a process or a treatment, and must not be

mistaken as research where a hypothesis will be tested. A thematic review of a particular part of patients' medical treatment will be undertaken, for instance how well discharge information about a patient's medication is transferred to the community pharmacist, or the pharmacist's role in smoking cessation. In this clinical audit the pharmacist documentation of pharmaceutical care is evaluated.

1.10.2 Action research

The action research approach used in this project consisted of an audit design cycle and an evaluation and validation of data in a focus group meeting. An audit design is a cyclical process, consisting of reviewing and monitoring current practice and evaluation against agreed predefined standards [33]. This cyclical design allows service evaluation to be done continuously through the survey, and describes how pharmaceutical care is provided at the same time as it aims to improve it.

Focus groups are a qualitative research tool used to ensure content validity in descriptive studies. They are employed to make sure that all factors regarded as important by the population (here the pharmacists at the Ayr Hospital) are taken into consideration, and not just the ones discovered by the investigator. A focus group can correct and supplement the information and the comprehensions the investigator have, and strengthen the validity of the content in this manner.

A facilitator or moderator will lead the focus groups and aim to ensure that all topics agreed upon prior to the focus group meeting are discussed. The facilitator should also encourage that all the group members participate in the discussion, by giving the participants enough time to discuss each topic adequately, and by asking open questions that invite members to contribute with their view on the topic. If all the participants have felt that they have been able to express their opinions and that they have been heard, the focus group as a research tool can be regarded as valid. Ideally the participants will be given time before the focus group to reflect on the agreed topics, and one or more group meetings before the focus group will also contribute to increased validity for the findings in the final focus group.

A co-facilitator will be responsible for recording who states what in the group, as it is important the be aware of any group member(s) that may have been dominating the others through out the discussion. Dominant participants may lead to bias of the conclusions made by the focus group, as the content and findings should reflect the hole group’s view points. The group discussion should be tape recorded, in order to ensure that all important viewpoints are documented.

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

Review the literature on cardiology, 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.

To describe the operational delivery of the clinical service using a process map that is validated by pharmacists involved in care delivery.

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.

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

Test utility and validity of the modified system.

Conduct a content analysis in a formal survey of the care plans in order to categorise the care issues.

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

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.

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

3 Methods

The project was designed as a prospective, clinical audit of documentation of pharmaceutical care and the distribution of care issues in two different settings. The investigator and a co-investigator gathered data from one setting each by using an action research approach. All patients that received pharmaceutical care during the inclusion period in the two populations, were asked to give consent for the use of their medical notes. Patients that were unable to or declined to give their consent were excluded from the project.

A guideline for a categorisation system was developed, and the data was subsequently subject to content analysis by this categorisation system. All results were evaluated in a focus group.

3.1 Pilot phase

The investigator trained on making standardised care plans in the period from October to December 2007, together with co-investigator MRR based at the orthopaedic ward at TAH. The investigators together made 28 pharmaceutical care plans from the cardiology ward and the orthopaedic ward, and then 2 care plans alone for the same two patients, one in each setting, in order to check if the data gathering process was performed in the same way. At the cardiology ward the investigators worked alongside the pharmacists MC and KW, and at the orthopaedic ward alongside pharmacist SMCK.

A need for the development of a guideline for categorisation of care issues was identified when the investigators trained on categorising the care issues from the 30 care plans. There was limited and relatively unspecific information available about the triangularised categorisation system used by previous students at the University of Strathclyde. The categorisation system the investigators were presented to is added as appendix 2. The investigators tried out this categorisation system in the beginning of the training period, but thought that it was difficult to comprehend and a decision to make a guideline was therefore made.

During this period the investigator also observed how pharmaceutical care was delivered in:

- Medical receiving ward
- Medical cardiology ward
- Orthopaedic ward
- Orthopaedic pre-op ward
- Dispensary

Based on observations from the medical cardiology ward drafts for process maps were made in Microsoft Visio ®. These maps were later altered based on feedback and verified to be valid for both the medical cardiology ward and the coronary care unit, by pharmacists MC and KW at the medical cardiology ward and GJ at the coronary care unit. The process maps are included in the introduction part of the project paper.

3.2 Ethical approval

An application for ethical approval of the survey was sent to Ayrshire and Arran Health Board Ethics Committee. The committee considered the application together with the project protocol, the consent form and the patient information sheet, and approved the survey late in January 2008.

The consent form and the patient information sheet were developed at the pharmacy department at the Ayr Hospital. The form was filed together with the patient's medical notes, and the patient got to keep a copy of it together with the patient information sheet. A second copy of the consent form was filed together with the researchers notes. The patient information sheet contained a short presentation of the project and the investigators and informed the patients about the practical consequences of giving consent.

The investigator personally asked all the newly admitted patients for consent to inclusion, and all patients were given verbal and written information about the project

by the investigator. The patients were given time to read the patient information sheet and urged to ask questions if they had any, before signing the consent form. If a patient didn't want to be included in the survey, this was respected and the patient was thanked for taking the time talking with the investigator.

3.3 Inclusion of patients

During the inclusion period all patients that were admitted/transferred to the two wards and who received pharmaceutical care, were invited to participate in the survey. Patients with dementia or confusion documented in their medical notes or nurses notes were assessed as unable to give consent, and were therefore not asked to take part in the survey. In some cases the state of confusion improved during the hospital stay, and the patient were then asked to participate after the confusion had ceased. For one patient with dementia a relative signed the consent form, but otherwise this group of patients were excluded.

3.4 Use of a care plan template for data gathering

It was necessary for the investigator and the co-investigator to gather data in a common way, and a care plan template was therefore used. A standardised care plan template was custom made with elements from several templates developed at the University of Strathclyde. The investigator and the co-investigator developed the care plan template together, and both used it for the data gathering.

The issue section of the care plan arranged for a common way of presenting the care issues among the investigators. In the care plans produced by the clinical pharmacist, the course of processes might be diffuse, several issues were often written together as one, and key information for categorising was sometimes missing. The investigator therefore invested a lot of time in rewriting all the care plans. This had to be done since a precise way of stating desired outcome, action and outcome was crucial when the issues later were subjects for content analysis. The template also contained a section for noting patient demographics, important for the subsequent comparison of

the two populations. The NICE guideline on harmful drinking was used to categorise alcohol consumption. This guideline defines "at-risk drinking" for women as 3 units of alcohol per day, and as 5 units per day for men[35].

The template used for the data gathering also served as a starting point for finding a template that could be used in an electronic prescribing system.

An example of a free text care plan as it was written in the electronic prescribing system and data presented in the care plan template used for the data gathering can be found in appendices 3 and 4

3.5 Data gathering

The initial aim was to include 120-150 patients from the medical cardiology ward at the Ayr Hospital during a recruitment period of maximum 8 weeks, starting in January 2008. However, the approval from the ethical committee at the Ayr Hospital came through later than expected and so the recruitment started first in February. After the first week the investigator at the medical cardiology ward only had managed to include 3 out of 7 patients, and then the ward was closed for the next 8 days due to an outbreak of a gastroenteritis endemic caused by a norovirus. Due to these unexpected events, a decision was made to also include patients from the coronary care unit into the survey. In the result part the two wards will be analysed as if they were one ward.

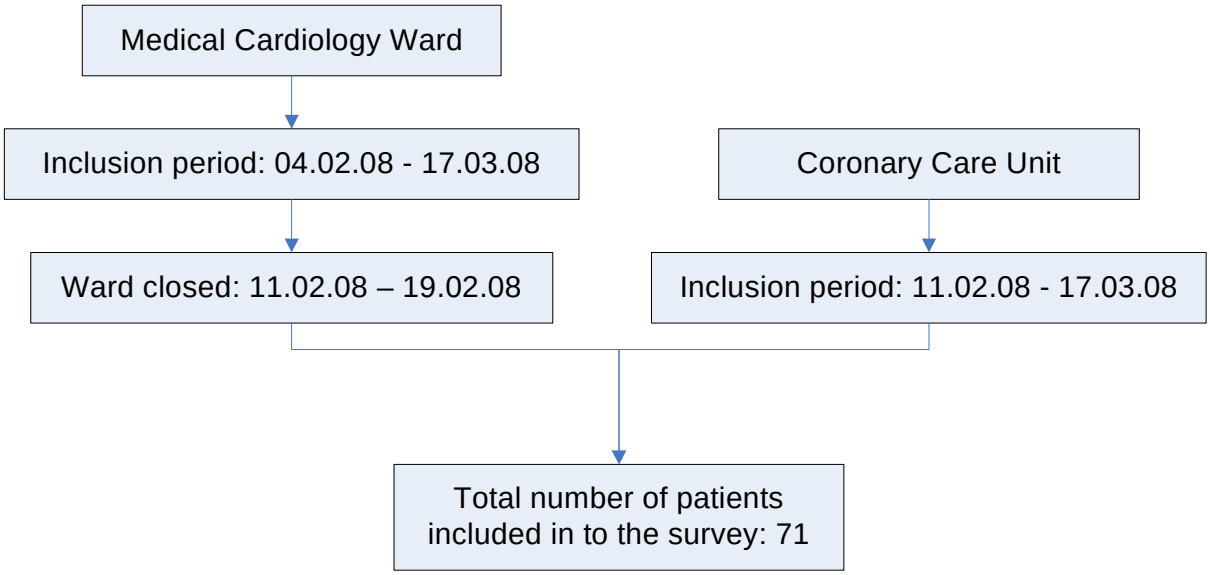

Figure 6 Number of patients included at the cardiology ward

The included patients were followed prospectively from admission to the wards till discharge or transfer to another ward. Patients that were admitted to the wards during the inclusion period were identified through the daily bed state at the wards and the electronic prescribing system. The investigator kept track of how many patients that were admitted to the wards during the period, how many of them that were provided with pharmaceutical care, and the reasons why patients that had received pharmaceutical care were not included. The patients' data were made anonym and coded, so that it was possible for the investigator to identify the patients when gathering clinical relevant information.

Standardised care plans were made by the investigator for all of the 71 included patients during the prospective monitoring of the pharmaceutical provision. These care plans were made based on:

- Pharmacist authors' free text notes within the electronic prescribing system
- Interviews with the pharmacist authors with reviews of the paper profiles when necessary to verify the accuracy of the description of care delivered
- The prescription data on the electronic prescribing system
- Medical notes
- Nurses' notes
- Discharge letter

With the above specified approach the investigator hoped to overcome gaps in the free text electronic records, and so document the care delivered in a precise manner. The action research approach was used during the survey, with the aim of giving the pharmacists feedback on their work at the same time as the investigator got feedback on their work.

3.6 Development of a guideline for the categorisation system

The investigators in Ayr cooperated on developing a guideline and making changes to the categorisation system with KJH and MBC, who both were doing a similar project at the Royal Infirmary in Glasgow. SH and CF at the University of Strathclyde gave guidance and inputs during this process. The guideline and the categorisation system was revised several times, and a lot of effort was invested in the development phase. During the development of the categorisation system it was continuously tested on samples of care issues, aiming that it would be possible to categorise all types if care issues in the system. The care issues were sampled from the 30 care plans made during the pilot phase at the Ayr Hospital and from care plans that the investigators in Glasgow used for their training. As the process continued, a set with practical examples for use of the categorisation system was made.

3.6.1 Drug Therapy Problems

It was specified in the guideline that only actual Drug Therapy Problems (DTP) would be categorised in this category. This decision was made since possible DTPs often could be assigned to more than one category, and the system needed to have categories that weren't ambiguous. Especially for issues were the pharmacist were monitoring drug use and physiologic functions, a Drug Therapy Problem (DTP) category was difficult to assign.

3.6.2 Check and Change

The intention behind using a categorisation system was to measure clinical pharmacy/pharmaceutical care in a quantitative manner, and it was therefore decided that not all of the checks the pharmacist performed would be categorised. Checks performed during the verification process of drug regimens were not defined as care issues, since those checks are a part of the pharmacists routine, and are performed for every patient that receives pharmaceutical care. For patients using a many of drugs, the number of checks performed in the verification process would be very high. A high number of verification checks could mean that all the other checks and changes performed would "drown" in all the information provided about the verification process, and this could potentially give a false picture of the pharmaceutical care provided.

In appendix 2 a 5th check category, formulary adherence inquiry, were added to the 4 original categories described by Strand et. al[5]. Using the same argumentation as for verification checks, it would not be interesting to categorise the number of times the pharmacist checks formulary adherence, and this category was therefore removed.

A few of the sub categories for changes were altered, and extra categories were also added. It was decided to split the change category into 2 categories, since some changes could be further categorised into DTP categories while others could not be. A change that would fall outside the definition of DTPs would for instance be to increase the level of patient monitoring or to update the patients drug history. The new change categories was named:

- "Changes in Drug Therapy", could be further categorised in to DTP sub categories
- "Changes in Drug Therapy Processes", could not be assigned to a DTP sub category.

3.6.3 Quality Assurance Descriptors

Since Quality Assurance Descriptors are used to the describe how pharmaceutical care is provided throughout the patients drug therapy, from start of therapy and until it is stopped, it was necessary to specify how the descriptors could be used in a hospital setting were the pharmacist sees the patients in interim episodes.

3.7 Verification of the categorisation system

The categorisation system was subject for discussion and evaluation in a focus group held at the University of Strathclyde. The method part on focus group is described later.

100 care issues, 50 issues from each setting, were randomly chosen to be categorised by each co-investigator, and Cohen's Kappa was used for measurement of inter rater agreement within the system. Inter rater agreement describes how the raters classify subjects into groups, compared to what is expected exclusively from chance. A poor Kappa can either mean that the system is ambiguous or that the raters them selves fail to use the system as intended.

Before the raters performed the Cohen's Kappa test all the hundred care issues were plotted into a matrix table similar to that used for finding Cohen's Kappa. It was checked for if most of the categories had at least one care issue assigned to them, and since the care issues were distributed between nearly all the different categories, the raters concluded that the number of care issues were high enough for testing of Cohen's Kappa.

Table 15 Matrix for calculating Cohen's Kappa

		Rater 2				
Rater 1		**A**	**B**	**C**	**D**	**Total**
	A	A.A	A.B	A.C	A.D	$\mathbf{X_1}$
	B	B.A	B.B	B.C	B.D	$\mathbf{X_2}$
	C	C.A	C.B	C.C	C.D	$\mathbf{X_3}$
	D	D.A	D.B	D.C	D.D	$\mathbf{X_4}$
	Total	$\mathbf{Z_1}$	$\mathbf{Z_2}$	$\mathbf{Z_3}$	$\mathbf{Z_4}$	**N**

Exact number of agreements observed:

A_{tot} = A.A + B.B + C.C + D.D

Total eexpected frequencies by chance:

$(X_1+Z_1/N) +(X_2+Z_2/N)+(X_3+Z_3/N)+(X_4+Z_4/N)$

$A_{c\ tot} = [(X_1+Z_1/N) +(X_2+Z_2/N)+(X_3+Z_3/N)+(X_4+Z_4/N)] / N$

Maximum agreement is 1,00

Max agreement by chance = 1,00 - $A_{c\ tot}$

The observed agreement is = A_{tot} - $A_{c\ tot}$

Kappa: (= A_{tot} - $A_{c\ tot}$) / (1,00 - $A_{c\ tot}$)

Table 16 Interpretation of Kappa

Value of Kappa	Strength of agreement
< 0,20	Poor
0,21 – 0,40	Fair
0,41 – 0,60	Moderate
0,61 – 0,80	Good
0,81 – 1,00	Highly good

3.8 Quantitative analysis of care provision in cardiology ward and orthopaedic ward

The care issues and the patient demographics were plotted in to an Microsoft Access® database, and the care issues were then categorised according to the guideline. The investigators made queries in the data base, and each investigator subsequently processed the findings in Microsoft Excel ® and by using a GraphPad calculator[36].

The quantitative measures found for the cardiology ward and the orthopaedic ward were compared, and the distribution of care issues were evaluated statistically by chi quadrate- an t-tests. A zero hypothesis stating that there were no differences in the distribution of care issues between the two wards were set.

3.9 Development of an care plan template

The investigator and the co-investigator cooperated on arranging a group meeting for the pharmacists at the Ayr Hospital, where the development of an electronic care plan template was discussed. This meeting was held 21.04.08, one week prior to the focus group meeting held at the University of Strathclyde. The investigators presented some ideas for a template through a power point presentation and by handing out examples of care plans in use at different sites and settings. The meeting was structured as a workshop for discussion around ideas for an electronic care plan template, and it also encouraged the pharmacist to come with new inputs. Besides from the investigators and the clinical pharmacy manager, 4 of the clinical pharmacist attended the meeting.

It was commented that some of the content in the proposed care plan template had resemblances with the Medicines Reconciliation Form in use at the present, and it requested by the pharmacists for this form to be implemented in to the care plan template.

After the first group meeting the investigators changed the template based on the feedback from the pharmaceutical team at the Ayr Hospital. The final template was presented at the focus group one week later, and the pharmacists from the Ayr Hospital were then asked to comment this draft as a verification of the template.

3.10 Focus group

A focus group meeting was held at the University of Strathclyde 28.04.08. The focus group was held by the investigators at TAH together with KJH and MBC at the Glasgow Royal Infirmary. The main focus for the meeting was to evaluate the categorisation system and the guideline, but some time was also spent on getting feedback on the final care plan template. The meeting was structured around a power point presentation of the categorisation system and the results from the content analysis, and questions were asked for the different parts of the system and the following results. All four authors of the categorisation guideline shared on presenting and asking questions/being moderator. The focus group was tape recorded and the tape was transcribed for content analysis.

4 Results

4.1 Inter rater agreement

The following tables shows the Cohen's Kappa-values found for main categories and subcategories of check and changes and all subcategories for Quality Assurance Descriptors. Kappa-values are presented with a guiding interpretation of strength of agreement, but more importantly the values should also be evaluated by width of confidence intervals.

Pr(e) denotes the proportion of agreement you can expect to find by chance alone, and Pr(o) the agreement observed.

Table 17 Cohen's Kappa tested for main categories of checks and changes

	Investigator B			
Investigator A	**Checks**	**Changes in Drug Therapy Process**	**Changes in Drug Therapy**	**Total**
Checks	55	0	0	55
Changes in Drug Therapy Process	0	17	0	17
Changes in Drug Therapy	2	2	24	28
Total	57	19	24	100

κ (CI)	0,93 (0,87-1,00)
Strength of agreement	Highly good
Pr(o)	0,96
Pr(e)	0,41

Table 18 Cohen's Kappa tested for 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							
		MED	EFF	SAFE	COMP	CHAR	DH	CONT	MON	INF	SEL	DOSE	FORM	INT	DUR	STOP	EDU	Total
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
	INF									0								0
Changes in Drug Therapy	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

K (CI)	0,87 (0,46-1,28)
Strength of agreement:	Highly Good
Pr(o)	0,89
Pr(e)	0,85

Table 19 Cohen's Kappa tested for Quality Assurance Descriptors: Time Perspective

Investigator A	Investigator B			
	Verification	Monitoring	Confirmation	Total
Verification	44	1	0	45
Monitoring	7	42	4	53
Confirmation	0	1	1	2
Total	51	44	5	100

κ (CI)	0,76 (0,64-0,88)
Strength of agreement	Good
Pr(o)	0,87
Pr(e)	0,46

Table 20 Cohen's Kappa tested for Quality assurance descriptors: Degree of change

Investigator A	Investigator B			Total
	Adjustment	Modification	Review	
Adjustment	16	2	0	18
Modification	3	2	0	5
Review	0	0	1	1
Total	19	4	1	24

κ (CI)	0,44 (0,18-0,69)
Strength of agreement	Good
Pr(o)	0,79
Pr(e)	0,63

4.1.2 Results from the Focus group regarding the categorisation system

The following table lists the participants in the focus group meeting held at the University of Strathclyde 28.04.08.

Table 21 Participants of the Focus Group

Title	Work place	Initials
Professor of pharmaceutical care	University of Strathclyde	SH
Clinical pharmacist	Glasgow Royal Infirmary	CF^
Clinical pharmacist	Glasgow Royal Infirmary	LS
Investigator	Glasgow Royal Infirmary	KJH
Investigator	Glasgow Royal Infirmary	MBC
Clinical pharmacy manager/ Clinical pharmacist	The Ayr Hospital	GJ*
Clinical pharmacist	The Ayr Hospital	KW
Investigator	The Ayr Hospital	ROH
Investigator	The Ayr Hospital	MRR

^Said he had not read the whole guideline prior to the focus group meeting.

* Came in late and only attended half the focus group meeting.

Recommendations for improving the categorisation system

The participants in the focus group had several recommendations for an improvement of the categorisation system. One of the main things that were emphasised in the focus group meeting were the need for a proper language for describing pharmaceutical care, and that some changes will have to be made in the categorisation system in order to meet this need. It was also said there is a need to train pharmacists in care planning, including the use of categories.

It was pointed out that the category name *Change in Drug Therapy Process* was misleading, since the pharmacists considered their contributions in the subcategories as a part of the drug therapy process it self. It was therefore suggested that this

category should be renamed *Contribution to Drug Therapy Process*, and there was general agreement for this proposal. It was remarked that the overall class still will be *Change*, because if not you would be saying that these contributions are neither checks nor changes.

None of the investigators had categorised any issues into the *Duration* subcategory, and they had all used the *Stop* and *Start* categories in stead of this category. The focus group participants were therefore asked for their opinion regarding the need for this subcategory. It was stated that the pharmacists usually talk about duration of therapy, and it was expressed that it is desirable to categorise changes made to the duration of therapy. It was therefore suggested to alter the name of this category, so that it would be easier to categorise duration issues as such, and the proposed new name was *Change in the length of course*.

It was raised concerns about the category *Unclassified DTP*, since this is an addition to the original seven Drug Therapy Problem categories, a system which shouldn't be altered without talking to the authors first. It was also suggested to give this category a more specific name, so it becomes easier to see that this category is only for non-formulary drug changes, and not for any other issues that are hard to categorise. The focus group participants were asked if they thought this category had a place in the categorisation system since it doesn't describe clinical care issues. The feedback emphasised that switching to formulary drugs is something that the pharmacists spend time on doing, and that you would loose a part of the pharmacists actions if you didn't have a category for them. It was also asked rhetorically to what extent you want to separate out impact on cost and impact on patient's symptoms.

In addition to categorising care issues as described in the guideline, the number of care issues where an interaction was mentioned, and the number of recommendations made to the prescriber were counted. The focus group participants were asked to comment if an interaction category should be a part of the system, and there was agreement for that there is no need for such a category. It was pointed out that checking for interactions is just one of the actions the pharmacist undertakes in order to identify care issues, and that the information you really are interested in are

the outcomes. The pharmacists also stated that they won't write it down when they check for interactions.

The focus group participants also asked to comment if it would be useful to implement recording of recommendations made to the prescriber in the categorisation system. The participants had trouble understanding and interpreting the data the way they were presented here, and the final conclusion to this question was therefore that measuring recommendations could be useful, but that usefulness depends on what you are using the data for.

The general feedback on *Quality Assurance Descriptor* categories as they were described in the guideline, were that they were hard to comprehend. It was suggested that the *Time Perspective* categories both should be redescribed and renamed. It was suggested to rename them *Change in Design Stage, Change in Delivery Stage* and *Change in Evaluation Stage*, since the present names are used for other resembling processes and this gets confusing. It was expressed that an agreed language is very important here, and that it is a problem that this is lacking today. For the *Degree of Change* categories it was stated that the difference between categories were hard to comprehend, and it was also suggested to separate modifications made in the design stage as opposed to the evaluation phase.

In the table on the next page the recommendations made for improving the categorisation system are summarised.

Table 22 Summary of recommendations made about the categorisation system

• Rename the category *Change in Drug Therapy Process* to *Contribution to Drug Therapy*
• Make a clearer division between starting/stopping a drug by and altering the duration of therapy by renaming the *Duration* subcategory to *Change of the length of Course*
• Keep a subcategory for categorising non-formulary issues, but move the it out of *Drug Therapy Problems*
• Useful to categorise the outcomes seen from checking for interactions, but no purpose in recording the number of interactions found per se
• Recording the number of recommendations made can be useful
• The subcategories in *Quality Assurance Descriptors, Time Perspective* should be renamed as *Change in Design Stage, Change in delivery Stage* and *Change in Evaluation Stage*. These subcategories should also be re-described
• Finding a way of separating the modifications that were documented in the design stage as opposed to in the evaluation stage

Strengths and weaknesses with the categorisation system

Some of the comments from the focus group participants regarding the strengths and weaknesses of the categorisation system is gathered in the table 29.

Some of the comments from the focus group participants explaining the results seen in the quantitative analysis of care issues is gathered in table 30.

Table 23 Strengths and weaknesses of the categorisation system

Question/ Topic	Comments
What is your first impression of the guideline?	- I think the concept of time perspective is a little bit unfocused (SH) - I find it a bit complex, reading it (LS)
Is it possible to use the system after reading the guideline?	- I think checks and changes, that's fine. But if you are actually modifying or adjusting things, or confirming and verifying things, that means two different things? You would need to know what language to use in this context (LS) - I agree with that. Reading it through, initially I got the whole check and change thing. But then, I had to read it three times to understand the range of it (KW)
Are any categories you would like to see or that are missing?	- I think you got the basis of a degree of describing a lot of the activity ofpharmacist contributions to care (…)There's a quite a difference between Ayr and Glasgow (CF) - It's useful for a pharmacist to see as well (…)You need to start to think is that because of my patient case load, or is it because that's something I don't do often enough? (LS)
Which potential uses you can think of for this system? *Can you mention anything positive and negative sides about the system?*	- Pharmacist can benchmark their practice and see what they need to be working on. (..) It makes you thinking: it makes you thinking about process (LS) - The negative is that's quit complex (LS, KW, GJ) - I think that it could potentially lead to inter-rater problems. I know you guys have been working quit closely, but if you were isolated from each other and you came back together: would you probable be the same way? (LS) - The more intuitive you can make it, the better. (LS, agreement)

Table 24 Results from focus group regarding outcomes from categorisation of care issues

Question/ Topic	Comments
Distribution of care issues in the sub categories of checks varies, can this be explained? Is it expected?	- The expected compliance is quite high in care of the elderly, it is not really that surprising in all (LS)
Distribution of care issues in the sub categories of Change in Drug Therapy Processes varies, can this be explained? Is it expected?	- I think the clinical, sort of shared record, drug history, ist 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)
Electronic prescribing and a high number of stopped drugs	- That is due to a problem with the electronic prescribing system, because the doctor can easily suspend the drug on the electronic system, so that we think the drug should probably be stopped, but they often just suspend it and that generates some extra care issues (….) Basically, another problem with the electronic prescribing system. So that's why its so high. And if its not stopped it will appear in the discharge letter, so there is a risk attached to it (KW) - So, electronic prescribing brings in problems of it's own. That's an interesting finding. (CF) - Actually, we need to go back to our service to make sure (…) It's a new sort of error, to suspend drugs (GJ)
Quality Assurance Descriptors, Time perspective	- You probably have more confirmation checks than you are actually documenting (CF)
Quality Assurance Descriptors, Degree of Change	- I'm surprised there were not many reviews, generally. (SH) - Maybe the patients are, I just think that cardiology has quiet short stay. There are also sort of simple treatments, treatments as per, after a set of guidelines. (KW) - I would thought that prompting a review is much more likely if you are attending a ward round (SH)
Documenting care issues	- I wouldn't routinely write down checking for everything. (LS) - I wouldn't write down a drug interaction (CF)

4.2 Ward descriptions and quantitative comparison of two hospital wards

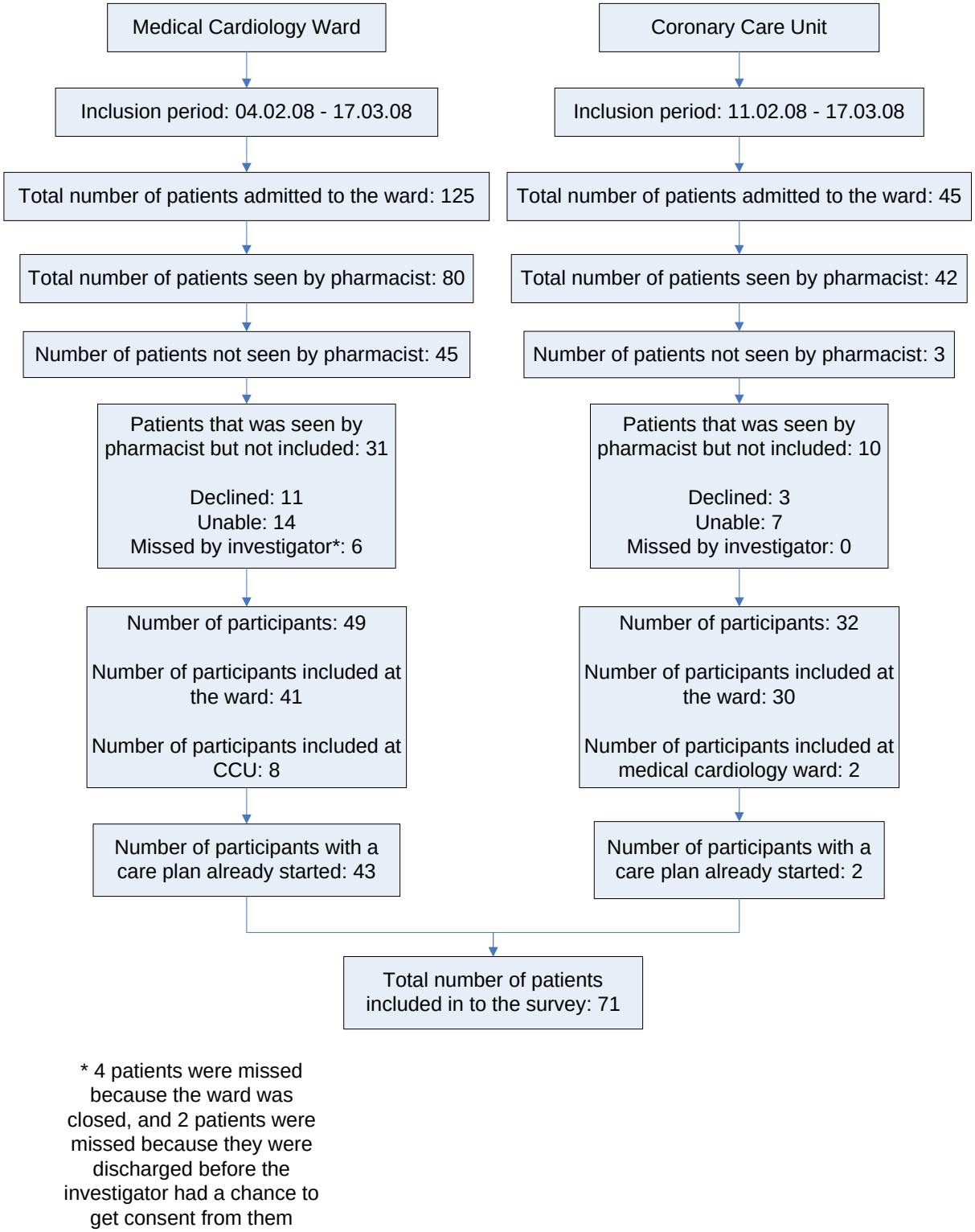

Figure 7 Patients included from the cardiology ward

71 patients were included from the cardiology ward while 90 patients were included from the orthopaedic ward, and 63% of the patients included from the cardiology ward were male compared to 40 % at the orthopaedic ward. The orthopaedic ward is bigger than the cardiology ward, with 36 beds compared to 30 beds on the latter ward. 7.0% of the admissions to the cardiology ward were panned. Table 16 shows the most common presenting complaints for the patients included from the cardiology ward.

Table 25 Most common presenting complaints at the cardiology ward

	Patients (%)
CP	11 (15,5)
AF	9 (12,7)
Chest Infection/ Exacerbation of COPD	8 (11,3)
STEMI	7 (9,9)
ACS	7 (9,9)

Patients with STEMI and ACS usually also had CP, but these cases are not counted in the category *CP*. The *CP* category includes only the cases where CP was presented without ACS, NSTEMI or STEMI suspected.

Table 26 Alcohol consumption, smoking status and alcohol consumption

	Alcohol consumption			
	None	Within recommended limits	Above recommended limits	Unknown
Cardiology	29	29	5	8
Orthopaedic	21	42	6	21
	Smoking status			
	Never	Ex-Smoker	Smoker	Unknown
Cardiology	19	12	31	9
Orthopaedic	44	7	21	18
	BMI			
Parameter (per patient)^	Mean (CI)		Median (IQR)	Range
Cardiology	24.7 (23.0,26.4)		24.2 (20.5,28.7)	11.4,40.0

*****BMI was not available from the orthopaedic ward

^n=56, numbers were not available for all 71 included patients

Number of drugs on admission and drug history (DH) sources are summarised in the table below. The to biggest contributions to the category *Other* are electronic care summaries and repeat lists.

Table 27 Sources for drug history

	Cardiology	**Orthopaedic**
Total number of drugs on admission	398	468
Mean (CI)	5.6 (4.4-6.8)	5.2 (4.4-5.9)
Median (IQR)	4.0 (1.5-9.0)	5.0 (2.3-7.0)
Range	0-23	0-14
p = 0.53		
	Frequency distribution (% of total number of patients)	
Number of patients	n=71	n=90
Number of sources used per patient		
0	0 (0.0)	9 (10.0)
1	26 (36.6)	23 (25.6)
2	40 (56.3)	52 (57.8)
3	5 (7.0)	5 (5.56)
4	0 (0)	1 (1.1)
	Frequency distribution (% of total DH sources)	
Total number of sources used to obtain patient drug history (DH)	n=123	n=146
Patient	39 (31.7)	56 (38.4)
Patient's own drugs (PODs)	14 (11.4)	40 (27.4)
Patient's relatives	5 (4.0)	2 (1.4)
General Practitioner Surgery	16 (13.0)	19 (13.0)
General Practitioner letter	8 (6.5)	8 (5.5)
Community Pharmacy	5 (4.0)	2 (1.4)
Previous discharge letter	12 (9.8)	4 (2.7)
Notes	7 (5.7)	0 (0.0)
Other	15 (12.2)	15 (10.6)

A comparison of patient characteristics and pharmaceutical care activity is presented in the table below. The table presents the results per patient in mean values with confidence intervals (CI), median values with inter quartile range (IQR) and range of parameter. The p-value denotes if there are any significant deifferences between the two wards.

Table 28 Comparison of Patient Characteristics and Pharmaceutical care activity

	Cardiology			Orthopaedic			t-test
Parameter (per patient)	Mean (CI)	Median (IQR)	Range	Mean (CI)	Median (IQR)	Range	p-value
Age	67.2 (64.0-70.4)	66.0 (59.0-79.0)	27-89	64.5 (61.2-67.8)	68.0 (59.0-74.8)	23-92	0.25
Length of Stay	7.2 (5.5-8.9)	5.0 (4.0-9.0)	1-45	9.0 (7.5-10.5)	8.0 (4.0-11.8)	1-35	0.16
Number of diagnoses	3.8 (3.3-4.2)	3.0 (2.0-5.0)	0-9	4.0 (3.5-4.5)	4.0 (2.3-5.0)	0-11	0.28
Total care issues*	5.3 (4.2-6.5)	5.0 (2.0-7.5)	0-29	3.0 (2.6-3.4)	2.0 (1.0-4.0)	0-15	<0.001
Care issues with no outcome^	0.9 (0.6-1.1)	1.0 (0.0-1.0)	0-4	0.7 (0.4-0.9)	0.0 (0.0-1.0)	0-5	0.23
Checks	3.8 (3.0-4.5)	3.0 (2.0-6.0)	0-16	1.1 (0.8-1.4)	1.0 (0.0-2.0)	0-7	<0.0001
Changes in Drug Therapy Processes	1.0 (0.6-1.4)	0.0 (0.0-1.0)	0-9	0.9 (0.5-1.2)	0.0 (0.0-1.0)	0-9	0.67
Changes in Drug Therapy	0.6 (0.3-0.8)	0.0 (0.0-1.0)	0-5	1.0 (0.8-1.3)	1.0 (0.0-2-75)	0-7	0.019

* Total number of care issues = Total number of categorised care issues.

^ Care issues with no outcome = Total number of care issues not categorised.

α=0.05 have been used for 95% CI.

p>0.05 means that the null hypothesis remains, and that there is no demonstrable difference between the to 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.

The proportion of care issues distributed in subcategories for check and changes are given in the table below. The proportions are given as percents with confidence intervals. A chi square test was performed to test statistical significance of distribution, and the p-values found are presented in the table.

Table 29 Comparison of distribution of care issues in subcategories of checks and changes

	Cardiology		Orthopaedic		
	n	% (95 % CI)	n	% (95 % CI)	p-value (chi square)
Checks					
Total	267		99		
Medication need inquiry	27	10.1 (7.0, 14.4)	59	59.6 (49.7, 68.7)	< 0.0001
Effectiveness inquiry	83	31.1 (25.8, 36.9)	15	15.1 (9.3, 23.6)	0.0021
Safety inquiry	142	53.2 (47.2, 59.1)	23	23.2 (16.0, 32.5)	< 0.0001
Compliance inquiry	15	5.6 (3.4, 9.1)	2	2.0 (0.1, 7.5)	0.17
Changes in Drug Therapy Process					
Total	69		77		
Clinical (shared) record of patient characteristics	11	15.9 (9.0, 26.5)	0	0.0 (0.0, 5.7)	< 0.001
Clinical (shared) record of drug history	37	53.6 (42.0, 64.9)	63	81.8 (71.6, 89.0)	<0.001
Continuity of information/ care between clinical settings	11	15.9 (9.0, 26.5)	5	6.5 (2.5, 14.7)	0.11
Level of patient monitoring	2	2.9 (0.2, 10.6)	3	3.9 (0.9, 11.3)	1.0
Health care team member(s) information/education	8	11.6 (5.7, 21.5)	6	7.8 (3.3, 16.3)	0.57

Table 35 (cont.) Comparison of distribution of care issues in subcategories of checks and changes

	Cardiology		Orthopaedic		
	n	% (95 % CI)	n	% (95 % CI)	p-value (chi square)
Drug selection (starting new or changing drug)	6	14.3 (6.3, 28.2)	35	37.2 (28.1, 47.3)	0.0082
Dose	6	14.3 (6.3, 28.2)	6	6.4 (2.7, 13.5)	0.19
Route/ dose-form	0	0.0 (0.0, 10.0)	13	13.8 (8.1, 22.4)	0.0095
Dose interval/timing	0	0.0 (0.0, 10.0)	5	5.3 (2.0, 12.2)	0.32
Duration	0	0.0 (0.0, 10.0)	0	0.0 (0.0, 4.7)	1.0
Stop drug temporarily/ permanently	23	54.7 (40.0, 68.8)	30	31.9 (23.3, 41.9)	0.014
Patient or carer level of education (Understanding/compliance)	7	16.7 (8.0, 30.9)	5	5.3 (2.0, 12.2)	0.047

The proportions of care issues distributed within the Drug Therapy Problem subcategories are presented in table 29

Table 30 Distribution of Drug Therapy Problems within the cardiology ward and the Orthopaedic ward

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

The distribution of care issues into Quality Assurance Descriptors were tested the same way as in check and changes, and the results are presented in table 37.

Table 31 Categorisation of all issues into QA Descriptors

	Cardiology		Orthopaedic		
	n	% (95% CI)	n	% (95% CI)	p value (chi square)
Checks					
Verification	68	25.5 (20.6, 31.0)	27	30.7 (22.0, 41.0)	0.79
Monitoring	199	74.5 (69.0, 79.4)	50	56.8 (46.4, 66.7)	< 0.0001
Confirmation	0	0.0 (0.0, 1.7)	22	25.0 (17.1, 35.0)	< 0.0001
Total	267		88		
Changes in Drug Therapy Process					
Verification	49	71.0 (59.4, 80.4)	69	89.6 (80.6, 94.9)	0.0058
Monitoring	20	29.0 (19.6, 40.6)	8	10.4 (5.1, 19.4)	0.0058
Confirmation	0	0.0 (0.0, 6.3)	0	0.0 (0.0, 5.7)	< 0.0001
Total	69		77		
Changes in Drug Therapy					
Verification	22	52.4 (37.7, 66.6)	55	58.5 (48.4, 68.0)	0.58
Monitoring	15	35.7 (22.9, 50.9)	30	31.9 (23.3, 41.9)	0.70
Confirmation	5	11.9 (47.3, 25.5)	9	9.6 (4.9, 17.4)	0.76
Total	42		94		
Adjustment	31	73.8 (58.8, 84.8)	81	86, 2 (77.6, 91.9)	0.092
Modification	9	21.4 (11.5, 36.2)	13	13.8 (8.1, 22.4)	0.32
Review	2	4.8 (0.5, 16.7)	0	0.0 (0.0, 4.7)	0.094
Total	42		94		

In addition to categorising the care issues identified for the patients included into the survey, it was recorded every time the pharmacist made a recommendation to the prescriber. A recommendation lead to a change in Drug Therapy or Drug

Therapy Process when the prescriber acted upon it, and if it wasn't acted upon the care issue remained a check.

Table 32 Pharmacist's drug therapy recommendations

	Cardiology	Orthopaedic
Total recommendations		
Count	80	171
% of total care issues	21,2	63,3
Recommendations made for which the care issue remained a check		
Count	9	15
% of total recommendations	11,3	8,8
Recommendations which lead to a change in Drug Therapy Process		
Count	37	67
% of total recommendations	46,2	39,2
Recommendations which lead to a change in Drug Therapy		
Count	34	89
% of total recommendations	42,5	52,0

4.3 Care plan template

The following figure shows the suggestion for a care plan template as it was presented in the focus group meeting 28.04.08:

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
[sign/ date]

❒ GP surgery
❒ GP letter
❒ Discharge letter
❒ Patient
❒ Patient's family
❒ Community pharmacy
❒ PODs
❒ Nursing home
❒ Medical notes
❒ Electronic Care Summary System

[freetext box]
[freetext box]

Investigations

	Date			**Date**	**Date**	**Date**	**Date**	**Date**
Weight				BP				
Height				HR				
BMI								

Laboratory Results

			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

Active 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] Discharge
		[sign/ date]	[free text space for planning/documenting action]	[sign/ date]	[free text]	[# days] Discharge

Active 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] Discharge
		[sign/ date]	[free text space for planning/documenting action]	[sign/ date]	[free text]	[# days] Discharge

Figure 8 Pharmaceutical care plan template

4.2.1 Structure and functions for the template

Free text boxes was chosen for “Presenting Complaints”, “Past Medical History” and “Relevant Drug History”, as it was regarded that no more structure is necessary in these sections.

The section “Admission Medicines” have structures resembling those in the “Medicines Reconciliation Form”, except for the omission of columns for making comments, and noting alterations that needs to be done. It is desired to have an inter connection between the prescribing section in POE and this part, so that when the pharmacist verifies the medicines on admission, and marks them as such in POE, these same drugs will appear in the care plan.

The pharmacists wanted to have a box for allergy status even though there is one already in POE, since they always check allergies for patient on admission and want to document this.

It is desired that only the ticked boxes for “drug history” sources should appear in the care plan.

It should be possible to make an intra link between the “patient demographics” part in POE to the “Investigations” section in the care plan template, so that weight and height measures can pop up in the care plan as well. With an electronic template it will also be possible to add a function that calculates BMI or body surface area from both metric measures and stones/feet. Other calculations that it would be useful to have functions for is eGFR, digoxin level, through concentrations and etc.
A similar inter link could be made between the electronic lab result reporting system (Skye by JAC Computers) and the care plan template. Values chosen to be relevant by the pharmacist could then pop up in the care plan once they are plotted into the lab result reporting system. It is also desired that all values out of range automatically are presented to the pharmacist in this way.

The care issue section where the template intentionally splits the issues in to desired outcomes, actions and outcome, were pointed out to be the most important part in a new care plan by the pharmacists at TAH. This section of the template also have many potentials for further development; an intra link could ensure that drugs the pharmacist withhold verification for, automatically are presented as care issues in the care plan. The pharmacist can then later go back in the care plan and write out the care issue, state why the verification was withheld and how the care issue further is to be handled.

Every care issue should be assigned a review date, and the issues could subsequently easily be prioritised by these dates. Tick boxes for active or inactive issues can similarly be sorted to the top and the bottom of the care plan respectively. The first coming review date would automatically be chosen as the whole care plan's review date and appear at the top of the care plan. If the patient is not seen on this specific date, then the review date automatically will be updated until the patient is seen again or discharged. It might also be of interest to have ward summaries made, that list inpatients and their review dates. This overview will also include patients with no care plan started, indicating that they have not been seen by a pharmacist yet.

It is desirable to have the possibility for writing the number of days till review in the "review" box, and then have this date converted to the specific date for the review. Issues relevant for discharge can be marked by ticking the discharge box, and these issues will be prioritised between the other active issues and the inactive ones.

The Medicine Reconciliation Form in use at present have some sections that intentionally are omitted in addition to the columns for planned changes to the patients drug regimen, and these are sections that notes the need for a compliance aid, information about their community pharmacy and etc. The intention is that this information should be written in the care issue section of the template, and thereby also treated as care issues.

An example of how a free text care plan can be rewritten in the template is showed in appendices 7 and 8.

4.2.2 Feedback from the Focus group on the final care plan template

There was just a little time to discuss the care plan template at the end of the focus group, and most of this time was spent on presenting the template to the group participants. The key comments are listed in the table below.

Table 33 Key comments from focus group on the care plan template

- Ideally don't want duplication of information, want implementation - Information presented in the Medicines Reconciliation Form should make - the basis for a care plan - The care plan template that was presented captured the needs - Connecting the categorisation system to the care plan template would - make the date base complex - Unfortunately there is little interest from the software supplier's side to - make a care plan template, since suppliers primary user group in - England don't generally utilise care plans

5 Discussion

5.1 The categorisation system

5.1.1 Utility and validity of the categorisation system

The utility of the categorisation system affected the inter-raters ability to categorise the care issues into the same categories. The strength of agreement for the main categories of check and changes were highly good, with both the confidence interval and the Kappa value being within an interval for 0.81-1.0. The strength of agreement for categorisation into all the subcategories for check and changes also had a highly good strength of agreement, but the confidence interval in this test was very wide and had a lower limit within moderate strength of agreement. The observed proportion agreement was just a little higher than what you could expect from chance alone. The raters showed the highest inconsistency between the medication need and the effectiveness subcategories for check.

Inter-rater agreement were not performed for DTPs, since this is a well known categorisation system. The focus for the evaluation of the validity was therefore the altered check and change system and the new system with Quality Assurance Descriptors. Since Cohen's Kappa both tests the validity of systems but also the raters understanding of it, a poor inter-rater agreement can be seen when well known systems are used. The raters have assumed that their agreement would have been good or highly good.

The tested Cohen's Kappa for Quality Assurance Descriptors, Time Perspective gave a good strength of agreement, with the lower limit of the confidence interval also being within the interval for "good".

Quality Assurance Descriptors, Degree of Change had a moderate strength of agreement, with a wide confidence interval that had its lower limit within the "poor

strength of agreement" interval. The raters showed inconsistency in categorising issues to adjustment and modification categories.

The inter raters had worked close together during the development of the guideline and with the data gathering, and this may have contributed to a better inter-rater agreement than what otherwise would have been found. The fact that the raters had developed the guideline that was used them selves, may also have contributed to a better agreement. The inter-rater agreement found here can be used to evaluate the data found by the quantitative analysis of care issues, but not necessarily for a measuring how good the categorisation system per se would be for other raters than the investigators in this project.

The type of issues that most often were categorised inconsistently are presented in section 5.1.2

5.1.2 Type of care issues categorised inconsistently

Some trends were recognised regarding the type of care issues that were categorised differently between the raters.

The most abundant type of categorisation mismatches were the following:

- There was found 5 checks that had been categorised as both medication need and effectiveness. Example:
  - The desired outcome was to ensure that a treatment with K supplements were effective. The pharmacist monitored K levels and subsequently advised the doctor to stop these supplements, an advice which didn't lead to any changes. The check here was categorised as a medication need inquiry by one rater and as an effectiveness inquiry by the other rater.
  - Either category can be chosen for this issue, since the pharmacist actually checks for both medication need and effectiveness. The medication need will however depend on the effect the patient experiences, and the guideline should therefore state that the effectiveness category is the preferred one.

- There was found 8 changes in Quality Assurance Descriptors, time perspective that had been categorised as verification and monitoring. Example:
  - A care issue describes that the pharmacist monitors if antibiotics should be started, and this decision depends on test answers from the laboratory. The results from the test shows that there is no need to start antibiotic treatment. This issue was categorised as a verification by one rater and as a monitoring by the other, while both raters recognised a check for medication need.
  - The definition of verification in the guideline says that a verification is done when the pharmacist first see the patient, and refers to a time aspect for when a check is performed. The word verification can be misleading in this situation, since it is easy to think that it has been *verified* that there is no need for antibiotic treatment. This is not a verification since the patient has been seen by the pharmacist for this care issues once before when the results from the laboratory comes.
  - One of the raters recognised that the pharmacist was monitoring the need for medication, but once the results from the laboratory was reported and a decision regarding the need for drug therapy was made, the need for drug therapy was no longer monitored for, and the care issue was no longer be in the monitoring phase.
  - The definition of confirmation as it is in the guideline today, specifies that confirmations are made when drug therapy is started and then later reviewed, so this category doesn't either really fit this issue, since the drug therapy never was initiated.
  - In this case the pharmacist monitors for the initiation of a drug, but the issue remains a check since the outcome was that there is no need for drug therapy. There is no category for issues such as these in the guideline today, and this can explain why the raters had categorised it differently.

- There was found 5 changes in Quality Assurance Descriptors, time perspective that had been categorised as monitoring and confirmation. Example:
  - The pharmacist monitors for duration of Flucloxacillin and think that the planned stop date stop date makes the duration of therapy too long. The pharmacist asks the doctor if the long duration is intentional, and receives an ambiguous answer. The pharmacist therefore assumes that the stop date is intentional.
  - One rater thought that an assumption can't be regarded as an confirmation and categorised the issue as an monitoring, while the other categorised it as a confirmation.

  Example:
  - The pharmacist monitors use of laxatives and checks discharge prescription of Senna with administration details. The patient had not used Senna and the drug was therefore not supplied for discharge. One rater categorized this as a confirmation while the other as a monitoring.
  - The word monitoring in the care issue text probably leaded the rater to give this care issue the time aspect monitoring.

- There was found 5 changes in Quality Assurance Descriptors, Degree of Change that had been categorised as adjustment and modification. Example:
  - In a care issue where the dose interval was changed from tid to PRN for diclofenac due to poor renal function, the outcome was categorised as an adjustment and a modification.
  - The the two terms are vague and subjective, and that is probably why the raters have used both categories for this an other issues. An adjustment is a change within a treatment plan while a modification is made outside the treatment plan and is an unexpected event. The problem with Degrees of Change is that a detailed treatment plan often don't exist for many drugs, and therefore it is hard to categorise issues into adjustments and modifications. The raters were students with little clinical experience, and they therefore had trouble recognising a treatment plan based on information available from the patient's care plan. It was stated in the focus

group by an experienced clinical pharmacist that the two terms seemed similar to him also, and there were general agreement among the participants that degrees of changes was difficult to comprehend without reading the guideline several times first.

Other typical differences in categorising between the raters:

- Some issues that were categorised into two different subcategories necessarily also had to be categorised differently in the following category/categories. An example of this is a care issue where Lactulose was suspended and the pharmacist prompted that it was stopped in stead. One of the raters categorised the change as a confirmation and an modification, while the second rater categorised it as a monitoring and an adjustment. Referring to table 9 in the guideline one can see that a care issue categorised as a monitoring subsequently can't be categorised as modification. A confirmation can not be categorised as an adjustment. What have happened in this care issue was the following:
    - One rater regarded the change to be an adjustment and therefore chose the monitoring category, even though this category don't fit
    - The other rater recognised that the change was made in the confirmation time aspect, and therefore also had to chose the modification category

  It would probably be more appropriate to categorise this issue as an confirmation and an adjustment, and the guideline should therefore be changed so that this become possible.

- The patient is on several analgesic drugs, and there is a duplication of regular dihydrocodeine, regular paracetamol and Co-codamol PRN. On the pharmacists initiative this is changed to regular dihydrocodeine and paracetamol PRN. This care issue was categorised in the DTP sub categories unnecessary drug therapy and dose too high. Co-Codamol contains paracetamol and codeine, and so multiple drugs are used to treat the same condition, which goes under the unnecessary drug therapy class. To drugs

containing paracetamol is however also used, and the category *dose too high* was therefore used. A guideline will never be able to give specific information on how every possible care issues should be categorised, but the goal is to find a categorisation system that is so intuitive as possible as this will increase the inter-rater reliability.

- If the two raters did not agree on whether a check or a change was performed, the care issue would also subsequently be categorised into different issue Co-Codamol was changed to Paracetamol on the pharmacist's request, and the raters categorised this change as a *stop* and a *drug selection*. While the actual outcome was that Co-Codamol was changed to Paracetamol, the outcome stated in the database was that co-codamol was stopped. Since one rater knew what the actual outcome was and the other did not, this lead the second rater to categorise the issue into the wrong category. Mistakes like this one could have been avoided if all issues were stated precisely.

5.2 Ward descriptions and quantitative comparison of pharmaceutical care provided at two hospital wards

There were no statistically significant differences between the two patient populations with regards to age, number of diagnoses on admission and number of drugs on admission. More men were admitted to the cardiology ward than the orthopaedic ward, and this can be partly explained by the correlation between men and cardiovascular diseases, and between women and osteoporosis. Length of stay was a little higher at the orthopaedic ward than at the cardiology ward.

5.2.1 Drug History

Sources used for confirming drug history was documented in the care plans for all patients at the cardiology ward, while this information was missing for 10% of the patients at the orthopaedic ward.

On both wards the most commonly used sources for drug history were the patient, PODs (patient's own drugs) and the GP surgery. The patient their selves was asked about drug history in 54.9% (39/71) of the cases on the cardiology ward. This number was expected to be higher, since all except one patient included in the survey were able to give consent for this their selves. The patient's own explanation of how the drugs actually are used, if all the prescribed drugs are used and if any additional OTCs or herbals are used, is of great value whenthe validation of the drug history, and the patient should therefore ideally always be interviewed about drug history. PODs were more often used for confirmation of drug history at the orthopaedic ward, and this was as expected since PODs are used by inpatients at the orthopaedic ward and not at the cardiology ward. GP letters were not commonly used in either ward, and this may be explained by the fact that GP letters are regarded as unreliable in addition to the fact that many of the admissions weren't planned and a GP letter therefore never was sent.

5.2.2 Quantitative comparison of the distribution of care issues

The quantitative comparison of the wards are based on the care issues the pharmacists have documented in the care plans, and a bias to the interpretation of results would be if certain types of issues don't get documented.

The pharmacists at the cardiology ward identified and documented more care issues than the pharmacists at the orthopaedic ward, with a mean value of 5.3 care issues found per patient compared to 3.0. There was no difference between the two wards in the number of care issues that were started but had no documented outcome, and a contributing factor to this may be that care issues that were followed up at the dispensary, were categorised for the cardiology

ward. The higher number of care issues per patient at the cardiology ward can be explained by a higher number of documented Checks. The pharmacist coverage were lower than it usually is on both wards during the survey period, and it is not likely that this have affected one ward more than the other.

Checks

The distribution within the Check categories differed between the two wards, with differences seen in the distribution of Medication need, Effectiveness and Safety inquiries.

A higher percentage of Effectiveness and Safety checks and a lower percentage of Medication need checks at the cardiology ward is seen. This can be explained by the fact that most medication need checks at the cardiology ward are for the adherence of treatment protocols, which makes one check, while the pharmacists at the orthopaedic ward often checks several separate needs that have no superior protocol. A pharmacist at the cardiology ward will for instance check if an ACS or STEMI protocol is followed, while a pharmacist at the orthopaedic ward will check if the patient is on optimal analgesic treatment, needs thromboprophylaxis for immobilisation and have aspirin prescribed for 5 weeks post-operation.

The higher percentage of effectiveness and safety checks may be explained by the fact that drugs such as beta blockers and ACE inhibitors are started for newly diagnosed cardiovascular conditions, and that these needs to be titrated. During the titration phase tolerance and effect will be closely monitored.

No significant differences were found for compliance checks, and these can possibly be explained by the fact that there were no difference in age between the two populations.

Change in Drug Therapy Processes

There was no overall difference in the mean value of Changes in Drug Therapy Processes between the two wards. The distribution to the subcategory for the clinical shared records differed between the two wards. While the pharmacists at the cardiology ward performed 15.9% changes in shared clinical records of patient characteristics, the pharmacists at the orthopaedic ward performed 0 changes. These changes consists of updating the allergy status on the electronic prescribing system when new allergies or sensitivities have occurred since last admission or when allergy status is undetermined. In the orthopaedic ward more changes in shared clinical records of drug history was made than at the cardiology ward.

One of the pharmacists from the cardiology ward explained in the focus group that the doctors at TAH leaves the job of sorting drug history and updating allergy status to the pharmacists. Changes in shared clinical records of drug history largely predominates this category.

Change in Drug Therapy

There was almost twice as many Changes in Drug Therapy at the orthopaedic ward as on the cardiology ward. The difference in number of changes mainly involved that more drug selections were prompted at the orthopaedic ward, and a possible explanation to why less drug selections were prompted at the cardiology ward may be the same as for why there were less medication need inquiries there, namely the usage of treatment protocols. At the orthopaedic ward 29.8% of DTPs were “Need for additional medicine”, while the proportion was 7.1% at the cardiology ward. The differences can possibly also be explained by the type of wards; the cardiology ward is a medical ward, and the focus on pharmacotherapy may therefore be higher than it is on an orthopaedic ward. A higher number of total checks and the need for fewer changes, may imply that prescribing errors have been prevented from earlier on during the admission to the cardiology ward. A fifth of the DTPs documented for the cardiology ward were in addition compliance issues.

The changes seen in route/dose-form at the orthopaedic ward is due to the comprehensive use of IV antibiotics in the post-operation phase. A number of drugs are also used IV at the cardiology ward. The pharmacists documented monitoring of this use, but did not prompt any changes for any patients included in the survey. Since the pharmacists were monitoring IV drug use at both wards, the number of changes seen prompted for at the orthopaedic ward can be explained by doctors that lag on changing administration form, and not by the lack of monitoring from the pharmacists side at the cardiology ward. A change of administration route in these cases were categorised into the DTP subcategory “Ineffective drug”, and while 2.4% of DTPs were categorised into this category at the cardiology ward, the proportion was 9.6% at the orthopaedic ward.

42 percent of the changes in drug therapy were stopping of a drug temporarily or permanently. The two pharmacists that participated in the focus group from TAH explained this result by a new type of error that the electronic prescribing system (EPS) is prompting; the suspension of drugs that really should be stopped. Technically it is as simple to suspend a drug as to stop it on the EPS, and this function is seen used more than the pharmacists think is ideal. Since a suspended drug easily can be prescribed in error for discharge, the pharmacists wants to limit the use of suspensions, and usually advices the doctors to stop these drugs. The DTP category “Unnecessary drug” was used to categorise these issues, and had high proportions at both wards.

Quality Assurance Descriptors, Time Perspective for Checks:

A higher proportion of checks were categorised to take place during the monitoring phase at the cardiology ward than at the orthopaedic ward, while no checks were categorised as a confirmation at the cardiology ward. The inter rater reliability test showed that the raters commonly differed from each other when categorising issues into monitoring and confirmation, with the rater from the cardiology ward categorising issues into monitoring while the rater from the orthopaedic ward categorised them into confirmations. This difference can probably be explained by the rater not focusing on categorising checks further

into confirmations. When this is the case, the results from table 25 comparing the distribution of checks within time perspective will have no value.

A high proportion of changes in Drug Therapy Processes were performed in the verification phase at both wards, and as seen before changes in Drug Therapy Processes mainly consisted of updating clinical shared records of patient characteristics and drug history, and it is natural that these changes are done when the pharmacist first meets the patient. More changes were done in the monitoring phase at the cardiology ward than at the orthopaedic ward, and this can be explained by a higher proportion of issues regarding continuity of care and health care team members education, activities that typically proceeds in the monitoring phase.

Quality Assurance Descriptors, Degree of Change

No differences were seen between the wards when the distribution into Quality Assurance Descriptors for Changes in Drug Therapy were tested. A possible explanation for this can be that the two biggest subcategories for these changes, Drug Selection and Stop Drug, combined accounted for nearly 70% of the care issues at both wards, and the assumption that the distribution of these changes are similar can therefore be made.

Recommendations

A recommendation to the prescriber was made in trice as many care issues at the orthopaedic ward as on the cardiology ward. About 90% of the recommendations lead to a change at both wards.

5.3 An electronic care plan template

5.3.1 The proposed template

Since only a little time was left for discussing the care plan template after discussing the categorisation guideline in the focus group held at Strathclyde 28.04.08, the number of comments on the template is limited. The quality of the audiotape is also varying, so it was hard to transcribe whole statements. Key comments are therefore presented in table (?), and the analysis will be based on these key comments and notes taken from the group meeting at TAH 21.04.08. The investigator perceived that there were agreement about that the template have captured the information as discussed on the first group meeting, and this was also confirmed on a direct question in the focus group meeting.

The care plan template presented here is a draft made as a Excel® document, so there is still work to be done before it can be tried out by clinical pharmacists. This project merely states what the content for such a template should be, and the technical issues that would arise when making software for an electronic template have not been looked upon. Since the final template haven't been developed yet, the investigator can only assume that it will be applicable for its use, based on the fact that the template is developed with starting points in care plan templates and the Medicines Reconciliation Form which already are in use. The biggest intervention in this template compared to other templates that are used at present, will be that it is electronic.

As an electronic prescribing system has both advantages and disadvantages, an electronic care plan template will probably also have features that are both favourable and unfavourable. The templates interface will for instance affect it's usefulness, and this interface should be therefore be developed in association with the pharmacists that actually will use the template. As for all systems there is always the danger that functions intended to be helpful turns out not to be, for instance are decision support system with pop-up windows regarded as troublesome by some of the users and therefore ignored. A potential downside with inter connecting the lab result reporting system with the care plan template,

could for instance be that this makes the pharmacist more passive. When transcribing values to the care plan the pharmacist may have more time to reflect on this information, and this aspect of the process gets lost with the automation. On the other side will inter and intra linking between electronic systems reduce transcribing errors and save time, so a full evaluation of the electronic care plan template can first be made after experiences from its use have been made.

Another potential disadvantage would be if the care plan structure turns out to be to strict. When designing the template a decision was made to omit certain part of the Medicines Reconciliation Form for instance, in order to exclude the possibility of presenting care issues other places than in the care issue section. It was also decided not to have a general free text box on the first group meeting held at TAH 21.04.08, because the investigators and the pharmacists couldn't think of any instances were this would be needed. The care plan is a tool for structuring pharmaceutical care and documenting care issues, and the assumption was therefore made that all relevant problems should and can be presented in the care issues section. This assumption can however be proven to be wrong. Even though this care plan template resembles paper templates that already are in use, new problems could arise within an electronic interface, since when a paper care plan is used, it is always possible to present information on the back page of the sheet if no other places are applicable, and this will not be possible electronically.

The introduction part of this paper attach weight to the importance of considering patient demographics such as living situation and occupation in addition to age, gender, weight and so on, and while the latter demographics already will be noted in the POE, together with a complete drug regimen, there is no space for presenting living situation, occupation and certain other demographics in the template. The idea behind this is to limit the writing of information that is not relevant, and promote that relevant information is presented as care issues. It is thereby assumed that living situation only is relevant when there is a need to arrange for home care and etc. At the group meeting in Ayr it was also expressed from the pharmacists side that tick boxes to note if the patient have home care,

needs an blister pack on discharge and etc, could fragment information to much and therefore be troublesome.

When making the care plan template and developing the guideline for the categorisation system, the investigators hoped that the categorisation database could be implemented in the final template, so that this audit could then be repeated from time to time. If the care plan template could be directly linked up to a database like access, this would make it easier to this audit, since the investigators wouldn't have to plot all the data in to the data base manually, and instead just concentrate on the categorisation part. The use of such a system would however be limited since an audit such as this still is a lot of work, and doubtfully wont be performed routinely. In the focus group held at Strathclyde 28.04.08 one of the key comments confirmed this, stating that "Connecting the categorisation system to the care plan template, would make the date base complex".

It is however possible to do smaller audits by using data from an electronic care plan template. Subjects for audits can i.e. be how well the pharmacists documents sources for drug history, how often they document that they have asked the patient for use of herbal and OTC drugs and etc. A spare tick box could also be used occasionally for audits where data can't be gathered directly from existing sections, for instance the pharmacists can be asked to record it by ticking the box, every time they educate a patient about drug use or do a generic switch according to local formularies. Electronic data gathering reduces the workload when processing the information.

5.3.2 There is a great potential for an electronic care plan

The investigator hope to have showed what a great potential there is for developing an electronic care plan template. Both clinical pharmacy and electronic prescribing are here to stay, and the development of an electronic care plan template will therefore be a good investment.

A problem that was highlighted in the focus group meeting at Stratclyde, was that there is little interest for the use of care plans England at the moment. The four other hospitals that use software from the same producer as TAH and have full electronic prescribing, are English, and the soft ware producer therefore don't see a marked for an electronic care plan template. At the group meeting held in Ayr one week prior to the focus group, it was emphasised that the most important thing to ask the software supplier for, if only to ask for one thing, is a table for presenting care issues. There was agreement on that a table for presenting issues would be of great help, and that it should not be a lot of work for the software suppliers to have this within POE.

An electronic care plan template would also be a valuable learning tool for pharmacy students, and software for such a potential template could also be used at the universities when training students in documenting pharmaceutical care. The need to train pharmacists in care planning, including the use of categories for describing care issues was empathised in the focus group meeting, as both documentation and structured care planning are very important tasks in a clinical pharmacists provision of pharmaceutical care.

6 Conclusion

The categorisation system and the guideline that was developed were evaluated based on the investigators experience with it and in a focus group meeting. While check, changes and DTP categories were practical achievable to use, suggestions were made to how the Quality Assurance Descriptor system could be improved. It was empathised how important it is to use intuitive terms when describing pharmaceutical care. Cohen's Kappa was tested for the system and it was confirmed that the Quality Assurance Descriptors subcategories is ambiguous. Inter rater agreement was found to be highly good for the subcategories of check, changes and DTPs.

The quantitative content analysis showed certain differences between the provision of pharmaceutical care at the cardiology ward and at the orthopaedic ward. A higher mean value of care issues per patient was found at the cardiology ward, and this can be explained by the fact that more drugs are started at the cardiology ward that needs close monitoring in the titration phase. The more extensive use of treatment protocols at the cardiology ward can explain that a lower number of changes in drug therapy is seen at this ward than at the orthopaedic ward. A new type of error that the electronic prescribing system promotes is that drugs often are suspended in stead of stopped.

A proposal for what an electronic care plan template should and can contain was made, based on feedback from the clinical pharmacists at Ayr Hospital. There is a great potential for developing such a template within the electronic prescribing system used at Ayr Hospital today; a template will help the pharmacists document pharmaceutical care in a structured way, and functions that save the pharmacists time and increases the quality of the care planning can potentially be implemented in the template.

7 Appendices

Appendix 1. Time spent on pharmaceutical care processes at the medical cardiology ward and the coronary care unit

#	Process	Description	Time spent, MC	Time spent, KW	Action per day
1	Review medical records Take medication history Initiate care plan Clarify current drug regime and allergies	The pharmacist reviews medical records and take relevant medical history. This serves as a starting point for initiating a care plan The pharmacist checks: • GP referal letter/calls GP • Speaks with patient/relatives • Community pharmacy • Prevoius dc letter • PODs if brought in The pharmacist usually checks with two or more sources, but this isn't always necessary	15-20 min per patient	15-20 min per patient	Medical cardiology ward: 3-4 patients are admitted daily to the ward 87.8 % of the included patients had a care plan already started on admission, and already had their drugs on admission reviewed prior to transfer to the ward Coronary care unit: 1-2 patients are admitted daily to the ward 6.3 % of the included patients had a care plan already started on admission, and already had their drugs on admission reviewed prior to transfer to the ward
2	Transcribe drugs to EPS Verification of transcribed and newly prescribed drugs	The pharmacist transcribe current drug regime if this is not al ready done The pharmacist checks for: • Indication for all the drug therapies • Right medicine • Right dose • Dosing intervall • Course duration • Need for additional medicine • Unnecessary medication • Interactions • Non formulary prescribing	10-15 min per patient	10 min per patient	

3	Review patient care plans Identify pharmaceutical care issues	The pharmacist reviews care plans that already are started for transferred patients, and all care plans with a review date that day All care issues identified and that are dealt with through monitoring or simple changes in the drug regime done by the pharmacist (ex generics, dosage form etc)	1 – 1 ½ hr per day	1 hr per day	Medical cardiology ward: Care plans where usually reviewed every 2nd or 3 rd day during the survey period. Coronary care unit: Care plans where usually reviewed every weekday during the survey period
4	Speaking with Dr (and other health care workers)	All care issues that requires pharmacist to confer with Dr/health care workers, and all questions that are passed from Dr/health care workers to pharmacist	10-15 min per day for review of changes. For ad hoc questions –time varies depending on issue		
5	Patient education	Explaining to the patient why he/she needs drug therapy and the effect/side effects the medication may have	5 min per patient	30-40 min per day	
6	Continuity of care Documenting pharmaceutical care issues and their outcomes in the care plan	Making sure that patients are followed up, ex by arranging for warfarin clinic, notifying community pharmacy of changes in drug regime and pt discharge Documenting identified care issues Documenting actions that are done and that need to be done in the care plan. Documenting outcomes Writing information for the dispensary in the care plan	5 min per pasient	15 – 30 min per day	

7	Verification of TTA and review of discharge letter	TTA: The pharmacist checks for: • Indication for all the drug therapies • Right medicine • Right dose • Dosing intervall • Course duration • Need for additional medicine • Unnecessary medication • Interactions • Non formulary prescribing • Sedatives etc Dc letter: The pharmacist checks for: • Continuity of care		Never uses time on verification of TTA and never reads discharge letter	

Appendix 2 Guideline for categorisation of pharmaceutical care issues before the altering

DATA COLLECTION FOR MSC PROJECT

CATEGORIES OF PHARMACEUTICAL CARE ISSUES

Checks (CK)
Changes (CG)

CHECKS

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

CATEGORISATION OF CHECKS

Type of check	Code
Verification	VER
Monitoring	MON
Confirmations	CON

CHANGES

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

CATEGORISATION OF CHANGES

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

CATEGORISATION OF DRUG THERAPY PROBLEMS (DTP)

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

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 3 Data gathering: Free text version of care plan for patient 6-27

CARE PLAN REVIEW DAILY

PC
Increased SOB, Inf bronchiecstasis, dehydration, lethargic. Finished course of ciprofloxacin and steroids.

PMH
Bronchiecstais, Paroxsymal AF, COPD

DH
NKDA
Pt sheet - verapamil (Vertab) 240mg od, ipratropium 0.5mg and salbutamol 5mg nebs QID, Salbutamol MDI 2puffs prn, flixotide 250 One dose BD, Serevent 50 One puff BD, ciprofloxacin 500mg BD and prednisolone 50mg mane (both now stopped)
ECS - does not state verapamil or flixotide, Others above mentioned. Serevent dry powder = accuhaler. Also states erdosteine 300mg BD.
Phoned GP- Confirmed verpamil 240mg mr od, fluticasone 250 MDI one puff BD last had March 07. Erdosteine first prescription Jan 08 - 300mg BD also had in Feb 08. Aspirin 75mg od started Jan 08. (Pharm 1) 19/2

Bloods
19/2 u 8.8 Crt 90 K 4.6 Hb 13.3 wcc 12.5 plts 239 JS
20/2 Cr 95 wcc 12.5 CRP 31

Issues
*1. Not well enough to use inhalers or speak today. Check need for **fluticasone** (Pharm1) 19/2

*2 Not well enough to take many orals today - although managing. Will manage the ciprofloxacin. Currently prescribed carbocisteine not **erdosteine**. Erdosteine N/F. Have now confirmed with GP review tomorrow switch or leave as carbocisteine. (Pharm1)19/2 Erdosteine intended for 10 day course only. Would have been nearing end of this when admitted. Left as carbocisteine. Also review if **aspirin** to start tomorrow. (Pharm 1) 19/2 Note left in medical notes (Pharm 2) 20/2

3. Salbutamol nebs dose reduced to 2.5mg PRN intentionally and ipratropium increased to 6 times daily confirmed with nurse since tachycardia. (Pharm 1) 19/2

4. Home nebuliser (Pharm 1) 19/2

*5 Monitor antibiotics switch to oral and inf markers (Pharm 1) 19/2
Switched to oral - monitor duration 27/2 (Pharm 3)

*6 Last night svt/paf - Electrical cardioversion on heparin inf - prescribed as charted on EP. Dr Rose has asked for cardiologist review of antiarrythmic - monitor heparin and watch for antiarrythmic change. Now changed to amiodarone - **check notes tomorrow - verified** (Pharm 1) 19/2 Changed to amiodarone on Dr (X)'s advice (Pharm 2) 20/2
Warfarin added for anticoagulation - **COUNSELLED** (Pharm 3)

Appendix 4
Data gathering: Care plan documented in template for patient 6-27

Only issues contributed to by pharmacist 3 is included in this version of the care plan, since the other pharmacist don't work at the cardiology ward.

PATIENT PAPER PROFILE

PATIENT DETAILS			
Number 6-27	Sex M		Age 60
Height 5 ft 6	Weight 10 st 2	BMI	Ability to self medicate
Allergies/Sensitivities		Type of reaction	
NKDA		-	
Social History Married, lives at home Retired No alcohol, smokes 5 cpd			

PATIENT STAY		Presenting Complaints	Notes
Admitted/Transferred from	Med high care	Increased SOB, Infective exacerbation of bronchiecstasis, dehydration, lethargic, productive cough	Finished course of ciprofloxacin and steroids
Date of admission to ward 5			
First seen by pharmacist At ward 5			
Date of admission to ward 6	20.02		
First seen by pharmacist At ward 6	27.02		
Discharge date	28.02		
Discharged to	Home		

RELEVANT MEDICAL HISTORY		RELEVANT DRUG HISTORY	
Date	Problem Description	Medication on admission	Comments
	Paroxsymal AF	Verapamil (Vertab) 240mg od Aspirin 75mg od	
	Bronchiecstais	Ipratropium 0.5mg and Salbutamol 5mg nebs QID, Salbutamol MDI 2puffs prn, Flixotide 250 One dose BD, Serevent 50 One puff BD Erdosteine 300mg BD	Was treated with ciprofloxacin 500mg BD and prednisolone 50mg mane on admission also (both now stopped)
	COPD		

Drugs on admittance verified with	GP	ECS

OTCs:

RELEVANT NON DRUG TREATMENT	
Treatment Description	Comments

#	Date and sign	Care Issue/ Desired Output	Date and sign	Action	Date and sign	Output
1	27.02 MC	Pt is on antibiotics switched to oral from IV 25.02	27.02 MC	monitor duration	Researcher	Pt dc, not done
2	27.02 MC	Warfarin added for anticoagulation, amd pt needs counselling	27.02 MC	Counsel pt	27.02 MC	**Pt COUNSELLED** by pharm

REVIEWS							
Review Dates (Planned)	28.02						
Review Dates (Actual)	Pt dc						

Appendix 5 Guideline for categorisitaion of pharmaceutical care issues

GUIDELINE FOR CATEGORISATION OF PHARMACEUTICAL CARE ISSUES

1 Introduction

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

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

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

1. The care issue is found not to be an actual or potential drug therapy problem that needs further follow up at this point.
2. There is an identified need to take action(s) to prevent future drug therapy problems.

3. A drug therapy problem is identified and there is a need for a change in the patient's drug therapy at this point .

2 Definition of a pharmaceutical care issue

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

3 The categorisation system – a short summary

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

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

Each care issue is categorised in three such dimensions;

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

The care issue is further categorised into:

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

The third dimension in the system is
(3) Drug Therapy Problem[2] and only a care issue identified as a Change in Drug Therapy will be categorised as such.

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

Table 1. Categorisation set-up

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

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

4 'Check' and 'Change' categories

4.1 Checks

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

The pharmacist's intentions behind making the check constitute the basis for the number of care issues identified and for the categorisation of the identified

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

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

Table 2. Checks

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

4.2 Changes

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

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

5 Change in Drug Therapy Process

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

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

Table 3 Change in Drug Therapy Process categories

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

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

Clinical (shared) record of patient characteristics

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

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

up-dated record, this is recognised as one care issue for each drug that is changed.

Clinical (shared) record of drug history

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

Continuity of information/care between clinical settings

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

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

Level of patient monitoring

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

Health care team member(s) education / information

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

6 Change in Drug Therapy

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

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

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

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

Table 4. Change in Drug Therapy categories

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

7 Drug Therapy Problems (DTP)

The categories of Drug Therapy Problems are those defined in the book *Pharmaceutical Care Practice – The Clinician's Guide* [2] by Cipolle et al. The categories are given examples here to include a broader range of care issues. In

addition they are modified to enhance the correlation between the heading of the DTP subcategories and the type of care issues included in them. An additional subcategory *Unclassified* has been added in order to categorise care issues where the change is not patient specific. For instance due to non-adherence with local formularies and with only cost-control implications, rather than medication safety or effectiveness.

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

Table 5. Categories and common causes of drug therapy problems

Drug Therapy Problem		**Common causes of drug therapy problems**	
1	**Unnecessary drug therapy**	a	*There is no valid medical indication for the drug therapy at this tim*
		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

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

Table 5 (cont.) Categories and common causes of drug therapy problems			
7	**Inappropriate compliance**	a	The patient prefers not to take the medication
		b	The patient does not understand the instructions
		c	The patient forgets to take the medication
		d	The drug product is too expensive for the patient
		e	The patient cannot swallow or self-administer the drug product appropriately
		f	The drug product is not available for the patient
		g	The time of dosing or the dosing interval is decreasing compliance.
8	**Unclassified i.e. Non-DTP**	a	Formulary adherence, e.g. generic switch

8 Quality Assurance Descriptors

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

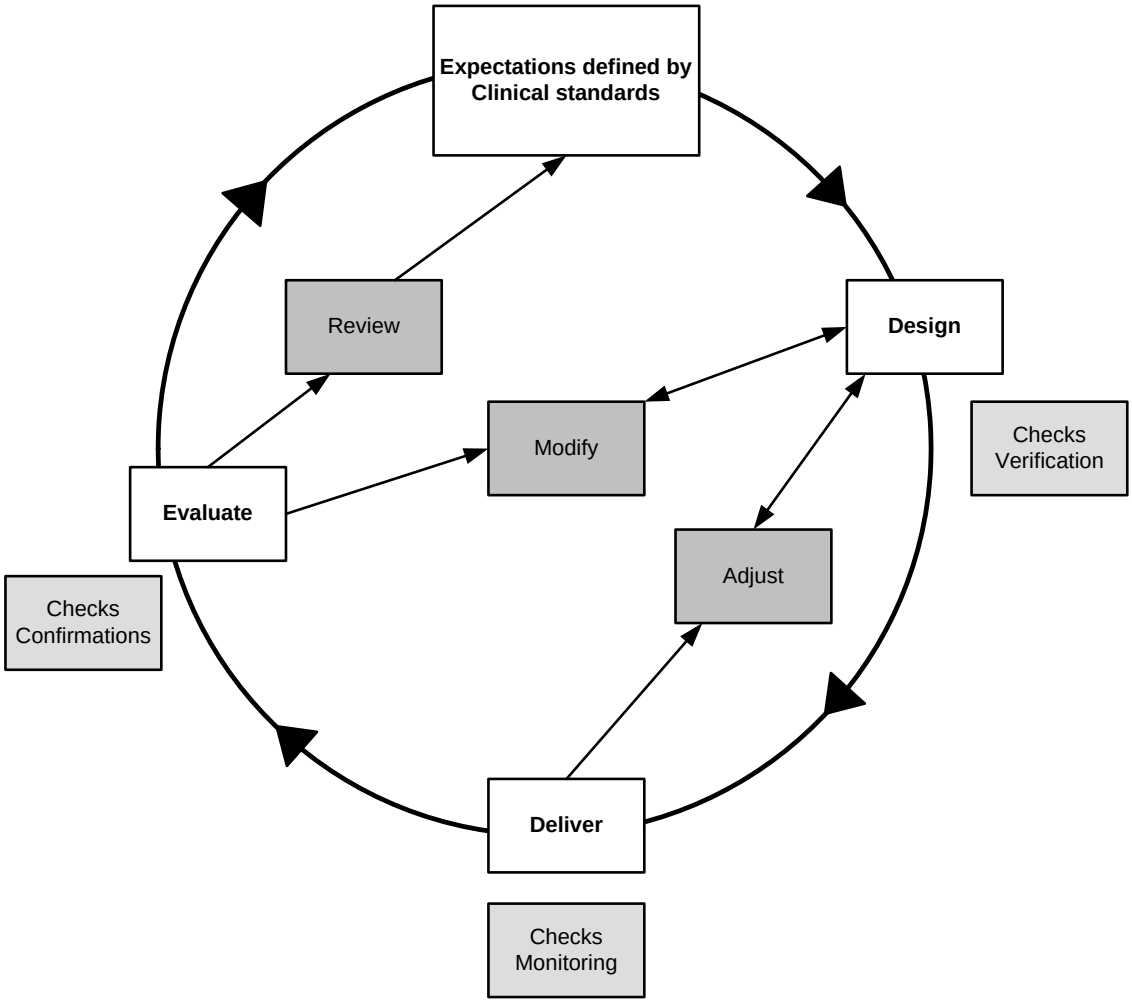

Figure 1 Pharmaceutical care model

The Quality Assurance (QA) Descriptors identify both the points in the feedback loop at which the care issues (the *Checks* or *Changes*) are implemented and the extent of changes in drug therapy. To emphasise what they describe, the subcategories for *QA Descriptors* are designated *Time Perspective* and *Degree of Change*.

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

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

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

8.1 Time Perspective

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

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

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

Verification

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

- In chronic disease management, for instance by a clinical pharmacist at an outpatient clinic or a community pharmacy, 'Verification' is done at the first

episode of care with the pharmacist. That may or may not be at the start of the patient's treatment but must be undertaken for the pharmacist to assure himself or herself that the proposed treatment plan is suitable for the patient's need.

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

Monitoring

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

Confirmation

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

8.2 Degree of Change

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

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

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

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

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

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

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

Adjustment

Adjustment is defined as a recommended change to patient behaviour, treatment regimen or process of continuity of care that individualises pharmaceutical care *within* the agreed treatment plan. 'Adjustments' are anticipated within the protocol/clinical management plan, and the regimen is not

markedly changed to an alternative treatment regimen. Most supplementary prescribing decisions made by pharmacists would probably fall into this category.

Modification

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

Prompt a Review

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

References:

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

Appendix 6 Transcribing of focus group

Focus group, key points

Question:
What is your first impression of the guideline?
Is it possible to use the system after reading the guideline?
Comments:
I think the concept of time perspective is a little bit unfocused (SH)
I find it a bit complex, reading it (LS)
I think checks and changes, that's fine. But if you are actually modifying or adjusting things, or confirming and verifying things, that means two different things? You would need to know what language to use in this context (LS)
I agree with that. Reading it through, initially I got the whole check and change thing. But then, I had to read it three times to understand the range of it (KW)
That could possible translate into problems with inter-rater reliability (LS)

Topic:
Definition of a care issue when categorising
Comments:
I'm not aware of any training courses on documentation that is provided by the NHS. (SH)
The thing is, quite usually the pharmacist would write down things and not have the time to follow that up (LS)

Question:
We've divided the changes category in two:
Changes in Drug Therapy Process, and
Changes in Drug Therapy,
and we would like to have your thoughts about a division like that.
It was explained that giving a health care workers information for a patient related problem is a change in Drug Therapy Process
Comments:
A lot of the time we give information about how to give i.v. infusions. If something is a bit different we often put that on the care plans and also in the system. I don't know if that also would, I guess it doesn't really fit into changes in drug therapy does it? Because, you are not actually changing anything (KW)
I would just write it on the drug chart, I would never write that in the care plan (LS)
It's not a change in the drug therapy process, it is the drug therapy process (…)so I'm just wondering if we should….actually call these changes? (CF)
A way of thinking about it as contribution to the drug therapy process. (CF)
So would that work then? Under the general heading of changes you've got contributions to drug therapy processes and changes in drug therapy (SH)
General agreement can be heard.
It will still be classified under the overall changes. Cause you can't avoid that unless you say this is neither a check or a change, it is something else. (SH)
And what about under changes in drug therapy 'patient or carer level of education'. Is that really changing drug therapy? (KW)

I think there is a understanding in Cipolle and Strand that there is a section that changes that should be drug therapy problems because patient is being unable, having problems understanding…. (CF)

Question:
Distribution of care issues in the sub categories of checks varies, can this be explained? Is it expected?
Comments:
The expected compliance is quite high in care of the elderly, it is not really that surprising in all (LS)

Topic:
Documentation of checks
Comments:
the pharmacist, they are not documenting everything they do (CF)
I think there is a journey to be made in getting more consistency in the documentation made, and that people can decide for them selves when they get exposed to other peoples practice (SH)

Question:
Distribution of care issues in the sub categories of Drug Therapy Processes varies, can this be explained? Is it expected?
Comments:
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)

Topic:
Documentation of continuity of care
Comments:
It's actually medical, legally one of the things that you would want to make sure was documented. It shows that you have all the informations passed on. (SH)

Question:
Do you think there is a need for the duration subcategory, you can see that we have not used it, but numbers in this category were small
Comments:
That's a surprise as well (LS)
It is so that we usually talk about duration of therapy (CF)
We have categorised everything about duration as stop drug or start drug and not as duration (KJH)
I think there is a overlap here, and the definition potentially needs tidying up. (CF)
You probably would want to have that in there, and call them both stop drugs, and have division between stop the duration and stop for drug therapy problems (CF)
A problem with the electronic prescribing system is that drugs are suspended in stead of stopped, that generates extra care issues(KW)
So duration is a change of the length of the course, that is more a subtle (SH)

Would the stop drug category be split into two, so that the duration is qualified within stop drug, as length of course necessarily can go on, or something like that. (SH)

Question:
Is there a need for the eight Drug Therapy Problem category (unclassified DTP), where change to formulary can be categorised?
Comments:
This is a standard categorisation system and so I don't think we want to change it without talking to the authors (SH)
I would say if someone is on a non-formulary drug that would be a care issue, and it's something that we do spend time on (LS)
to what extent you want to separate out impact on cost and impact on patient's symptoms? (SH)
If you've got a category called unclassified it would just be a bin, people would just put anything in it (…) call it something a little bit more specific (LS)

Question:
Do you think interactions should be integrated into the system?
Comments:
similarly the patient interview is potentially going to capture patient side effects and patient non-compliance. So then you would have different scenarios that sort of prompting the patient, no the pharmacist to pick up various issues. (CF)
I think it is the outcome you're writing down. (GJ)
I wouldn't routinely write down checking for everything. (LS)
I wouldn't write down a drug interaction (CF)

Question:
Should recommendations be implemented into the system?
Comments:
I think that can be useful, it depends on what you are going to do with that (LS)

Question:
Do these categories describe the pharmaceutical care delivered?
Comments:
Obvious you would get documented problem, individual practice is various at the moment. (SH)
General agreement from the participants

Question:
Or we could ask, if there are any categories you would like to see or that are missing so far?
Comments:
I think you got the basis of a degree of describing a lot of the activity of pharmaceutical...pharmacist contributions to care (…)There's a quite a difference between Ayr and Glasgow (CF)
So, electronic prescribing brings in problems of it's own. That's an interesting finding. (CF)
Actually, we need to go back to our service to make sure (…) It's a new sort of error, to suspend drugs (GJ)

It's useful for a pharmacist to see as well (…)You need to start to think is that because of my patient case load, or is it because that's something I don't do often enough? (LS)
I'm not writing up all I do (CF)
No, I know. I have no chance to do it either (GJ)

Topic:
Quality Assurance Descriptors, Time perspective
Comments:
You got problem (…) we have to swallow the idea verification, monitoring and confirmation (…) now you are asking people to use the same terms to explaining changes and maybe what we are talking about… different..times in…treatment cycle (SH)
Verification…..which mean…….you lost me completely (GJ)
if you say it happen at the design stage or the delivery stage or the evaluation stage. Could you do that? Then you avoid the duplication of using the same word (LS)
you probably have more confirmation checks than you are actually documenting (CF)
I think you can do what LS suggested just redescribe …what you were attending to do to put the changes into design, delivery and evaluation (…)we don't have an agreed language….and the language is very important (SH)

Topic:
Quality Assurance Descriptors, Degree of Change
Comments:
I'm surprised there were not many reviews, generally. (SH)
Maybe the patients are, I just think that cardiology has quiet short stay. There are also sort of simple treatments, treatments as per, after a set of guidelines. (KW)
adjustments that were doing routinely (…) but that would give you quit a lot of insight into opportunities of pharmaceutical prescribing. (SH)
I think if we had a way of separating the modifications that..were documented in the design stage as opposed in the evaluation stage…cause you got two categories there..that that would also give you interesting, new information about whether the doctors or the prescribers on the ward and.. they get)..ehh.. what they're prescribing in a prompted way..because if the modifications are beeing made at the design stage.. I think that the pharmacists is affecting some changes early on. (SH)
you want to be correct early on to prevent doses totally wrong, (GJ)

Question:
Do you think there is a difference in opportunity for making changes when you do ward round and if the pharmacist is not doing ward rounds?
Comments:
mmm (KW)
Yes, a lot (GJ)
I would thought that prompting a review is much more likely if you are attending a ward round (SH)

Question:
Which potential uses you can think of for this system?
Can you mention anything positive and negative sides about the system?
Comments:
Pharmacist can benchmark their practice and see what they need to be working on. (..) It makes you thinking: it makes you thinking about process (LS)
The negative is that's quit complex (LS, KW, GJ)
I think that could potentially lead to inter-rater problems ?you have. I know you guys have been working quit closely, but if you were isolated from each other and you came back together: would you probable be (host!) the same way? Or would you think all in different ways? And what Kari thought was a review that's the same as you would thought? (LS)
The more intuitive you can make it, the better. (LS, Agreement)

Appendix 7 Free text version of care plan for patient 6-45

CARE PLAN REVIEW WARFARIN 12.03

PC- chest tightness and palpitations for last ?2 months
PMH- MI, IHD, CVA, hypertension, hypothyroid, admission Jan 08 with VT (emergency cardioversion)

DH
Confirmed with Dr (X) letter and discharge 16/1/08, BLISTER PACK –(Community pharmacy and number to this) and phoned pharmacy as some changes but pack dated 21/1/08.
Trazodone stopped due to arrhythmia last admission, fluoxetine in pack -started by GP as alternative.
Warfarin - in on . Used to go in pack but was not stable so outwith pack and daughter was going to help with warfarin. Still outwith pack -pt now manages herself. On 1mg/2mg alt days but from INR written in yellow book has been unstable since discharge and some dose changes don't make sense. Patient knows her dose and says coping ok. GP manages
NKDA

BLOODS
6/3 Ur 11.6, Cr 171, K 3.5, FBC ok, Trop T 0.10, INR 3.3

ISSUES
*1. Warfarin - monitor INR and try to stablise dose. Has been on 1mg od, 2mg od or 1mg/2mg alt since discharge but INR seems to be going up and down. ? better on 1mg most days and 2mg one or two days per week. (Pharm 1) 7/3 No INR yesterday - to check today, 1mg od over weekend (Pharm 1) 8/3

*2. Renal function -weight - 58kg, est CrCl 21ml/min (ur 9.7, Cr 138 Jan) -to cont usual meds for now inc furosemide and ACEI -r/v if deteriorates (Pharm 1) 7/3
10/3 cr 157 k 4.9 - worse now 79y 58kg est creat cl 23ml/min (Pharm 2) 10.3

*3. Trop T +ve - not for further anti-coagulation, on warfarin. ? Trop T related to arrhythmia rather than ACS. Amiodarone was missed off so now added and for telemetry and cardiology r/v (Pharm 1) 7/3

*4. Contact community pharmacy on discharge -BLISTER PACK (Pharm 1) 7/3

5. amiodarone dose increased as palpitations

Appendix 8 Template version of care plan for patient 6-45

PHARMACEUTICAL CARE PLAN

Review
10.03

[Patient identification]

Presenting Complaints chest tightness and palpitations for last ?2 months	Pharm 1 07.03

Past Medical History MI, IHD, CVA, hypertension, hypothyroid, admission Jan 08 with VT (emergency cardioversion)	Pharm 1 07.03

Relevant Drug History Trazodone stopped due to arrhythmia last admission, and fluoxetine started by GP as alternative	Pharm 1 07.03]

Admission Medicines

Name, Form	Route specify if not oral	Dose	Frequency	Sign
Atorvastatin 20 mg Tablets Furosemide 40 mg Tablets Lisinopril 2,5 mg Tablets Warfarin Tablets GTN Spray Levothyroxine 100 µg Tablets Senna 15 mg Tablets Zopiclone 3,75 mg Tablets Fluoxetine 20 mg Tablets		20 mg 40 mg 2.5 mg 1mg/2 mg alt days 1 spray 100µg 15 mg 3.75 mg 20 mg	1 x 22.00 1 x 07.00 1 x 07.00 PRN 1 x 07.00 1 x 07.00 1 x 22.00 1 x 07.00	Pharm 1 07.03]

OTC / Herbal / Homeopathic / Illicit substances

Name, Form	Route specify if not oral	Dose	Frequency	Sign
				[sign/ date]

Allergies

Medicine/Substance	Reaction	Sign
NKDA		Pharm 1 07.03]

Drug History

Sign
[sign/ date]

❒ GP surgery
❒ GP letter
❒ Discharge letter
❒ Patient
❒ Patient's family
❒ Community pharmacy
❒ PODs
❒ Nursing home
❒ Medical notes
❒ Electronic Care Summary System

[freetext box]
[freetext box]

Investigations

	Date	Date	Date		Date	Date	Date	Date
	06.03							
Weight	58			BP				
Height				HR				
BMI								

Laboratory Results

			Date	Date	Date	Date	Date	Date
Test	**Range**	**Units**	06.03 (Exact time)					
Urea	2.5-7.5	mmol/l	11.6					
Creatinine	50-125	µmol/l	171					
Serum Potassium	3.5-5.0	mmol/l	3.5					
Troponin T		µg/l	0.10					
Free text								
FBC			Ok					
INR	3.0 (2.5-3.5)		3.3					

Pharmaceutical Care Issues

Active Inactive	**Care issue/ Desired Outcome**	Pharm 1 07.03	Warfarin on admission	**Outcome**		**Review date**
	Action	Pharm 1 07.03	Monitor INR and try to stablise dose.	Pharm 1 07.03	Has been on 1mg od, 2mg od or 1mg/2mg alt since discharge but INR seems to be going up and down.	[# days] Discharge
		Pharm 1 07.03	? better on 1mg most days and 2mg one or two days per week. Advice on dosing	Pharm 1 08.03	1mg od over weekend	[# days] Discharge
		Pharm 1 08.03	No INR yesterday - to check today	[sign/ date]	[free text]	10.03 Discharge

Active Inactive	**Care issue/ Desired Outcome**	Pharm 1 07.03	Patient has poor renal function	**Outcome**		**Review date**
	Action	Pharm 1 07.03	Monitor renal function and medication	Pharm 1 07.03	est CrCl 21ml/min To cont usual meds for now. Including furosemide and ACEI	[# days] Discharge
		Pharm 1 07.03	Monitor renal function: r/v furosemide and ACEi if deteriorates	Pharm 2 10.03	RF worse now est creat cl 23ml/min cr 157 k 4.9 -	[# days] Discharge
		Pharm 2 10.03	Monitor renal function: r/v furosemide and ACEi if deteriorates	[sign/ date]	[free text]	10.03 Discharge

Active Inactive	**Care issue/ Desired Outcome**	Pharm 1 07.03	Pt needs BLISTER PACK	**Outcome**		**Review date**
	Action	Pharm 1 07.03	Contacted community pharmacy, informed there might be changes to medication regimen	Pharm 1 07.03	Done	[# days] Discharge
		Pharm 1 07.03	Contact community pharmacy again on discharge	[sign/ date]	[free text]	[# days] Discharge
		Pharm 1 07.03	Dispense TTA's in a blister pack	[sign/ date]	[free text]	[# days] Discharge

Active Inactive	**Care issue/ Desired Outcome**	Pharm 1 07.03	Trop T +ve	*Outcome*		**Review date**
	Action	Pharm 1 07.03	? Trop T related to arrhythmia rather than ACS.	Pharm 1 07.03	Amiodarone was missed off so now added.	[# days] Discharge
		Pharm 1 07.03	Pt for telemetry and cardiology r/v Amiodarone accordingly	Pharm 2 10.03	Amiodarone dose increased as palpitations	[# days] Discharge

9 References

1. Hepler C, Strand L. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm. 1990;47:533-43.
2. Smith W. Clinical Pharmacy: Reflections and forecast. AnnPharmacother. 2007;41:425-8.
3. Hudson S, McAnaw J, Johnson B. The Changing Roles Of Pharmacists In Society. IeJSME. 2007;1:22-34.
4. NHS. Audit Commission Report. A Spoonful of Sugar. Medicines management in NHS hospitals. London, 2001 NHS; 2001.
5. Cipolle R, Strand L, Morley P. Pharmaceutical Care Practice – The Clinician's Guide. New York: McGraw Hill; 2004.
6. McFadzean E, Isles C, Moffat J, Norrie J, Syewart D. Is there a role for a prescribing pharmacist in preventing prescribing errors in amedical admission unit? The Pharmaceutical Journal. 2003;270:896-9.
7. Cook RI RM, Woods DD. Gaps in the continuity of care and progress of patient safety. BMJ. 2000;320:791-4.
8. Coleman EA BC. Improving the Quality of Transitional Care for Persons with Complex Care Needs. Journal of American Geriatric Society. 2003;51:556-7.
9. Centre NPCaNPCRaD. Modernicing Medicines Management: A guide to achieving benefits for patients, professionals and the NHS. 2002.
10. Lee J. Effects of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial JAMA. 2006 May 15;296(21):2563-71.
11. Altman D. Practical statistics for medical research. London: Chapman & Hall; 1991.
12. Murray M. Pharmacist intervention to improve medication adherence in heart failure: a randomized trial. Ann Intern Med. 2007 May 15;146(10):714-25.
13. Forster A, Murff H, Peterson J. The incidence and severity of adverse events affecting patients after discharge from hospital. Annals of internal medicine. 2003;138:161-7.
14. Hobson R. UK survey of discharge prescriptions, transcribing and development of the hospital pharmacist-prescribing role. The International Journal of Pharmacy Practice. 2002;10:R12.
15. Sexton J, Nickless G, Green C. Pharmaceutical Care Made Easy. 1st ed: Pharmaceutical Press; 2006.
16. Health Do. Pharmacy in the Future. NHS; 2000.
17. Strand L, Cipolle R, Morley P, Ramsey R, Lamsam G. Drug-related problems: their structure and function. DICP Ann Pharmother. 1990;24:1093-97.
18. McAnaw J. Development of novel approaches to demonstrate the quality of drug therapy use [Ph.D]. Glasgow: University of Strathclyde; 2003.
19. Macintyre J, Dalrymple H, MacLean F, Lanningan N, Hudson S. Development of a system for reporting pharmaceuticalcare issues in cancer patients receiving chemotherapy. The Pharmaceutical Journal. 2003 30 August;271:266-7.
20. Gandecha R, Klecun E, Jacklin A, Williams S. What the National IT programme means for pharmacy and pharmacists. Pharmaceutical Journal. 2005;275:56-60.

21. Foot R, L T. Electronic prescribing and patient records - getting the balance right. Pharmaceutical Journal. 2005;274:210-2.
22. Summers V. Electronic prescribing, the way forward. In: Pharmacists AoSC, editor. Electronic prescribing; 2000; Stirling: Pharmaceutical Journal; 2000. p. 834.
23. Limited JCS. Our Customers. 2008 [cited; Available from: http://www.jac-pharmacy.co.uk/html/customers_1.html
24. Fowlie F, Bennie M, Jardine G, Bicknell S, Toner D, Caldwell M. Evaluation of an electronic prescribing and administration system in a British hospital. Pharmaceutical Journal. 2000;265(Suppl.):R16.
25. Goundrey-Smith S. Electronic prescribing - experiences in the UK and system design issues. The Pharmaceutical Journal. 2006;277:485-9.
26. Spina J, Glassman P, Belperio P, Cader R, Asch S. Clinical Relevance of Automated Drug Alerts From the Perapective of Medical Providers. American Journal of Medical Quality. 2005;20(1):7-14.
27. Koppel R, Metlay J, Cohen A. Role of Computerized Physichian Order Entry Systems in Facilitating Medication Errors. JAMA. 2005;293:1197-203.
28. Information OoPS. Health and Social Care Act 2001.
29. Anonymous. News feature. First prescription signed by a hospital pharmacist. Pharmaceutical Journal. 2004;272:369.
30. Guillaume. Supplementary prescribing by community and primary care pharmacists: an analysis of PACT data, 2004 - 2006. Journal of clinical pharmacy and therapeutics. 2008;33:11-6.
31. Britain RPSoG. Postgraduate Courses. 2008 [cited; Available from: http://www.rpsgb.org.uk/registrationandsupport/postgraduatecourses/
32. Centre NP. PCT responsibilities around prescribing and medicines management, A scoping and supporting guide. In: Health Do, editor.: NHS; 2003.
33. Smith F. Research Methods in Pharmacy Practice. London: Pharmaceutical Press; 2002.
34. Society RP. Guide to audit. The Pharmaceutical Journal; 2005. p. 203-4.
35. guideline S. The management of harmful drinking and alcohol dependence in primary care. In: Scotland N, editor.: Scottish Intercollegiate Guidelines Network; 2004.
36. GraphPad Software I. QuickCalcs. 2002-2005.