An Evaluation of Pharmaceutical Care Delivery to Patients with Diabetes and Development of Standardised Assessment Tools

A research project

A partial fulfilment of the Norwegian degree
Master of Pharmacy
University of Tromsø, May 2008

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Acknowledgments

I would like to thank my academic supervisor Professor Steve Hudson for guiding this project in the right direction and his advice during the final write up of this project.

I would also like to express my gratitude towards Moira Kinnear, my co-academic supervisor, for her advice and encouragement during the writing of this project. Many thanks go also to Alison Cockburn, Lead Pharmacist Diabetes Cardiovascular Risk clinics, for her thoughtful advice and interesting discussions in the clinic. This project would also not have been possible without the help of the other DCVR clinic pharmacists, so thanks to you all.

For the making of the database and analysis of my data great help was provided by Elaine Blackie. She has also been of huge help in sorting out practical issues during my stay here in Edinburgh.

Thanks to Kari, Marit, Reidun and Maren for all of the interesting discussions and for all the great laughs. Especial thanks go to my roommate Mona, my stay here in Scotland would not have been the same without you.

I would also like to thank my family and friends for listening to my complaints and being there for me. Lastly, I would also like to thank Espen for his support and encouragement throughout these months.

Ingrid Lian, June 2008

Abstract

Background

Diabetes is a rapidly and serious health problem in Scotland. This chronic condition is associated with serious long-term complications, including higher risk of heart disease and stroke. Aggressive treatment of hypertension and hyperlipideamia can result in a substantial reduction in cardiovascular events in patients with diabetes [1]. Consequently pharmacist-led diabetes cardiovascular risk (DCVR) clinics have been established in both primary and secondary care sights in NHS Lothian during the past five years. An audit of the pharmaceutical care delivery at the clinics was conducted in order to evaluate practice and to standardise the pharmacists' documentation of outcomes.

Methods

Pharmaceutical care issues (PCI) and patient details were collected both prospectively and retrospectively from three DCVR clinics. The PCI`s were categorised according to a triangularised system consisting of multiple categories. These were 'checks', 'changes' ('change in drug therapy process' and 'change in drug therapy'), 'drug therapy problems' and 'quality assurance descriptors' ('timer perspective' and 'degree of change'). A verified medication assessment tool (MAT) for patients with chronic cardiovascular disease was applied to the patients from one of the clinics. The tool was used to quantify PCI`s and pharmacist actions that were centred on implementing or enforcing clinical guideline standards. A database was developed to be used as an assessment tool and to standardise the documentation of achievement of outcomes. Feedback on the audit of the pharmaceutical care delivery and the database was received from the DCVR clinic pharmacist at a focus group meeting.

Results

For the 47 study patients (44.7% male, 85.1% type 2 diabetes mellitus) mean (SD) age was 65.7 (12.6) years and mean (SD) time since diagnosis of diabetes was 14.9 (8.9) years. Overall number of identified care issues was 727 with mean (SD) 3.91 (1.27) care issues per care episode. Of the total care issues, 373 (51.3%) were 'checks', 211 (29.0%) were 'changes in drug therapy process' and 147 (19.7%) were 'changes in drug therapy' and an identified 'drug therapy problem' (DTP). Of the checks, 519 (88.9%) were 'monitoring' checks, while all changes, 143 (100%), were 'adjustments'. The number of patients included in the application of the MAT guideline standards was 33. A total of 51 care issues leading to a change in the medication was identified and resulted in 130 guideline standards that were directing the goal of the medication change.

Conclusion

The results from the audit showed that the pharmacist made a major contribution to ensure effective and safe treatment for the patients and optimising drug doses. Lack of pharmacist documentation was the reason for discrepancy from practice in some areas of the pharmaceutical care delivery. A database would help to standardise the documentation of pharmacist actions and identification of pharmaceutical care issues. Further refinement of the tool will likely improve the ease of use and minimise the time required for application.

Abbreviations

ACE	-	Angiotensin Converting Enzyme
ACR	-	Albumin Creatinin Ratio
AF	-	Atrial Fibrillation
ARB	-	Angiotensin – II Receptor Antagonist
BHS	-	British Hypertension Society
BMI	-	Body Mass Index
BP	-	Blood Pressure
CI	-	Confidence Interval
CVD	-	Cardiovascular Disease
CHD	-	Coronary Heart Disease
DCVR	-	Diabetes Cardiovascular Risk
DTP	-	Drug Therapy Problem
eGFR	-	Estimated Glomerular Filtration Rate
GP	-	General Practitioner
HDL	-	High Density Lipoprotein
IHD	-	Ischemic Heart Disease
IQR	-	Inter Quartile Range
LDL	-	Low Density Lipoprotein
LFTs	-	Liver Function Tests
MAT	-	Medication Assessment Tool
MI	-	Myocardial Infarction
NHS	-	National Health Service
OTC	-	Over The Counter
PCI	-	Pharmaceutical Care Issue
PVD	-	Peripheral Vascular Disease
SCI-DC	-	Scottish Care Information – Diabetes Collaboration
SD	-	Standard Deviation
SIGN	-	Scottish Intercollegiate Guideline Network
TIA	-	Transient Ischemic Attack
QA	-	Quality Assurance
U & E`s	-	Urine and Electrolytes

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1 Introduction

1.1 Pharmaceutical care

1.1.1 The concept of pharmaceutical care

Pharmaceutical care has been defined by Hepler and Strand in 1990, as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are (1) cure of disease, (2) elimination or reduction of a patient's symptomatology, (3) arresting or slowing of a disease process, or (4) preventing a disease or symptomatology" [2]. The word 'pharmacist' is not part of the definition. Pharmaceutical care can therefore be regarded as achievable through the performances of a team of healthcare professionals, including pharmacists, but also including technicians, doctors and nurses. It also enables pharmaceutical care to be delivered in different ways, in different clinical settings e.g. hospital wards, primary care settings and community pharmacies. The concept of pharmaceutical care is therefore a description of what the patient should receive and not what the pharmacist does [3]. It is this model which has been mainly used and adapted within the UK to shape the delivery of pharmacy practice and the delivery of pharmaceutical care.

Cipolle et *al* later refined Hepler and Strand's philosophy of pharmaceutical care to be defined as a patient-centred practice [4]. In both these definitions the emphasis is on the patient and the pharmacist's responsibility to ensure good quality of the care they provide to the patient and to achieve better patient outcomes.

The pharmacist's role has evolved over the twentieth century from mainly being product focused, preparing and dispensing drugs, into a more patient –orientated care provider, and pharmaceutical care may be the target for the pharmacy profession world-wide.

Even though pharmaceutical care is delivered by many different healthcare professionals, the pharmacists can be regarded as specialists in this practice as their focus is on pharmacology and pharmacotherapy, important skills to provide

pharmaceutical care. The need for a practitioner focused on drug therapy has become urgent, since the responsibilities associated with drug therapy have become numerous and complex. A pharmacist has the possibility to focus on pharmaceutical care on a full-time basis, and is therefore expected to take the primary role as the pharmaceutical care provider. However, it is important that the pharmaceutical care practitioners understand each patient's medication experience better than all other healthcare professionals, only then is it possible to have a positive impact on the patients decisions and experiences with their drug therapy. The patient's medical experience includes patient's expectations, wants, concerns, preferences, attitudes, and beliefs, as well as the cultural, ethical, and religious influences on his/her medication taking behaviour. It is the pharmacist's primary role to optimise this experience. Only when a patient's medication experience is known and understood can the pharmacist successfully take on the responsibilities of identifying, resolving and preventing drug-therapy problems. As a result the patient understands and achieves the desired therapeutic goal for each medical condition being treated. [5]

Since the pharmacist is part of the multidisciplinary team which delivers pharmaceutical care to the patient, it is important that they share a common vocabulary. This facilitates good communication between the different members of the healthcare team and continuity of care.[4]

"*The Right Medicine*" [6] is the Scottish Executive strategy (2002-2005) for pharmacy, both for hospital pharmacy services and community pharmacies. It outlined how pharmacists can contribute to improve services to the public and to patients, by better utilising their skills within the use of medicines. The strategy also supports pharmacists in their work with helping patients get the maximum benefit from their medicines and shows where action has to be taken to achieve that goal. It highlighted the need to modernise and strengthen pharmacists' education and training, to ensure patients' receive professional standards of the care. A systematic approach in the delivery of pharmaceutical care ensures that the patient gets "the right medicines, in the right dose, at the right time and for the right reasons" [6].

1.1.2 Documentation in pharmaceutical care

Continuity of pharmaceutical care depends on good communication between healthcare professionals, which in turn depends on reliable records. All practitioners are required to document the care they provide. Pharmacists have developed their own ways of documenting the information necessary to carry out their part in the care of the patient. The Pharmaceutical Care Plan is extensively used within the UK. These care plans are used to organise each patient's identified goals of therapy, interventions to resolve drug therapy problems, how to achieve goals of therapy and to prevent new drug therapy problems from developing. Every intervention made by the pharmacist should be documented, and is best done at the time the patient is seen by the pharmacist or shortly thereafter. A valid documentation system is necessary to justify decisions made regarding the patients treatment plan and to evaluate outcomes [4]. Standardised pharmaceutical care plans used to document pharmaceutical care issues would be useful to standardise the provision of care to different patient groups. Work in this area has been done in Scotland in the provision of pharmaceutical care to cancer patients receiving chemotherapy [7].

The use of electronic documentation systems is much more effective and efficient than a paper system. Development of an electronic hand-held pharmaceutical care plan would facilitate prospective data capture at the patient's bedside [7]. The data entered in a database are better standardised and would help to generate a more consistent delivery of care. The information needs only to be entered into the database once and reports could be generated to assess the delivery of pharmaceutical care [4].

1.1.3 Pharmaceutical care for patients with diabetes

There are an ever increasing number of people with diabetes and long-term conditions in Scotland [8]. The complexity of the condition clearly points out the need for support from a variety of healthcare professionals in the delivery of pharmaceutical care, such as the clinician supervising treatment, diabetes specialist nurse, GP, dietician, podiatrist, community pharmacist, consultant and ophthalmologist [9]. In Scotland, the Scottish Executive has published the "*Scottish Diabetes Framework Action Plan*" [8], which acknowledges the burden of diabetes on

Society and aims to raise standards of diabetes care in Scotland. It calls attention to the need to facilitate self-management and delivery of services closer to the patient, by expanding community pharmacists' roles and integrating them into the multidisciplinary team.

It is estimated that 600 000 people across Scotland visit their local community pharmacy every day [6]. The community pharmacy is often the first point of call for people with newly diagnosed diabetes, and the community pharmacist is in a position to deliver pharmaceutical care, rather than solely supplying medicine [9]. With pharmacists' prescribing rights being extended from supplementary prescribers to independent prescribers [10], this could open new doors to greater opportunities in the delivery of pharmaceutical care. The new community pharmacy contract that is being introduced in Scotland includes a chronic medication service, giving pharmacists increased responsibility in providing pharmaceutical care to patients with long term conditions, including diabetes [11]. Pharmaceutical care services for diabetes patients are developing in Scotland although these are not consistent [12].

Pharmaceutical care is very difficult to evaluate because of its complexity, and the amount of published work is therefore limited [13]. There is little known about the feasibility and impact of the community pharmacist input in the multidisciplinary team in both primary and secondary health care settings [14]. One pilot study, of the integration of the community pharmacist in the healthcare team, showed that pharmacist are effective and well accepted by GP`s and patients [14]. During the study period the pharmacist supported patients by giving medication advice to improve patient understanding of their medicines and also collaborated with physicians to optimise the pharmacological management of glycaemia, hypertension and dyslipidaemia in patients with type 2 diabetes. The patients had an initial and final assessment where the main outcome measures were HbA1c, blood pressure, lipid profile and medication compliance. Over the study period a reduction in all biological measures was observed and patients' knowledge of their medication improved. No analyses were done however to assess if this intervention was cost-effective and sustainable.

Three other studies [15-17] have shown that pharmacist-led clinics have a positive impact on cardiovascular risk factors, like blood pressure, hyperlipidaemia and glycaemic control for patients with type 2 diabetes and consequently on their risk of cardiovascular disease. The patients in these studies were seen by the clinic pharmacist every 4-8 weeks, where necessary adjustments to their treatment were made. This aggressive approach to optimise patients' treatment led to a reduction in blood pressure, lipid levels and HbA1c. One of the studies also assessed the cost-effectiveness of such a model and found it comparable to other healthcare interventions [16].

1.2 Diabetes mellitus

Diabetes mellitus is a chronic metabolic disease characterised by disorders in carbohydrate, fat and protein metabolism and resulting hyperglycaemia. Hyperglycaemia is caused by defects in insulin secretion, insulin action or both. Over time chronic hyperglycaemia can lead to severe long-term complications, affecting several organ systems. Abnormalities in insulin secretion and insulin action occur due to several pathogenic processes, which range from autoimmune destruction of pancreatic β-cells to abnormalities that result in resistance to insulin action.

There are several different categorises of diabetes according to the underlying etiologic cause of the disorder. Most cases of diabetes mellitus fall into two main categorises: type 1 diabetes and type 2 diabetes. Another common type of diabetes is gestational diabetes mellitus (GDM) which refers to glucose intolerance first recognised during pregnancy. [18, 19]

1.2.1 Type 1 diabetes mellitus

Type 1 diabetes mellitus is recognised by an absolute deficiency of insulin resulting from immune-mediated destruction of the β-cells of the pancreas. Only 5 to 10% of people with diabetes fall into this category previously know as insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. It usually presents in early childhood and has a peak incidence around puberty, however it can present at any age.

The autoimmune destruction of the β-cells is related to multiple genetic predispositions and environmental factors that are still poorly defined. The rate of β-cells destruction is quite variable and the patient becomes overly diabetic only when more than 90% of the β-cells have been destroyed [20]. Onset of the disease is in most cases abrupt and may present with ketoacidosis as the first manifestation of the disease. The patient also typically presents with all of the classical symptoms: polydipsia, polyuria, polyphagia, weakness, weight loss and dry skin, which makes it easy to diagnose. The majority of these patients require insulin for survival, even though some patients may briefly return to normoglycaemia. [18, 19]

1.2.2 Type 2 diabetes mellitus

Type 2 diabetes mellitus is the most common type of diabetes. It is responsible to approximately 90 to 95% of all cases. This form of diabetes was previously referred to as non-insulin dependent diabetes (NIDDM) or maturity onset diabetes. The main characteristics of type 2 diabetes are impaired insulin secretion and some degree of insulin resistance of target tissues, primarily the liver and skeletal muscle. Many patients therefore have normal to elevated levels of insulin, due to increased secretion of insulin in an attempt to compensate for the diminished activity of insulin. Despite this blood glucose levels rise due to the insulin resistance. These pathological and functional changes may be present over a long period of time without any clinical symptoms before diabetes is detected. Such patients are at increased risk of developing macrovascular and microvascular complications. [19-21]

Typically type 2 patients are over 40 years of age and most of them are obese, and obesity itself causes some degree of insulin resistance. Weight loss and or/ oral hypoglycaemic drugs may improve insulin resistance. The risk of developing this form of diabetes increases with age, obesity and lack of physical activity. Today there are an increasing number of people in younger age groups with type 2 diabetes due to obesity and sedentary lifestyle [22]. The International Diabetes Federation (IDF) has stated that up to 80 % of type 2 diabetes is preventable by adopting a healthy lifestyle, in terms of nutrition, physical activity and ideal body weight.[23]

1.2.3 Epidemiology of diabetes mellitus

Prevalence of diabetes world wide

Diabetes is a serious condition not only for the individual, but for Society as a whole. It currently affects 246 million people world-wide and this number is expected to increase to 380 million by 2025 [23]. Developed countries have a higher prevalence of diabetes than developing countries, but the increase of people with diabetes is projected to increase in both. Developing countries will be hit the hardest by the growing diabetes epidemic. An aging population, a shift towards a more sedentary lifestyle, increasing numbers of overweight and obese people and unhealthy diet are possible factors contributing to this alarming increase of diabetes prevalence. Growing urbanisation is also believed to be a possible contributing factor to the problem. According to the International Diabetes Federation, the five countries with the highest diabetes prevalence in 2007 are Nauru (30.7%), United Arab Emirates (19.5%), Saudi Arabia (16.7%), Bahrain (15.2%) and Kuwait (14.4%) [24].

Prevalence of diabetes in the United Kingdom (UK) and Scotland

In the annual 2005 Scottish Diabetes Survey, more than 170 000 people were identified from data submitted by all the NHS Boards, which represents 3.4% of the Scottish population. Nearly half of those patients identified were aged 65 years or more, and more than 80% had type 2 diabetes [25]. Within 25 years it is assumed that as many as one in 10 people in Scotland will have diabetes [8]. UK prevalence for diagnosed diabetes has been estimated to be in the region of 1.8 million people or approximately 3% of the population. As many as 765 000 to 1 million people in the UK are suspected of having undiagnosed type 2 diabetes [22].

Ethnicity is also linked to diabetes. It has been shown in the UK that certain ethnic minority groups are more likely to develop type 2 diabetes than the indigenous population, to develop it earlier and present with its complications. This is particularly evident in South Asians, but also in people from African and Caribbean backgrounds. In these communities the prevalence of diabetes is at least five times higher or more. If we compare these two ethnic communities with the whole UK population, the prevalence of diabetes in South Asians and Afro-Caribbean's, are 20% and 17%,

respectively, in contrast to the prevalence of three percent in the UK population as a whole. [22, 26]

1.2.4 Diabetic complications

Diabetes is associated with serious long-term effects which could have a huge impact on the quality of life of patients, especially when both microvascular and macrovascular complications are present. The risk factors for developing microvascular complications include; duration of diabetes, glycaemic control and hypertension, whilst the strongest risk factors for the development of macrovascular complications include hypertension, hyperlipidaemia, smoking and albuminuria. Figure 1 [27] illustrates the factors contributing to cardiometabolic risk.

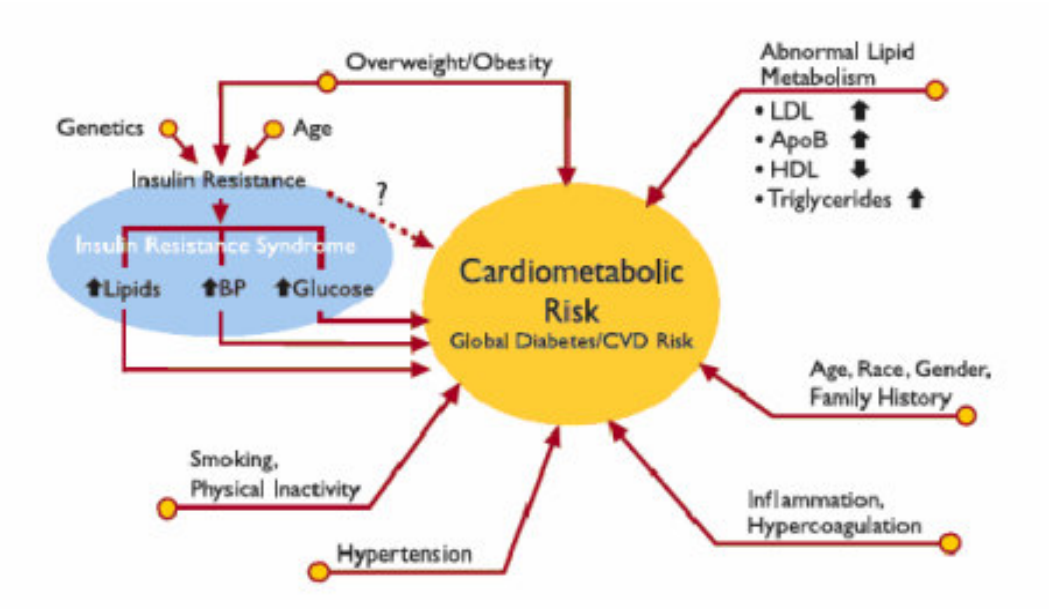

Figure 1. Factors contributing to cardiometabolic risk

Microvascular complications affect the small blood vessels and comprise of retinopathy, nephropathy and neuropathy. Macrovascular complications encompass cerebrovascular disease, ischemic heart disease and peripheral arterial disease [28].

The risk for macrovascular diseases tend to manifest in people with type 2 diabetes more than those diagnosed with type 1 diabetes, and as hyperglycaemia contributes to the development of these complications, studies have proved the relationship

between the degree of glycaemic control and the development of these complications [29]. The first goal in the management of both type 1 and type 2 diabetes is therefore management of hyperglycaemia.

Two trials, The Diabetes Control and Complications Trial (DCCT) [30] and the United Kingdom Prospective Diabetes study (UKPDS) [1], have both confirmed the benefit of tight glycaemic and blood pressure control on the reduction of long term complications. In the UKPDS study, the group assigned to tight blood pressure control showed a 37% reduction in incidence of microvascular complications and significant reduction in risk of 24% for any endpoint related to diabetes [1].

1.3 Guideline recommendation for primary and secondary prevention of cardiovascular disease with main focus on diabetes

Guidelines exist locally in Scotland developed by Scottish Intercollegiate Guideline Network (SIGN). These are evidence-based clinical guidelines derived from a systematic review of the scientific literature. For the prevention of cardiovascular diseases revised guidelines were published in February 2007 [31]. There is also a guideline for the management of diabetes, SIGN 55 [32], which is currently under review and new guidelines are imminent.

To reduce cardiovascular risk, both guidelines emphasise the importance of:

- Diet by altering dietary fat intake and reducing dietary salt – which could help to lower blood pressure; and increase fruit and vegetable intake
- Encouraging people to increase their activity level
- Giving advice and help on how to stop smoking
- Moderate alcohol intake

There are three main focus areas on the pharmacological treatment of the primary and secondary prevention of cardiovascular disease: (1) antiplatelet therapy, (2) lipid lowering therapy and (3) blood pressure lowering.

1.3.1 Antiplatelet therapy

In the secondary prevention of cardiovascular disease the use of aspirin is well established. A low dose of aspirin at 75 mg is indicated for all individuals with established atherosclerotic disease. The benefit of using low dose of antiplatelet therapy is that it reduces the risk of gastrointestinal bleeding compared to higher doses. There is no clinical evidence to support long-term treatment, but the perceived benefit of treatment means life-long treatment with aspirin is usual. Individuals with a history of stroke or transient ischemic attack (TIA) should also have a low dose of aspirin in addition to dipyridamole (200 mg twice daily). In both situations, people who have an intolerance or hypersensitivity to aspirin or where aspirin causes unacceptable side-effects, clopidogrel should be considered as an alternative.

In the primary prevention of cardiovascular disease, in asymptomatic individuals with no established atherosclerotic disease, but whose estimated CVD risk is ≥ 20% over ten years, should be considered for aspirin therapy.[31]

In the use of aspirin in the primary prevention of cardiovascular disease among people with diabetes, there are few data. The guideline recommends aspirin 75 mg daily for all patients with diabetes type 2 who are older than 50 years of age, and also in younger individuals with diabetes believed to have a high cardiovascular risk.[31, 32]

People with hypertension should be treated with aspirin if their 10 year risk of cardiovascular disease is above 20%, and only if their blood pressure is well controlled and treated to <150/90 mmHg. The blood pressure has to be under that level to reduce the risk of cerebral haemorrhage.[31]

1.3.2 Lipid lowering therapy

The use of statins (HMG-CoA reductase inhibitors) is central to lipid lowering therapy in both primary and secondary prevention of vascular events. Their primary action is to reduce LDL cholesterol, and only small reductions in HDL cholesterol and triglyceride levels.

For individuals with high cardiovascular risk, the use of simvastatin 40 mg/day is indicated and considered to be used in treatment of all adults > 40 years of age with an estimated ten year CVD risk over 20% [31]. In people with diabetes type 2 without evidence of nephropathy with CVD risk ≥30%, lipid-lowering therapy should be considered as the same as for non-diabetics [32]. For patients with type 1 diabetes and patients with type 2 diabetes and nephropathy, the current assessment methods may underestimate the cardiovascular risk. In these individuals lipid-lowering therapy should be considered at a lower risk threshold [32].

The existing target for total cholesterol < 5 mmol/l in individuals with established symptomatic cardiovascular disease, should only be regarded as the minimum standard of care [31]. This is also the treatment goal for individuals with diabetes [32].

In people who do not tolerate higher doses of statin, the use of a standard statin dose in combination with an anion exchange resin or ezetimibe should be considered. Other lipid lowering agents, like a fibrate or a nicotinic acid, should be used in individuals with hypertriglyceridaemia (>1.7 mmol/l) and/or low HDL cholesterol level (< 1 mmol/ l in men and < 1.2 mmol/l in women).

Combined dyslipidaemia is particularly characteristic of the metabolic syndrome and in diabetes mellitus. This condition is characterised by elevated plasma triglycerides, low HDL cholesterol and smaller, denser and more atherogenic LDL particles than normal. This condition is associated with an even greater risk of cardiovascular events, than when only LDL cholesterol is raised. The use of a statin is the drug of choice in this condition, and in some cases a combination with a fibrate is necessary.[31]

1.3.3 Blood pressure lowering therapy

Blood pressure lowering therapy should be considered for individuals with established cardiovascular disease or with ten year CVD risk > 20%, and who has sustained blood pressure >140 mmHg systolic and/or diastolic blood pressure > 90 mmHg. In these individuals the target blood pressure is <140/85 mmHg [31]. In individuals with diabetes without any complications, diastolic blood pressure should

be reduced further to 80 mmHg [32]. For individuals with established cardiovascular disease and who also have diabetes with complications (e.g. nephropathy) or chronic renal disease or target organ damage, the limit for initiation of blood pressure therapy is >130 mmHg systolic and/or > 80 mmHg diastolic. Target blood pressure in this group is <130/80 mmHg.

There are four major classes of antihypertensive agent: (1) thiazides, (2) angiotensin converting enzymes (ACE) inhibitors, (3) angiotensin-II-receptor antagonists (ARB) and (4) calcium channels blockers. Beta-blockers are also used in treatment of hypertension, but is regarded as being less effective than the other four groups.[31]

In the treatment of hypertension the use of two or more than two antihypertensive agents, in half to standard doses, is often considered to achieve additive blood pressure lowering effect and to reduce the adverse effect profile.

The British Hypertension Society (BHS) AB/CD algorithm for blood pressure incorporates all classes of antihypertensive drugs, and is widely accepted for deciding drug therapy for the individual. In June 2006, NICE (The National Institute for Health and Clinical Excellence) and BHS released a new revised guideline with updated clinical evidence and a cost-effectiveness analysis [31]. The new recommendations based on this evidence are summarised in the A/CD algorithm [31] in figure 2 on the next page.

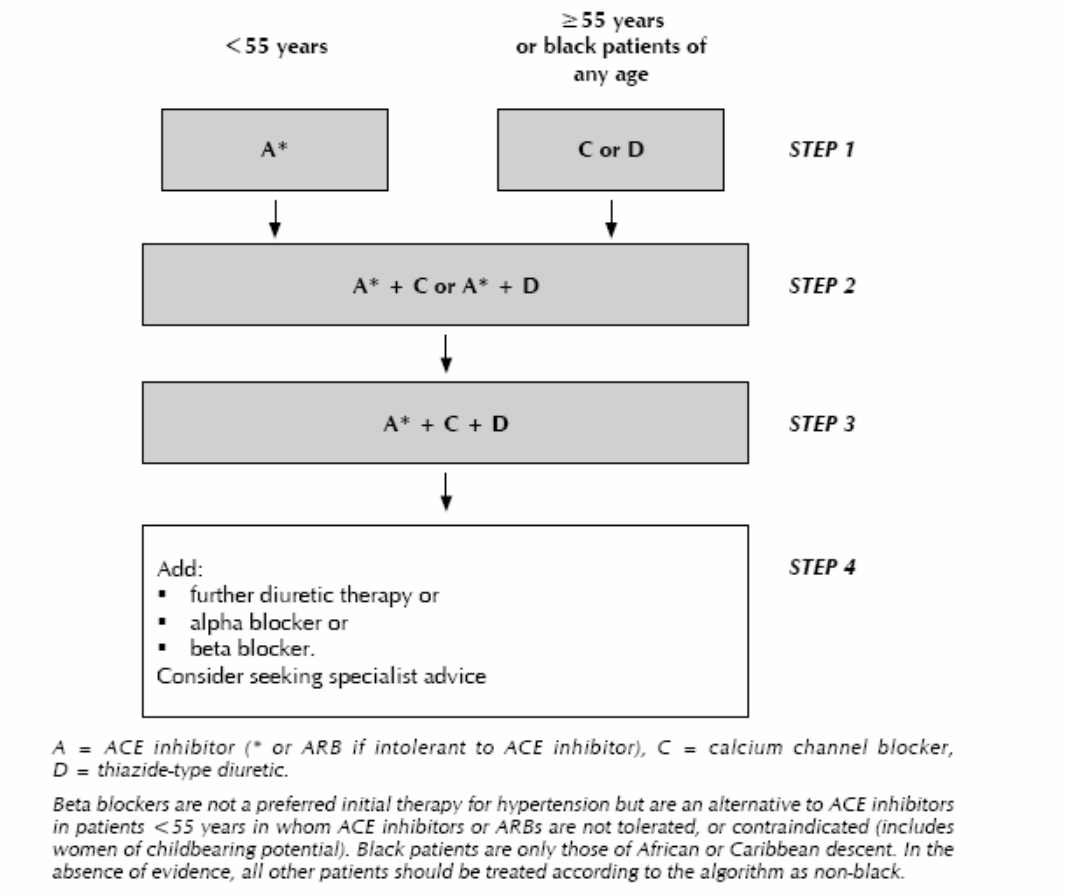

Figure 2. British Hypertension Society A/CD algorithm for blood pressure

In patients with diabetes, an ACE-inhibitor should be given to individuals >55 years of age, and who also smoke, have total cholesterol > 5.2 mmol/l, HDL cholesterol ≤ 0.9 mmol/l, microalbuminuria, proteinuria or hypertension. The use of ACE-inhibitors is also indicated in diabetic patients who have had a myocardial infarction (MI) and/or heart failure due to left ventricular dysfunction.[32]

In the case of significant bilateral renal artery stenosis, ACE-inhibitors are contraindicated because it is associated with acute renal failure.[32]

Following MI patients should be prescribed long-term treatment with a beta-blocker [33] and diabetes is not considered to be a contraindication for use of this class of antihypertensive drug [32]. Beta-blockers are also considered as first line treatment for the relief of symptoms of stable angina – and should therefore be used in secondary prevention of cardiovascular disease [34].

1.4 Clinical audit

The goal for all NHS health care professionals is to improve the quality of patient care and to continue to improve; clinical audit is the method believed to provide the framework in which this can be done. Clinical audit can be defined as [35]: "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change". Clinical audits are therefore a method which can be used to provide evidence on current practice against guideline standards (i.e. SIGN) or quality improvement standards defined by NHS Quality Improvement Scotland. It can provide information about the structures, the process or outcomes of a health care service and also serve as a check concerning: "Are we actually doing what we think we are doing?" Finally, clinical audits can provide evidence on the quality of care delivered in a service. This enables stakeholders like, other staff, carers, patients and management to have confidence in the quality of care that is provided. [36]

In 1996-1997 clinical audit was integrated in clinical government systems, and by 1998 full participation off all hospital doctors was made an explicit component of this system. After this, in 2000, "*The NHS Plan*" [37] took it one step further and supported the involvement of other staff members, including nurses and midwives. In a report by the "*Bristol Royal Infirmary Inquiry*" [38] , which followed excess deaths associated with paediatric surgery and linked to questions about competence of practitioners, several recommendations were made. The recommendations that are especially interesting are [35]:

- "The process of clinical audit, which is now widely practised within trusts, should be at the core of a system of local monitoring of performance".

- "Clinical audit must be fully supported by trusts. They should ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively. All trusts should have a central clinical audit office that coordinates audit activity, provides advice and support for the audit process, and brings together the results of audit for the trust as a whole".

- "Clinical audit should be compulsory for all healthcare professionals providing clinical care and the requirement to participate in it should be included as part of the contract employment".

Clinical audit can be viewed as a cyclical process (figure 3 [36]), where the cycle is divided into different stages. The stages follow a systematic process of establishing best practice, measuring against criteria, taking actions to improve care, and monitoring to sustain care. As the process continues, each cycle can be regarded as trying to reach a higher level of quality. In order to execute a successful clinical audit, the methods used should be well understood and the organisational environment has to be supportive.

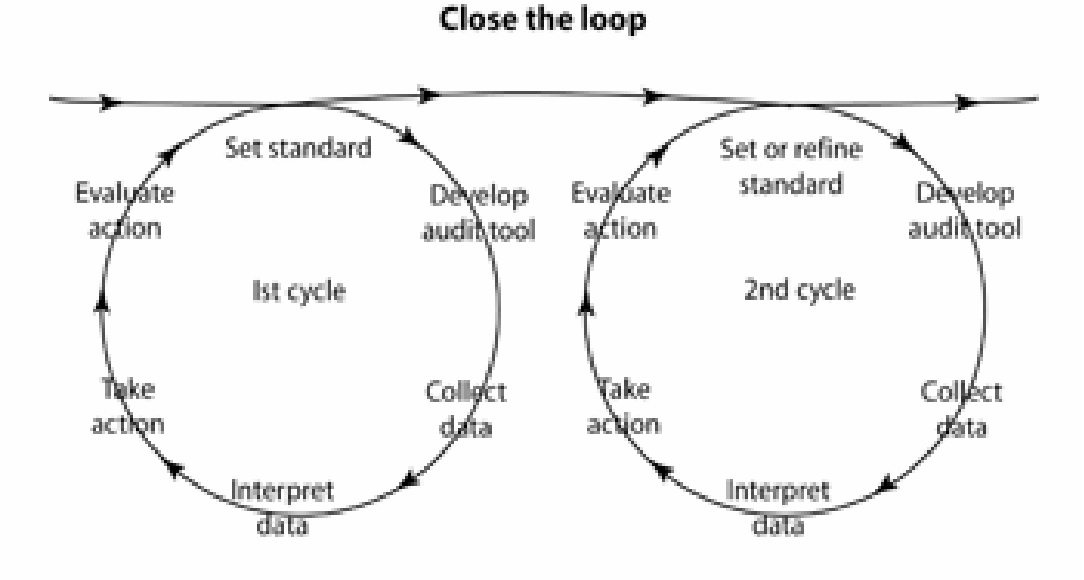

Figure 3. Clinical audit cycle

A clinical audit can be divided into five steps [35]:

- Preparing for audit
- Selecting criteria
- Measuring performance
- Making improvements
- Sustaining improvements

Good preparation is crucial to the success of an audit. The first thing that needs to be done is selection of a topic. In the decision making of this process participating staff could be used, but is not necessary. Participation could however have an important role in creating the necessary supportive environment that is needed. The topics selected are priorities within a given service, and an audit is conducted with the means of improving the service provided to the users of that care, or to confirm that current practice meets the expected level of performance. Healthcare members involved have to have the skills to execute the audit and must be given enough time to participate fully in the project. [35]

For the selected criteria to be valid and lead to improvement in the quality of care, the criteria should be based on evidence, relate to important aspects of care and be measurable. To achieve this, explicit rather than implicit criteria are preferred to give a more reliable audit. This means that one should study for specific, detailed part of the care. The specification of appropriate care should be done by referring to recommendations in clinical guidelines. Clinical guidelines are based on review of relevant research evidence, and the criteria are therefore likely to be valid. Both the process and the outcome can be used in the assessment of clinical audits. The choice however depends on the topic and objectives of the audit. Measurement of outcomes can for example be used to identify problems with care, and is often the method of choice when the outcome is clear. [35]

In order to measure performance, patients have to be identified. Patient registers are used in this process. Clinical records are frequently used to gather necessary data. Such records are often incomplete and several sources may have to be used to collect the data. However an audit could also be used as a method of improving

documentation, which is of great importance in the quality of care of patients. If routinely collected data are available, they may be appropriate for use in an audit and makes the whole process much easier. Another way of getting information is to use sheets recorded by the healthcare provider at the time of delivery of care. Various statistical methods are used to analyse the audit data. [35]

The data collected are compared with criteria and standards, and the outcome of the audit are used to draw conclusions on how well the standards are met or identifying reasons for why the standard are not met in all cases. In the end, an audit will therefore result in some sort of change in practice in order to make improvements for the future. After some time, when changes have been implemented the audit cycle usually should be repeated in order to assess if the proposed change have been put in practice and improvements are seen. [35]

1.5 Project focus

Evaluating pharmaceutical care is difficult. The process of pharmaceutical care is multi-factorial and involves many different healthcare providers. It is therefore difficult to attribute any change in outcome solely from the contribution of the pharmacist. The thought process and actions performed by the pharmacists while providing pharmaceutical care is also not easy to measure. A defined standardised way of achieving just that is therefore sought after. Categorisation of drug related pharmaceutical care issues is a way to put the pharmacists input into a system. Profiles like these can be used to compare clinical settings and evaluate services. Such profiles can provide the evidence of the added benefit of integrating pharmacists into the multidisciplinary team. As policy makers and higher management contemplate reimbursement of pharmacist services it is necessary for pharmacists to prove their worth. An important tool used in this process would be increased use of standardised documentation systems integrating evidence-based clinical guidelines. By transferring current paper systems over to computer-based systems the standard of documentation would be increased further.

The focus of this project was to evaluate the pharmaceutical care delivery to patients attending the DCVR clinics. A previous study of one of the pharmacists pharmaceutical care activities resulted in production of a pharmaceutical care plan incorporating clinical guidelines [39]. The incorporation of guideline standards in the pharmaceutical care plan would facilitate the quality of prescribing as routine practice and provide continuous quality monitoring. The pharmaceutical care plan has now been implemented in some of the clinics. There is now a need to extend the implementation to other sites and for a continuous audit of practice. A profile of the pharmaceutical care provided by three chosen clinics will be produced. The project will also result in a database suitable to record clinical outcomes and pharmaceutical care issues addressed by the pharmacists. The database will facilitate the recording of achievement of outcomes and serve as an assessment tool in further practice.

1.5.1 Diabetes Cardiovascular Risk Clinics, Lothian

Pharmacist-led clinics have been established within both primary and secondary care sites in NHS Lothian since 2003. These have achieved significant reductions in patients' blood pressure (mean 34 ± 17 mmHg systolic and 16 ± 11 mmHg diastolic) and improved lipid profiles [17]. The patients are referred to the clinic from the general diabetes clinic. Referral criteria are broad, but the clinics are primarily aimed to patients not achieving target blood pressure and/or lipid profile and with high cardiovascular risk. In a busy diabetes clinic correct blood pressure monitoring is difficult due to time constraints, which could lead to reluctance to recommend treatment [40]. A closer follow-up at a pharmacist-led clinic could be beneficial to reduce cardiovascular risk.

At the clinic the pharmacists [17]:

- Measure blood pressure, including the use of ambulatory 24-hour monitors
- Review the patient cardiovascular medication in accordance with a treatment protocol based on SIGN guideline 55.
- Review lipid profiles
- Subjectively assess patients compliance with medication

- Take blood and urine samples to monitor the effect of patients medication on their U & E and LFT consentrations

- Assess body weight, smoking status and exercise level, and provide advice on adoption of a healthy lifestyle. When appropriate referrals are made to a clinic dietician or a smoking cessation facilitator

- Play a role in achieving compliance and concordance with the patient.

After each clinic the pharmacist discusses each case with the consultant responsible for the clinic, before making written treatment recommendations to their GP. Patients GP and/or community pharmacist are frequently contacted to check compliance.

A recent study showed that patients previously thought to be "resistant" to treatment had a significant reduction in cardiovascular risk factor targets when attending an intense clinical setting [40]. Patients previously attending one of the DCVR clinics were followed up at least six months after discharge to determine the efficacy and long-term effect of the interventions. The study showed that improvement in blood pressure and total cholesterol level was sustained after discharge [40].

1.6 Focus group

Focus groups interviews are a form of qualitative research methodology used to generate data on a specific topic [41]. The interview has the form of a discussion with a selected group of individuals and the researcher, to gain information about their views and experiences on the selected topic. This approach enables the researcher to obtain a larger amount of information over a shorter period of time compared to individual interviews [42]. Group discussions can also make it easier for people to explore and clarify their views in ways that would be less easy in a face-to-face interview. The interviewer usually presents a series of open-ended questions with the intention to encourage the participants to explore the issues of importance to them, generating their own questions and pursuing their own priorities. Using focus groups makes it impossible to identify the views of individuals from the group view, since they are expressing their opinions in a specific context [42].

The person conducting the interview has a two part role. His or her responsibility is to moderate by keeping the discussion focused and if necessary steer the discussion back on course. The other role is to function as a facilitator to ensure that the group runs effectively [42, 43]. These are not easy tasks and call for good leadership and considerable skill and experience in order to be done well. Focus groups interviews typically extend over at least an hour, possibly two. Usually the person running the focus group has another person helping with taking detailed notes, administering the tape-recorder and helping in handling unexpected interruptions and asking questions where important and relevant.[43]

1.6.1 Group composition

Typically the focus group is composed of six to ten individuals, but it can have as few as four or as many as 15 people. The group has to be small enough so that everyone gets a chance to express their opinion, but large enough so that the group comprises participants with different perceptions. The group can be composed in two ways, as a homogenous group or as a heterogeneous group. Most researchers recommend aiming for a homogenous group [41]. In a homogenous group the participants have a common background, position or experience and could also often be "naturally occurring", for example consist of people who work together. This facilitates communication, promotes an exchange of ideas and experiences and also gives a sense of safety in expressing their own views. However, homogenous group can also result in "group think", so that diverse opinions and experiences may not be revealed.[41-43]

In a heterogeneous group, where the participants have a different background, position and experience, these differences can stimulate and enrich the discussion. It can also inspire the other group members to look at a topic in a different light. Some of the disadvantages with a heterogeneous group are the risk of power imbalances within the group, which can affect who speaks and what they say. It can also lead to lack of respect for the opinions expressed by some members of the group. A particular problem arises when one or two persons dominate the group, which can destroy the group process. This phenomenon is not only restricted to heterogeneous group, but can also be a problem in homogeneous groups. [41, 43]

1.6.2 Advantages and disadvantages

There are several advantages in the use of focus group interviews. It enables the researcher to collect data from several people at the same time, and is therefore both an effective and inexpensive research method. Group dynamics help in focusing on the most important topics and extreme views tend to be held under some control because the participants will often check and control each other. The rest of the group can also encourage people who normally do not express their own opinion, because they feel they have nothing to say, to do so. The participants can express their views in their own words, and the method therefore does not discriminate against people who cannot read or write. Participants tend to enjoy the experience, and they are also stimulated by thoughts and comments of others in the group.

Use of focus groups also has disadvantages. Due to the limited amount of time, the number of questions that can be asked are limited. Typically fewer than 10 questions can be asked in an hour. If one or two people dominate the group, the results can be biased by their view. The discussion therefore needs to be well managed and this requires considerable skills. Another disadvantage is that the results cannot be regarded as representative for the wider population, and therefore cannot be generalised. Confidentiality can be a problem in “group settings” and the participants need to be encouraged to keep confidential what they hear under the meeting. The researcher also has to emphasise to the participants that all data will be kept anonymous.

2 Aim and objectives

2.1 Aim

- Evaluate practice within pharmacist-led Diabetes Cardiovascular Risk Clinics and identify benefits from implementation of a standardised pharmaceutical care plan.
- Develop a database tool for reporting pharmaceutical care needs and actions for wider application in pharmacist-led Diabetes Cardiovascular Risk clinics and pharmacist-led Diabetes Management clinics.

2.2 Objectives

1. Review the literature on models of pharmaceutical care to patients with diabetes. Review documentation from local services to characterise service provision in hospital and primary care settings.

2. Conduct a prospective and retrospective audit of pharmaceutical care episodes at three chosen clinics. Quantify guideline standards addressed by the pharmaceutical care issues identified by the pharmacist at the clinic located at Western General Hospital.

3. Develop and populate a database using pharmaceutical care data from three chosen sites to quantify the pharmaceutical care issues addressed by the pharmacists and to standardise the recording of achievement of outcomes. Ensure that the database is suitable for recording data from pharmacist-led Diabetes Cardiovascular Risk (DCVR) risk clinics and pharmacist-led Diabetes Management clinics.

4. Receive feedback from a focus group of the DCVR clinic pharmacists to identify opportunities to standardise the approach of the pharmacists and the audit tools.

3 Subjects and Settings

The setting was three chosen outpatient Diabetes Cardiovascular Risk Clinics (DCVR) in Edinburgh located at Western General Hospital, Royal Infirmary of Edinburgh and Leith Community Treatment Centre. The three clinics will be referred to as clinic A, B and C, respectively hereafter. Clinics A and B are run on a weekly basis, while clinic C runs every fourth week. Patients are referred to the clinic by the Diabetes Clinic consultant physicians when they are considered to have high cardiovascular risk, and need a closer follow-up of their blood pressure and/or lipid profile. The pharmacists have the capacity to see six patients every clinic day, and the patients are asked to attend the clinic every 6-8 weeks.

For the purpose of this study, the researcher sat in at the three different clinics and collected patient details and pharmaceutical care issues prospectively. For patients previously seen by the pharmacist, the researcher also collected pharmaceutical care issues addressed by the pharmacists retrospectively. The data collection period was from February 5th until March 19th. A total number of 35 patients were seen by the pharmacists during this period. This patient sample reflects an opportunistic sample of patients under current care at the time the researcher visited the clinics. Of the 35 patients, three were new patients (two patients from clinic A, including one patient who was previously discharged from the clinic, and one patient from clinic B).

From clinic A, the researcher also retrospectively collected pharmaceutical care issues on a random selection of patients under current care (6 patients) and previously discharged patients from the pharmacists' private filing system (6 patients). In total 12 pharmaceutical care plans and patients notes were inspected retrospectively.

In total 47 patients' pharmaceutical care plans were reviewed. This comprised 33 pharmaceutical care plans from site A, 8 care plans from site B and 6 care plans from site C.

4 Methods

4.1 Literature review

A literature review was performed to try and identify models of pharmaceutical care used for patients with diabetes including local service provision in primary and secondary care.

The search was performed using MeSH terms in PubMed. In addition searches in Embase and freetext searches in PubMed were done. A search in Google was also done using similar terms as in PubMed. Examples of terms used are: *pharmaceutical care model, pharmaceutical care model AND diabetes, pharmaceutical care model AND cardiovascular disease, pharmaceutical care, pharmaceutical care AND diabetes, pharmaceutical care AND cardiovascular disease, diabetes AND cardiovascular disease.*

With the help of co-supervisor, pharmacist at clinic A, and co-ordinator of the other clinics, other pharmacists who run similar clinics as the study sites were contacted by e-mail, to obtain other pharmaceutical care plans to be reviewed.

Furthermore, a review of previous local projects undertaken in this field was done. Information about this was provided by the co-supervisor.

Finally searches in sights like The Pharmaceutical Journal (www.pjonline.com), British Medical Journal (www.bmj.com), American Diabetes Association (www.diabetes.org) and journals like Diabetes Care and Diabetic Medicine were performed. Some articles were also found by review of relevant articles reference list.

4.2 Evaluating the pharmaceutical care delivery

4.2.1 Ethics approval and patient confidentiality

The study received management approval from the NHS Lothian Director of Pharmacy and the Head of Pharmacy Education, Research and Development. As the

study was an audit, research Ethics Committee approval was not required. The protocol was also approved by the University of Tromsø in collaboration with the University of Strathclyde. Patient confidentiality and anonymity was maintained by giving each patient a study ID. All identifiable patient information was recorded in a separate coding sheet kept with the pharmaceutical care plans at each clinic. The data collection code sheet will be destroyed shortly after submitting this thesis.

4.2.2 Data collection form

A draft data collection form to be used to collect patient data and pharmaceutical care issues was developed by the researcher. The draft data collection form was based on the pharmaceutical care plan developed from a previous local project (Jude McEntire et *al* 2006 and Caroline Warnock et *al* 2006) (appendix 1), and now in use at clinic A and B, and a diabetes pharmaceutical care plan developed to be used in community settings (Dalal Taweel 2007 [44]) (appendix 2). The data collection form was e-mailed to the rest of the project co-supervisors to get feedback on the data fields included. Suggestions on changes to the data collection form were implemented in the form prior to the data collection period.

4.2.3 Pharmaceutical care issues

The researcher sat in at three chosen clinics (A, B and C) and recorded patient data and pharmaceutical care issues prospectively for the patients seen by the pharmacists during the period from 5th of February until 19th of March 2008. Clinic A and B run on a weekly basis on different weekdays and would generate many patients over a short time period. Clinic C runs only on a monthly basis, but was included since this clinic also comprises ethnic minority patients. A comparison of possible differences between the clinics could therefore be described. During a seven week data collection period the anticipated number of patients would be 96. According to the Head Pharmacist of the DCVR clinics the mean number of care issues per care episode is four, which would result in approximately a total of 400 care issues. A temporarily reduction in patients at clinic B, due to many patients being discharged from the clinic right before the data collection period started, cancellation of clinic dates and patients not showing up for their appointments

resulted in a lower number of prospectively included patients. Retrospectively patients were therefore also included in the study. Prospectively included patients who had a history of clinic attendance prior to the data collection period were also studied retrospectively to identify pharmaceutical care issues addressed by the pharmacist for a maximum of four previous consecutive clinic visits. Four consecutive clinic visits were set as a cut-off point, since this is the mean number of care episodes at the clinics [40]. All of the patients in the prospective part of the study were seen by the pharmacist at least once.

If possible pharmaceutical care plans and patients notes were reviewed by the researcher prior to the clinic day. After each patient consultation, the pharmaceutical care issues for each patient were discussed by the clinic pharmacist and the researcher to ensure that all of the care issues were recorded correctly. After the researcher had identified each patient's retrospective care issues through inspection of pharmaceutical care plans, the care issues were discussed with the individual pharmacist. This enabled each pharmacist to verify their own pharmaceutical care issues.

For the retrospective included patients, a random sample of pharmaceutical care plans of 12 patients were collected by the researcher at clinic A from the pharmacists' private filing cabinet. The only inclusion criterion was that the patients had to have attended the clinics for more than three care episodes. Patients included were both patients under current care by the pharmacist and patients now discharged from the clinic. Pharmaceutical care issues were identified from the pharmaceutical care plan and with the aid of patient notes. Any questions needed to interpret the care issue due to lack of clarity about the documented pharmaceutical care issues was discussed with the pharmacist, and the final interpretation verified by her.

All of the included patients from the three different clinics were pooled together (n = 47), and identified pharmaceutical care issues from the care plans were put in a Microsoft Access® database. The pharmaceutical care issues were categorised using standardised categories of 'checks' and 'changes', 'drug therapy problems' (DTP) and 'quality assurance (QA) descriptors'. The categorisation of DTP was based on a system of Cipolle et *al* [4] and the categorisation of care issues was undertaken using

a guideline (appendix 3) developed by fellow Norwegian student group whose project objective was to review the definitions (Kari Husabø, Marit Bergheim Christensen, Maren Rambøl Ruud and Reidun Os Husteli). Both the 'checks' and the 'changes' were divided into subcategories and categorised according to the 'QA descriptors' (see appendix 3). Care issues and the different categories of the categorisation system were quantified per care episode. It was not suitable to present the data expressed per patient, since most of the recruited patients were still under current care by the clinic pharmacists.

Descriptive information was prepared in order to describe the study patient sample. This included mean age, weight and BMI, distribution of male and female patients, distribution of type of diabetes and mean duration of diabetes since time of diagnosis.

4.2.4 Assessment of pharmaceutical care actions in relation to guideline standards at clinic A

Patients' (n = 33) care issues identified from pharmaceutical care plans from clinic A were also categorised according to any guideline standard it was addressing for patients with chronic cardiovascular disease. Only clinic A was chosen to execute this part of the project due to easy access to patients' notes at this site. The tool used is developed at the University of Strathclyde and has been published by Kamyar et *al* [45]. The guideline standards used were those included in an extended validated medication assessment tool (MAT_{CVD}) (see appendix 4) developed to measure compliance with guideline recommendations for chronic cardiovascular diseases developed by PhD student Tobias Dreischulte. The MAT_{CVD} could not be applied as an audit tool; that is it could not be used to assess patients' medication in terms of patients' needs and guideline recommendations. This was because documentation of the patients was not comprehensive enough to allow that and it was impractical to access and interrogate patients' notes during visits to enable full audit. Rather the MAT_{CVD} provided a categorisation system for those care issues and those pharmacists' actions that were centred on implementing or enforcing guideline standards.

The tool is divided into six different sections. The different sections are: miscellaneous (covering criteria relating to primary prevention and common to different cardiovascular diseases), hypertension, coronary heart disease (CHD), chronic heart failure, atrial fibrillation (AF) and warfarin use. All of the patients were regarded as falling in the miscellaneous and hypertension category, independent of any recorded diagnosis of hypertension. To fall in one of the other categories the patient had to have a recorded diagnosis of CHD, chronic heart failure, AF or been prescribed warfarin. Only care issues where the outcome was a change in the drug therapy of the patient, that is starting a new drug or increasing the dose of a drug, were categorised in terms of the guideline standard addressed. Agreement on how to categorise the different pharmaceutical actions was decided by the researcher together with academic supervisor and co-supervisors.

Examples on how to categorise:

- If a dose increase was done, this was viewed as an attempt to meet the target dose specified in the guideline.

- If a dose increase was not addressing a target dose, because there is no target dose specified in a guideline, e.g. calcium channel blockers, then the care issue was not categorised as addressing a standard even though it may be optimising dose to improve clinical outcomes. The goal, of optimising dose would be reflected in any dose change actioned (Change – dose increase subcategory).

- Any addition of antihypertensive therapy (including spironolactone and furosemide) or dose increase was a regarded as trying to meet guideline standard for target blood pressure, *"Achieved a blood pressure of ≤ 130 systolic AND ≤ 80mmHg diastolic"* and *"Achieved a blood pressure of ≤ 140 systolic AND ≤ 85 mmHg diastolic"*.

- Any addition of new medication for hypertension was regarded as meeting guideline standard 2, "*prescribed antihypertensive therapy*".

- Patient started for the first time on a statin was categorised as trying to meet guideline standard 3 and 4 "*prescribed a statin*", 5 and 6 "*prescribed simvastatin at a*

dose of at least 40 mg or equivalent dose of alternative statin or a documented maximum tolerable statin dose" and 8 "*total cholesterol ≤ 4 mmol/l*".

- Any increase in statin dose was categorised as addressing guideline standard 5, 6 and 8. Standard 5 and 6 are, "*prescribed simvastatin at a dose of at least 40 mg or equivalent dose of alternative statin or a documented maximum tolerable statin dose",* standard 8 is *"total cholesterol < 4 mmol/L*".

Some care issues therefore address no guideline standard; some care issues address one standard and some more than one standard. The frequency of standards being addressed is reported as per care episode and in relation to total number of guideline standards addressed in each section.

4.2.5 Development of the database

To develop a database suitable for recording data from both pharmacist-led diabetes cardiovascular risk clinics and from pharmacist-led Diabetes Management clinics, the researcher reviewed a pharmaceutical care plan developed in a project by Dalal Al-Taweel [44]. This care plan was developed for diabetes type 2 patients and systematically based on SCI-DC (Scottish Clinical Information Diabetes Collaboration) data fields. The data fields from this care plan (appendix 2) and the care plan under current implementation in the different DCVR clinics (appendix 1) were compared. Any data fields in the DCVR clinic pharmaceutical care plan which were not included in the type 2 diabetes care plan was regarded as essential and included in the final database. By combining the data fields from both of the pharmaceutical care plans, the completed database may include most of the information that the pharmacist would find useful in their pharmaceutical care of the patients. The program used to develop the database was Microsoft Access®.

Reports that were wanted from the database were: clinical details about the patients – blood pressure at first and final visit, number of patients with blood pressure above 140/80 mmHg, lipid levels (cholesterol and triglycerides) at first and final visit, body weight and BMI, number of smokers, high alcohol consumption patients, number of medications patients receive at first and final visit, type of medication patients are on,

number of patients on specific therapies e.g. ACE- inhibitors, patients renal function (eGFR and urine ACR) at first and last visit and also being able to link this to number of patients receiving e.g. ACE-inhibitors, liver function and glycaemic control (HbA1c). In addition reports on patients receiving dietary and exercise advise, patients referred on to other healthcare professionals (nurses, dieticians) and pharmaceutical care issues were wanted.

The database was tested for suitability to generate reports on pharmaceutical care activities and achievement of outcomes. Completed data collection forms for a few numbers of patients were entered retrospectively into the database and different test queries were performed, with assistance from the NHS Lothian ERD (Education Research and Development) administrator. Throughout the development of the database several minor adjustments were made. Tick-boxes were added in some of the forms of the database in order to make it easier to generate the desired reports.

4.3 Focus group

A focus group meeting was held 30th of April 2008 at the Royal Infirmary of Edinburgh, in order to receive feedback from the DCVR clinic pharmacists. This date was already scheduled for a regular meeting of this group. An invitation (appendix 7) to the focus group discussion was sent to the participants (see table 1) a week in advance, in addition to the project protocol (appendix 8). The researcher together with co-supervisors agreed a series of prompt questions to be discussed by the participants. The researcher was moderator for the meeting with the help of co-supervisors.

Table 1. Participants invited to the focus group meeting

Patient Care Setting	Initials
Secondary care	JR
Secondary care	RA/AM
Secondary care	CP
Primary care	LK
Primary care (GP practice)	PW
Secondary care	IB
Secondary care	AM

The researcher presented the results from the prospective and retrospective collection of pharmaceutical care activity at the three different clinics to the participants of the focus group (appendix 10). Then the results and questions about the relevance of audit for their practice and documentation of pharmaceutical care activity were discussed. Feedback on how relevant the participants thought a standardised care plan and a database were to their practice was also sought after. The discussion was tape-recorded with the consent of the participants and subsequently transcribed.

5 Results

5.1 Literature review

Studies and articles about diabetes and cardiovascular disease, pharmaceutical care models in diabetes and treatment recommendations in guidelines were found, and used in this thesis. Literature on previous local projects were also reviewed and used in different parts of this thesis to describe the delivery of pharmaceutical care provided to diabetes patients. These sources were also used to describe how the need for this project has developed.

Pharmaceutical care plans from other similar pharmacist-led clinics were sought after. Unfortunately none of the pharmacists that were contacted responded to the e-mail request. A reminder e-mail was sent out, but this also gave no response.

5.2 Evaluation of the pharmaceutical care delivery

5.2.1 Data collection form

The data collection form was designed to easily collect patient demographics, medical history, drug history and laboratory results from pharmaceutical care plans when sitting in the clinic with the patient (appendix 5). Data fields included in the data collection form were those included in the developed data base, which facilitated easy input of data.

5.2.2 Patient sample characteristics

During the data collection period from 5th of February until March 19th 2008 the researcher reviewed pharmaceutical care plans for 47 patients from the three different clinics (A, B and C). From clinic A, there were 21 prospective patients and 12 retrospective patients. At clinic B the number of prospective patients was eight in the same period, and six for clinic C. Of the 47 patients, three were new patients, three were discharged during the data collection period and six of the retrospective

patients were already discharged from clinic A. Basic demographic data of the total patient sample can be seen in table 2

Table 2. Demographic data of the total patient sample (n = 47)

Variable		Number (%)
Age (years)		
	Mean	65.7
	SD	12.6
	Range	36-84
	Median (IQR)	69 (56,77)
Gender		
	Male	21 (44.7)
	Female	26 (55.3)
Weight (kg)[1]		
	Mean	92.8
	SD	22.4
	Range	50-158
	Median (IQR)	93 (77,103)
BMI (kg/m^2)[2]		
	Mean	34.7
	SD	6.3
	Range	22-51
	Median (IQR)	34 (30,38)
Type of diabetes		
	Type 1	7 (14.9)
	Type 2	40 (85.1)
Time since diagnosis of diabetes (years)[3]		
	Mean	14.9
	SD	8.9
	Range	1-38
	Median (IQR)	13 (9,19)

1 Calculations from 44 patients with documented weight
2 Calculations from 40 patients with documented BMI
3 Calculations from 42 patients with documented time of diagnosis of diabetes

5.2.3 Categorisation of pharmaceutical care issues

Of the 47 patients recruited to the study the number of care episodes ranged from one to six. This gave a total number of 186 care episodes. From the pharmaceutical care plans and the prospective collection of data, 727 care issues were identified. This reflected a mean (SD) of 3.91 (1.27) care issues per care episode.

The pharmaceutical care issues were categorised as checks or changes, where changes were divided into *Change in drug therapy process* and *Change in drug therapy*. All of the care issues categorised as a 'change in drug therapy' were also categorised according to type of drug therapy problem. In addition the care issues were further categorised into *quality assurance descriptors*. Appendix 3 gives an explanation of the different parts of the categorisation system and the different subgroups. Table 3-10 summarises the results of the categorisation of care issues.

Table 3. Distribution of types of pharmaceutical care Checks (n = 373) in 47 patients managed over 186 care episodes

Type of check	**Count**	**Checks (%)**	**Per care episode**
- Medication needs inquiry	19	5.1	0.10
- Effectiveness inquiry	196	52.5	1.05
- Safety inquiry	144	38.6	0.77
- Compliance inquiry	14	3.8	0.08
Total	**373**	**100.0**	**2.00**
SD			1.17
CI (95 %)			(1.84,2.17)
Median (IQR)			2.00 (1.00,3.00)

A total of 373 checks were made in order to assess the need for additional medication, effectiveness and safety of treatment and patient compliance. None of these checks revealed any potential or actual drug therapy problems that needed further follow-up at this point or change in drug therapy. Most of the checks (91.5%) performed by the pharmacist were concerning the effectiveness of patients antihypertensive treatment (50.8%) and the safety of treatment (40.7%). The number of 'checks' performed by the pharmacists is higher than the total number of 'changes' (373 checks against a total of 354 changes over the overall 186 care episodes, see table 4 and 5). Per care episode there were 2.00 (SD 1.17) 'checks' made. This is not surprising since the most important objective of pharmaceutical care is to prevent potential drug therapy problems and therefore many routine checks have to be performed. 'Compliance inquiries' are performed on a routine basis, and especially if there are, for example, any unexpected blood pressure results or cholesterol

measurements. The number of 'compliance inquiries' is quite low; only 14 inquiries are documented over 186 care episodes.

Table 4. Distribution of types of Change in drug therapy process (n = 211) in 47 managed over 186 care episodes

Changes made to	**Count**	**Changes (%)**	**Per care episode**
- Clinical (shared) record of patient characteristics	4	1.9	0.02
- Clinical (shared) record of drug history	0	0.0	0.00
- Continuity of information/care between clinical settings	192	91.0	1.03
- Level of patient monitoring	15	7.1	0.08
- Health care team member(s) education/information	0	0.0	0.00
Total	**211**	**100.0**	**1.13**
SD			0.36
CI (95 %)			(1.08,1.19)
Median (IQR)			1.00 (1.00,1.00)

Table 4 shows that the total number of *changes in drug therapy process* was 211. As many as 192 (91%) were due to 'continuity of care/information between clinical settings'. This is not surprising in an out-patient clinic where recommendations for prescribing are provided to the GP. In addition 15 (7.1%) care issues identified the need for increased 'level of patient monitoring'. Over 186 care episodes the clinical shared records of patients' characteristics were changed four times. This accounts for 1.9% of the changes made in drug therapy process.

Table 5. Distribution of type of Change in drug therapy (n = 143) in 47 patients managed over 186 care episodes

Changes made to	**Count**	**Changes (%)**	**Per care episode**
- Drug selection (starting new or changing drug)	35	24.5	0.19
- Dose	55	38.4	0.30
- Route/dose form	0	0.0	0.00
- Dose interval/timing	2	1.4	0.01
- Duration	0	0.0	0.00
- Stop drug temporarily/permanently	7	4.9	0.04
- Patient or Carer understanding/compliance	44	30.8	0.24
Total number of change in drug therapy	**143**	**100.0**	**0.78**
SD			0.84.
CI (95 %)			(0.65,0.89)
Median (IQR)			1.00 (0.00,1.00)

Looking at table 5, changes to the patient's drug therapy were performed 143 times with a mean (SD) of 0.78 (0.84) per care episode. Most of these changes were dose adjustments, which were performed 55 times (38.4%). This is not surprising since the nature of the clinic is to provide close follow-up of the patients to achieve control of blood pressure by titrating drug doses. A new drug or a change in drug was done 35 times (24.5%). Again not surprising for those patients whose blood pressure is resistant to optimal doses of initial therapy. Of the total number of *changes in drug therapy*, 44 were related to 'patient or carer understanding/compliance'. This example illustrates the lack of documentation of educational activity. It would be expected that patients would be provided educational advice on every care episode. There are no changes made to the duration of treatment, this is because all of these changes were categorised in either 'dose interval/timing' or 'stop drug temporarily permanently'.

Table 6. Distribution of Drug therapy problems (n = 143) in 47 patients managed over 186 care episodes

Type of drug therapy problem (DTP)	Count	DTPs (%)	Per care episode
- Unnecessary drug therapy	1	0.7	~ 0.00
- Need for additional drug therapy	31	21.7	0.16
- Ineffective drug	2	1.4	0.01
- Dosage too low	45	31.5	0.24
- Adverse drug reaction	6	4.2	0.03
- Dosage too high	10	7.0	0.05
- Inappropriate compliance	48	33.5	0.26
- Unclassified non-DTP	0	0.0	0.00
Total	**143**	**100.0**	**0.75**
SD			0.84
CI (95 %)			(0.65,´0.89)
Median (IQR)			1.00 (0.00, 1.00)

All care issues categorised as *change in drug therapy* were also categorised as a *drug therapy problem*, which explains the total number of DTP of 143. Table 6 shows that every care issue categorised as a change in dose (n = 55) in table 5, was either due to too high dose (n = 10) or too low dose (n = 45). The distribution of DTP also illustrates that discontinuation of a drug, either permanently or temporarily (n = 7), was due to 'unnecessary drug therapy' (n = 1) and 'adverse drug reactions' (n = 6). All of the pharmacists' efforts to increase compliance are categorised as 'inappropriate compliance' (48, 33.5%) and includes all of the care issues categorised as 'patient or carer understanding/compliance' in change in drug therapy process. The pharmacists document a mean (SD) of 0.75 (0.84) DTP`s per care episode.

Each pharmaceutical care issues were also categorised according to *quality assurance descriptors*. This part of the categorisation system illustrates that pharmaceutical care delivery is a cyclical process. The pharmacist's role is to contribute to improve the quality of this process. The quality assurance descriptors

are therefore a tool which helps to identify when in the pharmaceutical care process the checks are made and the extent of the changes made to the drug therapy.

Table 7. Distribution of total number of pharmaceutical Checks (n = 727) in the quality system feedback loop in 47 patients managed over 186 care episodes

Type of check according to the quality system feedback loop	**Count**	**Checks (%)**	**Per care episode**
- Verification	64	8.8	0.34
- Monitoring	646	88.9	3.47
- Confirmation	17	2.3	0.09
Total	**727**	**100.0**	**3.90**
SD			1.27
CI (95 %)			(3.73, 4.09)
Median (IQR)			4.00 (3.00, 5.00)

From table 7 one can see that, of the total 727 care issues, 64 (8.8%) 'verifications' were performed by the pharmacists at the start of a patient treatment/ when the pharmacists first assessed the patient. Almost all of the checks made were 'monitoring' checks, 646 (88.9%), made during the patient treatment. Evaluations of the patient treatment, 'confirmations', were only done 17 times (2.3%), which is not surprising in an out-patient setting.

Table 8. Distribution of true pharmaceutical Checks (n = 584) in the quality system feedback loop in 47 patients managed over 186 care episodes

Time perspective according to the quality system feedback loop	**Count**	**Checks (%)**	**Per care episode**
- Verification	48	8.2	0.26
- Monitoring	519	88.9	2.79
- Confirmation	17	2.9	0.09
Total	**584**	**100.0**	**3.14**
SD			1.21
CI (95 %)			(2.97, 3.31)
Median (IQR)			3.00 (2.00, 4.00)

Table 8 shows the breakdown to true checks, i.e. time of checks that did not lead to a change in the patient's drug treatment. Most of these checks were 'monitoring' checks performed to ensure effectiveness and safety of patients' treatment. In total the pharmacists perform 3.14 checks per care episode.

Table 9. Distribution of Changes in drug therapy (n = 143) in the quality system feedbackloop in 47 patients managed over 186 care episodes

Degree of change according to the quality system feedback loop	Count	Change (%)	Per care episode
- Adjustment	143	100.0	0.77
- Modification	0	0.0	0.00
- Prompt a review	0	0.0	0.00
Total number of degree of change	143	100	0.77
SD			0.84
CI (95 %)			(0.65, 0.89)
Median (IQR)			1.00 (0.00, 1.00)

All of the changes made to the patient's treatment were categorised as an 'adjustment', 143 (100%). This number reflects that every change made to a patient's treatment was made according to the agreed treatment plan. None of the changes in drug therapy identified the need for a change in a patient treatment plan ('modification') or a need for re-assessment of a patient treatment.

Table 10. Distribution of Degree of changes (n = 147) in the quality system feedbackloop, linked to the preceding Timer perspective in 47 patients managed over 186 care episodes

Type of check	Type of associated change	Count	Check (%)	Per care episode
- Verification	Adjustment	16	11.2	0.09
	Modification	0	0.0	0.00
- Monitoring	Adjustment	127	88.8	0.68
- Confirmation	Modification	0	0.0	0.00
	Prompt a review	0	0.0	0.00
Total		**143**	**100**	**0.77**
SD				0.77
CI (95 %)				(0.65, 0.89)
Median (IQR)				1.00 (0.00, 1.00)

'Adjustments' to patients' treatment were done 16 times (11.2%) as a result of a 'verification' check done by the pharmacist when they first saw the patient. All of the other 'adjustments' were performed during the patients' attendance to the clinic, and were the result of 'monitoring' checks, 127 (88.8%).

5.2.4 Differences between the three clinics

No statistical comparison of the different clinics and the pharmacists was done in this study. All of the clinics focus on the same main areas; blood pressure lowering, control of lipid levels, compliance, and education on disease management and drug therapy. The researcher did however when sitting in at the clinic see that the pharmacists had different ways of approaching the patients. Mostly these differences are directly linked to how the clinic is run. Although there are differences between how the clinics are run and types of patient, this may not have any impact on types of care issues that are identified by the pharmacists. The following sections are therefore the researcher's own interpretation of the differences between the clinics.

Clinic A is run on a weekly basis and the pharmacist is also there the following day. Laboratory results can therefore be checked the day after the clinic, so that the patient will be notified quickly if any changes to the treatment have to be done, or if any new arrangements have to be made. Dictating or writing letters to the GP`s and updating SCI-DC does not necessarily have to be done during the clinic, but could be done the next day. On a busy clinic day, this releases extra time to be used on patient consultation, writing in the pharmaceutical care plans and discussion of the outcome of the clinic with the diabetes consultant. Preparation for next week's clinic is done the second day by review of the care plans and patients' notes.

Clinic B is also run on a weekly basis, but the pharmacist is just there one day of the week. Any results from laboratory tests are therefore checked the following week. Changes to patients' medication is usually made one week after the clinic visit, because the results have to be verified before any changes can be made. Writing letters to the GP`s and updating SCI-DC are done on the clinic day after discussion of the outcomes from the clinic with the diabetes consultant. Preparations for next week's clinic have to be done in the morning of the clinic day. The pharmacist at this

clinic does not always have access to the patient notes, so she has to rely more on her own notes in the care plans. As a result of this the pharmacist writes more complete notes in her care plans, and this made it easier for the researcher to identify PCI`s.

Looking at clinic C, this is a monthly clinic, which also includes ethnic minority patients. Many of the patients attending the clinic do not have English as their first language. A huge part of the pharmacist's job is therefore to provide education on diabetes management, cardiovascular risks, drug therapy and other educational advice in the patient's own language. This is information that is important for the patient to have knowledge about, but that can be difficult for other healthcare personnel to provide to this patient group because of the language barrier. A few of the patients referred to the clinic do not necessarily have increased cardiovascular risk, but are attending the clinic to prevent that. In contrast to the other clinics, the pharmacist at clinic C also focuses more on HbA1c and dietary advice. Just like clinic B, dictation of GP letters are done on the clinic day and preparation for next clinic is done in the morning before the clinic.

5.2.5 Pharmaceutical care actions in relation to guideline standards at clinic A

From clinic A, 33 patients and their pharmaceutical care plans were reviewed, which gave a total of 129 care episodes. The researcher wanted to find out how many of the pharmacist's actions which resulted in a change in a patients medication was an attempt to implement or enforce guideline standards. An overview of the distribution of cardiovascular diseases in the study sample can be seen in table 11.

Table 11. Distribution of cardiovascular diseases and hypertension in the patient sample from clinic A (n = 65 diseases in 33 patients)

Type of disease	Distribution of diseases (%) n=65	Frequency among patients (%) n = 33
Hypertension[1]	33 (50.8)	33 (100.0)
Ischaemic heart disease (IHD)[2]	8 (12.3)	8 (24.2)
- Angina	6 (9.2)	6 (18.2)
- Myocardial infarction (MI)	2 (3.1)	2 (6.1)
Coronary artery bypass graft (CABG)	4 (6.2)	4 (12.1)
Peripheral vascular disease (PVD)	5 (7.7)	5 (15.2)
Stroke/TIA[3]	3 (4.6)	3 (9.1)
- cerebrovascular disease	3 (4.6)	3 (9.1)
Atrial fibrillation	1 (1.5)	1 (3.0)
Total	**65 (100.0)**	

1 All of the patients were regarded as having hypertension independent of having a recorded diagnosis of such in patient notes
2 In the patients notes both diagnosis of IHD, angina and MI were used, so no clear indication of what type of IHD the patients in the IHD group have
3 Both Stroke/TIA and cerebrovascular disease were used in patients' notes

None of the patients in the patient sample were on warfarin and none of the patients had a diagnosis of chronic heart failure. These two sections of the MAT tool criteria were therefore not included in the survey of criteria addressed by the pharmacists' actions.

Care issues with an outcome of a change in medication to the patient were categorised according to if they addressed any guideline standard. There were 51 care issues leading to a change in drug therapy, which resulted in a total of 130 guideline standards tried to be met. The frequency of standards tried to be met and frequency per care episode are shown in table 12. The table shows only the guideline standard adopted from the MAT_{CVD} tool, the whole tool can be viewed in appendix 4.

Table 12. Distribution of identified pharmacist care issues (medication changes) in 33 patients in 129 care episodes at clinic A addressing clinical guideline standards

#	Care issues addressing the guideline standards below	Count (%)	Per care episode
	Miscellaneous		
1	Invited to join smoking cessation program	0 (0.0)	0.000
2	Prescribed antihypertensive therapy	16 (51.7)	0.124
3	Prescribed a statin	1 (3.2)	0.008
4	Prescribed a statin	1 (3.2)	0.008
5	Prescribed simvastatin 40 mg or equivalent dose of alternative statin or maximum documented tolerated dose	4 (12.9)	0.031
6	Prescribed simvastatin 40 mg or equivalent dose of alternative statin or maximum documented tolerated dose	4 (12.9)	0.031
7	Prescribed an acceptable statin (…)	0 (0.0)	0.000
8	TC ≤ 4 mmol/l	4 (12.9)	0.031
9	Prescribed aspirin 75 mg	0 (0.0)	0.000
10	Prescribed aspirin 75 mg	0 (0.0)	0.000
11	Prescribed aspirin 75 mg	0 (0.0)	0.000
12	Achieved a blood pressure ≤ 150/90 mmHg	0 (0.0)	0.000
13	Prescribed a combination of aspirin plus dipyridamole	0 (0.0)	0.000
14	Prescribed clopidogrel at a dose of 75 mg instead of aspirin	0 (0.0)	0.000
15	Prescribed an ACE-inhibitor	1 (3.2)	0.008
16	Prescribed metformin	0 (0.0)	0.000
Subtotal		**31 (100.0)**	**(0.241)**
Mean (SD)			0.015 (0.031)
CI (95 %)			*
Median (IQR)			0.000 (0.000, 0.014)
	Hypertension		
17	Achieved a BP of ≤ 130 mmHg systolic AND ≤ 80 mmHg diastolic	45 (47.3)	0.349
18	Achieved a BP of ≤ 140 mmHg systolic AND ≤ 85 mmHg diastolic	45 (47.3)	0.349
19	Prescribed a calcium channel blocker or ACE-inhibitor	0 (0.0)	0.000
20	Prescribed an ACE inhibitor	1 (1.1)	0.008
21	Prescribed an AII antagonist	0 (0.0)	0.000
22	Prescribed a thiazide diuretic or calcium channel blocker	4 (4.3)	0.031
23	NOT prescribed a combination of a thiazide diuretic and a BB	0 (0.0)	0.000
24	Drugs on specified list are avoided	0 (0.0)	0.000
Subtotal		**95 (100.0)**	**(0.737)**
Mean (SD)			0.092 (0.159)
CI (95 %)			*
Median (IQR)			0.004 (0.000, 0.111)
	CHD		
25	Prescribed a beta-blocker	0 (0.0)	0.000
26	Prescribed a rate-limiting calcium channel blocker, long acting nitrates or nicorandil	0 (0.0)	0.000
27	Prescribed a long acting nitrate or nicorandil	0 (0.0)	0.000
28	Prescribed sublingual glyceryl trinitrate or glyceryl trinitrate spray	0 (0.0)	0.000
29	Prescribed a calcium channel blocker	0 (0.0)	0.000
30	Prescribed amlodipine or felodipine	1 (25.0)	0.008
31	Uses a dosing regimen which avoids the development of tolerance	0	0.000
32	Prescribed target dose (C 50 mg bd, E 20-40 od, L or R 10 mg od) or a documented maximum tolerated dose	3 (75.0)	0.023
Subtotal		**4 (100.0)**	**0.031**
Mean (SD)			0.004 (0.008)
CI (95 %)			*
Median (IQR)			0.000(0.000, 0.0042

Table 12. Continues

#	Care issues addressing the guideline standards below	Count (%)	Per care episode
	Chronic heart failure		
33	Prescribed target dose (C 50 mg tds, E 10-20 mg bd, L 20 od, R 10 mg od, P 8 mg od or T 4 mg od) or a documented maximum tolerated dose	x	x
34	Drugs on specified list are avoided	x	x
35	Prescribed an AII antagonist	x	x
36	Prescribed candesartan	x	x
37	Prescribed combination of hydralazine and ISDN	x	x
38	Prescribed target dose (L 50 mg od, C 32 mg od, V 160 mg bd) or a documented maximum tolerated dose	x	x
39	Prescribed a beta blocker (except metoprolol tartrate)	x	x
40	Prescribed target dose (C 25-50 mg bd, B or N od) or a documented maximum tolerated dose	x	x
41	Prescribed diuretic treatment	x	x
42	Prescribed spironolactone	x	x
43	Prescribed eplerenone	x	x
44	Prescribed eplerenone	x	x
45	Prescribed target dose (S 25-50 mg od, E 50 mg od) or a documented maximum tolerated dose	x	x
46	Prescribed digoxin	x	x
47	Receives an annual influenza vaccination	x	x
48	Received a once-only pneumococcal vaccination	x	x
49	Prescribed a beta blocker or digoxin	x	x
	AF		
50	Prescribed either a beta-blocker, verapamil, diltiazem or digoxin	0 (0.0)	0.000
51	Prescribed warfarin	0 (0.0)	0.000
52	Is prescribed antiplatelet therapy	0 (0.0)	0.000
Subtotal		**0 (0.0)**	**0.000**
Mean (SD)			-
CI (95 %)			-
Median (IQR)			-
	Warfarin		
53	INR measured in intervals of which none > 12 weeks	x	x
54	INR measured within 1 week after dose change or starting each drug	x	x
55	INR measured within 1 week after dose change or starting each drug	x	x
56	INR history with at least 60 % of INRs witin target range	x	x

* Unable to calculate confidence interval because the proportion is too small or too large

The reason that the number of guideline standards is higher than the number of care issues is that each pharmacist action has the possibility to try and meet several guideline standards.

Most of the pharmacist actions resulted in dose adjustments and can therefore be viewed as an attempt to met guideline standard 17 and 18. Any new addition of antihypertensive therapy is also an attempt to meet the same two standards. The number of times standard 17 and 18 was tried to be met was 45 (in 34.9% of the total

number of care episodes), which gives a total of 90 standards that were tried to be met. All of the patients have a degree of hypertension, which explains why as many as 95 of the guideline standards tried to be met fall into the hypertension section, with a mean (SD) of 0.092 (0.159) per care episode.

When looking at the atrial fibrillation section, no guideline standards were addressed by the pharmacists identified pharmaceutical care issues in this section. This was because only one of the 33 patients had a diagnosis of atrial fibrillation, and this patient was only on an antiplatelet agent. Issues regarding warfarin and INR (international normalized ratio) measurements are addressed in separate warfarin management clinics. Necessary scrutiny does however have to be made in decisions regarding changes in medication or drug doses, since warfarin interacts with many different medicines. Results from recent INR measurements can be verified if necessary from Apex, but these actions would not be regarded as a monitoring check and therefore not reflected in these results.

5.3 Pharmaceutical care delivery assessment tool

The care plan in use at clinic A and B (appendix 1) was compared to the diabetes pharmaceutical care plan to be used in community settings (appendix 2). The diabetes care plan covered most of the data that were recorded at the clinic, but a few data fields had to be added from the DCVR pharmaceutical care plan. These were: *Date of first visit, referral BP, target BP, BP on final visit, target weight, referred to dietician and medication checked and verified by*. The database is divided into different forms; these are outlined in bold in table 13 below. The data fields included in each form are also outlined in the table.

Table 13. Data fields included in the completed database

Included data fields
Patient details
- Study ID - Clinic ID - Date of birth - Gender - Age - Height - Weight - Target weight - BMI - Date of first visit - Number of clinic visits - Blood pressure measurements • Referral blood pressure, target blood pressure, final blood pressure - Family history • Cardiovascular disease, diabetes, other – specify, unknown - Ethnic origin • White, black, asian, chinese, other - specify - Social history • Living alone, living with partner/family, pregnant, breastfeeding, other - specify - Special needs • Sight, hearing, speech, physical, none, other – specify - Smoking habit • Never smoked, ex-smoker > 5 years, ex-smoker ≤ 5 years, current smoker < 10 cpd, current smoker ≥ 10 cpd, unknown • Smoking advice given - Alcohol consumption • No alcohol, within limit, excess limit, unknown • Alcohol advice given - History of complications • Neuropathy, retinopathy, nephropathy, amputations, foot ulcers, erectile dysfunction, mood disorder, recurrent infection, microalbuminuria[1] • Comments

Table 13. Continues

- Medication checked and verified by
    - SCI-DC, GP letter, GP practice, patient, patients own drugs, repeat prescription

Educational needs assessment

- General advice
    - Diabetes, diabetes control, cardiovascular, complications, diet, exercise, smoking cessation

- Self medication
    - Oral agent timing, missed doses, insulin administration, injection sites, written information on medicines

- Self management
    - Glucose monitoring, monitoring diary, hypos, foot care, intercurrent illness, compliance aid, compliance – good, poor or unknown

- Self management assessment
    - Concordance, comprehension, dexterity
- Comments
- Referred to dietician

Relevant medical history

- Year of diagnosis
- Diagnosis
- Cardiovascular history and diabetes history tic-boxes[2]

Drug history

- Start date
- Stop date
- Drug (tic-box for cardiovascular medicines, diabetes medicines, other relevant medicines including OTC, first clinic visit, last clinic visit, vaccine)[2]
- Dose, route, frequency
- Status: annual, current, history
- Indication
- Allergic reaction
- Comments

Laboratory investigations

- Date
- Laboratory investigation/marker
- Result (tic box for first clinic visit, last clinic visit, out of range)[2]
- Category: Biochemical, LFT`s, lipids, general

Table 13. Continues

Annual review GP/hospital
- Date attended - Screen: Eye, foot, renal - Comment - Date due
Pharmaceutical care activity
- Care issue - Action - Output
Categorisation of pharmaceutical care issues[3]
- Check: Medication need, effectiveness, safety, compliance - Change in drug therapy process: Record of patient characteristics, record of drug history, continuity of care information/care between clinical settings, level of patient monitoring, health care team member(s) education/information - Change in drug therapy: Drug selection, dose, route/dose form, dose interval/ timing, duration, stop drug temporarily/permanently, patient or carer understanding/ compliance - DTP code: Unnecessary drug therapy, need for additional drug therapy, ineffective drug, dosage too low, adverse drug reaction, dosage too high, inappropriate compliance, unclassified non-DTP - Quality assurance – Time perspective: Verification, monitoring, confirmation - Quality assurance – degree of change: Adjustment, modification, review

1 Added after field testing of data collection form
2 Added to be able to do relevant queries
3 Added as part of project – could be used in later audits

5.4 Focus group

The focus group meeting was held on the 30th of April at Royal Infirmary of Edinburgh. Not all the pharmacists from the different DCVR clinics were able to attend the meeting. This was not necessary to get a useful discussion of the topics of the focus group. However all of the pharmacists involved in the data collection were present. All of the pharmacists present can be viewed in table 14.

In addition the academic co-supervisor was present to take notes and helped guide the discussion together with the researcher. To allow external validation, the whole discussion was tape recorded and subsequently transcribed (appendix 6). The transcript does not include the researcher's presentation of the results, only the questions asked to initiate the discussion.

Table 14. Participants (pharmacists) present at the focus group

Type of Patient Care Setting	Initials
Secondary care	JR
Secondary care	RA
Secondary care	CP
Primary care	LK
Secondary care	AC

Results as a reflection of practice

The findings from the focus group revealed that the pharmacists thought that the results did reflect what they did in practice. However questions were raised in regards of how they record pharmaceutical actions. Not all of their actions are written in the care plans and that was taken up as a reason for some of the discrepancy from the results. Instead of writing it on the care plans, many of the actions performed by the pharmacist are written directly into SCI-DC, or in some cases not written down at all.

" … I know I change the drug from SCI-DC, but I don't always say that in my notes care plan, cause you do it, and you say increase dose and then you go and make it

in SCI-DC, but you then don't go back and say: changed it in SCI-DC, because you already said dose changed." (Pharmacist 1)

"(…) the thing with me is I don't write down enough of what I say. Because I mean I'm not- I'm doing it, but it's not clear enough that I'm doing it… (…)." (Pharmacist 2)

"And also if seeing patients notes, sometimes you don't write everything in your own notes, but when your dictating the letter. You know it's gonna be in the letter, so if (…)." (Pharmacist 1)

The relevance of this kind of audit to their practice

Many of the pharmacists did think auditing their practice was relevant. This was mainly because the results made them reflect on how they performed their job and also ways to improve the service they are providing. One of the pharmacists thought that it was quite interesting that there was such a big difference in the different categories; that the high numbers were so much higher than the low numbers.

"(…) whether we are not touching on it or whether it is not necessary or (…)." (Pharmacist 2) *"… Or if it's not documented, and that's the numbers of record of drug history."* (Pharmacist 5) *"We're doing that (clinical shared record of patient characteristics and clinical shared record of drug history), but we are not documenting it."* (Pharmacist 2 and 5)

Another pharmacist felt that the low number of compliance inquiries was an important issue. This was also recognised by many of the other participants. Without sufficient information about the medicines the patients are taking, pharmacists are unable to review their treatment.

"The thing is I'm having more problems with the compliance inquiries illuming, because a huge part of the patients don't know what they're taking. And unless they bring in their medicine…their actually (…) having complications I think, I would have to look it over (…). I'm going to ask them to bring them in (…). That should be quite interesting, but the whole interaction is based on the quality of everything of what they're taking, and why (…) taking." (Pharmacist 3)

"I only always do a (medication review) if they bring their tablets, because like you (Pharmacist 3), I just don't trust them." (Pharmacist 1)

"Next time, bring your tablets. All my tablets? Yes, all your tablets. And we'll go through… and then I get them to say, what's that for, what's that for? How do you

take it? And that's how I find out what their taking and if they know what it's for. And if they say: Oh, my daughter fills it. And I say: Well, can your daughter come in next time?" (Pharmacist 1)

"So I think that is something that we could probably build on and improve the problem." (Pharmacist 3)

It also came up in the discussion how one could continue to do audits in the future. As one pharmacist pointed out, it has to be easy to execute and feasible to do in the time available at the clinics.

"(…) so it's got to be useful and functional, but it's got to be slick. And then there is the other side of; should we do it all the time or should we do it periodically. You know again, if you do it all the time and people get tired and they are not good at filling in and all that. But if you actually want a good data collection do it for a (…) period (…)." (Pharmacist 3)

"(…)You were having to make assumptions based on what you could see and what you thought was going on…Ehm…so that might be a bit of a problem with it. The other way of doing it would be for us to, as we go along; categorise, but then again there is interperson variation of what we think…" (Pharmacist 3)

This kind of audit would help in the argument for pharmacist-led clinics rather than nurse-led clinics

Participants found it at first difficult to discuss the benefits about pharmacist-led clinics over nurse-led clinics. One of the pharmacists said that pharmacists are not promoting their success and that they therefore let themselves down. It was suggested that the comparison should be with doctors instead of nurses and importantly, as one pharmacist pointed out - does a comparison have to be made?

"But I think what we said about comparing it to nurses, you know, to promote the role of pharmacist-led clinics we need to say pharmacist do X, Y and Z and nurses actually do X. And you would get more value for money. But there would have to be a comparison which you could use to say, well this is the parameters we have measured and in a previous nurse study, this is what we measured, therefore…you are getting more value for money…" (Pharmacist 1)

"It is interesting, when the doctors see their patients in GP practices (…) and check their HbA1c, you know, and they've got ten, 15 minutes. A medication discussion can't be done in that time; we need a lot longer." (Pharmacist 5)

"(…) I think it is unfair for me to have to compare, we're constantly having to justify our position, but nurses don't have to justify their position, doctors don't have to justify their position (…)." (Pharmacist 3)

The value of documenting their contribution to pharmaceutical care

All of the pharmacists recognised the need to document their contribution to pharmaceutical care, but there was difference in opinion on what to document and to what extent. For example, not everything is written down in the pharmaceutical care plans, since they also document care on SCI-DC and write letters to the patients GP`s.

"If you don't document it, then it's pointless so, then…" (Pharmacist 3)

"Why don't we just write into patients notes?" (Pharmacist 1)

"I think if you are aware of the need to document, then you're probably in most cases to do so within your time constraint in the clinic. And I think X`s project has demonstrated quite (…) now, that there is a need to document effort over clinical outcomes…". (Pharmacist 4)

"Maybe there is a way of looking at the key, common care issues, coding them and having them on each care plan, so that you are just ticking it (…) so that it is not very labour intensive (…)." (Pharmacist 4)

Audit as a method to provide consistent practice

One pharmacist stated that the practice was consistent within the different clinics, but that this was probably not easily recognised.

"(…) the care is quite consistent, but we are maybe not, because we are not recording it, we maybe can't see as much of the consistency that is actually happening (…)." (Pharmacist 3)

Database as an assessment tool

Most of the pharmacists were positive about the database and felt that it contained most of the information/ data fields they would want to have in a tool like this. A

couple of limitations were raised regarding the usefulness of the database. The first was the absence of connection to SCI-DC and the second was that a database is much more labour intensive than the Microsoft Excel® spreadsheet that the pharmacists now use. The potential of the database to produce reports for use by the DCVR pharmacists, but also for higher management were suggested.

"And who else could have access to it? If you go to SCI-DC, you know who the last person was that was following that patient. Another clinician checks to see, oh I wonder what the pharmacist did? So you know, you still have to go to SCI-DC to do patients visits, so that it is recorded, but that you actually saw them (…)."
(Pharmacist 1)

"(…) other healthcare professionals need to have access to what we are doing, because if they are currently unaware of what we are doing, then they need to be able to see what we are doing. And if they don't have access to our paper notes (…)."
(Pharmacist 1)

A few of the pharmacists said that a database is labour intense, but pointed out that most of the workload would be only at the first clinic visit. It would therefore be possible to use it as an up to date database where audit data could be derived periodically. This would enable continuous audit of practice.

"(…) we talk about just using this as a first visit and final visit. It would be interesting to use it as an up to date database, it surely is (…)." (Pharmacist 3)

Prompted a change in practice

Many of the pharmacists gave the expression that this had prompted reconsideration of their views, both on how they document their activity and the need to continue auditing their practice.

"I think we need to look at (…) what we are doing and how we are auditing and how we would want to be auditing." (Pharmacist 4)

"I'll certainly contact X about what indicators (…) something like safety, that's an obvious one. And that we could easily construct from our figures now – patient safety (…) you know yourself there are so many incidents on a daily basis, where patients doses have to be reduced or adverse effects or you know (…)." (Pharmacist 4)

6 Discussion

6.1 Principal findings

Evaluation of the pharmaceutical care delivery to diabetes patients with high cardiovascular risk in this study, focused on pharmaceutical care issues addressing optimisation of pharmacotherapy, patient education and implementation of evidence-based guideline standards for reduction in cardiovascular risk factors.

As previously described, this study highlighted the lack of pharmacist documentation of pharmaceutical care issues and pharmacist actions in the pharmaceutical care plans. Only 14 compliance inquiries and 44 episodes of patient education were documented over the 186 care episodes. In addition, only four pharmaceutical care issues addressing updating the clinical shared records were identified. However, the number of effectiveness and safety inquiries was high. Starting patients on new drugs and dose adjustments were also high, suggesting that only the most important pharmaceutical care issues involving changes to the patients' treatment are documented in the pharmaceutical care plans. However, diabetes is associated with many serious long-term conditions which may have a huge impact on patients' quality of life. By providing structured patient education the patients will get equipped with the knowledge, skills and confidence to tackle their condition and ultimately prevent diabetes related complications.

Currently, within Scotland, the Government have trough "*The Diabetes Framework Action Plan*" pinned down patient education as a key issue in the management of diabetes patients [8]. This is best achieved through consistent standard information provided by healthcare professionals. Patients in this study had regular visits to the DCVR clinics (at least every 6 to 8) weeks to follow-up their treatment, and this should provide the opportunity for continuous reinforcement of information. Education on their condition, the need for treatment and how their medicines work may help improve compliance. Compliance is checked by the pharmacists through self-reporting and repeat prescriptions. As it was discussed at the focus group meeting, this is not a reliable method for measuring compliance. A better solution would be to ask the patients to bring with them all of their medications at the first clinic visit and

then do a full medication review. Assessment of compliance may then be carried out early in the care process and this could have a positive effect on compliance and consequently on clinical outcomes. Patients with diabetes and high cardiovascular risk, like this study population, frequently have very complicated drug regimens. This can result in adverse effects and potential compliance issues. Continuous assessment and surveillance is therefore important in the successful management of chronic diseases, illustrated by diabetes and related hypertension. Patients are provided with information and education during the clinic visits, but it is in many cases not written down in the pharmaceutical care plans. The same is true for changes made to clinical shared records; the records are updated, but the actions are not written down in the pharmaceutical care plan. The discrepancies from practice prompt the pharmacist's need to document identified pharmaceutical care issues and pharmacists actions. For pharmacists to demonstrate their worth, the standard of pharmacist documentation needs to improve. This study resulted in a database suitable for recording patient data and pharmaceutical care issues. A tool like this would help in standardising the approach and documentation of the pharmacists. Through practical use of the database in the handling of collected data, it has been demonstrated that useful reports on the pharmaceutical care delivery can be generated.

The study focused on the assessment and monitoring of three main focus areas: hypertension, dyslipidaemia and diabetes, but this was not to the exclusion of other pharmaceutical care issues related to other conditions identified in the assessment of the patients. This resulted in identification of a significant number of PCI`s necessitating drug alterations and/or dose adjustments to reach target blood pressure and lipid levels. The implementation of changes to the patients' treatments were discussed and agreed with the diabetes consultants before written recommendations were sent to the GP`s. Although many of the pharmacists in the DCVR clinics are supplementary prescribers, and some are on their way to become independent prescribers, changes to a patient's medication have to be done by written recommendations to their GP. Hospitals in Scotland do not provide out-patient prescriptions as the cost of the medications is paid for by the Community Health Partnerships which all GP surgeries belongs to. The only prescriptions provided are for specialist clinics where the medications are only available on the advice of a

specialist consultant, and/ or the medication has to be made in the hospital pharmacy e.g. oncology and dermatology clinics. The prescribing practice is in this way due to accountability, responsibility and economic reasons. All care issues categorised as *Change in drug therapy* (table 6) are therefore indirect changes initiated by the pharmacist to the GP`s. The GPs are the ones involved in the direct change, since they ultimately write the prescriptions. The implementation of changes to the treatment may therefore in many cases be delayed, due to the prolonged pathway the patients have to go through to receive their new medications. This may also be one contributing factor for poor compliance in some patients.

Periodically audits were recognised by the DCVR pharmacists as an important method to ensure consistent practice of delivery of pharmaceutical care. They also acknowledge the necessity to focus on not just clinical outcomes, but also their contribution to pharmaceutical care of the patients, by identifying pharmaceutical care issues. Categorisation of pharmaceutical care issues provides a basis of quantitative description of the care provided.

6.2 Strengths and limitations of the study

6.2.1 Pharmaceutical care delivery

Pharmaceutical care is difficult to evaluate due to its complexity. Since pharmaceutical care is provided through a multidisciplinary approach, it is difficult to attribute any change in outcome solely on the pharmacist. By identifying PCI`s and pharmacist actions and subsequently systematically categorise these, it is possible to quantify pharmacists contribution to pharmaceutical care. In this study, the care issues were divided into ‘checks’, ‘changes’, ‘DTP`s’ and ‘quality assurance descriptors’. The changes were again divided into ‘Change in drug therapy process’ and ‘Change in drug therapy’. This division makes it possible to distinguish between changes or activities performed by the pharmacist which do not result in any change in the drug therapy for the patient, and changes which do result in a change in the patient drug therapy. In clinics such as the DCVR clinics there are a lot of ‘Changes in drug therapy process’ which have to be performed every clinic visit. Treatment recommendations and letters to the GP`s, any referrals to other healthcare

professionals such as dieticians, and updating SCI-DC are all important examples of such activities performed by the pharmacist. These are activities that not directly lead to any change in the patient treatment, but still constitute a huge part of the pharmacists' contribution to pharmaceutical care. It is therefore important to also quantify these actions.

The data collection period was only over seven weeks, which resulted in 35 prospective patients included. This number of patients is much lower than the expected number of patients of 96. However, this is due to natural occurring incidences as mentioned earlier (see methods). Number of patients included from each of the clinics is also different. This was due to the limited project time frame. These circumstances are of importance to what conclusions that could be drawn from this project. Had the data collection period could have been prolonged it would have been possible to get comparable patient samples from all of the sites. In this study retrospective patients were also included and PCI`s were also collected retrospectively for the prospective patients included in the study. Consequently, the number of patients, 47 patients with a total number of 186 care episodes, would therefore be expected to give a reasonable resolution of the PCI`s identified by the DCVR clinic pharmacists.

Although PCI`s were collected prospectively, the majority of them were collected retrospectively from pharmaceutical care plans. The data from the categorisation are therefore regarded as an illustration of the documented pharmaceutical care activity of the pharmacists. Some of the PCI`s identified by the pharmacists are not written down in the pharmaceutical care plan, but in the letter detailing the outcome of the clinic visit to the GP. Since most of the data collection was limited to inspection of pharmaceutical care plans, these care issues would not have been picked up. Had only prospectively PCI`s been categorised, one would therefore suspect that the distribution of PCI`s would be different, due to the lack of documentation. A prospective approach would enable the data collection of PCI`s to be based on actual PCI`s identified by the pharmacists, and not from their memory and what is written down in the pharmaceutical care plan. This would also have shown a reflection of the exact standard of pharmaceutical care provided at the clinics within the data collection period.

Looking at the distribution of true 'time of check' as many as 88.9% were categorised as 'monitoring' checks performed during the patient treatment. As a comparison, only 8.2% and 2.9% were categorised as 'verification' and 'confirmation', respectively. This large variation in the frequency of each subcategory could be attributable to the study design. Most of the patients included were under current care in the clinics, and many first clinic visits did not match the inclusion criteria (maximum of four retrospective consecutive clinic visits). For the same reason, there were also not many patients discharged from the clinic during the data collection period. Most 'verifications' are done in the first care episode and the majority of 'confirmations' are done in the last care episode. The number of 'verifications' and 'confirmations' may therefore be an underestimate of the actual number of care issues categorised in these subgroups of the 'quality assurance descriptors'.

Over 186 care episodes a total number of 727 pharmaceutical care issues were identified and categorised. The only way of assuring the quality of categorisation was to strictly follow the guideline (appendix 3) and the examples of categorised pharmaceutical care issues developed by fellow Norwegian students. This ensured consistency in the categorisation process. Since the guideline has just recently been developed, the number of people with familiarity and experience in using this system is limited. It was therefore not possible to perform an inter-rater reliability test to ensure consistent application of the categorisation system. In future the researcher would therefore recommend having a training session for future students before starting on projects like this. In the researcher experience difficulties in the interpretation of different care issues are often easier to discover when applying the system in practice. Then problems in the application of the system can be dealt with early in the process, rather than during the use of the categorisation system. Through discussion, the different interpretations of the different parts of the categorisation system can be resolved. This will provide necessary quality assurance of the final results.

Pharmaceutical care issues with unknown outcomes are incomplete and were therefore not included in the categorisation system. This was because it is no way of knowing if the care issue was followed up by the pharmacist or if it was just not documented. By having a prospective research approach to the collection of care

issues this allowed most gaps in documentation to be filled by inquiry of the pharmacist responsible for the care of the patients in the study. Some outcomes could nevertheless not be categorised. This was due to an outcome that was not able to be verified by the pharmacist, or that the outcome of the care issue was still under investigation. One example of the first scenario is when the pharmacist asks the GP to recheck laboratory results and the GP surgery is not linked to the Apex system. The outcome of the care issue is then unknown if the patient cannot personally verify that the tests have been done. If there is no way of verifying the outcome, the pharmacist will in most cases then make sure new laboratory tests are done. The latter scenario is due to the close proximity of the termination of the data collection and the generation of the results. Some of the pharmaceutical care checks performed by the pharmacists take a long time to get the results from, and the outcomes were therefore unknown when the PCI`s were categorised. In both of these scenarios the care issues could not be included in the categorisation system.

No analysis of number of care issues without outcome was made in this study since all care issues without outcome were followed up by the researcher. It is therefore not possible to know if the care issue would have been followed up by the pharmacist or not if the researcher had not been so actively involved. If solely a retrospective approach was used, the number of care issues with no outcome may have been of interest. This could have provided information of the percentage of care issues the pharmacist has time to follow up.

6.2.2 Pharmaceutical care issues addressing guideline standards

The guideline standards included in the medication assessment tool is limited. This is because the tool is developed to be applied on the targeted population of the average practitioner and therefore the average patient. In specialised clinics, like the DCVR clinics, there are circumstances when it may be most appropriate to deviate from clinical guidelines. Especially in complex cases, such as the patients attending the clinic, where many of them have associated multiple comorbidities and are resistant to standard therapies. In these cases there is a need to clearly document prescribing decisions in the medical records. In an out-patient setting like this, it is

also important to justify these decisions to the GP`s, since they are the ones that ultimately writes the prescription and follows up the patient after discharge.

The most treatment-resistant patients at the clinic are prescribed spironolactone as a last step to try and lower their blood pressure. Spironolactone has no indication for use in the treatment of hypertension in the BNF (British National Formulary) and in cardiovascular diseases it is mainly used to treat congestive heart failure due to its diuretic effect [46]. However, in treatment-resistant cases of hypertension the use of spironolactone could have an impressive blood pressure lowering effect [47]. Loop-diuretics, e.g. furosemide, are also prescribed to many of the patients attending the clinic. This drug-class does not have a place in the treatment of hypertension except in patients with impaired renal function and/or heart failure [47]. These two drug classes were not included in the list of antihypertensive drugs defined in the MAT. For the purpose of this study, these drugs were included in the list of antihypertensive drugs. This is a good example of how a single MAT tool is not applicable in all patient populations.

Many of the standards in the MAT were not addressed by the pharmacist over the 129 care episodes. This is due to a number of reasons. To not include all care episodes for each patient in the study could be criticised for not providing the complete picture of the pharmacist's effort of implementing guideline standards. The patients referred to the clinic are also, in the majority of cases, already on antihypertensive drugs or have tried a lot of different ones, and many of the treatment standards are therefore already implemented. The pharmacist will in such cases review the patient's previous and current drug history to ensure that the treatment follows the treatment guidelines. Any changes that are recommended to the treatment would therefore follow the patient's subsequent treatment step. Because of the before mentioned reasons, no conclusion can be drawn by the researcher about what standards the pharmacist should be addressing, but is currently not addressing. It is however possible to see which standards are most frequently enforced.

The MAT could not be applied as an audit tool since it was not time to do a full medical record review. Pharmaceutical care issues were instead categorised according to which guideline standards were being enforced without any predefined

audit standard. The qualifying statement for each standard was also not taken under consideration to ensure that the standards were applicable. Instead the researcher together with the research group (comprising academic supervisor, clinical supervisor and co- academic supervisor) agreed a set of examples on how to categorise the care issues according to the standards. This ensured consistency in categorisation by the researcher. The results from this part of the project are therefore not based on a validated method. This method strictly shows the guideline standards which are frequently enforced by the pharmacists actions. In order to conduct a successful audit one have to set clear standards, observe current practice and compare practice against the preset standards. Findings can then identify problems areas or confirm either that current practice is effective or that there is an identified need to implement changes.

6.2.3 The database as an assessment tool

By entering in patient information and laboratory results, it is shown that the database can be used as an assessment tool in the achievement of clinical outcomes. Wider application of the possible uses of the database could therefore be explored. Another advantage is that data entered electronically are more standardised and would facilitate a more uniform way of recording patient data and outcomes.

Since the database comprises all data fields included in the current DCVR care plan, this could make it applicable as an up to date database. Its practical use would then not be restricted to be applied just as a periodically audit tool. As the categorisation system is already integrated into the database this could be used in the clinical utility of clinical recommendations and for quality improvement and research purposes. Currently, the pharmacist's main focus in the clinic is on cardiovascular risk factors, and to a lesser degree on diabetes management. This is because these patients are already receiving a multidisciplinary follow-up of their condition since they are a part of the out-patient diabetes clinic at the different sites.

In smaller communities and in the future, pharmacists will most likely provide a more holistic approach in patients' management of diabetes. The database already comprises most of the necessary data fields to record pharmaceutical care issues

related to diabetes since it is based on data fields derived from SCI-DC. It would therefore also be applicable for use in pharmacist-led Diabetes Management clinics.

The database has also several limitations. First, the development of this database began before it was completely made clear which reports were wanted to be produced. The person assisting in the practical development of the database also had only limited experience in Microsoft Access®. Adjustments were therefore made accordingly in each successive phase of the development. The desired reports for the purpose of this study were therefore able to be generated from the database. If more complex reports are wanted, it may be necessary to do some adjustment to the configuration. Careful planning and consideration of the nature of the reports one wants to produce is best done before the actual construction of the database begins. This will make it easier to create the necessary relationships between the different forms in the database. Furthermore, some of the patient data and especially the laboratory investigations take a lot of time to key in. Several changes to the database may have to be made before its potential could be fully utilised.

6.3 Comparison to other studies

6.3.1 Categorisation of pharmaceutical care issues

Currently there is not a universal agreed system which is systematically developed and tested for reliability and validity in categorisation of pharmaceutical care issues. This makes it difficult to compare different studies and patient populations. Most studies therefore create their own lists of categories when evaluating the pharmacists' contribution to pharmaceutical care.

One study [14], evaluated the feasibility and impact of a community pharmacist input as a member of the multidisciplinary team for 62 patients with type 2 diabetes. Pharmaceutical care issues were divided into three categories: (1) drug therapy problems (according to the Hepler and Strand classification [2]), (2) monitoring and (3) patient knowledge. In total 178 PCI`s were identified (mean [range] 2.9 [1-5] per patient). This represented 76 drug therapy problems, 21 monitoring checks and 81 care issues related to patient knowledge. The percentage of monitoring checks were

higher in our study, but since the categories and the care issues included in each category is different, it is not possible to speculate of any reason for this difference.

Another study [39] investigated the pharmaceutical care delivery at one of the DCVR clinics by retrospective review of pharmaceutical care plans for 134 patients. This led to the identification of 490 pharmaceutical care issues, 941 changes and 1034 monitoring checks. Although many of the categories included in that study are the same as in this study and the study population is the same, a statistical comparison cannot be made. This is due to that the fact that the categories have been slightly changed and so not been applied in the same way. The most frequent pharmaceutical care issues addressed by the pharmacist in that study were optimization of antihypertensive dosage, prescription of additional drug therapy and avoidance of adverse drug reactions. These are also the most frequent drug therapy problems identified in our study, suggesting that the pharmaceutical care delivery is nevertheless quite consistent even though the care issues are categorised somewhat differently.

A third study [7], developed and tested a system for documenting pharmaceutical care issues in the delivery of chemotherapy to cancer patients. From 171 pharmaceutical care plans, 430 recorded pharmaceutical care issues (0.7 per patient episode) were entered in the database. These PCI`s represented 238 monitoring checks, largely due to safety inquiries, and 192 pharmacist initiated changes to drug therapy. Of the documented drug therapy changes 48% addressed drug selection issues, 29% inappropriate doses and 15% inappropriate dosing intervals or duration of therapy. The categories used in that study, did also include many of the same categories used in our study, but as mentioned before, a comparison is hard to do because of different application of the categories and the unmatched study population.

6.3.2 Application of Medication Assessment Tools

A medication assessment tool (MAT) incorporates clinical guideline standards that should be met in relation to certain inclusion criteria. Tools like this is used in audits to optimise interventions based on evidence-based guidelines and through this enforce best clinical practise to improve patient outcomes. In one study [45], a previous

developed medication assessment tool for coronary heart disease (MAT-CHD) were applied to 208 diabetes type 2 patients, with or without ischemic heart disease, attending a primary care medical centre. The study showed that overall adherence to guideline criteria was significantly lower in secondary prevention than for primary prevention of coronary heart disease (74% vs. 80%, P< 0.05; Chi square). The tool highlighted areas for review and possible improvement in clinical guideline implementation for the prevention of CHD.

In another study, an evidence based MAT tool was applied in a diabetes out-patients clinic to 214 patients to measure the quality of prescribing of drug therapy for cardiovascular disease in diabetes patients [48]. The three criteria with the lowest adherence were "achievement of target blood pressure in patients on antihypertensives" (43%), "use of aspirin in primary prevention of CHD" (51%) and "use of ACE inhibitors in patients with defined risk factors" (55%). This highlighted the need to improve prescribing practice in antihypertensive management in patients with diabetes. It also reflected the known difficulties in achieving target blood pressures.

Since the MAT-CVD could not be applied as an audit tool in this study, it is difficult to compare any of the findings with the results from the two other studies. However, both these studies highlighted areas of the clinical guidelines which offer a means of co-operation between supplementary/independent prescribers and the GP. Guidelines implemented in this study did also highlight areas in which pharmacists play an important part in assuring the quality of care provided to these patients. The guideline standards most frequently addressed by the pharmacist in our study, "achievement of target blood pressure" and "prescribed antihypertensive therapy", are addressing some of the identified criteria with low adherence in the study situated in the diabetes out-patient setting [48]. This would suggest that the pharmacist contributes to improve implementation of guideline standards in areas with low adherence.

6.4 Future considerations

6.4.1 Implications of the study to practice

The categorisation of pharmaceutical care issues has provided a good method of evaluating the pharmaceutical care delivery at the clinics. Findings from the audit suggested lack of documentation of some pharmaceutical care issues and pharmacist activities. These were discussed in the focus group meeting comprising the DCVR clinic pharmacists. Discrepancies between the results and practice were highlighted and reviewed, and periodically audits were endorsed by the pharmacists as a method showing their contribution to the pharmaceutical care process. Although, the results can not be used to say if the pharmaceutical care delivery is consistent within the different clinics, due to limited number of clinics included, they do provide necessary evidence on the pharmacists' contribution to the management of cardiovascular risk factors in diabetes patients. However, increased emphasis on auditing of practice and standard ways of documentation will ensure consistent practice in the future.

As of now, the project has resulted in the development of a database suitable for recording patient details, clinical outcomes and pharmaceutical care issues. The aim would be to implement the necessary data fields for the pharmacist into the SCI-DC database. A shared medical record will make sure that pharmacists can be shown to be doing the right thing in individual patient care. Auditing the service and evaluating it through research will make sure that pharmacist can be shown to be doing the right thing to a group of patients. A clinical shared record would also enable other healthcare providers to more clearly see what the pharmacist contribute with, and ensure a more efficient communication pathway between pharmacists and GP`s, and also other members in the diabetes management multidisciplinary team.

This study has highlighted the need to improve pharmacist documentation. It is important that pharmacist document evidence showing positive outcomes in the management of diabetes patients. Broadcasting of this information would be valuable, because it may raise the awareness of other healthcare professionals regarding pharmacists as effective clinicians involved in the management of diabetes patients. This increased awareness could elevate pharmacists profile and support

their engagement in specialised clinics, as the DCVR clinics are, and also pharmacists' contribution to pharmaceutical care in other parts of the healthcare service. Pharmacists have already been endorsed as important healthcare providers through the expansion of prescribing rights to independent prescribing and though the chronic medication service in the new Scottish community pharmacy program [11].

The database can be used to generate reports of the pharmacists' activities when it comes to both clinical outcomes and pharmaceutical care issues. These reports can be provided to higher management to shown the added benefit of having pharmacists included in the multidisciplinary team, and possibly help secure reimbursement of pharmacist services.

The database can also be used as a tool to generate reports to demonstrate risk management activity, assess pharmaceutical care needs and may help to inform strategic decisions in the development of pharmaceutical care services. By showing positive reports on the pharmaceutical care delivery that is provided in the clinics, this could provide support for setting up more clinics within both primary and secondary care settings. Reports on pharmaceutical care needs can allow strategic planning of services to patient subgroups with the highest pharmaceutical care needs.

6.4.2 Categorisation of pharmaceutical care issues in clinical practice

In a busy clinical practice it can be difficult to make time to categorise care issues in addition to carry out all of the usual tasks. A categorisation system should therefore be easy to use, it should be fast and it should reflect reality. The first impression of the categorisation system used in this study is that it at first can seem complex and difficult to use straight away. It would therefore be difficult to get good inter-rater reliability when first starting to use the system. This obstacle could be managed by having peer review meetings where one could discuss how the different pharmacist would categorise different care issues. Over time this would facilitate increased consistency in the use of the categorisation system. Eventually, increased familiarity with the system would also make it easier and quicker to use in clinical practice. Auditing of practice would then not be depending on students coming in to do the work periodically. Another benefit of self auditing is that the pharmacists know each

patient and their pharmaceutical care issues well. The standard of documentation would then not influence the outcome of the audit.

Implementation of self auditing of practice would take time. Every pharmacist have to be equally involved in the work, the methods that are going to be used have to be clear and consistent and the results have to be followed up. Auditing is of no benefit if there is no evident point of why it is executed. One possible negative side of self auditing could be the risk of bias if the results are an overestimate of the pharmacists' true contribution to the pharmaceutical care delivery. This would be an argument for having an independent data analyst coming in to conduct the audit.

6.5 Future work and unanswered questions

As a natural part of the audit cycle the results from the evaluation of the pharmaceutical care delivery needs to be presented to the Lothian Managed Clinical Network through Lothian Diabetes Service Advisory Group (LDSAG) following review by the Pharmacy Diabetes Strategy Group.

Populating the database with more patients will allow assessment of pharmaceutical care needs for different patient populations e.g. diabetes ethnic minority patients. An audit comprising all of the DCVR clinics could provide information on if the pharmaceutical care provided is consistent. Since this project clearly demonstrated lack of documentation in the pharmaceutical care plans, it would be interesting to do an audit comparing retrospectively and prospectively collected pharmaceutical care issues. This will make it possible to assess if the level of documentation has been improved and/or highlight the areas which still needs improvement.

Audits of the pharmaceutical care delivery need to be done periodically to ensure that the proposed changes have been implemented, and that the pharmaceutical care of the patients has been improved. This is the only way to reach a higher level of quality of care.

The patients gets close follow-up of their treatment by the pharmacist when they attend the clinics, and after discharge the pharmaceutical care of the patients is the

GP`s responsibility. It is therefore a need to ensure continuity of pharmaceutical care after discharge. Due to the new community pharmacist contract for management of chronic diseases [11], community pharmacists are expected to provide a specified level of pharmaceutical care. The medication assessment tool can be used to characterise and quantify pharmaceutical care issues outstanding in patients discharged from the DCVR clinic. This information can be used to develop documentation which can be used in the discharge process from the DCVR clinics.

The database has to be tried out in practice by the DCVR clinical pharmacists. Feedback after the trial period will provide information on any necessary changes that has to be made in order to make it more easy to use, able to generate more useful reports and comprise all necessary data fields.

7 Conclusion

By conducting an audit of the pharmaceutical care delivery at three of the DCVR clinics, a profile of the care provided was made. The results showed little contribution by the pharmacists in some areas of the pharmaceutical care delivery, suggesting lack of pharmacist documentation. This was acknowledged by the DCVR pharmacists in the focus group meeting as the reason for the discrepancy from clinical practice.

The standard of pharmacist documentation has to improve for pharmacists to prove their worth. A database, as developed in this project, would greatly help to achieve that. Further refinement of the instrument is likely to improve the ease of use and minimize the time required for entering in data. Populating the database with more patients will make it possible to use as a tool to identify pharmaceutical care needs and help in strategic planning of services.

Clinical audit is a valuable tool to ensure continuous quality improvement in the management of diabetes patients with high cardiovascular risk. The results from this audit served as a prompt for the DCVR clinic pharmacist in how to best provide the patients with optimum pharmaceutical care.

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9 Appendices

Appendix 1: Diabetic Cardiovascular Risk Clinic - Patient Care Plan

Addressograph	Date of first visit: _____ Referral BP: _____ Target BP: _____

Diagnosis:
Referral Information including Relevant Medical History:

Weight: _____ Target weight:_____ BMI:_____

Smoker: ☐ Yes ☐ No If yes (_____ cigarettes /day) **Ex-smoker**: ☐ Yes ☐ No Date stopped:_____

Alcohol: ☐ Yes ☐ No Units per week: _____ Advice:_____.

Exercise advice: _____ Conditions limiting exercise: _____

Diet advice _____ Referred to dietician ☐ Yes ☐ No

Compliance: ☐ Good ☐ Poor Action taken:_____

Allergies/Sensitivities:_____

Date	Previous Drug therapy	Pharmaceutical Issues

Medication checked and verified by: SCI-DC GP Letter GP practise Patient Patients own drugs Repeat Prescription
(Please circle)
Other _____

Patients Name:_____

Cardiovascular medicines (antihypertensives, lipid lowering agents, antiplatelet agents)

Start date	Medication	Dose/Directions	Stop	Indications/Comments

Other relevant medicines

Start Date	Medication	Dose/instructions	Stop	Indication/comments (can medication increase blood pressure/cholesterol)

	Date									
Biochemical	eGFR									
	Creat (55-150 µmol/l)									
	Urea (2.5-6.6 mmol/l)									
	Urine ACR									
	Na (132-144 mmol/l)									
	K (3.6-5.1 mmol/l)									
	Gluc (3.6-5.8 mmol/l)									
Lipids	Total chol									
	HDL									
	LDL (<2mmol/L)									
	TG (0.5-1.9mmol/L)									
	Total/HDL (<4 mmol)									
LFTs	ALT (10-40 u/l)									
	ALB (36-47g/l)									
	AlkP (40-125 u/l)									
	GGT (5-35 u/l)									
Other	CK									

Patients Name:_____

Patient admitted to clinic on what step of treatment process:_____

Note: If the patients' treatment is not following the step-wise process e.g. patient starting treatment at step 4, then any medication to be added should be done so starting at step 1 and continued according to the clinic guidelines.

CARE ISSUE: Treatment of Hypertension in patients WITH or WITHOUT macrovascular disease.

	Drug Name (Please tick the box if already on/tried this drug)	U&Es, BP checked Y/N?	Any C/I: Y/N	Drug initiated? Y/N	U&Es, BP checked after initiation Y/N?	Side effects: Y/N	Pharmacist Interventions / Comments
Step 1	**Lisinopril 2.5mg** Date:_____				After 1 wk	Cough?	
	Lisinopril 10mg/20mg Date:_____				After 1 wk	Cough?	
	Candersarten 8-16mg **or** **Irbesarten 150mg** (patients with diabetic nephropathy) **Max 300mg** Date:_____				After 2 wks		
Step 2	**Bendroflumethazide 2.5mg** Date:_____		CrCl < 30ml/min				
	Furosemide 20mg (↑ to 40mg after 4wks) Pts with macrovascular disease only Date:_____						
Step3	**Amlodipine 5mg** Increasing to 10mg OD after 4-6weeks Date:_____						
Step 4	**Atenolol 50mg** Date:_____						
Step 5	**Spironolactone 25mg** Increasing to 50mg then 100mg as necessary Date:_____				After 5 Days		
Step 6	**Doxazosin 1mg** Increased to 2mg OD after 1-2 wks then 4mg, 8mg and MAX 16mg Date:_____						

Patients Name:_____

CARE ISSUE: To ensure that patients who are candidates for ANTIPLATELET THERAPY receive appropriate treatment.

Indications for use:

All patients with diabetes should be on anti-platelet therapy unless contraindicated, once BP is relatively controlled (< 160/90 mmHg), due to 10 year risk of CVD > 20%.

Drug Name (Please tick the box if already on/tried this drug)	Any C/Is	Any S/Es	Treatment started? Y/N
Step 1: Aspirin 75mg daily Date:_____	Unstable BP or BP > 150/90 mmHg		
Step 2: Aspirin + PPI Date_____	Unstable BP or BP > 150/90 mmHg		
Step 3: Clopidogrel 75mg Date_____			

CARE ISSUE: To ensure that patients who are candidates for LIPID LOWERING THERAPY receive appropriate treatment.

Indications for use:

All patients with diabetes should be on lipid lowering therapy unless contraindiacted.

Drug Name (Please tick the box if already on/tried this drug)	LFTS checked before starting Y/N	Any C/Is or interactions?	Statin started? Y/N	LFTs and Chol checked after 2-3 months	Target Reached – Y/N If no go next step
Step 1: Simvastatin 20/80mg daily Date_____					
Step 2: Atorvastatin 10–80mg daily Date_____					
Step 3: Other statin _____					
Other: Combined Statin and Fibrate _____					

*If renally impaired - Use Lipantil micro 6

High Triglvcerides	Any C/Is? renal impairment*	Any S/Es	Treatment Started? – Y/N
Fenofibrate (Lipantil micro 267) Date_____			

First Visit:

Date:_____

BP (Sphyg)	BP (ABM)

Notes and Interventions:

Letter to GP ☐

Patients Name:_____

Visit no. 2

Date:_____

BP	U+E'S	Smoking /Alcohol	Exercise / Diet	Compliance	GP accepted advice	Pt taking new Rx

Notes and Interventions:

Letter to GP ☐

Visit no. 3

Date:_____

BP	U+E'S	Smoking /Alcohol	Exercise / Diet	Compliance	GP accepted advice	Pt taking new Rx

Notes and Interventions:

Letter to GP ☐

Visit no. 4

Date:_____

BP	U+E'S	Smoking /Alcohol	Exercise / Diet	Compliance	GP accepted advice	Pt taking new Rx

Notes and Interventions:

Letter to GP ☐

Visit no. 5

Date:_____

BP	U+E'S	Smoking /Alcohol	Exercise / Diet	Compliance	GP accepted advice	Pt taking new Rx

Notes and Interventions:

Letter to GP ☐

Appendix 2: PHARMACEUTICAL CARE PLAN: TYPE 2 DIABETES
PATIENT PROFILE

(Patient label) Name	CHI #	Gender	Social History	Family History
		Male ☐ Female ☐	Living alone ☐ Living with Partner/family ☐ Other:	
Address	**Date of birth/ Age**	**Weight/ kg** / **Height/m**	Pregnant ☐ Breastfeeding ☐	**Drug sensitivities**
Postcode		**BMI**	**Smoking status:** Smoker ☐	
DepCat	**Date diagnosed**	**Occupation**	Number/day:	**Vaccines:** **Date**
General practitioner	**Community Pharmacy**	**Ethnic origin** White ☐ Black ☐ Asian ☐ Chinese ☐ Other ☐ *Specify:*	Non-smoker ☐ Ex-smoker ☐ Since	Annual Flu ☐ Single Pneumococcal ☐
Address **Tel**	**Address** **Tel**		**Alcohol consumption** Y ☐ N ☐ Units/week:	Comment

Limitations/Special needs

Sight ☐ Hearing ☐ Speech☐ Language ☐ Physical ☐ Other☐

Comment

Annual Review:	**Date Attended**	**Date Due**	**Comment**
Eye			
Foot			
Renal			

History of complications

Neuropathy☐ Retinopathy☐ Nephropathy☐ Amputations☐ Foot ulcers☐ Erectile dysfunction☐ Mood disorder☐ Recurrent infections☐

Date/ Comment

DIABETES TREATMENT (PAST AND CURRENT)

Medication	Start	Stop	Reason	Medication	Start	Stop	Reason

CARDIOVASCULAR HISTORY AND CURRENT MEDICINES

Hypertension ☐ **Stroke/TIA** ☐ **IHD** ☐ [Angina ☐ MI ☐] Angioplasty ☐ CABG ☐ **PVD** ☐ **Other**

Dates:							
Aspirin 75-150mg ☐	**Oral nitrate** ☐ Specify		**ACE I** ☐ Specify		**Others/comments:**		
Clopidogrel 75mg ☐							
β-Blocker ☐ Specify	**Ca blocker** ☐ Specify		**Maximum tolerated?** ☐				
GTN ☐ Specify	**Statin** ☐ Specify		**ARB** ☐ Specify				
	Maximum tolerated? ☐		**Maximum tolerated?** ☐				

OTHER MEDICAL HISTORY	Date		Date	**OTHER DRUG HISTORY (including OTC)**	Date		Date

EPISODES OF CARE	Care Episode 1 Date: Values	Date	Care Episode 2 Date: Values	Date	Care Episode 3 Date: Values	Date	Care Episode 4 Date: Values	Date	Care Episode 5 Date: Values	Date	Care Episode 6 Date: Values	Date
HbA1c *(%)*												
TC *(mmol/L)*												
HDL *(mmol/L)*												
LDL *(mmol/L)*												
TG *(mmol/L)*												
TC:HDL												
K *(mmol/L)*												
Blood pressure (*mmHg)*												
LFTs ALT/AST												
Creatinine *(µmol/L)*												
Microalbuminuria *(M: ACR >2.5mg/mmol) (F: ACR > 3.5mg/mmol)*												
Proteinuria (*ACR>30mg/mmol)*												
Comment												

EDUCATIONAL NEEDS ASSESSMENT *Date of assessment:*

General advice		*Self-medication*		*Self-management*		*Self-management Assessment*
Diabetes	☐	Oral agent timing	☐	Glucose monitoring	☐	Concordance *(min)* + ☐ ++☐ +++☐ *(max)*
Cardiovascular	☐	Missed doses	☐	Monitoring diary	☐	Comprehension (*min*) 1 ☐☐☐☐ 4 (*max*)
Diabetes control	☐	Insulin administration	☐	Hypos	☐	Dexterity (*min*) 1 ☐☐☐☐ 4 (*max*)
Complications	☐	Injection sites	☐	Foot care	☐	*Comments:*
Diet/Exercise	☐	Insulin compliance	☐	Intercurrent illness	☐	
Smoking cessation	☐	Written information on medicines	☐	Compliance aid	☐	

INDIVIDUALISED CARE ISSUES

Week No + Date	Care Issue	Patient Education / Documentation changes and Therapeutic Plan Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Output (Initial)		

	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		
	Specify		
	Action		
	Output (Initial)		

Appendix 3: GUIDELINES FOR CATEGORISATION OF 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. Check

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

4.2 Changes

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

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

5 Change in Drug Therapy Process

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

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

Table 3 Change in Drug Therapy Process categories

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

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

Clinical (shared) record of patient characteristics

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

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

Clinical (shared) record of drug history

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

Continuity of information/care between clinical settings

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

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

Level of patient monitoring

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

Health care team member(s) education / information

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

6 Change in Drug Therapy

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

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

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

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

Table 4. Change in Drug Therapy categories

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

7 Drug Therapy Problems (DTP)

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

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

Table 5. Categories and common causes of drug therapy problems

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

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

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

8 Quality Assurance Descriptors

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

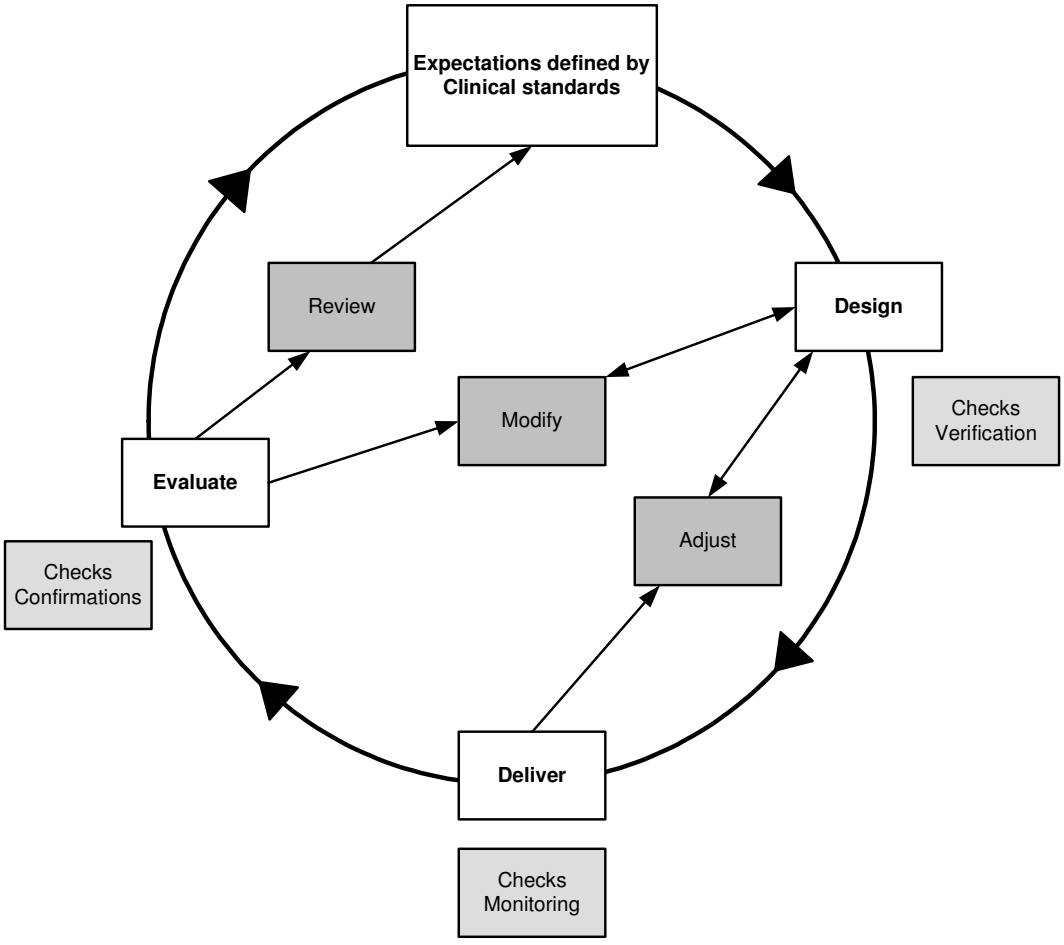

Figure 1 Pharmaceutical care model

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

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

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

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

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

8.1 Time Perspective

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

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

Time Perspective	**Code**	
Verification Verification of appropriateness of medications in the proposed treatment plan	**VER**	Checks at the start of the treatment to make sure that, for each medicine, the patient: - is on the right medicine - is on the right dose - is not on unnecessary medication - doesn't have any new needs for additional medication - is not receiving a combination of interacting medicines - understands how to take their medication and what it will do to them

Monitoring Implementation of treatment is appropriate and checking for safety and effectiveness	**MON**	Checks as treatment continues which should ensure that, for each medicine, the patient: - is on receiving medication as intended - continues to be on the most suitable dose - has no symptoms of unwanted(adverse) effects - understands how to take their medication
Confirmation Checking that medication is producing positive outcomes	**CON**	Confirmation and documentation to identify that medication is: - resulting in expected effects on the patient's condition - not failing to control condition - not producing unwanted effects requiring clinical review.

Verification

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

- In chronic disease management, for instance by a clinical pharmacist at an outpatient clinic or a community pharmacy, 'Verification' is done at the first episode of care with the pharmacist. That may or may not be at the start of the patient's treatment but must be undertaken for the pharmacist to assure himself or herself that the proposed treatment plan is suitable for the patient's need.
- When the patient is seen in an interim episode of care interrupting chronic disease management, for instance by a clinical pharmacist at a hospital ward during an acute admission, the verification category will relate to when the pharmacist first saw the patient. 'Verification' of the patient's drug treatment is done at admission, or when a new drug is started. All checks at this point in care should be categorised as 'Verification' even if the treatment has been going on for a long time prior to the hospitalisation.

Monitoring

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

Confirmation

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

8.2 Degree of Change

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

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

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

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

If a *Check* leads to a *Change,* the *Time Perspective* (i.e. at what time in the treatment cycle the check is done) will influence the choice of the subsequent *Degree of*

Change. As seen in figure 1 and table 9, a **Verification** can lead to either an **Adjustment** or a **Modification**. A **Monitoring** issue can only lead to an **Adjustmen**t. If a need for a bigger change in the treatment is identified, a **Confirmation** of the whole treatment of the patient is needed before a decision to either 'modify' or 'review' the treatment can be made. A **Confirmation** can lead to either a **Modification** or a **Review**, depending on the outcome of the 'confirmation'.

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

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

Adjustment

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

Modification

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

Prompt a Review

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

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 4: MAT for patients with chronic cardiovascular disease

	Qualifying criteria		Standards
1[i]	Current smoker	MISCELLANEOUS	Invited to join smoking cessation programme
2[ii]	Diagnosis of hypertension (HTN)		Prescribed antihypertensive therapy
3[i,iii]	Diagnosis of cardiovascular disease (CVD)		Prescribed a statin
4[i,3]	Patient without CVD who complies with at least one of the following: Aged >40 and estimated 10 year CVD risk ≥20%, aged >40 and Diabetes Mellitus (DM), familial hypercholesterolaemia		Prescribed a statin
5	Diagnosis of cardiovascular disease (CVD) and prescribed a statin		Prescribed simvastatin at a dose of at least 40mg or equivalent dose of alternative statin or a documented maximum tolerable statin dose
6	Patient without CVD and aged >40 and estimated 10year CVD risk ≥20% and prescribed a statin		Prescribed simvastatin at a dose of at least 40mg or equivalent dose of alternative statin or a documented maximum tolerable statin dose
7	Prescribed a statin and an interacting drug		Prescribed an acceptable statin or acceptable dose labelled as acceptable on specified list
8[1]	Prescribed a statin		TC ≤ 4mmol/L
9[3]	Diagnosis of cardiovascular disease (CVD)		Prescribed aspirin 75 mg
10[3]	Patient without CVD and without DM but estimated 10year CVD risk ≥20%		Prescribed aspirin 75 mg
11[iv]	Patient without CVD and WITH DM, who complies with at least one of the following: DM diagnosed ≥10 years ago, prescribed antihypertensive drug therapy, retinopathy, nephropathy		Prescribed aspirin 75 mg
12[2]	Prescribed aspirin		Achieved a blood pressure of ≤ 150/90mmHg
13[v]	Patient with a history of acute ischaemic stroke or transient ischaemic attack (TIA)		Prescribed a combination of aspirin (75-300 mg daily) plus dipyridamole (200 mg twice daily)
14[vi]	Patient with CVD who complies with at least one of the following: History of acute ischaemic stroke or TIA while on a combination of aspirin/dipyramidole therapy, contraindication/intolerance to aspirin		Prescribed clopidogrel at a dose of 75mg instead of aspirin
15[3,4,6]	At least one of the following: DM, stable angina, diagnosis of heart failure (HF)		Prescribed an ACE inhibitor
16[6]	NO diagnosis of HF, Diagnosis of DM, overweight and prescribed an oral anithyperglycaemic agent		Prescribed metformin
DIAGNOSIS OF HYPERTENSION, PRESCRIBED ANTIHYPERTENSIVE THERAPY…		HYPERTENSION	
17[2]	… and at least one of the following: diagnosis of CVD, DM, chronic renal failure		Achieved a blood pressure of ≤ 130 systolic AND ≤ 80mmHg diastolic
18[2]	… and NONE of the following: diagnosis of CVD, DM, chronic renal failure		Achieved a blood pressure of ≤ 140 systolic AND ≤ 85 mmHg diastolic
19[3]	… and prescribed a single antihypertensive agent and at least one of the following: gout, poor renal function, current hypokalaemia, dyslipidaemia		Prescribed a calcium channel blocker or ACE- inhibitor
DIAGNOSIS OF HYPERTENSION, PRESCRIBED ANTIHYPERTENSIVE THERAPY AND DOES NOT HAVE A DIAGNOSIS OF CVD OR CHRONIC HEART FAILURE…			
20[3]	… and ≤ 55 years old and non-black		Prescribed an ACE inhibitor
21[3]	… and ≤ 55 years old and non-black and an apparent contraindication or intolerance to an ACE inhibitor		Prescribed an AII antagonist
22[2]	… and at least one of the following: >55 years old, black		Prescribed a thiazide diuretic or calcium channel blocker
23[2]	…		NOT prescribed a combination of a thiazide diuretic and a BB
DIAGNOSIS OF HYPERTENSION (with or without CHD or chronic heart failure)…			
24[vii]	…		Drugs on specified list are avoided *
DIAGNOSIS OF ANGINA…		CHD	
25[viii]	… (not Prinzmetal angina)		Prescribed a beta-blocker
26[8]	… and NO heart failure AND apparent contraindication or intolerance to a beta-blocker		Prescribed a rate limiting calcium channel blocker, long acting nitrates or nicorandil
27[8]	… and heart failure AND apparent contraindication or intolerance to a beta-blocker		Prescribed a long acting nitrate or nicorandil
28[8]	…		Prescribed sublingual glyceryl trinitrate or glyceryl trinitrate spray
29[8]	…and NO heart failure and prescribed a beta-blocker AND a second agent for control of angina symptoms		Prescribed a calcium channel blocker
30[8]	… Patient with stable angina and heart failure prescribed a beta-blocker AND a second agent for control of angina symptoms		Prescribed amlodipine or felodipine
31[8]	… and prescribed regular nitrate		Uses a dosage regimen which avoids the development of tolerance
32[8]	… and a history of MI without heart failure and prescribed one of: captopril (C), enalapril (E), lisinopril (L) or ramipril (R)		Prescribed target dose (C 50mg bd, E 20-40od, L or R 10mg od) or a documented maximum tolerated dose
DIAGNOSIS OF CHRONIC HEART FAILURE…		CHRONIC HEART FAILURE	
33[ix]	… and prescribed one of the following: captopril (C), enalapril (E), lisinopril (L), perindopril (P), ramipril, (R) or trandolapril (T)		Prescribed target dose (C 50 mg tds, E 10-20 mg bd, L 20mg od, R 10 mg od, P 8 mg od or T 4mg od) or a documented maximum tolerated dose
34[9]	…		Drugs on specified list are avoided #
35[9]	… and NOT prescribed an ACE inhibitor		Prescribed an AII antagonist
36[9]	… mild to moderate or moderate heart failure and prescribed target or maximum tolerable doses (if less) of an ACE-Inhibitor and betablocker and remains symptomatic		Prescribed candesartan
37[9]	… and not prescribed an ACE inhibitor or AII Antagonist		Prescribed a combination of hydralazine and ISDN
38[9]	… and prescribed Losartan (L), Candesartan (C), Valsartan (V)		Prescribed target dose (L 50mg od, C 32mg od, V 160mg bd) or a documented maximum tolerated dose
39[9]	…		Prescribed a beta blocker (except metoprolol tartrate)
40[9]	… on Carvedilol (C), Bisoprolol (B) or Nebivolol (N)		Prescribed target dose (C 25-50mg bd, B or N 10od) or a documented maximum tolerated dose
41[9]	… and symptoms of heart failure		Prescribed diuretic treatment
42[9]	… moderate or moderate to severe heart failure and prescribed target or maximum tolerable doses (if less) of an ACE inhibitor and beta blocker and remains symptomatic		Prescribed spironolactone
43[9]	… moderate or moderate to severe heart failure and prescribed target or maximum tolerable doses (if less) of an ACE inhibitor and beta blocker and remains symptomatic and developed gynaecomastia		Prescribed eplerenone
44[9]	… and a history of MI and at least one of: HF symptoms or diabetes		Prescribed eplerenone
45[9]	… and on spironolactone (S) or eplerenone (E)		Prescribed target dose (S 25- 50mg od, E 50mg od) or a documented maximum tolerated dose
46[9]	… without AF and with current symptoms of heart failure despite optimal therapy		Prescribed digoxin
47[9]	…		Receives an annual influenza vaccination
48[9]	…		Received a once-only pneumococcal vaccination
49[x]	… and well tolerated atrial fibrillation (AF)		Prescribed a beta-blocker or digoxin

PATIENT WITH ATRIAL FIBRILLATION …			
50[10]	… and without heart failure and AF is well-tolerated	**AF**	Prescribed either a beta-blocker, verapamil, diltiazem or digoxin
51[10]	… and at least one additional risk factor for thromboembolism		Prescribed warfarin
52[10]	… and at least one additional risk factor for thromboembolism (aged >75 years, or >60 years with other risk factors such as hypertension, DM, or left ventricular dysfunction) and NOT prescribed warfarin		Is prescribed Antiplatelet therapy
PATIENT PRESCRIBED WARFARIN…		**WARFARIN**	
53[xi]	…		INR measured at intervals of which none > 12 weeks
54[11]	… and warfarin dose changed		INR measured within 1 week after dose change or starting each drug
55[11]	… prescribed a drug known to potentiate anticoagulant effect for >5 days		INR measured within 1 week after dose change or starting each drug
56[11]	…		INR history with at least 60% of INRs within target range

***** Corticosteroids (except inhaled or topical), sympathomimetics (except inhaled beta 2- agonists), oral contraceptives, Monoamine-oxidase inhibitors, NSAIDS (except aspirin as an antiplatelet),
carbenoxolone, high sodium-containing products eg. effervescent formulations, certain antacids, liquorice

Class I+III antiarrhythmics (except amiodarone), Verapamil and diltiazem, Calcium channel blockers (except amlodipine and felodipine), Minoxidil, Oral corticosteroids. NSAID'S (except aspirin as an
antiplatelet), Metformin, Thiazolidinediones (glitazones), Tricyclic antidepressants, Itraconazole, Fluconazole, Voriconazole, Carbenoxolone, Macrolide antibiotics, Terfenadine,

[1] Scottish Intercollegiate Guidelines Network (SIGN). Prevention of coronary heart disease (latest draft Draft May/June 2006)

[1] British Hypertension Society guidelines for hypertension management 2004 (BHS-IV). BMJ 2004;328; 634-640.

[1] British Hypertension Society and National Institute for Health and Clinical Excellence. Clinical Guideline 34: 'Hypertension: management of hypertension of adults in primary care: partial update. June 2006

[1] Joint British Society's guidelines on prevention of cardiovascular disease in clinical practice: summary 12/2005

[1] National Institute for Health and Clinical Excellence. Clopidogrel and modified release dipyridamole in the prevention of vascular occlusive events. Technology appraisal 90. May 2005. Accessed from nice.org.UK on 25/05/06

[1] Scottish Intercollegiate Guidelines Network (SIGN) Publ. No. 55.

[1] Scottish Intercollegiate Guidelines Network (SIGN) Publ. No. Hypertension in older people.

[1] Scottish Intercollegiate Guidelines Network (SIGN) Publ. No.SIGN 51. Management of stable angina. April 2001

[1] Scottish Intercollegiate Guidelines Network (SIGN). Management of chronic heart failure. (latest draft May/June 2006)

[1] Scottish Intercollegiate Guidelines Network (SIGN). Arrhythmias associated with chronic coronary artery disease/left ventriczular dysfunction (latest draft May/June 2006)

[1] Scottish Intercollegiate Guidelines Network (SIGN) Publ. No.36. Antithrombotic Therapy. March 1999

Appendix 5: DATA COLLECTION FORM

PATIENT DETAILS

Study ID	**Age**	**Hight (m)**	**Social history** Living alone……..☐ Living with partner/ Family……☐ Pregnant……...☐ Breastfeeding……...☐ Other……..☐ - specify:	**Smoking habit** Current smoker< 10 cpd……..☐ Current smoker >= 10 cpd…..☐ Ex-smoker >= 5 years……..☐ Ex-smoker < 5 years……☐ Never smoked……...☐ Unknown……☐ Smoking advise given: Y or N - specify:
		Weight (kg)		
	Gender Male ☐ Female ☐	**Target weight**		
DCVR clinic **Date:**	**Drug sensitivities**	**BMI**		

Date of first visit	**Family history** Diabetes ☐ Cardiovascular disease ☐ Other: - specify	**Alcohol consumption** (Limit 21 units men, 14 units women/week) Within limit (F/M)……...☐ Excess limit (F/M)……☐ No alcohol……..☐ Unknown……☐ Advice given: Y / N / unknown - specify:
No of clinic visits		
Referral BP		
Target BP		
BP final visit		

Ethnic origin White……☐ Black……..☐ Asian……☐ Chinese……☐ Other……☐ - specify:	**Limitations/special needs** Sight……☐ Hearing……..☐ Speech……..☐ Language……..☐ Physical……☐ Other……..☐ - specify:	**History of complications** Neuropathy……☐ Retinopathy……...☐ Nephropathy……..☐ Amputations……..☐ Foot ulcers……..☐ Erectile dysfunction……..☐ Mood disorder……☐ Recurrent infection……☐ Microalbuminurea…….....☐ Comments:
Medication checked and verified by: (please circle) SCI-DC GP letter GP practice Patient Patients own drugs Repeat prescription Other:		

EDUCATIONAL NEEDS ASSESSMENT

General advice	**Self-medication**	**Self-management**	Comments:
Diabetes……..……☐ Diabetes control……..……☐ Cardiovascular……☐ Complications……..……☐ Diet……☐ Exercise……☐ Smoking cessation……..☐	Oral agent timing…….☐ Missed doses……...☐ Written information on medicines……☐	Compliance: Good ☐ Poor ☐ Compliance aid needed……☐	

RELEVANT MEDICAL HISTORY

Diabetes	**Cardiovascular**	date		date		date	**Other/comments:**
Type 1 ☐ Type 2 ☐ Date:	Hypertension ……...☐ Angioplasty……☐ IHD……☐		Stroke/TIA…...☐ MI……..☐ PVD……..☐		Angina……..☐ CABG……☐ Other……☐ - specify		

RELEVANT DIABETES TREATMENT (PAST AND CURRENT)

Start date	Medication	Dose	Route	Administration interval	Stop date	Indication	Comments

CARDIOVASCULAR MEDICINES (antihypertensives, lipid lowering agents, antiplatelet agents)

Start date	Medication	Dose	Route	Administration interval	Stop date	Indication	Comments

OTHER RELEVANT MEDICINES (including OTC)

Start date	Medication	Dose	Route	Administration interval	Stop date	Indication	Comments

LABORATORY INVESTIGATIONS

	Date									
Biochemical	eGFR (/1.73 m^2)									
	Creat (55-150 µmol/l)									
	Urea (2.5-6.6 mmol/l)									
	Urine ACR									
	Na (132-144 mmol/l)									
	K (3.6-5.1 mmol/l)									
	HbA1c (<7 %)									
Lipids	Total chol									
	HDL									
	LDL (< 2 mmol/l)									
	TG (0.5-1.9 mmol/l)									
	Total/HDL (<4 mmol)									
LFT's	ALT (10-40 u/l)									
	ALB (36-47 g/l)									
	AlkP (40-125 u/l)									
	GGT (5-35 u/l)									
	Blood pressure (mmHg)									

IDENTIFIED CARE ISSUES

#	Clinic visit	Date	Care issue	Action	Date	Output

Appendix 6: FOCUS GROUP TRANSCRIPTION

"How do you think the result reflect what you do in practice?"

"I think from what Carol was saying about the recording in SCI-DC, we would… I know I change the drug from SCI-DC, but I don't always say that in my notes care plan, cause you do it, and you say increase dose and then you go and make it in SCI-DC, but you then don't go back and say: changed it in SCI-DC, because you already said dose changed" (Pharmacist 1) "We are maybe not recording stuff like we actually should do. I always do, I do aside of my list clinic, to see what they have done, but it's not in the care plan it's in my clinic letter. I use my memory; but you know you gonna" (Pharmacist 2) "Yeah yeah"(Pharmacist 3) "Yeah, but when you change it in SCI -DC, if it's a start date and a finish date and you are changing the dose, then you can do that, and then you can work out from SCI-DC who's changed it when" (Pharmacist 1) "Exactly, that's the same how its working for my care plan, but maybe we are not making it clear enough" (Pharmacist 2) "Yeah" (all) "I know certainly from the time I spent with Ingrid, the thing with me is I don't write down enough of what I say. Because I mean I'm not- I'm doing it, but it's not clear enough that I'm doing it… (…)" (Pharmacist 2) "Is that detail or is it specific?" (Pharmacist 3) "A sheet thing, was like, you know like, I suppose that we got the tic boxes that for, but maybe using them better. You know discussed diet, exercise and keep it as a mind keeper" (Pharmacist 2) "Because you take it a bit distracted" (Pharmacist 2) "And I sometime like to take a note for next week, if I've missed one thing, for next week" (Pharmacist 2). "And also if seeing patients notes, sometimes you don't write everything in your own notes, but when your dictating the letter. You know it's gonna be in the letter, so if, you know, when we are seeing our patient we are not just reading our own notes, we are also reading…I'll also check what I wrote the last time, you know cause that's a reminder for me" (Pharmacist 1) "Yeah, so do I" (Pharmacist 2) "And then we wouldn't checks the patient note letter, but we would just go on what we put there" (Pharmacist 1) " I suppose there's an argument there for actually putting our care plans in the notes, or a version of them that you are looking at. In supplementary prescribing or independent prescribing…in supplementary you have to have clinical management plan in the notes. Independent, not necessarily, but you know, you have to have your documentation in there" (Pharmacist 4) "Actually I don't like that with my notes, because I (…) (Pharmacist 2) "But that's what we thought now, to actually have a paper" (Pharmacist 4) "yeah, so that would maybe be the right (…)to put stuff in"(Pharmacist 2) "Yeah, but if you did that and then you didn't get the case notes, and you put all your guts away" (Pharmacist 1) "Yeah, that's an understanding thing, you know what, I can see where it would be beneficial, but often(…)"(Pharmacist 2) "Or you could enter in directly into SCI-DC, that would be lovely" (Pharmacist 4) (…) "Why don't we just write into patients notes? Your not using…have still have our own stuff, but you know, you just take blood pressure, cholesterol level, and just do like what the doctors. So it's a visit… (Pharmacist 1) "No, no, you can't do both" (unknown) "Well, we could make a pro-forma which could go in, I don't think you've seen the documentation of the use of the cardiovascular risk clinic. Called the (….) which is not unlike ours, with a lot of tic boxes on it. And, you know, they have things like, diet and cholesterol recorded etc, and then treatment recommendations. And that would've been (…) But, I think there is also (…) (Pharmacist 4) (…)(20 sec) "In another form, and keep your own notes" (Pharmacist 5) "Sometimes to write stuff is laborious. But, I do love (…) I do the care plan and the recommendations, and then I do (…) A, because I have the letters. So I use SCI-DC for that

purpose too. And then I write the out-patients notes…, because if the doctor is seeing in between time my letters wouldn't be typed up, or what ever, so I just put the brief thing in the…" (Pharmacist 3) (…) "I think I do that just for the out-patients, I don't (…)"(Pharmacist 1) (…) "I do the letter, the out-patient letter and I do the SCI-DC" (Pharmacist 3) (…) "We all do the three, the GP letter, our own notes and SCI-DC" (Pharmacist 4) (…).

"Do you think this kind of audit is relevant for your practice?"

"It's interesting that the areas that we don't seem to contribute are: Like two, like your high number are very much higher than your low numbers, if you see what I mean. So... you maybe tick, and then there is areas that…do you know what I mean? Whether we are not touching on it or whether it is not necessary or…" (Pharmacist 2)" Or if it's not documented, and that's the numbers of record of drug history" (Pharmacist 5)" We're doing that, but we are not documenting it (Pharmacist 2 and 5) "The healthcare team members' education/information, we're doing that to" (Pharmacist 1) "So, what is that about, Ingrid?" (Pharmacist 2) "To the doctors or the DSN, and the (…) you talk about what is recommended for a particular patient" (Pharmacist 1) "Is for example their giving advise on drug formularies and such, but that's maybe much more in hospital wards I think" (researcher)"That's just maybe something that we just…" (Pharmacist 2) "Something, there have been cases where by a GP (…) bendrofluazide 5 mg, and who I kind of interesting actually, you know (…), and there might be metabolic issues with it. Something that could run by talking to…so its not, so that's a medication thing like in the letter, rather in the care notes. And then you put, you know, bendrofluazide 5 mg explanation mark, in my care plan, and that's all it means. Ehm, but I don't know if you would do that about (…) put it in the care plan" (Pharmacist 3) "Or I would just say, dictate the letter, and send a copy to the dietician. So, you know, that wouldn't necessarily be recording that" (Pharmacist 1) (…)(23 sec) "The thing is I'm having more problems with the compliance inquiries illuming, because a huge part of the patients don't know what their taking. And unless they bring in their medicine…there actually (…) having complications I think, I would have to look it over (…) I'm going to ask them to bring them in (…) That should be quite interesting, but the whole interaction is based on the quality of everything of what their taking, and why (…) taking"(Pharmacist 3) "And if that's wrong, then…" (Pharmacist 2) "…(…) to my mind, the record, SCI-DC etc (…) what people are on, what they...(…) her blood pressure was really high, she's on everything, and it looks like she got 8 mg, but her daughter filled the dosett box… and I send an extra letter to her daughter, because I'm not completely convinced on the treatment she had been on. And the daughter phones me up, and she says my mum's doxazosin was stopped at Christmastime, and I said (…) and her metformin was stopped at Christmastime, because her GFR had been off, and we stopped that. But we had not stopped the doxazosin. We didn't know, the GP had done it and had not informed us. So here was me saying I'll put it up to 12 mg, and that was because I thought she was on 8 mg already. And, luckily she phoned me, so we could start with 4. But otherwise, I manage my patients completely wrong (…)" (Pharmacist 3) " That is the thing, you're purely relying on the information (...) But I tend to do a (…) dribbling on the notes…yeah you know different colours" (Pharmacist 2) "Relying on SCI-DC being up to date" (Pharmacist 5) "You could get them from GPASS and should be up to date" (Pharmacist 2) "I think

they should carry a bag" (Unknown) "You see I went through the united care summary" (Pharmacist 1) "You see I can't. And the other thing is, you remember how X was talking about two types of SCI-DC, clinical and (…). But in Roodland I think I use the clinical one. Is that updated through GPASS?" (Pharmacist 3) "Their both (…) directly in relation, except for patient specific (…) for apparently there is no interface with those (…) "(Pharmacist 4) (…) "And there are (…) who are still looking for that consistency. Not many, but there are a few" (Pharmacist 4) (…) "That would be on clinical SCI-DC, clinical" (Pharmacist 4) "But, I could go in from the hospital and (…) summary box" (Pharmacist 5)"I get the full (…) from the GP surgery" (Pharmacist 5) (…) "And that's good, but it's got wee, it's got limitations, because a part of the acute things that it's got on there, are not so up to date, so again (…) maybe extending that, there would be limitations but again (…)" (Pharmacist 3) "But at St.John`s you are on clinical infirm, you're not..?" (Pharmacist 4) "Yeah" (Pharmacist 5) "So you got both" (Pharmacist 4) "I only always do a (medication review) if they bring their tablets, because like you (Pharmacist 3), I just don't trust them" (Pharmacist 1) (…) "Next time, bring your tablets. All my tablets? Yes, all your tablets. And we'll go through. And then I get them to say, what's that for, what's that for? How do you take it? And that's how I find out if what their taking and if they know what it's for. And if they say: Oh, my daughter fills it. And I say: Well, can your daughter come in next time?"(Pharmacist 1) "So I think that something that we could probably build on and improve the problem" (Pharmacist 3) "I think that should (…) I don't know what your invite letters like. But I think in my it says to bring your repeat prescription (…)" (Pharmacist 3) (…) "Bring in all your tablets AND your repeat prescription form if you got it" (Pharmacist 4) (…)(33 sec).

"Do you think this might help in the argument for pharmacist-led clinics rather than nurse led clinics?"

"You would have to do a comparison then" (Pharmacist 3) (…)(21 sec) "I think in published though, that I'm aware of in the literature, where nurse-led clinics have actually provided this sort of information…" (Pharmacist 4) "They don't collect that information" (Pharmacist 1) "…most of the studies that have been published for nurse-led clinics, for which there are few. Ehm, have just (…) improvements in blood pressure and lipids levels etc. So this is where… added benefit of pharmacists" (Pharmacist 4) "…(…) contribute, so I think, including the discussion you have had so far, I think a strong argument for that could be that (mobile phone ringing)…(…) advantage of looking at comorbidities (…) medication review. And a huge part of your contribution would be related to medicine. More of knowledge about, even in like the diabetes or cardiovascular risk medicine…in like their comorbidities, which have had nurses can be well trained to run their clinics. But they don't have that other knowledge base. And I think that we are in a situation where we're asked for pharmacist management reports of the activity. And, you know, so you don't have (…) activity. And you don't have it to show (…)" (Pharmacist 6) "Finding it more an advantage" (Pharmacist 3) "Is it clinical pharmacist and nurses or pharmacist and doctors? Because, you know, all of the nurses (…) not contributing to, but use a lot of medicine (…), which the doctors don't touch on. So maybe it's that side of things" (Pharmacist 3) "I think there is an argument and the argument has to be there, and the argument has to be (…) how do we report that (…)" (Pharmacist 6) "And therefore I think that is what the impression

is about. How do this thing (…) help to (…) clinical pharmacist services" (Pharmacist 6) "But I think what we said about comparing it to nurses, you know, to promote the role of pharmacist-led clinics we need to say pharmacist do X, Y and Z and nurses actually do X. And you would get more value for money. But there would have to be a comparison which you could use to say, well this is the parameters we have measured and in a previous nurse study, this is what we measured therefore…you are getting more value for money" (Pharmacist 1) "And you think that would be an ethical study to do?" (Pharmacist 6) "No, I don't think we would actually do the study. I think we would actually look at, do a retrospective or whatever you call them. You know go back in the papers and see who's done what. And compare what nurses measured…" (Pharmacist 1) "So, what you're saying then is that there's an argument for auditing your practice?" (Pharmacist 6) (…) "There has to be" (Pharmacist 3) "But that why we don't do that as clinical pharmacists (…) we're not promoting our success. To say, when you actually look at that… But that's probably because we let our self down. And we're quite good at recording them. And we don't say, but I have never checked that and that. I'm coming from a community pharmacy (…) do the work…In the end of the day you count and the prescriptions and that's all you've got (…) it's getting there, but in clinical setting you don't have an excuse, you do have the time, you do have (…), and you do have…(…).You see I find it very interesting to spend time with Ingrid, because she's like: did you ask her about that?" (Pharmacist 3) "Yes, of course you did, but…" (Pharmacist 3) "Getting in to that, you see in my mind it can be interesting twice, the things you are doing, but maybe not recording" (Pharmacist 3) "When it comes to justification to service as well, you know nurse-led clinics are so prolific and nurses are cheaper than pharmacist basically. And (…) multiskilled as well, you know, that we are in danger of loosing our place as health care professionals. And our added value a (…) how do you demonstrate that, how do you justify your spot, when it comes to services form like (…) which have got a final budget, that is clearly important" (Pharmacist 4) "It is interesting, when the doctors see their patients in GP practices (…) and check their HbA1c, you know, and they've got ten, 15 minutes. A medication discussion can't be done in that time, we need a lot longer" (Pharmacist 5) "I think (Pharmacist 3) might be right, the comparison should be perhaps with the doctors, you know, rather than nurses" (Pharmacist 1) "I don't know, I think it is unfair for me to have to compare, we're constantly having to justify our position, but nurses don't have to justify their position, doctors don't have to justify their position (…)" (Pharmacist 3) "Frustrates me a bit, the numbers isn't, because there are an awful lot more nurses out there than pharmacists" (Pharmacist 4) "Yeah, of course" (Pharmacist 3) "And also traditionally doctors have always run clinics, you know, you go to your GP and measure your blood pressure. So there has not been a need to justify (…)" (Pharmacist 4) "yeah, the other thing is nurses have always been based at GP practices" (Pharmacist 3 and 4) (…) " …(…) goes by the population which we can pull" (Pharmacist 1) "I think that's changed (…) I don't think that's so much now, I mean certainly all together (…) where I work. You get a various set of people (…) the pharmacist is kind of the first health care profession you would go to. And that would change (…)" (Pharmacist 3) (…)(31 sec) "So its about, you don't want to make, you don't want to record so much that you are not actually (…) so its got to be useful and functional, but its got to be slick. And then there is the other side of; should we do it all the time or should we do it periodically. You know again, if you do it all the time and people get

tired and they are not good at filling in and all that. But if you actually want a good data collection do it for a (…) period. So it's a case of again, how do you want your(…)" (Pharmacist 3) "And also can you do it, within using, you know, the people we are actually (…) service documentation, periodically, or people like Ingrid coming in. But then she had difficulties because we were not documenting" (Pharmacist 4) "She couldn't read mine" (Pharmacist 1) (…) "But we are trying to do that, to go back to, publishing nature, we are trying to that on top of seeing our patients. You know cause, we only get paid to do the clinics, so if they here then say…I'm not, cause for the doctors its part of their job. You know, they see the patients, then they do the research, and its all, they are there for the whole week. So we are there for like, what, four hours. So I think we should be publishing that, its really really important, but its not (…)" (Pharmacist 1) (…) "it is not because we don't value our job, its not because we are not thankful, we're gonna have (…) that's fine, that's fine, here are our time to do that, so you know(…)" (Pharmacist 1) "if we make it a priority, we just have to attach it in to the service, and then (…)" (Pharmacist 4)

"How valuable do you think it is documenting your contribution to pharmaceutical care?"

"If you don't document it, then it's pointless so, then…" (Pharmacist 3) "I think its valuable, but do we want to temper that with not over burden (…) contribution" (Pharmacist 3) (…)

"What is your opinion on how this system of auditing pharmaceutical care from the different clinics provides a measure of consistent practice?"

"For me it seem that, that we are sort of probably in fact that maybe… the care is quite consistent, but we are maybe not, because we are not recording it, we maybe can't see as much of the consistency that are actually happening (…)" (Pharmacist 3) "We are not documenting it all, not (…)" (Pharmacist 5) "But I think (…) I suppose we should" (Pharmacist 3) "But lot of the variations are depending on the practical use (…) much of the difference in the way that, you know, the questions that I ask my patients, which come from an ethnic minority background. So the questions are different from the non-ethnic minorities" (Pharmacist 1) "Yeah, but at the end of the day (…)" (Unknown). "But then again, you could equally say that within (a patient group) (…) you have different questioning, so how much that actually acceptance to your recorded pharmaceutical care issues, I don't know. You know what I mean, the way to get there may be different, the approach (…) the care issues maybe not that different" (Pharmacist 3) "I suppose there is an issue there of providing consistent (…) we're in a service to (…) able to demonstrate that value (…) and yet the clinical outcome such as blood pressure and lipids and such…but we actually do what we are doing. And I think, your (Pharmacist 1) clinic is slightly different, but again the same standard" (Pharmacist 4) "Yeah, probably" (Pharmacist 1) "And this method provides, that Ingrid (…) makes out of what pharmaceutical care, how does it work. Where as, the only other way you could do it…it would be quite difficult to use if you were not documenting. You were having to make assumptions based on what you could see and what you thought was going on…Ehm…so that might be a bit of a problem with it. The other way of doing it would be for us to, as we go along; categorise, but then again there is inter-partial variation of what we think…" (Pharmacist 3) "Yeah, but we could get that through peer review, can't you? Periodically, we could say, take ten of

our care issues…how would you categorise that in your clinic? And then we would gradually get to a system where we all work (…)" (Pharmacist 4) (…)(36 sec) "…an audit a few years ago of prescribing, of the actual prescribing within the Diabetic clinic, and she came up with some interesting things. You could actually look at which of the doctors (…) were not using as much ACE-inhibitors than others (…)(33 sec) "Do you think that if we work, you have been involved in Ingrid's discussion about pharmaceutical care issues…got together to agree Ingrid's project, you know (…) not change it, but it interesting to think the categories aren't, you know, what we are doing. I think a change, and because of doing that, it is directly (…) of what (pharmacist 6 said), what should we do exactly to fit our purpose" (Pharmacist 5) (…) "I think if you are aware of the need to document, then your probably in most cases to do so within your time constrain in the clinic. And I think Ingrid's project has demonstrated quite now, that there is a need to document effort over clinical outcomes…" (Pharmacist 4)" "yeah, yeah" (unknown) "And then the follow-up, that would be we actually do something with the results (…)" (Pharmacist 4) "Documenting…that changes your practice" (Pharmacist 5) (…)(20 sec) "…(…) and running through that in (…) so now I put my boxes and then I check them and then I go through the care plan …(…) but I go through it" (Pharmacist 3) "That was the whole point of that care plan, to actually make sure that everybody was basically following the treatment guidelines to help you" (Pharmacist 4) (…)(19 sec) "The first time I see them I …(…)" (Pharmacist 3) "That could just like be that you would be able to document your pharmaceutical care issues then as you go, as you go along" (Pharmacist 4) "Ehm, it depends on lot of mine I wouldn't be sure before after speaking to my doc. So that what I do at the clinic, and then I am under pressure to get my letters signed, SCI-DC etc so…realistically, I guess if I had time prior to my next clinic, I could do that then when reviewing my patient (…)" (Pharmacist 3) "Maybe there is a way of looking at the key, common care issues, coding them and having them on each care plan, so that you are just ticking it (…) so that there's not very labour intense kind thing" (Pharmacist 4) (…)(30 sec). "The only other think would be…you know that (…) intervention form. You know to record…so that's kind of a (…) it could be in the patient…(…)…you could just go through"(Pharmacist 3) "That might work" (Pharmacist 4) (…) "First visit we have so much taking up with (…) and the number of (…) and then they are not interested in talking about (…) I mean their not…(…) more time in the second visit" (Pharmacist 5) (…)(17 sec).

Database assessment tool

(…)(24 sec) "It's quite different to the one that (Mr X) produced, if you remember, it had a quite user friendly approach, where you basically filled in in a (…). This is more like a traditional database" (Pharmacist 4) (…)(3 min 10 sec) "What is the point?" (Pharmacist 1) "Well, that is what we need to decide really…Ehm… ideally, we obviously, its time to input" (Pharmacist 4) "But, that's perfect" (Pharmacist 3) "Its very comprehensive…(…)"(Pharmacist 4) "…(…) SCI-DC to that format"(Pharmacist 3) (…)(34 sec). "I think ideally, this would fit on SCI-DC, so it would just be to sit in your clinic room and enter the data once. Its much more of an issue if you are having to, I mean, at the moment we have basically an excel spreadsheet, which we enter data into periodically. And this could fill our (…) if it was possible to email it around so that we could…(…) so that you then put in all your stuff, but actually to complete that is much more labour intensive than an excel spreadsheet"

(Pharmacist 4) “And who else could have access to it? If you go to SCI-DC, you know who the last person was that following that patient. Another clinician check to see, oh I wonder what the pharmacist did? So you know, you still have to go to SCI-DC to do patients visits, so that it is recorded, but that you actually saw them (…)”(Pharmacist 1) (…) “That could be like a drop down or something, where the pharmacist activity form”(Pharmacist 4) (…)(44 sec). “(…) you are ahead of that with SCI-DC with an electronic system, but the secret is, you can’t use that in an electronic system..(…) what can I do, and what you actually want, and what you want to record, what you want to record of activity in a paper system and then get that in…” (Pharmacist 6) “Yeah, care planning” (Pharmacist 3) “I think this is excellent (…)” (Pharmacist 6) “I think we should try it though (…) for SCI or a connection for SCI (…) ” (Pharmacist 5) “You mean, bring it down to a minimum?”(Pharmacist 4) (…) “You think it (…)…it could be a…we talk about just using this as a first visit and final visit. It would be interesting to use it as an up to date database, it surly is (…)” (Pharmacist 3) (…). “Recording first and after if it’s a new patient. And then after that it could (…)”(Pharmacist 2) “There has to be a link to SCI-DC, because if we are doing a change in the medication…(…)”(Pharmacist 1) “The problem with SCI-DC is that the field (…) we only know what they are currently on, so there’s no reference on the history (…) I think that’s a good point (…) and ideally we would have it interfacing with SCI-DC”(Pharmacist 4) “(…) other healthcare professionals need to have access to what we are doing, because if they are currently unaware of what we are doing, then they need to be able to see what we are doing. And if they don’t have access to our paper notes (…)” (Pharmacist 1) “(…) Pharmaceutical care is not what the pharmacist does (…)” (Pharmacist 6) “So would they (other healthcare professionals) contribute to this then?” (Pharmacist 1) “Yes” (Pharmacist 6) “What, do they currently complete anything electronically in SCI-DC the nurses? I know the dieticians, but…in the clinic (…)…but I don’t know about the nurses if they put anything on. All I ever see in case notes is their hand written (…) you know, altered their insulin (…)” (Pharmacist 4) (…) “the podiatrist do nothing, there’s not anything in the notes, there’s nothing electronic. And the retinal screeners with the reports on their eyes (…) that’s it” (Pharmacist 4) (…)(1 min 13 sec) “As regards Ingrid’s project are you planning on entering all these care issue into the database?”(Pharmacist 4) “I have entered all the care issues” (Researcher) “You have that, you’ve done that. So we are in a situation where we could actually print out reports” (Pharmacist 4) (…) “So we know that its functional (…)” (Pharmacist 3) “It works well obviously, but it’s how it going to work in practice (…)” (Pharmacist 3) (…)(18 sec) “..(…) so, you know kind of say like: we haven’t been doing this, and how can we achieve it in clinic?” (Pharmacist 2) (…) “In order that pharmaceutical care issues that we tick, we could actually get our paper versions, do it, say another person who could then enter them all in, and he or she could then put it all in this database and drop all the graphs for us. Rather than us doing all the time”(Pharmacist 1) “But if the format is appropriate…(…)” (Pharmacist 3) (…)(56 sec) “Its easy to write when the patients are there, because I can look at them and write on it all the time, but you can’t type and look at …(…)” (Pharmacist 1) (…) “We could actually just have it the care plan, couldn’t you, and then have the category…(…)…because you know who your patient is…(…)” (Pharmacist 3) “You know eventually, ultimately, if we had hand held pad instead of a care plan we could just dot in the details…and it all enters in to a database…”(Pharmacist 4) (…)(43 sec).

"Has what I have presented prompted you to change your practice?"

"Yes, I think so" (Pharmacist 2) "I think we need to look at (…) what we are doing and how we are auditing and how we would want to be auditing" (Pharmacist 4) "And if we are auditing, who would we report back to?" (Pharmacist 3) "You know if we are doing things that you really want to inform to…what forum would be interesting to (…)"(Pharmacist 3) "As a member of the Pharmacy clinical management team, I can tell you that (…) monthly reports (…) So X and Y have been looking at indicators (…) opportunity to input to that (…) its quite minimal at the moment, but I think it needs that basic level, because it needs to be developed and it needs to be developed (…) and what the line that we need. Everyone is used to their own practice (…) database (…) in terms of planning, because if (…) argument there for terms of the patients' pharmaceutical needs. So if you got information about patients' pharmaceutical needs, then it's far easier to (…) argument for (…) required to meet these needs. So you need to (…)(26 sec)" (Pharmacist 6) "(...) before we rush in to what format , I think, there is no point in developing a system that's not in the appropriate format" (Pharmacist 3) "Well, I think (…) say: we have provided this database for our practice, this is the reports that we believe demonstrates (…) and therefore we would want that (…)" (Pharmacist 6) (…)(14 sec) "NHSScotland has to meet the Heat Act, you know about the Heat Act? (…)(26 sec)" (Pharmacist 6) "From my understanding its that the Government is looking for a reduction in the number of anti (…) prescribed. You know, we are not recording…you know…we say "drug stopped", you know, but we're not auditing that. So if we want to show our usefulness to the Government, in financial terms, we should be able to say: "We stopped doxazosin (…) some of the patients and we saved so much money. Because that what we are, although we are meeting Heat targets, we are also looking at (…)" (Pharmacist 1) (…)(1 min 28 sec) " I'll certainly contact X about what indicators (…) something like safety, that's an obvious one. And that we could easily construct from our figures now – patient safety (…) you know yourself there are so many incidences on a daily basis, where patients doses has to be reduced or adverse effects or you know (…)" (Pharmacist 4) (…) "(…) we're not employed by NHS Lothian, so we (community pharmacies) are different in that perspective, you know its not money blown by NHS Lothian, but the thing is we are probably the biggest single force that prevent medication errors…contacting GP`s, reducing these problems…and we are not accountable to anybody, and we don't have to show to anybody. As long as (…) not loosing his money (…)" (Pharmacist 2) (…)(20 sec) "(…)how to show benefit from what we document (…)" (Pharmacist 5) (…) "And still after 30 odd years, we still haven't decided what to document" (Pharmacist 5) (…) "Outcomes of what our interventions are, clinical outcomes (…)" (Pharmacist 3) (…) "(…)all the time… forget to do, but you document after a week" (unknown) "You write down every single ting, bit you miss that huge intervention action thinking (…)" (Pharmacist 5) (…) "Should we document everything or should we just document interventions" (Pharmacist 5) "If you can do it on a paper, in a short hand way, in a pretty standardised thing, which can then be made electronic…then you got (…) in a database that Ingrid has developed. You have reports for who ever is asking for reports, if it's for your self for your own practice…being for management (…) but if you got your information there (…) developed a database that could do that (…)" (Pharmacist 6)

Appendix 7: Focus group invitation

Dear participants,

You are invited to participate in a focus group discussion regarding the finding from my audit at three of the DCVR clinics. The meeting will be held on the **30th of April at 1.00 pm** in **Seminar Room 2, Chancellors Building, RIE**.

My name is Ingrid Lian and I am a Norwegian pharmacy student in my final year. I am doing my project here in Scotland in collaboration with the University of Strathclyde. With the help of Alison Cockburn I have conducted a project to try and evaluate the pharmaceutical care delivered in the clinics and also worked on making a database to be used to standardise the recording of achievement of outcomes. Now I am interested to find out your point of views. The meeting is supposed to be an open discussion amongst you – I want to know what you think, both good and bad.

I would like to tape-record the discussion and also take notes, because I don't want to miss any of your comments, and this will help me when I am going to analyse the results. I will of course keep everything you say anonymous and therefore not use any names in my report. The results will be included in my thesis that I will submit to the University of Tromsø in Norway.

Schedule:

- Introductions
- Presentation of the findings from the audit and discussion
- Review of the database as an assessment tool
- The use of a standardised pharmaceutical care plan
- Summary of the meeting

Welcome!

Best regards

Ingrid Lian

Appendix 8:

PROJECT PROTOCOL

An Evaluation of Pharmaceutical Care Delivery to Patients with Diabetes and Development of Standardised Assessment Tools

Researcher

Ingrid Lian	Final Year Pharmacy Student, University of Tromsø, Norway.

Supervisors

Alison Cockburn	Lead Pharmacist Diabetes Cardiovascular Risk, Western General Hospital, Edinburgh.
Prof. Steve Hudson	Professor in Pharmaceutical Care, University of Strathclyde, Glasgow.
Moira Kinnear	Head of Service, Education, Research and Development, NHS Lothian.

Collaborators

Diabetes Cardiovascular Risk Clinic Pharmacists.
Members of the Pharmacy Diabetes Strategy Group, NHS Lothian.

Proposed duration of the project

Academic Year October 2007 – May 2008

Introduction

Recent clinical trials have clearly demonstrated that aggressive treatment of hypertension and hyperlipidaemia can result in a substantial reduction in cardiovascular events in patients with diabetes.[1] Consequently pharmacist-led diabetes cardiovascular risk reduction clinics (DCVR) have been established within both primary and secondary care sites in NHS Lothian during the past 3 years.

These have achieved significant reductions in patients' blood pressures (average reduction of 35 ±18mmHG systolic and 16 ±12mm Hg diastolic) and improved lipid profiles. Improvements in patient's blood pressure and lipid levels are achieved via treatment recommendations made to GP's, provision of advice on smoking cessation, diet and exercise and optimisation of patient compliance with their medications.[2]

There is limited published work on pharmaceutical care systems and therefore there is a need for testing suitably designed models of pharmaceutical care in particular patient groups such as those with diabetes.[3] Previous work within oncology has shown that development of a pharmaceutical care plan has standardised the provision of pharmaceutical care to patients receiving chemotherapy.[4] Studies of pharmaceutical care activities performed by the clinic pharmacist at one site in Lothian resulted in production of a pharmaceutical care plan incorporating evidence-based guidelines.[5] This has now been implemented at all the sites and there is now a need for continuous audit of practice and a method of reporting pharmaceutical care activities in order that a standard of practice can be established and evaluated.

Aim

To evaluate practice within pharmacist-led Diabetes Cardiovascular Risk clinics from implementation of a standardised pharmaceutical care plan and develop a tool for reporting pharmaceutical care needs and activities. The tool will be applicable to pharmacist-led Diabetes Cardiovascular Risk clinics and pharmacist-led Diabetes Management clinics.

Objectives

1. Review the literature on models of pharmaceutical care to patients with diabetes. Review documentation from local services to characterise service provision in hospital and primary care settings.

2. Develop and populate a database using pharmaceutical care data from several sites to quantify the pharmaceutical care issues addressed by the pharmacists and to standardise the recording of achievement of outcomes. Ensure that the database is suitable for recording data from pharmacist-led Diabetes Management clinics and Diabetes Cardiovascular Risk clinics. Extend the audit to include patients sampled from other participating sites.

3. Receive feedback from a focus group of the DCVR clinic pharmacists to identify opportunities to standardise the approach of the pharmacist and the audit tools.

Subjects and Settings

Patients will be recruited retrospectively and prospectively from the following clinical settings/pharmaceutical care providers

Table 1: Overview of patient care settings, pharmacists and patient sample

	Patient Care Setting	Pharmacist (s)	Patient sample
A	**Diabetes Cardiovascular Risk Clinic Western General Hospital**	**Alison Cockburn**	**30**
B	**Diabetes Cardiovascular Risk Clinic Royal Infirmary**	**Juliette Rose**	**30**
C	Diabetes Cardiovascular Risk Clinic St Johns	Ruth Armstrong/Alan Milarvie	20
D	Diabetes Cardiovascular Risk Clinic Roodlands	Carol Philip	10
E	**Diabetes Cardiovascular Risk Clinic Leith (including Ethnic Minorities Clinic)**	**Lubna Kerr**	**30**
F	Wester Hailes Medical Centre	Pauline Westwood	10
G	Colinton Health Centre	Ian Brown	10
H	Blackhall Medical Centre	Alpana Mair	10

Patient protection of privacy and confidentiality will be maintained by giving each patient a chronological number as they are enrolled in the study. The patient numbers will be kept together with any identifiable patient information in a physically secure place.

Protocol will be approved by University of Tromsø in collaboration with University of Strathclyde, NHS Lothian Research and Development Department and the Director of Pharmacy, NHS Lothian.

Methods

1. A literature review will be performed to identify models of pharmaceutical care used for patients with diabetes including local service provision in primary and secondary care. This will be done by:
    I. Conducting a literature review using Medline and Embase
    II. Contact other pharmacists, by e-mail, who run similar diabetes or DCVR clinics outside Lothian, to obtain other pharmaceutical care plans to be reviewed.
    III. Reviewing previous projects undertaken in this field

2. A prospective and retrospective audit of pharmaceutical care activities undertaken at sites A, B and E (table 1) will be completed. If necessary patient data will be gathered retrospectively from participating sites. To execute the audit the researcher will:
    I. Develop a draft data collection form which will be used to collect patient data and pharmaceutical activities. The form will be based on available pharmaceutical care plans, findings from the literature review and the data fields in the database.
    II. The final data collection form will be decided together with the rest of the research group to achieve face validity and field tested on a few number of patients. Any necessary changes to the data collection form will be done after the field testing.
    III. Attend the different clinics to collect data. This will enable the researcher to observe and to discuss with the pharmacist what changes that have been done. The data collected will then be based on actual events and not on the views and memory of individuals. Any available data on the patients will be recorded on the data collection form prior to the clinic visit, with the aid of SCI-DC, Apex, patient case notes and pharmaceutical care plans.
    IV. Categorise care issues identified by the pharmacist during the clinic visit and care issues documented in the pharmaceutical care plans. The categorisation of the care issues will be described and categorised using

an international classification of actual and potential drug therapy problems.[6] Pharmaceutical care activity will be documented as either checks or changes.[7]

V. A database, incorporating the activities from the audit and data from other participating sites, will be developed. The database will:

- Be based on previous databases developed in this field. The assessment tool will be remodelled to fit the pharmacists' practical needs.
- Comprise essential data fields from both pharmacist-led Diabetes Management clinics and Diabetes Cardiovascular Risk clinics.
- Include more comprehensive data fields associated with ethnic minorities.
- Be used to generate reports of the pharmaceutical care provided to diabetes patients, eg. comparison of different groups of patients, comparison of different clinical settings etc.

VI. Categorise each care issue according to which guideline standard in managing of cardiovascular disease it is trying to address. The guideline standards used will be based on a validated medication assessment tool (MAT_{CVD}) developed by PhD student Tobias Dreischulte at Strathclyde University, Glasgow.

3. The findings of the audit of pharmaceutical care activities will be reviewed in a focus group comprising the DCVR clinic pharmacists. The research group, comprising the supervisors and the researcher, will meet half way through the data collection to organize an interview schedule for the group interview. The time frame will be one hour and a maximum of 10 questions will be presented to the group by the researcher. The discussion will be audio recorded with consent of the participants and transcribed.

Analysis of Findings

Descriptive statistics will be used to describe the demographics of the sample in terms of age, gender, ethnicity, number of clinic attendance, number of medications, care issues etc. Each care issue will be categorised as either checks or changes. Reports from the database will also be used to compare eg. different groups of patients or clinical settings and pharmaceutical care activity.

Focus group outcomes will be identified using content analysis of the audio recorded interview. The analysis will generate themes taken up by the DCVR clinic pharmacists. A summary of their response and capture of different point of views will be made.

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Appendix 9:

Focus group interview – pharmaceutical care delivery and documentation

Findings from the audit of pharmaceutical care issues

1) How do you think the results reflect what you do in practice?

- If agreeing – "patient or carer understanding/compliance" (advice on diet, exercise, smoking) only 44 times over 186 care episodes. Important part of your delivery of pharmaceutical care. Low? Under-documented?

- This only presents what has been documented – do you feel there are activities you undertake which are not reflected in the results?
    - If yes – which activities?

- How relevant do you think this kind of audit is for your practice?
    - Demonstrates risk management activity
    - Assesses pharmaceutical care needs and may help in strategic planning of services
    - Shows contribution to pharmaceutical care provided by pharmacists

2) How valuable do you think it is documenting your contribution to pharmaceutical care?

- Do you think this is a good method to measure the process of pharmacists' activities?
    - If no – are there any other ways of reporting pharmacists' activities?
    - If yes – how so?
    - Do you think it might help the argument for pharmacist led clinics rather than nurse-led clinics (in the absence of comparable clinical outcome data)? How so? Why not?
    - In other clinical areas (e.g. stroke) the pharmaceutical care plan has been developed in tandem with a multidisciplinary integrated care plan. What's the potential for a similar development in your clinics?

- Evidence on patient safety issues – E.g. Patient been to clinic, develops acute renal failure next day – need to document what you have done.

- How do you feel that documentation in a standardised care plan would facilitate consistent delivery of care across the clinics? And would also support new clinic pharmacists? Would you explain further?

- What are your thoughts about documenting recommendations in a care plan for use by community pharmacists?
    - Identifying standard care issues may help develop SCI-DC with pharmaceutical care fields to ease information exchange.

- What are your thoughts about the standardised care plan forming the basis of a clinical management plan to support non-medical prescribing?

3) What is your opinion on how this system of auditing pharmaceutical care from the different clinics provides a measure of consistent practice?

Review of the database as a means of generating audit reports

4) At this time the database is a research tool which takes time to populate, but what are your thought about the benefits to your practice in using this tool?

- Benefits – easy to do queries on both clinical outcomes and pharmaceutical care delivery
- If it was quick and easy to use, would you use it?
- Why do you not want to use it?

Summary

5) Have what I have presented prompted you to change your practice?

- What is the next step?

6) How do you think an audit should be conducted in the future?

Appendix 10:

Overview of results presented at the focus group

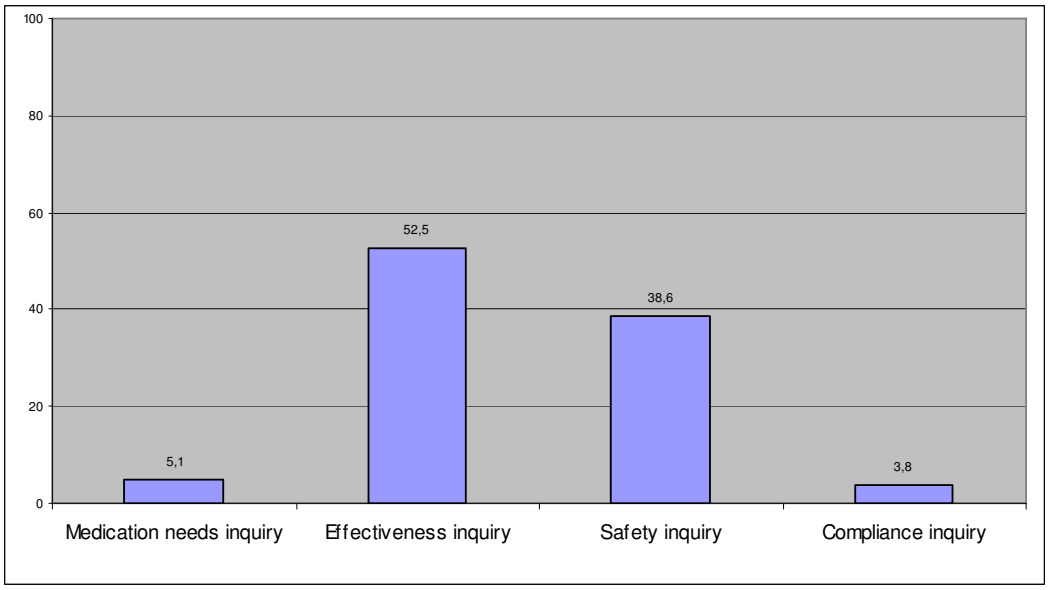

Figure 1. % distribution of documented pharmaceutical care checks (n = 373) in 47 patients over 186 care episodes

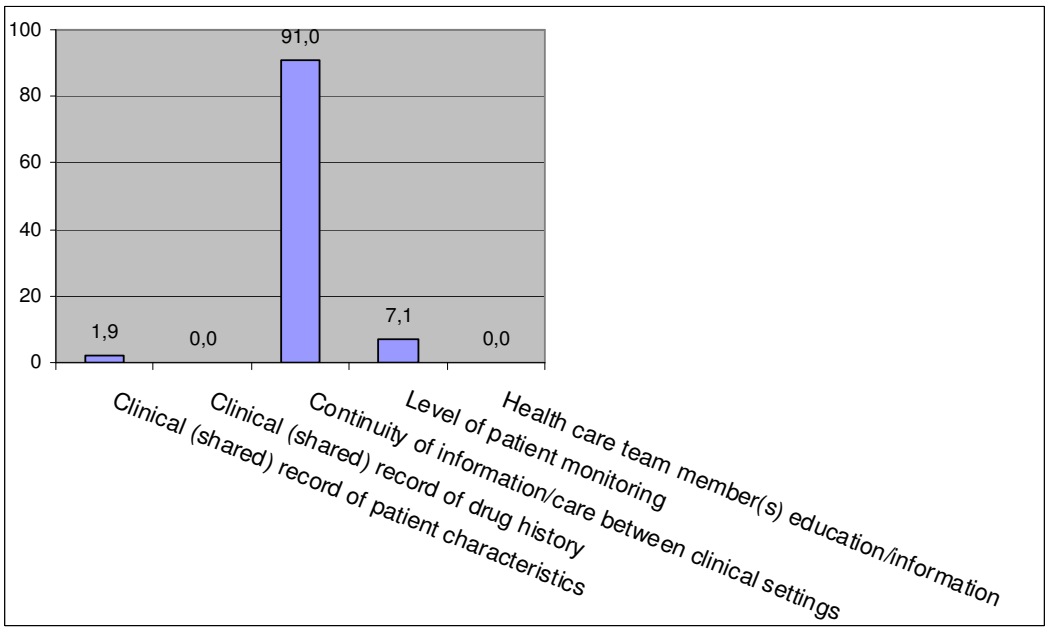

Figure 2. % distribution of documented Change in Drug Therapy Process (n = 211) in 47 patients over 186 care episodes

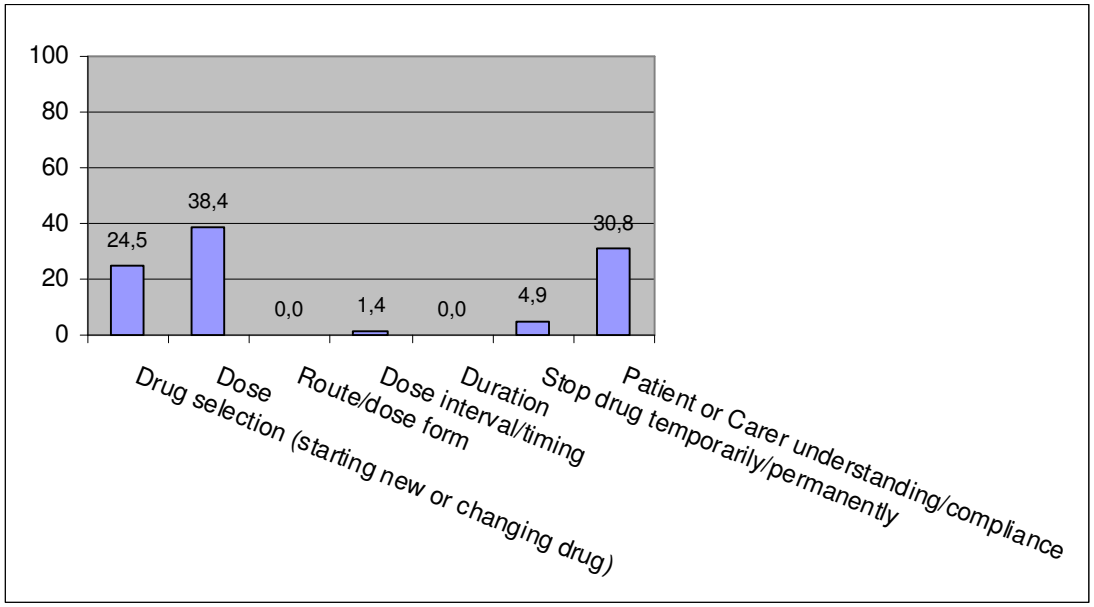

Figure 3. % distribution of documented Change in Drug Therapy (n = 143) in 47 patients over 186 care episodes

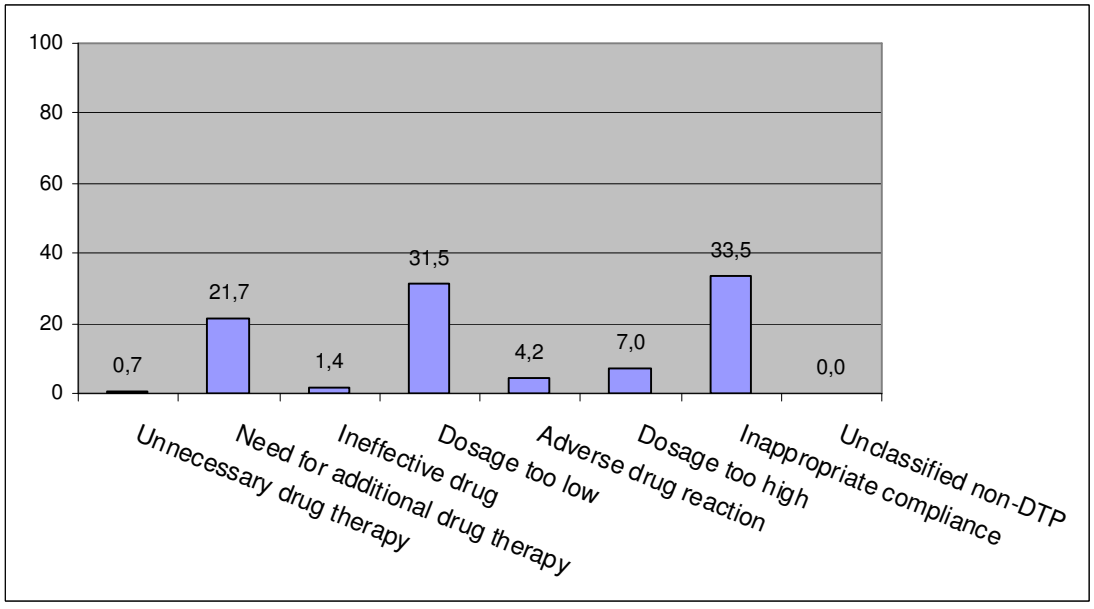

Figure 4. % distribution of documented Drug Therapy Problems (n = 143) in 47 patients over 186 care episodes