

Review and development of referral criteria used to identify patients with diabetes who would benefit from attending a pharmacist-led cardiovascular out-patient clinic

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Abstract

Development and validation of new referral criteria: a triangulation study at the Pharmacist-led Diabetes Cardiovascular risk Reduction Clinic, Edinburgh.

Background

The Pharmacist-led Diabetes Cardiovascular risk Reduction (DCVR) clinic has been established at the Western General Hospital (WGH), Edinburgh, for 8 years. Clinicians have the opportunity to refer patients to this clinic by completing a referral form. It is known that not all suitable patients are referred to the clinic so it was decided to review the referral process and the referral criteria.

Methods

Semi-structured interviews were performed with nine clinicians at the diabetes clinic, WGH. Staged analysis confirmed data saturation after nine interviews. The interviews were transcribed and analysed with thematic coding used to structure the interview schedule. Thematic codes were awareness of the clinic and referral form, process of referral, opinions about referral criteria and recommendations for management. New referral criteria were developed from information of the clinicians in discussion with lead pharmacist at the DCVR clinic. New referral criteria were applied to a cross-sectional survey of 1000 patients selected randomly from a total of 2911 patients registered at the diabetes clinic at WGH at the 19th of March 2012. Data was recorded on a specifically designed Access[®] database for 944 patients from the main list of 1000 patients identified from the Scottish Care Information – Diabetes Collaboration (SCI-DC). The data recorded was demographics, type of diabetes mellitus, referral to the DCVR clinic, systolic BP >130 mmHg, diastolic BP >75 mmHg, cholesterol >4 mmol/L, microalbumin >2.5 mg/mmol and signs of retinopathy.

Results

Eight clinicians were referring patients to the clinic and one clinician was not aware of the clinic. Only four of nine clinicians were aware of the referral form, and three clinicians stated they used the form when referring a patient. The interviews showed that clinicians' main reason for referring patients to the DCVR was blood pressure control in complicated patients. Analysis of the 944 patients identified that 48 had been referred to the DCVR clinic. No patients with solely hypertension (systolic BP >130 mmHg + diastolic BP >75 mmHg) were among the 48 referred. The combinations of criteria with the greatest yield of actually referred patients were 1) systolic BP >130 mmHg + diastolic BP >75 mmHg + microalbumin >2.5 mg/mmol, 2) systolic BP >130 mmHg + microalbumin >2.5 mg/mmol + retinopathy, 3) systolic BP >130 mmHg + cholesterol >4 mmol/L + microalbumin >2.5 mg/mmol, 4) systolic BP >130 mmHg + diastolic BP >75 mmHg + cholesterol >4 mmol/L + microalbumin >2.5 mg/mmol and 5) systolic BP >130 mmHg + diastolic BP >75 mmHg + microalbumin >2.5 mg/mmol + retinopathy. All five combinations had two criteria in common: systolic BP >130 mmHg and microalbumin >2.5 mg/mmol. One clinician stated that retinopathy should be a referral criterion, but the data showed that no patients were referred with retinopathy alone and all those with retinopathy met other criteria.

Conclusion

To provide a consistent service for patients there is a requirement for continuity in referral of patients to the pharmacist-led DCVR clinic. Our findings suggest there is a need to raise awareness of the clinic among physicians, particularly more junior physicians and to improve communication between physicians and pharmacist in terms of patient outcomes. More guidance is needed in terms of which patients to refer and this study attempted to analyse the referral yield from different combinations of criteria. These combinations require further discussion with the referring physicians and the options of using a scored cut-off for referral explored for future validation before application in practice.

Abbreviations

ACEI	-	Angiotensin Converting Enzyme Inhibitor
ARB	-	Angiotensin Receptor Blocker
BHS	-	British Hypertension Society
BP	-	Blood Pressure
C	-	Consultant
CCB	-	Calcium Channel Blocker
CCT	-	Certificate of Completion of Training
CVD	-	Cardiovascular Disease
DCVR	-	Diabetes Cardiovascular risk Reduction
ESH	-	European Society of Hypertension
FY2	-	Foundation doctor Year 2
GDSS	-	Glasgow Dyspepsia Severity Score
GFR	-	Glomerular Filtration Rate
GP	-	General Practitioner
HDL	-	High Density Lipoprotein
IGT	-	Impaired Glucose Tolerance
LDL	-	Low Density Lipoprotein
MS	-	Microsoft
NHS	-	National Health Service
NICE	-	National Institute for Health and Clinical Excellence
NPH	-	Neutral Protamine Hagedorm
ROC	-	Receiver Operator Characteristic
SCI-DC	-	Scottish Care Information – Diabetes Collaboration
SIGN	-	Scottish Intercollegiate Guideline Network
SMC	-	Scottish Medicine Consortium
SPR	-	Specialist Registrar
ST3	-	Specialist Trainee 3
UK	-	United Kingdom
UKPDS	-	United Kingdom Prospective Diabetes Study
WGH	-	Western General Hospital
WHO	-	World Health Organization

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1 Introduction

1.1 Epidemiology

Diabetes mellitus is a worldwide problem due to its persistence and economic impact¹. In 2009 2.6 million people were diagnosed with diabetes mellitus in the United Kingdom (UK) alone. It was estimated that 10% of adults had type 1, and 90% had type 2. Type 2 is more common in children and young adults; therefore overall 15% of patients had type 1 and 85% had type 2 diabetes mellitus. By 2025 approximately 4 million people will be living with diabetes mellitus in the UK and the majority will have type 2 diabetes mellitus since both the number of elderly patients and obese patients is increasing².

In Scotland in 2003 there were almost 1,900 young people under 15 years of age diagnosed with type 1 diabetes mellitus, with an annual incidence of 35 per 100,000 populations. In 2010 223,943 patients were identified as diabetic (type 1 and type 2 diabetes mellitus) which represent 4.1% of the Scottish population³. There are also more men than women with diabetes mellitus, 54.5% men and 45.5 % women².

Macrovascular complications account for 50% of deaths in patients with type 2 diabetes mellitus⁴. In Scotland, cardiovascular disease is responsible for deaths in more than 25% of all patients⁵, and in the whole of the UK cardiovascular diseases accounts for approximately 80% of the deaths in patients with type 2 diabetes mellitus. Hypertension affects 80% of patients with type 2 diabetes mellitus and is associated with both microvascular and macrovascular complications. The risk of developing a myocardial infarction in a patient with diabetes mellitus is the same as for a non-diabetic patient having a second myocardial infarction⁶. Diabetes mellitus is a long term condition and the World Health Organization (WHO) recommends healthy diet and exercise to prevent obesity and thereby further development of diabetes mellitus⁷.

1.2 Diabetes mellitus

Diabetes mellitus is a complex disease; its pathophysiology is not quite understood. The disease may have an impact on every cell in the body, e.g. endothelial cells, kidney cells and white blood cells. In the worst case diabetes may lead to disease in multiple organ systems, e.g. hypertension or other cardiovascular risks, nephropathy and poor wound healing^{8, 9}. Insulin is a hormone produced by the β -cells in the pancreas, which also store and release the insulin produced. The body use glucose

to generate energy in the skeletal muscles, the liver store glucose as glycogen and adipose tissue converts glucose to fat. Insulin promotes these processes by increasing the uptake of glucose from the bloodstream, the storage of glycogen and the conversion to fatty acids. Low blood glucose levels, called hypoglycaemia, can give symptoms such as tremor, sweating, tachycardia, or worsened symptoms such as seizures or personality changes ⁹. High blood glucose levels contribute to complications such as cardiovascular complications, foot ulcers or retinopathy discussed later in this project. Diabetes mellitus concerns several pathways such as impaired sensitivity of insulin, impaired effect of insulin's signalling capacity, the insulin production in the body and gestational diabetes mellitus which is associated with glucose intolerance during pregnancy ⁸.

1.2.1 Type 1 diabetes mellitus

Type 1 diabetes mellitus is an immune-mediated destruction of pancreatic β -cells which causes a decreased release of insulin, and on long-term a complete discontinuation of insulin-secretion¹⁰. β -cell dysfunction may be caused by two feasible pathways; defects in genes or by extracellular factors. The first pathway is a genetic disorder where there is a defect in genes controlling the production of two antigens. When one or both of these antigens are present the patient is more likely to develop type 1 diabetes mellitus. Among patients with type 1 diabetes mellitus 95% have one or both antigens; however 40% of non-diabetic patients also have either one or both of these antigens. The second pathway concerns destructive cytotoxins and antibodies or autodigestion from inflammatory disorders. Other external factors such as mumps or Coxsackie B4 are thought to be able to produce fatal insulinitis. Insulinitis is an inflammation, and is highly favourable towards the β -cells in the pancreas; thereby leading to β -cell dysfunctions⁸.

Treatment of type 1 diabetes mellitus requires insulin; at the moment there are no other medications effective in young people less than 16 years old¹¹. Insulin therapy is divided into three groups due to their onset of action; fast-acting, intermediate and long-acting. Fast-acting insulin are insulin lispro, insulin aspart and insulin glulisine. As a result of the short duration of action, they have reduced risk in developing hypoglycaemia (low blood glucose). Insulin lente and neutral protamine hagedorm (NPH) are examples of intermediate acting insulin; they have a longer onset of action, but there is an inter-patient variation in their duration of action.

Long acting insulin, for example insulin glargine and insulin detemir, give the patient a more fundamental level of insulin⁶. Intensive insulin therapy, which involves four injections or more administered throughout the day, improves glycaemic control over a period of time when compared to conventional therapies, which involves two injections throughout the day. Adult treatment should include either regular human or rapid-acting insulin. Basal insulin-analogues are recommended for adults who may experience severe hypoglycaemia or nocturnal hypoglycaemia, and NPH insulin is recommended in adults who do not experience severe or nocturnal hypoglycaemia. It is recommended that children and young adults use either one of the above mentioned medications or a combination of these. Insulin treatment should be targeted for each patient individually to gain the best possible glycaemic control, avoiding both hypoglycaemia and hyperglycaemia (high blood glucose) ¹¹.

1.2.2 Type 2 diabetes mellitus

Patients with type 2 diabetes mellitus have a combination of relative insulin deficiency and insulin resistance^{4,12}. Insulin deficiency develops from hyperinsulinaemia over longer period of time⁴, and insulin resistance is associated with decreased insulin sensitivity. This means the activity between the insulin hormone and the insulin receptor is reduced, and there is reduced activity in the signalling cascade, restraining insulin action¹⁰. Insulin sensitivity is decreased in target tissues such as liver, skeletal muscles and adipose tissues⁸. When a hyperglycaemic situation develops, this will stimulate the pancreas to produce even more insulin; however, since the target tissues are desensitised they will not respond normally to the insulin^{8, 12}. A decrease in function of the β -cells tends to progress during time and the β -cell lose their capacity to respond to elevated glucose levels¹². This may cause a need for insulin treatment. Type 2 diabetes mellitus is associated with higher age, obesity, physically inactivity, certain ethnicity, genetics or impaired glucose metabolism or tolerance (IGT)¹⁰.

There are several types of oral anti-diabetic drugs, divided into three main groups: sulfonylureas, biguanides and other antidiabetic drugs. The sulfonylureas act mainly by reinforcing insulin secretion from the β -cells and thereby the plasma glucose is reduced. This means that there must be some active pancreatic β -cells present. Hypoglycaemia is rare; however, if this occurs it may last for several hours, and the patient need hospital treatment.

Sulfonylureas are recommended for patients who are not overweight, as it may stimulate appetite probably through increased insulin secretion¹⁴.

The body excretes sulfonylureas through the urine, therefore elderly patients who often have reduced renal function and patients with renal impairment, should use sulfonylureas carefully^{13, 14}. A study performed on a Scottish population showed that 1 in every 100 patients treated with sulfonylurea suffered major episodes of hypoglycaemia; in comparison, this was reduced to 1 in 2000 patients treated with metformin¹¹.

Metformin is a biguanide; although the mechanism of action is not completely understood, it mainly works by decreasing hepatic glucose production, whilst increasing the glucose uptake in skeletal muscles. As a result of this uptake and utilisation of glucose, insulin resistance will be reduced. Metformin is recommended for overweight patients as it improves insulin sensitivity and may also assist with weight loss; if appropriate it may be used for other patients as well¹⁴. The United Kingdom Prospective Diabetes Study (UKPDS) 34 showed that overweight patients treated with metformin had a better outcome for diabetes-related death and myocardial infarction¹¹. Metformin does not cause hyperglycaemia or hypoglycaemia, side effects are generally gastro-intestinal problems such as diarrhoea and nausea, however these are usually transient. Metformin might decrease the transformation of lactate to glucose. If metformin is given to patients with renal or hepatic impairment, heart failure, or patients in shock, the drug may accumulate and increase the risk of lactic acidosis¹⁴.

Other oral antidiabetic agents are pioglitazone, saxagliptine, sitagliptine, vildagliptine, exenatide and liraglutide. They are not all in the same group of oral antidiabetics but they are all accepted or accepted for restricted use by the National Health Service (NHS) Scotland and Scottish Medicine Consortium (SMC)¹⁵. Pioglitazone reduces blood glucose by reducing insulin resistance peripherally; saxagliptine, sitagliptine and vildagliptine increases insulin secretion and reduces secretion of glucagon; and exenatide and liraglutide increase insulin secretion, inhibiting secretion of glucagon and reduces gastric emptying¹⁶.

1.3 Diabetic complications

1.3.1 Microvascular complications

Complications related to diabetes mellitus are classified as microvascular and macrovascular. Patients with type 1 diabetes mellitus have a higher risk of developing microvascular complications which is associated with a chronic hyperglycaemia and blood vessel degradation^{4, 10}. This may lead to poor blood circulation in the smallest blood vessels, especially in peripheral nerves which can lead to leg ulcers; kidneys, which can lead to nephropathy, and eyes, which can lead to retinopathy. Retinopathy causes blindness for 12 000 – 24 000 patients a year¹⁰. Patients should get their eyes examined annually especially since the symptoms of this disease do not come clear to the patient before the disease has evolved. A close control of glucose levels and blood pressure has shown to prevent the progression of the disease. It is important that every diabetes mellitus patient is educated about the complications of the disease to improve long term quality of life.

Patients with diabetes mellitus may develop nephropathy. An early sign of this renal disease is renal hypertrophy, in which the kidneys are enlarged. As the result of an increase in the volume of blood being filtrated by the glomerulus in the kidneys, the glomerular filtration rate (GFR) increases and the glomerular capillaries are damaged. A test to detect nephropathy is to measure the amount of protein in the urine. The first sign is albumin in the urine; microalbuminuria. If the nephropathy progresses, the leakage through the filtration membrane in the glomerulus leads to more complex proteinaceous molecules in the urine, a complication called proteinuria. Another common result of nephropathy is hypertension which may provide further damage to the kidneys⁶. Angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) have been shown to prevent microalbuminuria developing to proteinuria by dilating the arteriole leading into the glomerulus, reducing the intra-glomerular pressure and thereby the damage on the glomerulus and kidneys¹¹. Again it is only a close control of both blood glucose and intensive blood pressure treatment which can prevent development or at least depreciate the progress of nephropathy⁶. Screening the patients for both retinopathy and early signs of kidney disease related to diabetes are cost saving and may help the patient in the future.

1.3.2 Macrovascular complications

Macrovascular complications such as cardiovascular diseases (CVD), cerebrovascular disease and peripheral vascular disease are associated with hyperglycaemia, hypertension and hypercholesterolemia¹¹. These three conditions including coagulation factors and inflammatory factors should all be targeted in a patient with diabetes mellitus⁸. Diabetic patients have two to five times increased risk of developing cardiovascular complications

Disorders concerning the metabolism of lipids are an important contribution to the risk of developing CVD, along with other risk factors such as obesity and physical inactivity. There are several types of lipid-protein complexes, called lipoproteins. The two most important lipoproteins related to CVD are low density lipoproteins (LDL) and high density lipoproteins (HDL). LDL is at the same level of importance as blood glucose or blood pressure as being an indicator for disease in diabetic patients. LDL is the major transporter of cholesterol in the blood, and is also the main lipoprotein associated with atherosclerotic disease, therefore, LDL is considered as “the bad lipoprotein”. HDL carries cholesterol from peripheral tissues back to the liver for excretion, and is considered as “the good lipoprotein”⁶.

Dyslipidaemia, where LDL and cholesterol levels are elevated associated with decreased levels of HDL, can develop secondary to diabetes mellitus, obesity, high consumption of alcohol or chronic renal failure. The aim of treatment is to decrease levels of LDL and cholesterol, increasing the levels of HDL and thereby reducing risk of atherosclerosis and CVD⁶. The Scottish Intercollegiate Guideline Network (SIGN) recommend atorvastatin (10 mg) or simvastatin (40 mg) as lipid lowering therapy for patients over 40 years of age with type 2 diabetes mellitus regardless of baseline cholesterol. Patients over 40 years of age with type 2 diabetes mellitus or patients under 40 years of age with either type 1 or type 2 should be evaluated for treatment with simvastatin (40 mg)¹¹.

Peripheral vascular disease affects the vessels outside the heart. This may affect the arteries in the legs and the iliac vessels. If the latter occurs it may cause buttock pain or erectile dysfunction. A patient with both type 2 diabetes mellitus and peripheral vascular disease has a higher risk for developing more serious cardiovascular complications. About 20% of patients with peripheral vascular disease die within two years from myocardial infarction⁶.

Hypertension can be classified as essential (also called primary), secondary or malignant hypertension. Essential hypertension does not have a clear cause, and can be caused by genetic factors or environmental factors, such as obesity or stress. Secondary hypertension may be a result of endocrine diseases, renal diseases or pregnancy. If hypertension develop rapidly it is called malignant hypertension; also considered as severe hypertension. Without appropriate treatment for malignant hypertension the chance of survival within a year is less than 20% ¹³. The British Hypertension Society (BHS) has classified hypertension after blood pressure levels; as shown in table 1.3.2.

Table 1.3.2. The BHS classification on hypertension based on clinical values, corresponding to that of European Society of Hypertension (ESH) and WHO/International Society of Hypertension¹⁷.

<i>Category</i>	<i>Systolic blood pressure (mmHg)</i>	<i>Diastolic blood pressure (mmHg)</i>
Optimal blood pressure	< 120	< 80
Normal blood pressure	< 130	< 85
High-normal blood pressure	130-139	85-89
Grade 1 hypertension (mild)	140-159	90-99
Grade 2 hypertension (moderate)	160-179	100-109
Grade 3 hypertension (severe)	≥ 180	≥ 110
Isolated systolic hypertension (Grade 1)	140-159	< 90
Isolated systolic hypertension (Grade 2)	≥ 160	< 90

It must be made clear that table 1 shows the classification of hypertension independently of diabetes mellitus. The BHS has defined a first blood pressure target for patients with diabetes mellitus to be <140/80 mmHg. However, further reduction in cardiovascular risk is expected if blood pressure decreases to <130/80 mmHg ¹⁷. A study performed on randomised patients with hypertension stated that the group with diastolic blood pressure (BP) ≤90 mmHg had a two fold risk of major cardiovascular events, compared to the group with diastolic BP ≤80 mmHg¹⁸. The SIGN guidelines recommend a diastolic BP ≤80 mmHg and a target systolic BP <130 mmHg¹¹.

The SIGN guidelines and the BHS guidelines both recommend that patients with diabetes and hypertension should start on an ACE inhibitor or if ACE inhibitor is not tolerated, an ARB. If the blood pressure is not targeted or controlled, a calcium channel blocker (CCB) should be added^{11, 17}.

A study review summarising the evidence available on combination therapies with ACE inhibitors and ARBs found that there is not good enough evidence on the effect on reducing blood pressure with this combination therapy when compared to monotherapy¹⁹, and the SIGN guidelines and the BHS agree on not combining ACE inhibitors with ARBs as initial treatment for hypertension^{11, 17}. The SIGN guidelines also recommend a CCB or a thiazide diuretic as initial treatment for diabetic patients with hypertension¹¹. The use of CCBs has been questioned due to the safety and efficacy in their prevention of cardiovascular events in diabetic patients. There has also been a hesitation in the use of thiazide/thiazide-like diuretics because of observed side effects on insulin sensitivity and metabolic factors¹⁷ such as increase in serum glucose and lipid levels⁹. However, recent trials have alleviated several of these concerns¹⁷. A study on patients with type 2 diabetes mellitus which compared a thiazide-like diuretic with a CCB or an ACE inhibitor as first-line therapy showed that the ACE inhibitor was not superior to the thiazide-like diuretic in reducing coronary and cardiovascular episodes and the thiazide-like diuretic did not differ from the CCB in preventing overall CVD. Studies have shown that for patients with type 1 diabetes mellitus an ACE inhibitor protects more against further development of nephropathy than ARBs, however there was no evidence of the ACE inhibitor protecting more against cardiovascular episodes, other than the improvement of blood pressure. In patients with type 2 diabetes mellitus the data demonstrated that ARBs protect slightly more against cardiovascular episodes and progressive nephropathy than ACE inhibitors. Since both agents have these protective qualities they are strongly recommended as part of the combination therapy in patients with diabetes mellitus and hypertension requiring more than one agent¹⁷.

The National Institute for Health and Clinical Excellence (NICE) guidelines also recommends the same procedure in treatment of hypertension as SIGN guidelines and BHS guidelines, but it is important to state that even though the NICE guidelines in collaboration with BHS are the most recent guidelines, they do not consider treatment of patients with hypertension and diabetes mellitus²⁰.

The National Health Service (NHS) Lothian Pharmacist-led Diabetes Cardiovascular Risk Clinic at the Western General Hospital (WGH) has developed a treatment protocol in collaboration with the leading consultant diabetologist. These guidelines are based on the SIGN guidelines.

A study performed on patients with type 1 and type 2 diabetes mellitus to evaluate the prescribing of cardiovascular medications and the quality of the prescribing stated that prevention of heart disease is one of the most important factors in diabetes mellitus management. The study showed that the adherence to the prescribing guidelines was relatively high; however the study concluded that there is an urgent need to improve the prescribing in both cardiovascular disease and hypertensive therapy⁵.

A combination of microvascular complications such as peripheral neuropathy, and macrovascular complications such as peripheral vascular disease, may cause foot disease which is common in those patients with poor blood glucose control. Foot ulcers can be painless, called neuropathic wounds, which may not be detected until the damage has progressed too far. Ischaemic ulcers are painful and the wounds are a result of poor blood circulation and peripheral vascular disease. Diabetic foot ulcers are prone to infections by anaerobic bacteria. Educating the patient about prevention and care of the feet, and tight blood glucose control and blood pressure control may prevent the foot ulcers from developing⁶.

HbA1c is glycosylated haemoglobin, and is a good marker for chronic hyperglycaemia as it is possible to detect the average blood glucose level for approximately the last 120 days, which is the life span for haemoglobin⁶. A reduction in HbA1c is associated with a reduction in both microvascular and macrovascular complications. The target value of HbA1c is about 7.0 %, but this may vary between different institutions. Diabetic patients with hypertension should be treated aggressively with lifestyle changes and medications. The target blood pressure for these patients is a diastolic pressure equal to or less than 80 mmHg and a systolic pressure less than 130 mmHg¹¹.

1.4 Pharmaceutical care

Clinical pharmacy is a concept attended with pharmaceutical expertise where this expertise is used to help maximise drug efficacy and minimise drug toxicity. Clinical pharmacy requires quality assurance which can be obtained through testing with quality assurance systems based from approved clinical pharmacy 'service specifications' determined from patients' needs²¹.

Pharmaceutical care is described as a pharmacist's contribution to patient care, and to achieve pharmaceutical care communication and collaboration with the multidisciplinary team of healthcare professionals is essential²¹. Hepler and Strand defined pharmaceutical care as "*The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life*"²². By improving health through optimising drug therapy and working to minimize the risk of adverse drug reactions the pharmacist's knowledge can improve a patient's quality of life¹. Pharmacists should also collaborate with medical professionals to complement the knowledge and to secure and increase the efficiency of drug use.

It is well known that both hospital treatment and medications may be very expensive, and minimising costs relies on efficient, secure and cost-effective drug therapy, which needs competent diagnosis and prescribing, effective monitoring and evaluation of drug therapy. Additionally, an important factor is compliance and understanding from the patient. Several drug related problems have been revealed and reduced by clinical pharmacists. Clinical pharmacists have also improved patient compliance, drug prescribing, cost effectiveness and hospitalisation has been reduced²¹. Diabetes mellitus is becoming a more international healthcare crisis due to its complexity and there is an enormous need for more pharmacists who are specialised in this field¹.

Adherence is about the patient following the guidelines or advice from a general practitioner (GP), clinician or other healthcare professional. The responsibility to make sure the patient is following advised treatment lies with the healthcare professionals. Factors such as dosage form, polypharmacy, patient's knowledge, ability to go to a pharmacy or economic factors such as income, are just a few of many causes for non-adherence with medicines²³. To be able to avoid the diabetic complications as long as possible, the patient's adherence to the medication is very important. This might be a complex process since the therapy is complicated and some patients may find it hard to understand the importance²².

A study performed with elderly patients with diabetes mellitus and hypertension to evaluate a pharmaceutical care program found that the pharmacist was able to

improve the patient's individual determined outcome such as lowering blood pressure, glucose levels and cholesterol levels. Follow up appointments with the pharmacist were arranged, and the pharmacist organised educational group sessions for the patients. The study also found that the pharmacist was able to give better support for the patient through a pharmaceutical care program and by working in collaboration with both the patient and other healthcare professionals. The study stated that the barriers towards medication adherence included factors such as: complicated therapeutic plans; treating asymptomatic diseases; and the impairments elderly patients may live with such as reduced vision and hearing. Other barriers to medication adherence may be difficulties in understanding the prescriptions and how to use the medication. The study concluded that adherence improved by patient motivation and patient education²². Diabetic patients see a pharmacist more often than any other health professional, for example every time they go to the pharmacy for prescriptions; the pharmacist is therefore in a first-line position to interact with treatment, education and thereby the patient's quality of life⁸.

Another study performed on patients with type 2 diabetes mellitus to evaluate pharmaceutical care also found that the patients were more satisfied with their treatment and blood glucose values and blood pressure values were improved when the patients were managed by a clinical pharmacist. By following up the patients they were also less worried about the disease and the future¹.

1.5 The Pharmacist-led Diabetes Cardiovascular risk Reduction Clinic

The pharmacist-led Diabetes Cardiovascular Risk Reduction Clinic (DCVR) has been operating at the Western General Hospital (WGH) in Edinburgh for eight years. The clinicians refer patients who are resistant to hypertension treatment and who also need intensified and more frequent follow-up. These patients may also have dyslipidaemia, nephropathy or retinopathy.

A study was performed at the WGH to determine the efficacy of the pharmacist-led DCVR clinic. The study focused on reducing cardiovascular risk, and indicated that hypertension, hyperglycaemia and dyslipidaemia were associated with cardiovascular death in patients with diabetes mellitus.

The authors set up a pharmacist-led clinic where the pharmacist was monitoring both the blood pressure and the cholesterol, and also did the follow up of the patients every six weeks. The treatment was disrupted once targets were achieved or no

further improvements were made. The pharmacist advised the patients about healthy lifestyle which includes weight reduction, smoking cessation, reducing alcohol consumption and increasing activity and exercise, all to improve blood pressure and cholesterol. The study showed that patients had an average decrease in blood pressure by 13/9 mmHg²⁴.

A thesis was performed in 2008 to evaluate pharmaceutical care on patients with diabetes mellitus at the pharmacist-led DCVR clinic, WGH, Edinburgh. In the study 47 patients with type 2 diabetes mellitus were selected. The study found 51 pharmaceutical care issues resulting in changes in patient's medications and the study concluded that the pharmacists ensure safety and effectiveness in the treatment of diabetic patients²⁵.

Although the pharmacist-led DCVR clinic has been established for eight years, there is a need to review the referral process and the referral form (Appendix 1). Clinicians refer patients by completing this form. The two criteria on the current form are macrovascular disease or nephropathy. The clinician is also able to give a reason for the referral such as blood pressure control, antiplatelet therapy or lipid lowering therapy. It is known that not all suitable patients are referred to the clinic. Some suitable patients may never be referred at all, while non-suitable patients do get referred. It is one of the concerns that the origin of this situation may have something to do with the referral form, i.e. if it is not specific enough. Other factors of concern include the clinicians' use of the referral form, availability of the form in their office, and awareness of the referral form or the pharmacist-led DCVR clinic. It is also known that there are limited pharmaceutical resources to manage all patients, therefore it is very important that the proper patients get referred to the clinic.

An initial step is to establish the working practices of those who use the pharmacist-led DCVR clinic, and it was considered to use qualitative methods to explore clinicians decisions when referring patients and their opinions about the current referral criteria. In this study a focus group session would have been the ideal methodology as it would generate discussions and different opinions between the clinicians. Some of the clinicians also work in clinics at other hospitals in Edinburgh. As a result they have limited time resources, and gathering 10-12 clinicians for a focus group session seemed impossible.

Developing a questionnaire for completion would reach a higher number of clinicians. However, the clinicians own opinions and thoughts are important in establishing their work process; a questionnaire with open questions would be too time consuming to

complete, and a questionnaire with closed questions would be too narrow. This will be discussed further in following chapters.

Therefore, one-to-one semi-structured interviews are the most feasible way to gather the information needed. Having established their opinions, and assuming that those patients referral were appropriate it was planned to design new referral criteria and test their sensitivity and specificity in a population of patients who attend the diabetes clinic using those referred to the pharmacist-led DCVR clinic as the gold standard.

1.6 Qualitative research

“Quality refers to the what, how, when and where of a thing – it’s essence and ambience. Qualitative research thus refers to the meanings, concepts, definitions, characteristics, metaphors, symbols and descriptive of things.” (Berg, 2007)²⁶.

Qualitative research has become more pronounced in medical research. The research question focuses on depth, meanings and characteristics of incidents, people or experience, and thereby allows a more thorough understanding of people’s experiences and behaviour^{26, 27}.

This is essential in this study since the clinicians’ opinions and thoughts about the referral process are to be investigated; it is crucial to gather as much data as possible and this will be more achievable if the clinicians are allowed to express themselves in own words. The data of the study are collected through interviews, focus groups or observations. Analysis of the data can be performed with thematic coding, where information from an interview is coded in different themes and analysed; a content analysis, which is used when analysing documents; or analysis of frequency^{26, 27}.

1.6.1 Semi-structured interviews

Semi-structured interviews allow the interviewer to have a discussion with the interviewee. During the interview the interviewee is allowed to present their own opinions and thoughts about a subject, while the interviewer remains in control of the session. The questions are planned before the interview starts, but they can be altered during the interview or the interviewer can ask new questions.

The most important thing during semi-structured interviews is to never ask leading questions, but more open questions and guide the interviewee into more specific subheadings.

By explaining the confidential nature of the interview and how the collected data will be used, the interviewer creates a professional but safe environment for the interviewee, and the interview may generate important information uninfluenced by anything else but the interviewee's own mind²⁸. In this study semi-structured interviews are the best method to conduct the data required because of the clinicians tight schedule. Therefore, arranging a for example 15 minute interview one-to-one is more achievable than a two hours focus group.

1.6.2 Focus groups

A focus group is an interview-session where the participants are encouraged to discuss topics with each other and the interviewer. The group is composed of 7 to 12 participants who are allowed to discuss their own opinions and views. This is a major advantage with focus groups. The interaction between the participants, influencing and discussing each others thoughts, may generate important information that may not have been possible through other methods²⁹. Arranging a focus group in this study would have been the most ideal thing to do.

One clinician's opinion may not be the same as another, but this would generate a discussion where information gathered from possibly several clinicians may have been a common agreement on how for example the referral process should be over how it was initially. From that information it may be easier deciding on new referral criteria, because it is an agreement between several clinicians and not only one and one clinician's opinion, as it will be from one-to-one semi-structured interviews. If a disagreement were developed, it may still be easier to decide on new referral criteria because there still would have been generated a lot of information. Another advantage is that the interviewer could have asked questions guiding the clinicians to at least some agreement of the referral process.

However there may be some disadvantages. When establishing a focus group it is very important that there are participants with different grades in a professional field to get more width in the information generated during the discussion. The participants also need to feel comfortable with each other and not feel dominated by one member in the group²⁹. The participants need to be available at the same time for the same

period of time. This might be quite difficult depending on which type of professional the focus group is set from.

In this study it was not anticipated that the clinicians may feel uncomfortable with each other, since they all work together on a daily basis. The main issue is as stated above: they have a tight schedule, making it difficult to arrange a focus group session. This is why the semi-structured interviews were chosen instead of a focus group.

1.6.3 Questionnaire

A questionnaire may be designed from only open or only closed questions. The results from a questionnaire can be both qualitative and quantitative; depending on the types of questions used. Completing the questionnaire may be time consuming as the participant may have to complete a large number of questions to yield the information needed. Using closed questions may generate several pages of questions to ensure the information obtained is specific enough to be validated. The advantages of questionnaires are that they generate a large amount of data and can be sent out to a larger population and get a wider sample of data; subject to response²⁹. If a questionnaire with closed questions was to be conducted in this study, it would have firstly generated too unspecific information since the clinicians would not be able to express their own thoughts, secondly been too difficult to develop since the clinicians themselves are the only one who knows their own process and finally been too time consuming to complete for the clinicians. Open questions would also have been too time consuming since the clinicians would have to write everything and may have resulted in no participants. These are the reasons why a questionnaire was not used in this study.

1.7 Quantitative research

Quantitative research focuses on the use specific terms, how to generate a value on people's knowledge and to test the strength between values or measures. Examples of data sources are surveys, reports, test scores or observations. The values from different data sets can be analysed through descriptive statistics or regression. The results generated in quantitative research have more width than depth, and rely on how the investigator chooses to define a variable and which variables are to include^{26, 27}. Quantitative methods are more appropriate when validating a tool such as referral criteria because it is possible to assign a value or score to the data investigated.

1.7.1 Cross-sectional survey

When performing a cross-sectional survey, the data are collected from one point in time. This type of survey is used when collecting data or exposures that are persistent, and the focus is quantitative variables from a single group of patients^{30, 31}. In this study, cross-sectional survey was used to collect data from one point in time of the study sample. An advantage of using a cross-sectional survey in this study is that there is no need for a follow-up of the patients as it is limited time to perform this study.

1.7.2 Triangulation

Triangulation means using several methods to generate information. Combining quantitative and qualitative methods can be beneficial in the development of theoretical terms. When extracting and connecting information from both methods, this can result in a more profound understanding of the subject being investigated^{27,31}. Triangulation occurred in this study as both quantitative and qualitative research methods were used, this opened up the possibility to approach the data from several angles, and thus gain a deeper understanding of the referral process and of what actually has been done.

1.8 Validation of criteria

1.8.1 Sensitivity, specificity and Receiver Operator Characteristic curve

Sensitivity and specificity are used to evaluate the validity of a diagnostic test and its usefulness. It could therefore also be used to validate screening criteria. Sensitivity refers to how good a test is at correctly identifying who has the disease, and specificity refers to how good a test is at correctly identifying people who are well^{32, 33} or those who should not be screened out (not for referral). A test should ideally have both high sensitivity and high specificity, but this may be difficult³² and a balance is sought. In a population of healthy people and people with the disease, there may be some people having the disease but are testing negative, and the other way around, there might also be some people testing positive but are disease-free. These are referred to as false negatives and false positives, respectively³⁴. Receiver operating characteristic (ROC) curve is a method to test if the sensitivity and specificity are able to discriminate between the presence and absence of the fact of interest³⁵.

By determining different cut-offs from the collected data, and calculating the sensitivity and specificity between every cut-off point; an ROC curve can be generated. The y-axis is sensitivity, and the x-axis is 1-specificity; as shown in figure 1.8.1³⁶.

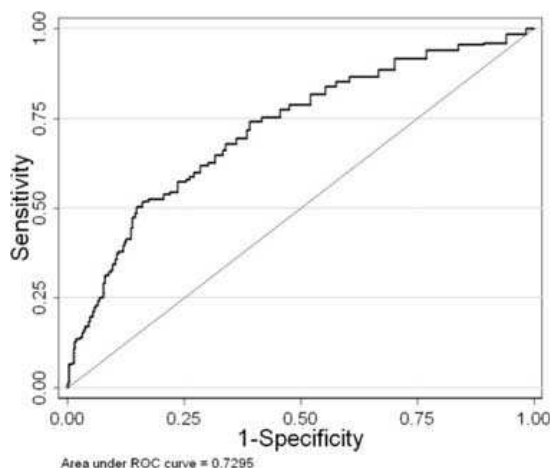


Figure 1.8.1 Receiving operator characteristic curve³⁶.

In figure 1, the diagonal line (grey coloured line) going from the origin and to the top, represents a test that is unable to distinguish between healthy people and people with the disease. The steeper the curve (black line) is at the initial stage, the more accurate the test will be, that is, more true positives (sensitivity) and less false positives (1-specificity)^{33, 36}. A study performed to investigate patient compliance through an assessment tool used sensitivity, specificity and ROC analysis to

determine cut-off points of scores in compliant and non-compliant patients³⁷. In this study it was anticipated that scores could potentially be allocated to referral criteria for the pharmacist-led DCVR clinic and sensitivity and specificity of different cut-off scores could be analysed to support use of a scoring system for referral of patients.

1.8.2 Scoring tool

Scoring tools are widely used in different medical fields. Several types of design have been developed, for example to evaluate severity of illness, predicting mortality and to help clinicians allocate patients to required intensive care services³⁸. A study performed in 2003 investigating possible barriers against shared care between pharmacists and GP for patients with dyspepsia used the Glasgow Dyspepsia Severity Score (GDSS) as the basis of a referral tool between pharmacists and GPs³⁹.

The GDSS is a scoring tool used to score the incidence and the intensity of dyspepsia, the use of over-the-counter drugs and the incidence of prescribed drugs. Each answer is given a score, and a total score will lead to a solution⁴⁰.

In a similar way, a scoring tool could potentially be used to assess patients for referral from the diabetes clinic to the pharmacist-led DCVR clinic and would help target the patients that would benefit the most from getting referred to the pharmacist-led DCVR clinic. The different referral criteria would be given a number, for example a systolic BP >130 mmHg would give a score of one, and systolic BP >150 mmHg would give a score of three. When combining systolic BP and diastolic BP and cholesterol and other important factors such as co-morbidities for example, the total score would guide to a possible referral set at a cut-off score. The pharmacist would also be able to see from the referral form what are the main issues with the patient. In this study a scoring of referral was proposed to the clinicians.

1.9 Sampling methods

If a scoring system were to be tested using quantitative methods, the criteria would need to be applied to a large number of patients attending the diabetes clinic. Ideally this should be done prospectively as patients attend the clinic but in a short period of time, retrospective methods are more achievable. Retrospective methods allow the whole clinic population to be included which is very large so a sampling method must

be selected. In cross-sectional studies it is possible to choose the population from variables that will answer the research question³¹.

Randomised sampling involves a random selection of a number of patients from the whole population or study sample. A list of the total population or study sample is required, and every patient on the list has equal chance of being selected. Randomisation tools can be found on the internet, but a simple lottery method can also be used. Randomised sampling method and a randomisation tool were considered the best sampling method in this study. Systematic sample means randomising the initial patient, and from that patient choose every n^{th} patient. In stratified random sampling, the population is divided into groups where the patients in each group share a specific criterion. From these groups, patients are randomly selected to the study.

These three methods, among others, are probability sampling; the probability of a patient being included can be specified. In non-probability sampling the probability cannot be specified. Methods under this category are used for small-scale studies, and where a result being general to a population beyond the study sample is not the intention or needed. In convenience sampling the nearest most convenient patients are included in the study. This might not be a very scientific sampling method, since it is unclear if findings are representative or not. Snowball sampling involves the investigator identifying suitable patients to be included in the study. These patients then functions as informants, selecting new patients to be included. This sampling method is useful when identifying patients in the population is more difficult³¹.

2 Aim and objectives

2.1 Aim

Develop new referral criteria which will be used to refer patients to the pharmacist-led DCVR clinic by clinicians at the diabetes clinic. To test the sensitivity and specificity of the new referral criteria against patients previously referred with the old referral criteria.

2.2 Objectives

1. To identify obstacles in referring patients to the pharmacist-led DCVR clinic by gathering perceptions of hospital clinicians about the current referral form and its use through semi-structured interviews.
2. Develop new referral criteria and referral form from the results of objective 1, and to discuss them with consultant diabetologist and lead pharmacist for the pharmacist-led DCVR clinic.
3. To test the sensitivity and specificity of various cut-off measures to inform reliability of new referral criteria.

3 Subjects and settings

Investigator was an exchange student from University of Tromsø through ERASMUS and Strathclyde University whom had an honorary contract with NHS Lothian.

3.1 Ethics approval and confidentiality

Advice was sought from the officer for the South East Scotland Research Ethics Service on whether application for research ethics approval was necessary or not, but this was not necessary (Appendix 2). A clinical governance project proposal was submitted to Pharmacy Quality Improvement Team (QIT) for approval.

Each clinician was ensured confidentiality before performing the interview, given a unique number and had to write down contact details for the researcher to be able to contact the clinicians when the interview was transcribed and ready for review. The list of clinician number and contact details were safely kept in office at Education, Research and Development (ERD) department to be destroyed on completion of the project.

3.2 Clinician interview

The setting was the pharmacist-led DCVR clinic at WGH, Edinburgh. Clinicians (n=18) who may refer patients to this clinic from the diabetes Clinic at the Metabolic cUnit were invited to take part in semi-structured interviews which would provide data for developing the new referral criteria.

An invitation letter was sent out to the secretaries at the Diabetes clinic so they could contact the clinicians and arrange appointments (Appendix 3). Nine clinicians agreed to perform the interview. This number of clinicians is relevant as the data was considered saturated after interviewing clinician number nine, when no new information was generated from the three most recent interviews. The interviews took place from the 17th of January 2012 to the 15th of February 2012.

3.3 Patient record

A total of 34,065 patients are registered with the diabetes clinic across Lothian. The referral criteria were to be applied to patients who had attended the diabetes clinic to assess if they would have been referred to the pharmacist-led DCVR clinic. In the absence of a gold standard it was considered to use the patients who had been referred as the gold standard with cognisance of that limitation. It is estimated that approximately 3% of patients are referred to the DCVR clinic. Those who attend the WGH diabetes clinic were identified from SCI-DC and a list provided from lead pharmacist of those registered on an agreed date (19th March 2012). This generated a list of 2911 patients. A sample size of 1000 patients was agreed with the anticipation that approximately 30 of those patients should have attended the DCVR. The 1000 patients were randomly selected using a randomisation tool from the internet⁴¹. To generate the randomised list, sets of numbers, numbers per set and the range of numbers of patients was entered in the randomiser. Each patient randomised was given a unique study number and a decipher code was stored securely within the Pharmacy Department until completion of the study. The randomiser was set to sort the numbers from least to greatest and set markers by each randomised number. The data was recorded into a Microsoft (MS) access database.

3.4 Inclusion and exclusion criteria

Inclusion criteria were all patients who were registered at the diabetes clinic on 19th of March 2012, and had attended the diabetes clinic and/or the pharmacist-led DCVR clinic at Western General Hospital, Edinburgh. Exclusion criteria were patients the investigator was not allowed access to, errors in patient names on the list which made it impossible to identify the patient on SCI-DC, and those with incomplete recordings in laboratory values or blood pressure on SCI-DC.

4 Methods

4.1 Interview of participants

The invitation letter (Appendix 3) to the clinicians and the questionnaire (Appendix 4) for the semi-structured interviews was developed by investigator in close collaboration with supervisors. When developing the questionnaire, the investigator focused on what information the clinician needs to make a referral and the clinician's opinion about the current referral form. Literature about semi-structured interviews and the types of questions used in semi-structured interview were reviewed. The current referral form was also reviewed to generate questions about the current referral form.

During development of the questionnaire, four themes were generated to analyse the transcriptions of the interviews. For ease of analysis each theme was colour coded. The themes and colour coding were:

- Awareness of the pharmacist-led clinic (orange)
- Referral practice (own process) (pink)
- Referral criteria (blue)
- Recommendations for improvement (green)

These themes were also vital in developing structure in the questionnaire.

Before starting the interview, the investigator explained the background for the interview, and obtained verbal consent for the interview to be recorded. The investigator assured participants that all data would be anonymised and following transcription the recordings would be destroyed. Participants were informed that personal details would be kept securely until the end of the study so that the investigator could contact participants if they wanted to review the transcripts and make any necessary changes. The current referral form was also used to give the interviewee something tangible to express opinions upon during the interviews. All nine participants agreed to review the transcription (Appendix 5), and all were happy to receive it by email. Only one clinician made a few changes.

4.2 Development of new referral criteria and referral form

When analysing the transcriptions important statements were identified and categorised under each theme. During this process new themes were generated:

- Subthemes under referral practice:
 - o Reasons for referral
 - o Considerations
- The already defined theme “Referral criteria” was divided into
 - o Referral criteria
 - o Referral form

After the nine transcriptions were analysed (Appendix 6), the new referral criteria and new referral form were developed by the investigator, in close collaboration with supervisors. Several drafts and discussions with supervisors were necessary to generate the final referral criteria. The investigator reviewed the current referral form for the pharmacist-led DCVR, along with diabetes liaison nurse referral sheet (Appendix 7), the diabetes dietician referral sheet (Appendix 8) and the rheumatology nurse specialist referral form (Appendix 9). The current referral criteria, macrovascular disease and nephropathy, were defined as systolic BP >130 mmHg + diastolic BP >75 mmHg and microalbumin >2.5 mg/mmol, respectively.

4.3 Validation of referral criteria

As most of the clinicians stated in the interviews the referral form should not be too time consuming. Referring patients by using the new referral form and criteria should be easy for the clinicians, but at the same time, the referral form needs to be specific enough for the proper patients to be referred, and to help completion by newly qualified and/or new doctors to the diabetes clinic.

At the beginning of this project, it was thought that a scoring system would suit the referral form best. That is, every referral criteria was to be given a score, and once all applicable referral criteria for the patient had been completed the clinician would have a total score, which would be used to determine if patients should be referred or not. The clinicians stated that a scoring system would not be helpful (as a result of a misunderstanding discussed later), and the patients already referred to the pharmacist-led clinic could not be used as a gold standard, because the exact reason for their referral were not clear; it was not possible to define them as a gold standard to be compared to.

The chosen alternative was to make tick boxes (yes/no) with the referral criteria, and test the validity of each referral criterion. The study supervisor designed a Microsoft (MS) Access® database specifically for this study. Data was retrieved by accessing the SCI-DC. Data from the exact date of 19th of March 2012 was recorded. The information recorded in the database was

- The patient's number from the new patient list
- Age
- Sex
- Diabetes mellitus type 1 or 2
- Patient been referred to the pharmacist-led DCVR or not
- If the patient has systolic blood pressure greater than 130 mmHg and the exact value
- If the patient has diastolic blood pressure greater than 75 mmHg and the exact value
- If the patient has cholesterol greater than 4 mmol/l and the exact value
- If the patient has sign of retinopathy or not
- If the patient has microalbumin greater than 2.5 mg/mmol and the exact value.

On completion of data collection, the data was analysed using MS Access® and MS Excel®.

The results identified that 733 of 944 patients met at least one of the current referral criteria but only 44 were actually referred. It was therefore decided that receiver operator curve analysis would not be meaningful and alternative analysis was applied to make judgements about appropriate criteria. It was decided to look at the numbers of patients screened by combinations of criteria and examine the yield of those who were actually referred to the pharmacist-led clinic.

Tables of patient demographics and numbers of patients meeting each criterion and different combinations of the criteria were generated to investigate the frequency of each criterion.

5 Results

5.1 Perceptions of hospital clinic about current referral form

Identification of obstacles in referring patients to the pharmacist-led DCVR clinic by gathering perceptions of hospital clinicians about the current referral form and its use through semi-structured interview. Table 5.1 illustrates the grade of the nine clinicians that participated.

Table 5.1 Number of clinicians and their grade.

	Grade						Total
	GP ¹	FY2 ²	SPR ³	CCT ⁴	ST3 ⁵	C ⁶	
Number	1	1	1	1	1	4	9

¹General Practitioner, ²Foundation Doctor Year 2, ³Specialist Registrar, ⁴Certificate of Completion of Training, ⁵Specialist Trainee 3, ⁶Consultant.

5.1.1 Awareness of the clinic

It was important to establish the awareness of the clinic and referral form among the clinicians as this would have an impact on referral of patients. This is summarised in table 5.1.1.

Table 5.1.1 Number of clinicians aware of the pharmacist-led DCVR clinic and the referral form.

Variables	Number (n=9)	
	Yes	No
Aware of the DCVR	8	1 (FY2)
Refer patients to DCVR	8	1 (FY2)
Aware of the referral form	4	5
Using the referral form	3	6

One clinician (C) who was aware of the referral form did not use it because he would rather send a copy of the clinic letter.

When asked if the clinicians refer patients to the pharmacist-led DCVR clinic, one clinician stated:

"... probably not very often, I just do the clinic here once a week

(...) so I would probably see fewer patients than the other clinicians based here all of the time, but yes, I have referred some patients to the clinic in the past." Clinician 9

One clinician did not refer patients to the pharmacist-led DCVR clinic, but he was not aware of the pharmacist-led DCVR clinic. A reason that so many did not use the form relates to their unawareness of the form, but a few clinicians mentioned the completion of referral forms in general as being time-consuming, and a barrier for referral:

"... to create a form which requires more filling in will be a bigger barrier to referral. I have to say this is added work to fill in a form, I tend to use a copy of my last letter, which should summarise what the thinking is at the time." Clinician 8

"... I'm not sure I'd use the form; I think I may send a copy of the clinic letter rather than the form. (...) it's just a lot more convenient whenever you're dictating a letter that you copy to the pharmacist with a couple of sentences of the reason for referral." Clinician 5

Other clinicians were also aware of the completing of referral forms being time-consuming:

".. but I think it's not unreasonable when you're referring somebody to another service to have a quick summary of the main issues. (...) not wanting to make the form too cumbersome, but I suppose it wouldn't be unreasonable from your point of view to ask what their (the patients) cholesterol was or what their blood pressure was." Clinician 9

Finding a balance between these was important for some of the clinicians:

"I'm a junior doctor, so for me, I would perhaps like a bit more detail, in terms of what specifically would fit these three categories. (...) Also, when you've made a couple of referrals, it would be familiar to you and shouldn't take more time while for the uninitiated who haven't seen the referral before it has all the information." Clinician 3

The eight clinicians aware of the clinic stated that the pharmacist-led DCVR clinic is a valuable service and a good help if there were some complications, or the patient was in need for more frequent follow up.

“The obvious reason for attending the clinic is because you have more frequent follow-up that you can monitor BP, you can monitor response to lipid lowering therapy, and adjust it at a more regular interval than you can with the standard hospital clinic.” Clinician 1

“... patients can also speak to a pharmacist, and they’re given a different perspective, (...) and it gives extra knowledge to the patient about diabetes, BP, lipids and puts them all together.” Clinician 2

5.1.2 Referral practice – their own process

The main reason for referral to the pharmacist-led DCVR clinic was problems in controlling hypertension in patients. On questioning as what criteria the clinicians would use for referring a patient, the clinicians stated:

“Somebody who’s blood pressure was not well controlled, either because they were having difficulties in their medication or because they’re on a number of drugs already.” Clinician 7

“I refer patients who have difficult to control hypertension in the main, and that’s not very often. (...) I usually think if they’re on two agents already with uncontrolled hypertension, that’s the point when I generally refer.” Clinician 6

Other reasons for referral were persistently high lipid profile or proteinuria. One clinician expressed a need for a new referral criterion, which was not specified on the current form:

“To my mind, it probably would be good to add a third referral criteria which would be retinopathy, for you know, patients who have retinopathy, good control of blood pressure is beneficial and they would be another group that would, I think, benefit from access to the clinic, and technically they don’t necessarily need to have either of those two criteria (macrovascular disease or nephropathy), although in fact very often these patients with retinopathy also have nephropathy.” Clinician 9

Other clinicians mentioned nephropathy as an important field where the pharmacist-led DCVR clinic could help the patient:

“... but I think the pharmacist would contribute a very additional important role here because when nephropathy develops, depending on the extent, then you obviously have renal doses of various medications (...).” Clinician 2

“Nephropathy to me would indicate that we’re missing maybe people who’ve got microalbuminuria with high cardiovascular risk. (...) I think that they’re an important subgroup that we potentially under treat to be honest.” Clinician 5

Criteria on which the clinicians would not make a referral were smoking cessation and anti-platelet therapy. If the patient needed smoking cessation advice, they would refer the patient to the smoking cessation officer, and anti-platelet therapy is something they would decide themselves.

“I would say the main one that I would be dealing with when I refer would be the blood pressure. Anti-platelet therapy, I decide that myself.” Clinician 8

“... Anti-platelet therapy is often a decision we can make there and then in the clinic (...).” Clinician 9

When asked about when in the patient journey they would refer, none of the nine clinicians had a specific number. The decision to refer was made with new patients, patients who had been in the system for a longer period of time; all depending on when the clinicians felt that they needed a second opinion from the pharmacist, and the patient needed more frequent follow-up.

5.1.3 Referral criteria and form

The opinions were also divided regarding adding cut-offs or scores to the form to help make the decision when to refer:

“I think it would have to be fairly open-ended rather than something, you know, kind of one-size fits all approach, that probably wouldn’t be helpful.” Clinician 1

“... just put in a couple of numbers. It gives you guidance, you can always break from the guidance but at least you know which group of patient are of interest.” Clinician 3

"I think we're all pretty aware of cut-offs and targets for blood pressure and lipids for our various patients so I'm not sure that that necessarily be helpful."
Clinician 9

Several clinicians did agree on having an own comment field on the form:

"... but it might actually be useful just to insert a sort of a free text box for any comments. I mean, the comments would be in the previous letters, but for efficiency for the person who's been seeing this patient in the cardiovascular clinic, it would be useful to have something along the lines of "previously tried amlodipine, got peripheral oedema, developed cough on ACE inhibitor and hyperkalemia on ARB". Just to sort of note down perhaps some of the challenges or difficulties in the past (...)." Clinician 9

"Because it would allow you to give a little of the patient's history, ehm, and why you were concerned about them, and what you wanted to achieve by referring them." Clinician 2

"... a reasonable thought, you could extend your reason for referral (...)." Clinician 3

"I wouldn't let that inhibit me (not having a comment field on the current form), I just write on it." Clinician 4

5.1.4 Recommendations for improvement

At the end of the interview they were asked if they had anything to comment on or add. Some of the clinicians expressed the need for more information about the clinic, to themselves and clinicians new to the pharmacist-led DCVR clinic and the system:

"I think it's the thinking it's a good idea to refer, and that reminding us all about the profile of the clinic. (...) I think the added value of this clinic is frequent review, pharmacy expertise to educate the patient about the medications and to look at compliance and concordance issues. And I think that, that's the added value for patients." Clinician 8

"I'm very supportive of the clinic; I think it's very very important, I think it provides us with a lot of help and information, and to achieve a number of things that we wouldn't be able to achieve in the clinic." Clinician 5

“I think, maybe at the start of each attachment, if there could be just a very short introduction session for the new doctors to say this is what the cardiovascular risk clinic is for, and this is who you can refer, and also when the pharmacist is here on a weekly basis, just maybe to ask about any patients that they’re worried about so continually you know, offering the clinic to the new doctors and make it sure they understand what it is for would be helpful too.” Clinician 6

One clinician would like to have a better communication with the pharmacist at the DCVR clinic and feedback on the patients referred:

“Somewhere if there is a bit more of a dialogue; is this referral appropriate. (...) I think that just occasionally if there was some feedback from referrals or feedback about outcomes from the clinic.” Clinician 7

5.2 New referral criteria

From the results of the semi-structured interviews new referral criteria were agreed and a referral form generated (Appendix 10).

5.3 Validation of proposed criteria

After applying the new proposed referral criteria on the total study sample, patient demographics were generated and described in table 5.3.1.

Table 5.3.1 Demographics of study sample and patients referred to the pharmacist-led DCVR clinic.

Variable	Study sample (n=944)	Patients referred to the DCVR (n=48)	p-value
Age (years)			
Mean (SD ¹)	56.3 (17.0)	68.8 (10.9)	0.764 (z-test)
Median (IQR ²)	58 (24)	69 (14)	
Range	14-91	40-87	
Gender			
Males (%)	484 (51.3)	22 (45.8)	
Diabetes Mellitus			
Type 2 (%)	663 (70.2)	41 (85.4)	
Systolic BP³			
>130 mmHg (%)	492 (52.1)	29 (60.4)	0.24 (Chi-square test)
Mean (SD; 95% CI ⁴)	133.1 (17.0; 132.0, 134.1)	138.0 (23.0; 131.5, 144.5)	
Range (mmHg)	74-232	102-232	

Continuation of demographics table 5.3.1

Variable	Study sample (n=944)	Patients referred to the DCVR (n=48)	p-value
Diastolic BP			0.02
>75 mmHg (%)	508 (53.8)	18 (37.5)	(Chi-square test)
Mean (SD; 95% CI)	76.0 (10.0; 75.3, 76.6)	71.7 (11.8; 68.4, 75.1)	
Range (mmHg)	40-110	40-92	
<hr/>			
Cholesterol			0.55
>4 mmol/L (%)	550 (58.3)	26 (54.2)	(Chi-square test)
Mean (SD; 95% CI)	4.4 (1.7; 4.3, 4.5)	4.3 (1.2; 4.0, 4.7)	
Range (mmol/L)	0.70-45.01	2.10-7.22	
<hr/>			
Microalbumin			< 0.0001
>2.5 mg/mmol (%)	239 (25.3)	30 (62.5)	(Chi-square test)
Median (IQR)	1.0 (2.0)	7.4 (45.1)	
Range (mg/mmol)	0-744.60	0-453.30	
<hr/>			
Retinopathy			0.21
Yes (%)	221 (23.4)	14 (29.2)	(Chi-square test)

¹Standard Deviation, ²Interquartile Range, ³Blood Pressure, ⁴Confidence Interval.

The number and proportion of patients from the total study sample identified by each possible combination of the new proposed referral criteria is displayed in table 5.3.2. The table also summarises the number of referred patients identified by each combination.

The three combinations with highest proportions of patients identified from the study sample and also have the highest proportions of referred patients identified in table 5.3.2 are:

- Systolic BP > 130 mmHg + Diastolic BP > 75 mmHg + Cholesterol > 4 mmol/L; 125 patients identified from total study sample, 4 referred patients identified
- Systolic BP > 130 mmHg; 48 patients identified from total study sample, 5 referred patients identified
- Systolic BP > 130 mmHg + Diastolic BP > 75 mmHg + Cholesterol > 4 mmol/L + Microalbumin > 2.5 mg/mmol; 37 patients identified from total study sample, 4 referred patients identified

There is however some combinations with high numbers of identified patients from the study sample, but no patients referred meet the same combinations. These are:

- Cholesterol > 4 mmol/L; 91 patients identified
- Systolic BP > 130 mmHg + Diastolic BP > 75 mmHg; 68 patients identified
- Diastolic BP > 75 mmHg + Cholesterol > 4 mmol/L; 67 patients identified

Numbers of patients identified as meeting no combinations are 81 patients from the total study sample and 4 referred patients.

The referral criteria on the current referral form were macrovascular disease defined as systolic BP > 130 mmHg + diastolic BP > 75 mmHg and nephropathy defined as microalbumin > 2.5 mg/mmol. Table 5.3.3 illustrates combinations of criteria and the proportion identified as meeting at least one of the criteria in each combination. This table also shows that there are 733 patients identified as meeting at least one of the current referral criteria, and 44 patients referred meet at least one of these criteria (combination coloured blue).

The different combinations and number of patients identified shows which combination is most sensitive in identifying patients from the study sample.

Table 5.3.2 Number of patients identified by different combinations of new proposed referral criteria.

Number of criteria in each combination	SBP ¹ >130 mmHg	DBP ² >75 mmHg	Cholesterol > 4 mmol/L	Microalbumin >2.5 g/mmol	Retinopathy (yes)	Total number and proportion of patients meeting each combination n=944 (%)	Total number and proportion of referred patients meeting each combination of criterion n=48 (%)
5	X	X	X	X	X	16 (1.7)	2 (4.2)
4	X		X	X	X	7 (0.7)	2 (4.2)
4	X	X	X	X		37 (3.9)	4 (8.3)
4	X	X		X	X	12 (1.3)	1 (2.1)
4	X	X	X		X	36 (3.8)	2 (4.2)
4		X	X	X	X	5 (0.5)	0
3		X		X	X	6 (0.6)	2 (4.2)
3			X	X	X	11 (1.2)	2 (4.2)
3	X		X	X		18 (1.9)	3 (6.3)
3		X	X		X	28 (3.0)	2 (4.2)
3	X	X		X		27 (2.9)	1 (2.1)
3	X	X	X			125 (13.2)	4 (8.3)
3	X		X		X	14 (1.5)	0
3	X	X			X	14 (1.5)	0
3		X	X	X		11 (1.2)	0
3	X			X	X	5 (0.5)	0
2	X			X		18 (1.9)	4 (8.3)
2			X	X		24 (2.5)	4 (8.3)
2				X	X	8 (0.8)	1 (2.1)
2	X		X			37 (3.9)	1 (2.1)
2	X	X				68 (7.2)	0
2		X	X			67 (7.1)	0

Continuation of table 5.3.2

Number of criteria in each combination	SBP ¹ >130 mmHg	DBP ² > 75 mmHg	Cholesterol > 4 mmol/L	Microalbumin >2.5 g/mmol	Retinopathy (yes)	Total number and proportion of patient meeting each combination n=944 (%)	Total number and proportion of referred patients meeting each combination of criterion n=48 (%)
2			X		X	23 (2.4)	0
2	X				X	10 (1.1)	0
2		X			X	10 (1.1)	0
2		X		X		9 (1.0)	0
1				X		25 (2.6)	4 (8.3)
1	X					48 (5.1)	5 (10.4)
1			X			91 (9.6)	0
1		X				37 (3.9)	0
1					X	16 (1.7)	0
0						81 (8.6)	4 (8.3)
Total number of patients meeting each criterion	492	508	550	239	221		
Number of patients referred meeting each criterion (%)	29 (5.9)	18 (3.5)	26 (4.7)	30 (12.6)	14 (6.3)		
Total						944 (100%)	48 (100%)

¹Systolic Blood Pressure, ²Diastolic Blood Pressure

Table 5.3.3 Combinations of criteria and total numbers of patients meeting at least one criterion in each combination.

Criterion	Total numbers of patients meeting at least one criterion in each combination	Proportion of total study sample (%) (n=944)	Total number of patients referred meeting at least one criterion in each combination	Proportion of patients referred (%) (n=48)
SBP ¹ >130 mmHg +/- DBP ² >75 mmHg	665	70.4	33	68.8
SBP>130 mmHg +/- Cholesterol ³	752	79.7	37	77.1
SBP>130 mmHg +/- Microalbumin ⁴	591	62.6	42	87.5
SBP>130 mmHg +/- Retinopathy ⁵	599	63.5	36	75.0
Cholesterol +/- Microalbumin	660	69.9	39	81.3
Cholesterol +/- Retinopathy	631	66.8	30	62.5
Microalbumin +/- Retinopathy	390	41.3	34	70.8
DBP>75 mmHg +/- Cholesterol	733	77.6	30	62.5
DBP>75 mmHg +/- Microalbumin	624	66.1	38	79.2
DBP>75 mmHg +/- Retinopathy	602	63.8	23	47.9
SBP>130 mmHg +/- DBP>75 mmHg +/- Microalbumin	733	77.6	44	91.7
SBP>130 mmHg +/- DBP>75 mmHg +/- Cholesterol	814	86.2	39	81.3
DBP>75 mmHg +/- Cholesterol +/- Retinopathy	722	76.5	31	64.6
SBP>130 mmHg +/- Microalbumin +/- Retinopathy	668	70.8	44	91.7
SBP>130 mmHg +/- Cholesterol +/- Microalbumin	800	84.7	44	91.7
DBP>75 mmHg +/- Microalbumin +/- Retinopathy	687	72.8	38	79.2

Continuation of table 5.3.3

Criterion							Total numbers of patients meeting at least one criterion in each combination	Proportion of total study sample (%) (n=944)	Total number of patients referred meeting at least one criterion in each combination	Proportion of patients referred (%) (n=48)
Cholesterol	+/-	Microalbumin	+/-	Retinopathy			710	75.2	39	81.3
DBP>75 mmHg	+/-	Cholesterol	+/-	Microalbumin			789	83.6	39	81.3
SBP>130 mmHg	+/-	DBP>75 mmHg	+/-	Retinopathy			723	76.6	36	75.0
SBP>130 mmHg	+/-	DBP>75 mmHg	+/-	Cholesterol	+/-	Retinopathy	838	88.8	40	83.3
SBP>130 mmHg	+/-	DBP>75 mmHg	+/-	Cholesterol	+/-	Microalbumin	847	89.7	44	91.7
SBP>130 mmHg	+/-	DBP>75 mmHg	+/-	Microalbumin	+/-	Retinopathy	772	81.8	44	91.7

¹Systolic Blood Pressure, ²Diastolic Blood Pressure, ³Cholesterol above target (> 4mmol/L), ⁴Microalbumin above target (> 2.5 mg/mmol), ⁵Positive for retinopathy.

The combinations in table 5.3.3 have been based on the current referral criteria; which is the combination coloured blue. Of patients meeting at least one of the criterion in this combination, a total 733 patients were identified, and 44 of 48 patients referred (as stated above; 4 patients were referred without meeting any criteria or combinations).

The combinations with highest number of referred patients identified (n=44) in table 5.3.3, all have two criteria in common; systolic BP > 130 mmHg and microalbumin > 2.5 mg/mmol. Removal of diastolic BP and/or cholesterol and/or retinopathy criteria results in 42 patients referred meeting systolic BP and/or microalbumin.

When adding cholesterol criterion (orange colour) or retinopathy criterion (yellow colour), or replacing diastolic BP criterion with cholesterol criterion (green colour), more patients are identified, but there is no change in number of patients referred. Fewer patients are identified when replacing diastolic BP with retinopathy, but there is still no change in number of patients referred.

Each coloured combination from table 5.3.3 is linked with the corresponding coloured combinations in table 5.3.4. The criteria in table 5.3.4 have been modified to investigate if there is a change in number of patients identified.

For example: the combination coloured blue in table 5.3.3 (systolic BP >130 mmHg + diastolic BP >75 mmHg + microalbumin >2.5 mg/mmol) has been modified in table 5.3.4 by changing the cut-off to systolic BP to >135 mmHg or >140 mmHg, and diastolic BP >80 mmHg, and then generated new combinations to investigate what happens with the number of patients identified from the total study sample and patients referred.

Table 5.3.4 Summary of different combinations with modified criteria

Criterion	Total numbers of patients meeting at least one criterion in each combination	Proportion of total study sample (%) (n=944)	Total number of patients referred meeting at least one criterion in each combination	Proportion of patients referred (%) (n=48)
SBP ¹ >135mmHg	383	40.6	24	50.0
SBP>140mmHg	242	25.6	17	35.4
DBP ² >80 mmHg	266	28.2	10	20.8
Cholesterol ³	218	23.1	9	18.8
SBP>130mmHg +/- DBP>80 mmHg	548	58.1	30	62.5
SBP>135 mmHg +/- DBP>75 mmHg	623	66.0	29	60.4
SBP>140 mmHg +/- DBP>75 mmHg	574	60.8	26	54.2
SBP>135 mmHg +/- DBP>80 mmHg	476	50.4	26	54.2
SBP>140 mmHg +/- DBP>80 mmHg	378	40.0	19	39.6
SBP>135 mmHg +/- Microalbumin ³	507	53.7	40	83.3
SBP>140 mmHg +/- Microalbumin	398	42.2	37	77.1
SBP>130 mmHg +/- DBP>80 mmHg +/- Microalbumin	637	67.5	43	89.6
SBP>135 mmHg +/- DBP>75 mmHg +/- Microalbumin	694	73.5	42	87.5
SBP>135 mmHg +/- DBP>80 mmHg +/- Microalbumin	581	61.6	41	85.4
SBP>140 mmHg +/- DBP>75 mmHg +/- Microalbumin	665	70.4	41	85.4
SBP>140 mmHg +/- DBP>80 mmHg +/- Microalbumin	504	53.4	38	79.2

Continuation of table 5.3.4

Criterion					Total numbers of patients meeting at least one criterion in each combination	Proportion of total study sample (%) (n=944)	Total number of patients referred meeting at least one criterion in each combination	Proportion of patients referred (%) (n=48)		
SBP>135 mmHg	+/-	Microalbumin	+/-	Retinopathy ⁴	604	67.0	42	87.5		
SBP>140 mmHg	+/-	Microalbumin	+/-	Retinopathy	515	54.6	40	83.3		
SBP>140 mmHg	+/-	Cholesterol ⁵	+/-	Microalbumin	717	76.0	42	87.5		
SBP>140 mmHg	+/-	Cholesterol ⁶	+/-	Microalbumin	519	55.0	38	79.2		
SBP>130 mmHg	+/-	DBP>80 mmHg	+/-	Cholesterol ⁵	+/-	Microalbumin	810	85.8	44	91.7
SBP>130 mmHg	+/-	DBP>80 mmHg	+/-	Cholesterol ⁶	+/-	Microalbumin	700	74.2	43	89.6
SBP>140 mmHg	+/-	DBP>75 mmHg	+/-	Cholesterol ⁶	+/-	Microalbumin	712	75.4	41	85.4
SBP>140 mmHg	+/-	DBP>80 mmHg	+/-	Cholesterol ⁶	+/-	Microalbumin	591	62.6	38	79.2
SBP>130 mmHg	+/-	DBP>80 mmHg	+/-	Microalbumin	+/-	Retinopathy	705	74.7	44	91.7
SBP>140 mmHg	+/-	DBP>75 mmHg	+/-	Microalbumin	+/-	Retinopathy	720	76.3	41	85.4
SBP>140 mmHg	+/-	DBP>80 mmHg	+/-	Microalbumin	+/-	Retinopathy	600	63.6	40	83.3

¹Systolic Blood Pressure, ²Diastolic Blood Pressure, ³Microalbumin above target (>2.5 mg/mmol), ⁴Positive for retinopathy, ⁵Cholesterol above target (>4mmol/L), ⁶Cholesterol above new target (>5mmol/L).

The cut-off of systolic BP has been increased from >130 mmHg to >140 mmHg. This halves the number of patients identified from the total study sample (from 492 as shown in table 5.3.2 to 242 as shown in table 5.3.4), but also cuts down on number of patients referred (from 29 as shown in table 5.3.2 to 17 as shown in table 5.3.4). The same situation is seen when increasing the cut-off of diastolic BP from >75 mmHg to >80 mmHg (from 508 as shown in table 5.3.2 to 266 as shown in table 5.3.4 patients identified from the total study sample, and from 18 to 10 patients referred, respectively). A more pronounced change is seen with cholesterol when increasing the cut-off from >4 mmol/L to >5 mmol/L. The number of patients identified from the total study sample decreased from 550 to 218, and the number of referred patients decreased from 26 to nine.

No combinations managed to identify the 44 of 48 patients referred. The combinations with highest number of patients referred are:

- SBP >140 mmHg + Cholesterol >4 mmol/L + Microalbumin >2.5 mg/mmol (42 patients referred)
- SBP >140 mmHg + DBP >75 mmHg + Microalbumin >2.5 mg/mmol (41 patients referred)
- SBP >140 mmHg + DBP >75 mmHg + Cholesterol >4 mmol/L + Microalbumin >2.5 mg/mmol (41 patients referred)
- SBP >140 mmHg + DBP >75 mmHg + Microalbumin >2.5 mg/mmol + Retinopathy (41 patients referred)

Despite changing the cut-off of SBP to >140 mmHg halved the patients identified, the total number of patients identified did not decrease considerably in the combinations with other criterion in table 5.3.4. Changing the cut-offs for diastolic BP to >80 mmHg and cholesterol to >5 mmol/L resulted in a decrease in total patients identified, but also a more prominent decrease in patients referred.

Changing the cut-off of systolic BP to >135 mmHg resulted in 383 patients identified from the total sample and 24 patients referred. Systolic BP >135 mmHg in combination with diastolic BP >75 mmHg and microalbumin >2.5 mg/mmol did identify more patients from the total sample than systolic BP >140 mmHg combined with diastolic BP >75 mmHg and microalbumin >2.5 mg/mmol. However, the referred patients identified also increased by one patient. The combination systolic BP >135 mmHg + microalbumin >2.5 mg/mmol + retinopathy resulted in 604 patients identified from the total study sample, and 42 patients referred. This is a decrease from the corresponding combination from table 5.3.3 (systolic BP >130 mmHg + microalbumin >2.5 mg/mmol + retinopathy), by 64 patients from the total sample and 2 referred patients. It is also an increase from the combination systolic BP >140

mmHg + microalbumin >2.5 mg/mmol + retinopathy in the same table, by 89 patients from the total sample, and 2 referred patients.

From table 5.3.4 using the combination systolic BP >130 mmHg + diastolic BP >80 mmHg + microalbumin >2.5 mg/mmol as an initial combination with 637 patients identified from the total study sample and 43 referred patients identified, the addition of cholesterol >4 mmol/L resulted in all the referred patients being identified, but also an increase of almost 200 patients from the total study sample (n=810). Adding cholesterol >5 mmol/L resulted in no change in referred patients identified, but an increase in patients identified from the total study sample (700). Retinopathy also resulted in all the 44 referred patients identified and an increase of 63 patients from the total study sample.

6 Discussions

6.1 Statements of principal findings

Development of new referral criteria to refer patients to the pharmacist-led DCVR clinic in this study, focused on data from interviews of clinicians. Validation of the new proposed referral criteria was performed by investigation of different combinations of the new referral criteria applied to a study sample that consisted of patients previously referred to the pharmacist-led DCVR clinic and patients not referred.

In the interviews most clinicians stated that the main reason for referral of hypertensive patients to the pharmacist-led DCVR clinic was the requirement for more intensive and frequent patient follow-up. Systolic BP is seen as a criterion in the combinations with most referred patients in table 5.3.2, table 5.3.3 and table 5.3.4, regardless of cut-off >130 or >140 mmHg. A study performed by a colleague on patients at the pharmacist-led DCVR clinic and patients at the diabetes clinic, showed that there was a significant difference in mean decrease of systolic BP changes between the two groups⁴². However, the fact that no patients with only hypertension (systolic BP >130 mmHg and diastolic BP >75 mmHg) had actually been referred (table 5.3.2), that systolic BP and diastolic BP is not identifying enough referred patients even if the cut-offs are modified (table 5.3.3 and table 5.3.4), and that a combination of hypertension with other criteria resulted in more referrals, suggests that the clinicians may consider several other factors during decision of referral than stated in the interviews.

In table 5.3.4 the criteria cut-offs in the coloured combinations has been modified from the corresponding coloured combinations in table 5.3.3. Microalbumin has not been modified because the detection of microalbumin in the urine, identifies that nephropathy is present. Microalbumin is also a criterion to be seen in the combinations which identifies most referred patients. It was stated in the interviews that patients with microalbuminuria is a subgroup that may be undertreated. It is important to prevent microalbuminuria and reduce the risk of nephropathy, any further development of hypertension and reduce the cardiovascular risk. It was agreed to replace the current referral criterion of nephropathy with microalbumin >2.5 mg/mmol to make the referral form more specific. Table 5.3.1 also shows that there is a high proportion of patients with microalbumin >2.5 mg/mmol among those patients referred than from the study sample. This indicates that microalbumin >2.5 mg/mmol may be a decisive parameter in the referral process. Application of systolic BP (>130 mmHg) and microalbumin (>2.5 mmHg) identified a total of 591 patients from the total study sample and 42 patients referred to the pharmacist-led DCVR clinic who met at least one of these criteria. Systolic BP (>130 mmHg) and microalbumin (>2.5 mg/mmol) are also the only criteria that identify

referred patients without being in combinations with one of the three other criteria (table 5.3.2). It is clear that these two criteria are important. By adding the retinopathy criterion, the number of patients referred to the pharmacist-led DCVR clinic increased to 44, and the number of patients identified from the study sample increased to 668 patients (table 5.3.3). The addition of diastolic BP (>75 mmHg) or cholesterol (>4 mmol/L) criteria resulted in the same number of referred patients identified (n=44), but also a higher increase in patients identified from the total study sample (diastolic BP=733, cholesterol=800). This can be recognised as more patients actually have a diastolic BP >75 or cholesterol >4mmol/L than positive sign for retinopathy, and that retinopathy is not any more decisive than a diastolic BP or cholesterol.

One clinician stated that retinopathy should be a referral criterion. Although table 5.3.1 shows a higher proportion of patients with retinopathy amongst referred patients (29.2%) than in the total study sample (23.4%), the difference between the groups is not statistically significant ($p = 0.21$). In the study sample there were no patients with only retinopathy that were referred to the pharmacist-led DCVR clinic (Table 5.3.2). This strengthens the suggestion that retinopathy as a referral criterion may not affect the final decision about referral to the pharmacist-led DCVR clinic. However, in both table 5.3.3 and table 5.3.4 retinopathy is a frequent criterion in the combinations which identifies the highest number of patients referred, therefore it would be beneficial for the pharmacist to be aware of retinopathy in context with treatment of hypertension and prevention of further microvascular disease.

As stated above, the diastolic BP and cholesterol resulted in the same number of patients referred (n=44) as retinopathy. Changing the cut-off of diastolic BP from >75 mmHg to >80mmHg in combination with systolic BP >130 mmHg + microalbumin >2.5 mg/mmol yielded 43 referred patients identified, which is just a decrease on one patient from the initial combination of the current referral criteria systolic BP >130 mmHg + diastolic BP >75 mmHg + microalbumin >2.5 mg/mmol (n=44, coloured blue in table 5.3.3). When changing the systolic BP to either >135 mmHg or 140 mmHg in combination with microalbumin >2.5mg/mmol and diastolic BP >75 mmHg or >80 mmHg reduces the number of referred patients identified even more. The total number of patients identified from the total study sample varies without consistency, suggesting that the combination systolic BP >130 mmHg + diastolic BP >80 mmHg + microalbumin >2.5 mg/mmol which identifies 637 patients from the total study sample and 43 referred patients is important to consider when defining the new referral criteria.

The capacity of the pharmacist-led DCVR clinic needs to be considered when choosing a suitable combination of referral criteria. Treating 591 eligible patients (identified by

application of systolic BP >130 mmHg and microalbumin criteria) is more manageable than 668 patients (identified by application of systolic BP >130 mmHg, microalbumin and retinopathy criterion), which is more manageable than 733 patients (identified by diastolic BP >75 mmHg and cholesterol criteria) or 800 patients (identified by systolic BP >130 mmHg + cholesterol + microalbumin criteria).

From table 5.3.4 it is clear from the two cut-offs of systolic BP (>135mmHg resulted in 24 referred patients identified and >140mmHg resulted in 17 referred patients identified) that systolic BP alone is not identifying enough referred patients. Changing the systolic BP cut-off to >135 mmHg in combination with microalbumin >2.5 mg/mmol and retinopathy identified 42 referred patients and 604 patients from the total study sample, which is a more manageable number compared to systolic BP>130mmHg + microalbumin >2.5 mg/mmol + retinopathy which identified 44 referred patients and 668 patients from the total study sample. This means when changing the systolic BP cut-off from >130 mmHg to >135 mmHg there is a decrease of two patients referred, and a decrease of 64 patients identified from the whole study sample. From table 5.3.4, when increasing the cut-off of systolic BP to >140 mmHg, another two patients referred were unidentified, although the number of patients from the total study sample were more manageable (n=515). Further calculations with the combination systolic BP >135 mmHg + microalbumin >2.5 mg/mmol + retinopathy combined with other criteria did not give any prominent difference in referred patients. However, the numbers of patients identified from the total study sample were all above 650 patients (Appendix 11). This is too many eligible patients to be managed by the pharmacist-led DCVR clinic; at least when modifying the criteria and combinations do not give much impact.

It is suggested that the combination systolic BP >130 mmHg + diastolic BP + microalbumin >2.5 mg/mmol is the most practical combination to identify a theoretical number of patients eligible to be referred to the DCVR clinic. This combination results in 43 referred patients identified, and the number of patients identified from the total study sample (n=637) is more manageable than total numbers from other combinations. When modifying the cut-off of diastolic BP criterion to >80 mmHg, the combinations with this parameter identify more than 40 referred patients if the systolic BP >130 mmHg. The cholesterol criterion should also be modified to >5 mmol/L. The reason for this suggestion is that all diabetic patients are initiated with statin treatment regardless of baseline cholesterol value, and it is also a parameter the clinicians would manage themselves. The study performed by colleague showed that the patients referred to the DCVR clinic had a mean decrease in cholesterol values of 0.14 mmol/L, compared to the patients at the diabetes clinic which had a decrease of 0.69 mmol/L. This difference was not statistically significant (p=0.52). However, this suggests that

the patients in the pharmacist-led DCVR clinic already are on statin treatment and that there are more patients initiated on statin treatment in the diabetes clinic⁴².

6.2 Implications for practice

During clinician interviews it was identified that five clinicians were not aware of the form. Concerns were expressed that a new, more specific form would be too time consuming to complete. However, it is known that some clinicians are new to the diabetes clinic and unsure of the rationale for a referral to the pharmacist-led DCVR clinic, therefore further guidance for patient referral would be welcomed. Balancing between “referral form being sensitive enough” and “not too time-consuming” is important if clinicians are going to use the form, and at the same time identify the patients that would benefit the most from a referral to the pharmacist-led DCVR clinic.

Clinicians aware of the pharmacist-led DCVR clinic are those who work at the diabetes clinic permanently and most of the clinicians believe that the pharmacist-led DCVR clinic plays a very important part in the management of complicated diabetic patients with cardiovascular risk factors. There is a high turnover of clinicians at the diabetes clinic and from the interviews it is clear that this is a reason to why some clinicians are not aware of the pharmacist-led DCVR clinic, or the purpose of it. Increased awareness will make it easier for the clinician to complete an appropriate referral and lead to optimum pharmaceutical care, ultimately patient care will benefit. One clinician stated the need for feedback on their previous referral to the pharmacist-led DCVR clinic, for example when a patient is discharged from the pharmacist-led DCVR clinic; it would be beneficial for the referring clinician to know treatment plan followed and the outcome of treatment. Good communication between the clinician and the pharmacist contributes to patient safety and quality of care.

It would be beneficial to arrange a focus group with the clinicians involved in this study, where the results from both the interviews and the validation of the new proposed referral criteria would be presented. The clinicians would then be able to give feedback to the investigator and pharmacist around the new referral criteria, and be able to explain more about their referral process. There would also be an opportunity for the pharmacist to give feedback to the clinicians about the experience from referrals and the types of patients referred.

6.3 Strengths and weaknesses of the study

Both qualitative and quantitative research was conducted in this study in terms of the data from the semi-structured interviews and the recorded data from the application of the new referral criteria. Triangulation is a strength in this study; allowing information from the interviews to be compared with the recorded data and conversely.

Semi-structured interviews were chosen in this study as it was seen as the most viable means of gathering clinician perceptions of the clinic. During the interview process, there was slight misinterpretation between the investigator and the clinicians.

It is recognised that the best way to gather consensus and opinion would be to arrange a focus group with the clinicians. Through more discussion with each other and with investigator, misinterpretation may have been avoided. A focus group would possibly have generated more clear thoughts around referral process through the discussion.

During this study it became clear that testing the sensitivity and specificity of the referral criteria and generation of an ROC curve became too complicated since the sensitivity and specificity of the current referral criteria is unknown. The gold standard consisting of patients already referred to the DCVR clinic turned out to be too challenging to define, suggesting that the current criteria is not sensitive enough to identify those meeting the present referral criteria and patients that have been actually referred.

6.4 Limitations of the study

Factors such as co-morbidities, duration of treatment in the diabetes clinic or the pharmacist-led DCVR clinic, and number of medications currently prescribed is unknown in this study. It is therefore difficult to investigate properly what other factors the clinicians may consider when referring a patient. These may need to be investigated further to generate referral criteria sensitive enough to identify the right patients, and also clear enough to function as inclusion criteria in more comprehensive research.

Blood pressure, cholesterol and microalbumin levels change during time and with treatment. This study has recorded data from the exact date of 19th of March 2012; however, the time of referral to the pharmacist-led DCVR clinic, and the exact time of measured blood pressure, cholesterol and microalbumin, is unknown. It is difficult to be conclusive with this limitation. Patients referred to the pharmacist-led DCVR clinic may have been attending the clinic for a longer period of time receiving treatment. This may explain why there are referred patients

with values of each parameter below target, and thereby affecting the interpretation of the final results.

Another limitation in this study is the investigator's language barrier during the interviews. English is the investigators second language and this presents difficulties in following the clinicians' scientific language. There were misunderstandings between investigator and clinicians, although unfortunately this was not identified until interpreting the results with supervisors. On questioning about cut-offs or scores it is clear that the clinicians have related this to clinical scores. This is reasonable given their area of expertise; however this is not answering the question proposed to generate a score with a combination of several factors. After the first interview, there should have been a more thorough review of questions and transcription. This would have been beneficial to establish any questions misinterpreted by the clinician.

6.5 Strengths and weaknesses in relation to other studies

Unfortunately it was not possible to find other studies evaluating referral criteria.

6.6 Future research and studies

There have been new questions raised during the analysis of the results, and several factors need to be further investigated. More details of the clinicians' referral process, and the decision making process when making a referral would give a more specific understanding of the referral process. There is a need for more specific data for each referred patient to be able to give a clearer answer to changes in laboratory values and blood pressure values.

After analysing the results from the database (tables 5.3.3 and 5.3.4), a new referral with new changes in referral criteria were proposed (Appendix 12). On reflection the original concept of developing a scoring system to be applied to the referral criteria, should be considered in future studies in order to calculate a total cut-off score which could be tested for sensitivity and specificity, and thereby validate the criteria more thoroughly. A scoring system is an important tool that may generate more sensitive referral criteria to be used as inclusion criteria in future studies. On the new referral form there is a section of additional information and relevant past medical history, which may be factors the clinicians consider during a referral process. However, this needs to be further evaluated.

Application of a scoring system to the referral form could also include these additional co-morbidities, not just the referral criteria, which then could be conclusive in deciding whether to refer a patient or not.

If the new proposed referral form is implemented in the diabetes clinic a study or audit could be performed after a period of time, to see if the number of referred patients has been increased, and if there is other factors included in the referral. From this study and the interviews the awareness of the pharmacist-led DCVR clinic is likely to have been increased, which may contribute to more referrals.

At the very end of the study the results were discussed with the lead diabetologist at the diabetes clinic. There was an agreement that a scoring system applied on the referral form would be beneficial in detecting patients who would benefit from attending the pharmacist-led DCVR clinic.

7 Conclusion

This study generated more questions than answers. Since the gold standard was not able to perform as a gold standard, the process of analysis changed, and the expected validation of the new referral criteria did not become as thorough as thought in the beginning of the project.

Using the cross-sectional survey resulted in answers to how many patients meet each criterion or combinations of the criteria, however, the exact reason for referral for those patients referred remain unknown.

The study showed that there is a small difference between what the clinicians stated in the interviews and what they do in practice. There are several factors to investigate further. The clinicians' thoughts and gut-feeling when referring a patient to the DCVR needs to be made more clear. A gold standard needs to be generated to be able to validate the referral criteria properly. However, this requires implementation of the new referral form generated in the study.

There is a need to make the pharmacist-led DCVR clinic more prominent in the Diabetes Clinic and to new clinicians. The clinicians managing diabetic patients with cardiovascular risk are required to be aware of what the clinic can provide, the main purpose of it and the benefit to patient care.

To provide a consistent service for patients there is a requirement for continuity in referral of patients to the pharmacist-led DCVR clinic. Our findings suggest there is a need to raise awareness of the clinic among physicians, particularly more junior physicians and to improve communication between physicians and pharmacist in terms of patient outcomes. More guidance is needed in terms of which patients to refer and this study attempted to analyse the referral yield from different combinations of criteria. These combinations require further discussion with the referring physicians and the options of using a scored cut-off for referral explored for future validation before application in practice.

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Appendix 1: Current referral form

DIABETES CARDIOVASCULAR CLINIC -- REFERRAL FORM

PATIENT DETAILS	
NAME:	DOB:
ADDRESS:	PHONE NUMBER
REFERRING DOCTOR	
DATE OF REFERRAL:	
REFERRAL CRITERIA (Tick at least one):	
<input type="checkbox"/> Macrovascular disease	<input type="checkbox"/> Nephropathy
REASON FOR REFERRAL (Tick at least one)	
<input type="checkbox"/> Blood pressure control	<input type="checkbox"/> Lipid lowering therapy
<input type="checkbox"/> Anti-platelet therapy	<input type="checkbox"/> Smoking cessation advice
<input type="checkbox"/> General CVD advice	<input type="checkbox"/> Other
<i>APPOINTMENT DETAILS (A&C Staff to complete)</i>	
CLINIC:.....	

Please pass completed forms to ~~Sheila Amott~~; partially completed forms will be returned.

Dr. STRACHAN'S SECRETARY.

Appendix 2: Ethics approval letter

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG



Name: Moira Kinnear
Head of Pharmacy Education
Research & Development
Dept of Pharmacy
Western General Hospital
Edinburgh
EH4 2XU

Date: 31/08/2011
Your Ref:
Our Ref: NR/1108AB25
Enquiries to: Alex Bailey
Direct Line: 0131 465 5679
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Moira,

Full title of project: Review and development of referral criteria used to identify patients with diabetes who would benefit from attending a pharmacist-led cardiovascular risk out-patient clinic

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (Development of referral criteria draft 1.doc), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK. The advice is based on the following:

- *The project is an opinion survey seeking the views of NHS staff on service delivery.*

If this project is being conducted within NHS Lothian you should inform the relevant local Quality Improvement Team(s).

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that ethical approval is not required under NHS research governance arrangements. However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further. Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS.

You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

A handwritten signature in black ink that reads 'Alex Bailey'.

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

South East Scotland Research Ethics Service

DIFFERENTIATING AUDIT, SERVICE EVALUATION AND RESEARCH

November 2006

The "Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees" recommended NRES should develop guidelines to aid researchers and committees in deciding what is appropriate or inappropriate for submission to RECs, and NRES (with the Health Departments and with advice from REC members) has prepared the guidelines in the form of the attached table.

RESEARCH	CLINICAL AUDIT	SERVICE EVALUATION
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: “Does this service reach a predetermined standard?”	Designed to answer the question: “What standard does this service achieve?”
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research -may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.	No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.
May involve randomisation	No randomisation	No randomisation
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:-		
RESEARCH REQUIRES R.E.C. REVIEW	AUDIT DOES NOT REQUIRE R.E.C. REVIEW	SERVICE EVALUATION DOES NOT REQUIRE R.E.C. REVIEW

Appendix 3: Invitation letter

Department of Pharmacy Western General Hospital

Crewe Road South
Edinburgh
EH4 2XU



CERTIFICATE NO. FS 31228

Associate Director of Pharmacy
Lead Pharmacist WUGH
Head of Quality Assurance Services:
Head of Education, Research and Development:
Lead Pharmacist, South East Scotland Cancer Network
Principal Pharmacist, Dispensing Services
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Ewan Morrison	07812367932
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Main Switchboard Tel: 0131 537 1000

Dear Colleague

Project title: Review and development of referral criteria used to identify patients with diabetes who would benefit from attending the pharmacist-led Diabetes Cardiovascular Risk Out-Patient Clinic at Western General Hospital, Edinburgh.

I am a pharmacy student currently undertaking a project at the Diabetes Cardiovascular Risk Out-Patient Clinic as part of my MSc in Pharmacy at the University of Tromsø, Norway and an honorary member of pharmacy staff at NHS Lothian. The aim of this project is to revise existing referral criteria for the pharmacist-led Diabetes Cardiovascular Risk Out-Patient Clinic and test the sensitivity and specificity of the revised criteria using established methodology. Permission for completion of this project has been obtained from Dr. Mark Strachan and the Pharmacy Quality Improvement Team (QIT).

The first part of this study involves a short one to one interview (approximately 20 minutes) with a range of referring clinicians to explore perceptions of the current referral criteria and their use. All information collected during the study will remain confidential and be treated in accordance with data protection and Caldicott principals. I am working to tight deadlines and would like to conduct my interviews during January, if possible.

Please email Alison Cockburn by 6th of January 2012 to confirm your willingness to participate and we will be in contact with you to arrange a suitable time.

If you would like any information about this study please do not hesitate to get in touch with me or my supervisor, Alison Cockburn.

Kind regards,

Ingvild Risan Westerhus

Alison Cockburn
Lead pharmacist Diabetes Cardiovascular
Risk Clinic

Appendix 4: Questions for the semi-structured interviews

Questions

- Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?
 - **Yes:** Do you refer patients to this clinic?
 - **Yes:** Why do you refer patients to the clinic?
 - What do you consider when you refer patients to the clinic?
 - What criteria do you use to refer the patient?
 - When in the patient journey would you refer the patient?
 - **No,** I don't refer patients to this clinic.
 - To refer a patient to this clinic, the clinicians might use this referral form. My project is to find out if these referral criteria are helpful in referring a patient.
 - Would you take a look at this form and tell me what are your thoughts about these criteria?
 - Are they specific enough?
 - Do you think more detailed information should be added: BP levels, adherence, lifestyle management etc?
 - Do you think any information should be removed?
 - Do you think the form should include recommendations for management?
 - **No,** I'm not aware of the clinic
 - This is a pharmacist-led clinic, where clinicians refer patients for BP-control, help in managing lipids, help the patient adhere to medication.
 - To refer a patient to this clinic, the clinicians might use this referral form. My project is to find out if these referral criteria are helpful in referring a patient.
 - Would you take a look at this form and tell me what are your thoughts about these criteria?
 - Are they specific enough?
 - Do you think more detailed information should be added: BP levels, adherence, lifestyle management etc?
 - Do you think any information should be removed?
 - Do you think the form should include recommendations for management?
- Are you aware of the referral form?
 - **Yes:** Do you use the referral form?
 - **Yes:** what are your thoughts of the criteria?
 - Do you find them specific enough? If not, please explain.
 - Are the criteria easy to use? If not, please explain.
 - Is the "Reasons for referral" section detailed on the current form specific enough? If not, please explain.

- **No**, I don't use the referral form.
 - Could you tell me why you don't use the referral form?
 - Are the criteria not specific enough?
 - Would you use it if the criteria were improved?
 - How would you make the criteria more specific?
 - Is it easy to access the form in the clinic?
 - How could it be more accessible?
 - Any other reasons?
 - **No**: this is a referral form which is used to refer the patients to the pharmacist-led clinic.
 - What are your considerations when referring patients to the pharmacist-led clinic?
 - Would you take a look at this form and tell me what are your thoughts about these criteria?
 - Do you think more detailed information should be added: BP levels, adherence, lifestyle management etc?
 - Would cut/offs or scores be useful?
 - Do you think any information should be removed?
 - Do you think the form should include recommendations for management?
 - Would you consider using a referral form?
- Is there something you would change on the current referral form?
 - **Yes**: Make the criteria more specific?
 - Would cut/offs or scores be useful?
 - Should there be additional actions requested? Which?
 - Do you think more detailed information should be added: BP levels, adherence, lifestyle management etc?
 - Do you think any information could be removed?
 - Do you think the form should include recommendations for management?

Do you have anything else you would like to say or add?

Appendix 5: Transcriptions of interviews

Interview with Clinician 1

Clinician 1 (C1)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C1: Yes.

In: Do you refer patients to this clinic?

C1: Yes.

In: Why do you refer patients to the clinic?

C1: Primarily patients where we are having difficulties in controlling blood pressure, patients who are on multiple agents and we want to get the target.

In: What do you consider when you refer patients to the clinic? What's your own thoughts?

C1: I suppose we make up full assessments ourselves in the clinic about whether we think the patients are likely to be adhering to the therapy that are prescribed, but I think that it seems clear that they are doing that and we're still feeling that, well, if you want to get somewhere if someone's got very marked hypertension and you don't think the interval between clinical appointments or just that referral back to primary care would be enough then that would be, I mean, an indication.

In: What criteria do you use to refer the patient?

C1: I personally wouldn't use any specific criteria, which would be judged on an individual patient basis, I guess look back through the history to see whether there'd been long standing problems to achieving high blood pressure control, rather than looking down a check-list picking out features.

In: When in the patient journey would you refer the patient?

C1: Potentially new patient but also patients who's been attending for a while, where BP has become an issue and renal function has become an issue as well, I suppose it would be anywhere potentially.

In: Any number in general, like after two times or three times?

C1: Well, it would be unusual for anyone in this clinic to see the same patient two or three times in a row, because you would generally see different doctor each time, so it probably wouldn't be valid to see the patient every time.

In: Are you aware of the referral form?

C1: Yes.

In: Do you use the referral form?

C1: Yes, when I would refer someone I haven't referred before.

In: What are your thoughts of the criteria? Do you find them specific enough?

C1: Well, I suppose there are patients where you might want somebody reviewed where they don't necessarily have established macrovascular disease or nephropathy but still would potentially benefit from more intensive input, risk factor management, but when you think generally, having a fairly non-specific is probably a good thing for a referral form.

In: Do you think it is easy to use?

C1: Yes, I think it easy to use, and I think that is important for a referral form, cause I think the paper work you have to complete, the less effective these things are, cause a lot of the information is already available in the letters that we dictate about the patient. So having to duplicate a lot of that information on a referral form is probably not helpful, for the patient or the doctor I suspect.

In: Is the "reasons for referral" section detailed on the current form specific enough?

C1: Well, I suppose it's hard to say where do you stop because if you have a lot more information probably couldn't have less I think it's quite sparse, but I would say a lot of the information is already available on the SCI-DC, on the computer database so, it probably doesn't make sense to repeat a lot of that because a lot of patients current medications so, I suppose you could have something on the form that states what your ideal target would be for an individual patient, so maybe scope for having something like that.

In: So you wouldn't try making the criteria more specific?

C1: Well, I suppose if anything, then maybe having space for your own comments on whether you would see targets being for the individual patient, because there are guidelines. Separate from that, you know, there might be specific reasons for why, you wouldn't be so desperate for a patient to get right down to target, you know there are pragmatism involved in some patients.

In: Would cut-offs or scores be more beneficial or more useful?

C1: I'm not convinced about that. Not sure. I think it would have to be fairly open-ended rather than something, you know, kind of one-size fits all approach, that probably wouldn't be helpful.

In: Should there be any additional actions?

C1: No, I think it because the remit of the cardiovascular risk clinic is fairly clear, there are obviously other reasons than cardiovascular risk that fall under other services like weight loss and dietetics, I think that's fine.

In: Do you think any information should be removed?

C1: Well, I guess though I'm not sure how useful antiplatelet therapy is as a reason for referral for the risk clinic, you know, you either do that or you don't. I don't see the sense in that being a referral reason have, it's not that big deal for the risk clinic that we could not do in the clinic ourselves.

I mean the other thing, the obvious reason for attending the clinic is because you have more frequent follow-up that you can monitor BP, you can monitor response to lipid lowering therapy, and adjust it at a more regular interval than you can with the standard hospital clinic. Perhaps anti-platelet therapy doesn't really fall into it.

In: Should any recommendations for management be added? If the BP is over a certain value, you should refer or if the lipid value is above a certain value you should refer?

C1: I think if the people doing the risk clinic felt that was helpful in terms of stratifying the service and only seeing a specific group of people, that would be helpful. I think from a clinicians perspective you probably wouldn't look at that saying which patient should I look at, cause you already have an idea based on having seen the patient, whether for some he's going to benefit from aggressive reduction and blood pressure. But if you were having to ration the service out as a finite resource and saying, we preferentially see a patient with a fall in blood pressure or cholesterol level, then, yes, I would object to that.

In: So you have anything else you would like to say or add?

C1: Not particularly no.

In: Thank you very much.

Interview with Clinician 2

Clinician 2 (C2)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C2: Yes.

In: Do you refer patients to this clinic?

C2: Yes.

In: Why do you refer patients to this clinic?

C2 Quiet.

In: What is going through you're your mind when you are seeing a patient and you would like to refer him?

C2: If it is designated for risk factors it's like a numbers clinic, and, two things, because it's a pharmacist, patients can also speak to a pharmacist, and they're given a different

perspective, and secondly the fact that sort of there are cardiovascular risk equations or actually equations so it gives perhaps another perspective to the patient about long term risk if they don't comply with their first medications and it gives extra knowledge to the patient about diabetes, diabetes, BP, lipids, and puts them all together.

In: What specific would you consider when you refer patients to the clinic?

C2: If someone has persistently high lipid profile, if they have a very high BP and provided with secondary causes have been out ruled, such as renal artery stenosis fails, even at the setting of either a positive or negative family history like for example family history of dialysis, polycystic kidney disease, ruptured aneurism, stroke at a young age, and all these investigations have been out ruled. I come from the ***** system which based on the ***** system and perhaps cost, isn't, cost hasn't been as big a factor as now, with the recession. But that means quality of care and the practice of medicine, if you don't think of a cause, you don't investigate for it, such as secondly hypertension, particularly because diabetes is so rampant, the population you seeing could easily have a second hormonal problem such as a fail or hyperaldosteronism or whatever. So I would have a low threshold for investigating them for secondly hypertension.

In: What criteria do you use to refer the patient?

C2: I suppose high blood pressure which hasn't been controlled, after excluding secondary causes, lipids which are still suboptimal, having gone through maybe the spectrum of simvastatin, atorvastatin, rosuvastatin. And diabetes wise we are sort of (X) ourselves anyway and where possible in that setting we will get psychologists involved where it's appropriate, especially in the setting of type 1 diabetes.

In: When in the patient journey would you refer? After seeing a patient two times or three times?

C2: I suppose I wouldn't have specific point at the moment as I'm new to the system here, prior I worked in **** so this conflict of pharmacy clinic didn't exist (...) will probably be introduced in due course in **** it will be a welcome addition. (...) but I wouldn't have a specific point in time at the moment.

In: Are you aware of the referral form?

C2: No.

In: This is a referral form which is used to refer the patients to the pharmacist-led clinic. Would you take a look at this form and tell me what are your thoughts about these criteria?

C2: After first look I suppose certainly macrovascular disease would be a very strong reason for referring. When I see nephropathy I think we're getting the renal clinician along involved. Blood pressure certainly would be another one, general cardiovascular advice, not so much smoking cessation advise, lipid lowering yes, smoking cessation no cause there is a specific smoking cessation officer if a person isn't interested in giving up smoking, it's even pointless referring someone to the smoking cessation officer, so it's mostly blood pressure control, general cardiovascular advice, lipid lowering therapy and referred macrovascular disease, nephropathy would always put me in mind of getting the renal physician involved, but I think the pharmacist would contribute a very additional important role here because when

nephropathy develops, depending on the extent, then you obviously have renal doses of various medications, such as the new agents on the block like saxagliptin 2.5 rather than 5, sitagliptin which would be 50 rather than 100 BD, and even antibiotics or anything along the general spectrum, general medical conditions as well. So I think they would have a role to play there as well .

In: Do you think more detailed information should be added, like blood pressure levels, adherence, lifestyle management?

C2: Yes, I think blood pressure levels, yes. Two things: readings and maybe if it wasn't reason to maybe a colour coding of red in the high zone and green, almost like a traffic light, green going into yellow going into red. I think patient would have varying degrees of learning and of education and I think that probably something that will stand out with a big arrow, that should be our, red in the danger zone, maybe one or two blood pressure readings, without frightening them, but I think it might be a picture tells better the story. Perhaps a series of columns or tick boxes.

In: Would cut-offs or scores be useful?

C2: Again, in the general population it depends on the education, of the person, I'm not sure what you mean..

In: Education of the person?

C2: The background education or the background..

In: What you've seen in the future with the patient?

C2: No, if you don't separate out cut-off points it depends on whether, would every patient that attends of varying background, be able to understand us, or would it have the same significant with all those patients.

In: So, having cut-offs, or the blood pressure arrow you were talking about, would that be beneficial?

C2: Yes, on the form, yes.

In: Do you think any information should be removed?

C2: From the form?

In: Yes?

C2: I suppose less is more, but this is quite simple.

In: Do you think the form should include recommendations for management? Like if the blood pressure, you were talking about the blood pressure arrow, if the blood pressure value is above a certain value you should refer, if the lipid value was over a certain value you should refer?

C2: Ehm, numbers for points of refer?

In: No, like a range, if the value is above that range you should refer to the clinic?

C2: Ehm, yes that would probably be helpful.

In: So making the referral criteria more specific – is there something you would think of first?

C2: Ehm, the macrovascular is quite vague, if you use numbers for the nephropathy, the one concerns here would be you also include maybe creatinine or an eGFR maybe for renal referral so that when you see a renal, you know if something has deteriorated quite rapidly, key things are they for immediate admission, are they for urgent referral to the nephrologist, or you know, if the creatinine has gone up quite acutely is it a case of just admitting them directly from clinic, is it a case of referring them urgently like a fast track system to the nephrologist involved, or is it a case of, if it's not acute deterioration, just something that's been gradual, then I would put a form referring to the nephrologist and also refer to the pharmacist.

In: Would you consider using a referral form like this?

C2: Yes, provided there isn't too much that you have to tick off you know, but yes. There is already mountains of paperwork introduced extra layers, and layers.

In: A previous clinician said something about a comment field, to write your own comments, would that be beneficial?

C2: Yes, it would yes. Because it would allow you to give a little of the patient's history, ehm, and why you were concerned about them, and what you wanted to achieve by referring them.

In: Because this referral is to help you refer the patient to the clinic, but it is also to help the pharmacist understand what exactly do you want.

C2: Yes.

In: Anything else you would say or add?

C2: Not at the moment, no.

In: Thank you so much for your time.

Interview with Clinician 3

Clinician 3 (C3)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C3: No.

In: This is a pharmacist-led clinic, where clinicians refer patients for BP-control, help in managing lipids, help the patient adhere to medication. To refer a patient to this clinic, the clinicians might use this referral form. My project is to find out if these referral criteria are

helpful in referring a patient. Would you take a look at this form and tell me what are your thoughts about these criteria?

C3: Well, I'm a junior doctor, so for me, I would perhaps like a bit more detail, in terms of what specifically would fit these three categories. For instance BP control; if someone has an elevated Bp would you like them to be referred or would you like confirmation of BP to be monitored first, before the referral was made. Otherwise it seems pretty straight forward.

In: So you would like the referral criteria to be more specific. What would be good – switch the referral criteria and the reasons for referral? Or just apply the referral criteria with reasons for referral?

C3: Ehm..

In: Would that make them more specific or would you need more change to the referral criteria, more sub-questions to?

C3: Well, actually, deciding the difference between the two is actually a little bit unclear. But if, here, would I make a referral if it was just a blood pressure issue, that I'm not quite clear on actually, whether or not that would be a reason for a referral. But for me, a junior doctor, it might be a bit easier having these boxes the other way around.

In: Previous clinicians have said that more paper work, more paper to referral, more specific paper to complete, might be more time consuming, would that be an issue, if the form were more specific, for your sake?

C3: Ehm, I don't think so, just have a few key points with for example the macrovascular disease or nephropathy categories, in which case I don't think the form would actually change much. Also, once you've made a couple of referrals, it would be familiar to you and shouldn't take more time while for the uninitiated who haven't seen the referral before it has all the information.

In: So, you think more detailed information should be added, like BP levels, maybe adherence, and lifestyle management could be added as well?

C3: Possibly, yes. And to detail how many ticks before an appropriate referral can be made.

In: Would cut-offs or scores be more useful?

C3: I think so, I think it would yes. I think you could still keep the same format but just put in a couple of numbers. It gives you a guidance, you can always break from the guidance but at least you know which group of patient are of interest.

In: Another option is recommendations for management, like saying if the blood pressure is above a certain value you should refer, if combination with a high lipid value you should refer, if only the lipid value is above a certain value you should refer, would that be something to consider as well?

C3: It says here "tick at least one", and if the reason for referral is, "must tick at least one", then I think that kind of implies if there was just one issue then you could make an appropriate referral.

In: Do you think any information should be removed?

C3: I don't see why it should be no. ehm, most things on there are relevant.

In: Previous clinicians said something about an own comment field, that you can write down your own thoughts, give more explanations, maybe if you still think some things quite unclear you can write exactly why you are referring, or why you want help from the pharmacist?

C3: I'd say that that would be a reasonable thought, you could extend your reason for referral and just have a couple more lines above the boxes which would allow for maybe one or two lines if there was something peculiar about the referral that didn't fit into one of the boxes.

In: would you consider referring patients to the diabetes cardiovascular risk clinic?

C3: Yes, I have to say so far in my short period here I have referred quite a few diabetes patients back to the GP for blood pressure monitoring or control. In terms of smoking cessation, I have tried to council patients, but where they are not contemplating stopping I have suggested they go to see their GP practice regarding alternative smoking cessations groups or that sort of thing, I didn't actually realise it was available in-house...so that would be very useful. My worry would be that we swamp the in-house service, very quickly. So actually, no I think it is useful.

In: So you would consider using the referral form as well?

C3: Absolutely yes. Perhaps, ehm, it probably was discussed with me when I first started, and I obviously have met the Pharmacist before, but I didn't realise that this was the precise form that I'd use.

In: Thank you very much for your time.

Interview with Clinician 4

Clinician 4 (C4)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C4: Yes.

In: Do you refer patients to this clinic?

C4: Not very often.

In: But you have done in the past?

C4: I have indeed.

In: Why would you refer patients to this clinic?

C4: Well, there's some patients where you're really struggling with usually blood pressure rather than lipids, blood pressure, and it is quite difficult in the context of the ordinary diabetes clinic to get them back sufficiently often to titrate drugs, to change drugs, to see how they're doing. So it's a good way of passing them to somebody who can see them quite frequently and make sequential adjustments in doses or choice of drugs.

In: What do you consider when you are referring a patient to the clinic?

C4: Well, whether they have difficult to control blood pressure, or whether they have, would be on a few antihypertensives, and they haven't been effective, or whether they are somebody who'd be able to come back up to the clinic on a frequent basis.

In: So the blood pressure is one of the criteria you use when you refer a patient, so you've maybe answered that question?

C4: Yes, blood pressure would be the prime thing. Ideally if blood pressure is fine, they are not a person for the clinic. If the blood pressure as a one off is bad or awful then you would be aiming to start them on or change their drugs in conjunction with the GP. But in somebody where you've tried one or two approaches and you referred them to the GP or the practice nurse for some measurements, and you just not really somehow getting there then this clinic's a good option.

In: When in the patient journey would you refer the patient? In general, after seeing him one time or two times?

C4: Well, not after once, but maybe after you've seen them a couple of times.

In: Are you aware of the referral form?

C4: Ehm, yes. I haven't looked at it for a while.

In: This is the referral form. Do you use it?

C4: I have used it, when I last referred somebody which was probably a year or so ago.

In: What are your thoughts about the referral criteria?

C4: Ehm, that's fine. I would certainly feel that you would want to be targeting people with, either with macrovascular disease or very high risk of macrovascular disease. Interesting to see in the reason for referral that there's smoking cessation advice.

In: You haven't seen that before?

C4: That has, sort of... If I've seen it, I'd forgotten about it.

In: Do you find them specific enough, easy to use?

C4: Yes. And after all there's always scope for working an extra something onto the form if you want to explain a little bit more. And there will be the letters in the notes anyway which would amplify what information is needed.

In: Previous clinicians has said that they would probably like a comment field, an own comment field or a bit more space here (pointing at the reason for referral options).

C4: I wouldn't let that inhibit me, I just write on it.

In: Are the reasons for referral detailed on the current form specific enough?

C4: I think they're, specific? I think that there is scope for other things, again I'm not sure that I've fully taken in that nephropathy was on that form, I've been tending to think of the cardiovascular clinic as targeted at patients with uncontrolled blood pressure, or potentially lipids, who either have established cardiovascular disease or where at high risk of cardiovascular disease.

In: Is there something you would like to change on the current referral form?

C4: I think given the discussion having a little bit more space to write on would be useful. Although I would get that there will be, at the time you see the patient you're always going to look at the clinic letter anyway, and that clinic letter would be available and is likely to set out what the problems are.

In: One of our concerns are that some clinicians doesn't refer patient to this clinic. Another concern is that maybe not the proper patients get referred. Do you have any ideas around that, why that might be a problem?

C4: Ehm, I don't really, other than it's easy when you're sitting there in the clinic and you're making changes to peoples medications and management, it's easy to feel that you got some ideas and you're going to follow them through, and, so you forget that there is a way of actually achieving them a little more quickly by allowing the patients to be seen a bit more frequently.

In: If the referral form were more accessible, would that help?

C4: Well, I guess having them in pack of stuff is as accessible and we all use the yellow specialists letter referral forms on a regular basis, frequent basis, so it's in there alongside, that's probably good enough.

In: Would cut-offs or scores be more useful to the reasons for referral?

C4: Yes, that I guess would make it very obvious, in a sense who they want to see and maybe more specifically who they don't want to see.

In: Should there be additional actions requested, like adherence, lifestyle management?

C4: Well, I guess the lifestyle management patients often go to the dietician, or potentially the specialist nurses. I haven't thought of this clinic as being able to offer that sort of service, I attended to think of it quite specifically as a blood pressure medications optimisation clinic, and that's often what it does. But I guess maybe I'm displaying my ignorance, I need to see exactly what people are prepared to offer there.

In: Do you think the form should include recommendations for management, like if the blood pressure is above a certain value, you should refer, if the lipid level is above a certain value you should refer?

C4: Well, I think the trouble about that is that often if the blood pressure or the lipids are above a certain value you will per say, first time off, you're likely to have one or two things

that you are going to try anyway, that you hope will succeed, so it's not just a question on what the blood pressure and the lipids are, but the fact that your first line attempts of controlling them haven't been successful, would be the way I would attend to use that clinic.

In: Do you think any information could be removed?

C4: Ehm, no, I don't think so.

In: Do you have anything else you would like to say or add?

C4: No, I don't think so, beyond the fact that I think it is a useful adjunct to the clinic, and I, I admit that I haven't used it very much, but just occasionally it's just, a very useful service for patients where you yet somehow not quite winning and you can't see them all that often or they come back to this clinic several times to get things adjusted it is very useful.

In: What's the reason that you haven't used it that much? Is it because you haven't seen patients that often or?

C4: Well I guess, maybe I haven't seen that many patients where I felt I was really struggling. And just possibly that cause I forget about it. And a lot of patients that I see with, patient I see with clearly elevated blood pressure, yet likely to make a suggestion and offer the GP to start something, probably, you quite often don't see that person back in the clinic yourself. Patients with rather border line blood pressures you quite often say "Could you get your blood pressure checked at the practice nurse?", and when they come back to the clinic and you say "Did you do that?" they say "Yes, I can't remember what it was but they said it was OK", and that is one of those frustrations and maybe some of those patients could with benefit be seen or followed up with this clinic. But if you took all of those people with, who are on one or two drugs, whose blood pressure at the clinic isn't quite OK, but who say that at their GP it's OK, that's probably a rather large number of patients and probably more than the clinic want to deal with.

In: Thank you very much.

Interview with Clinician 5

Clinician 5 (C5)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C5: Yes.

In: Do you refer patients to this clinic?

C5: Yes.

In: Why do you refer patients to the clinic?

C5: Generally for, well, for cardiovascular risk management, which tend to be primarily blood pressure control.

In: What do you consider when you refer patients to the clinic? What are your own thoughts, what goes through your mind?

C5: The thoughts are that the clinic is a good way of achieving repeated reviews and it's quite a good way of achieving blood pressure target, which we struggle to achieve with a one-off clinic review, with a patient with diabetes.

In: What criteria would you use to refer the patient?

C5: Either the cardiovascular risk mainly, but also, you know, somebody with fairly heavy proteinuria who's got poor blood pressure control. I'll take that independently as cardiovascular risk. But those will be the two main groups that I would be referring.

In: What would you think, you said cardiovascular problems, would it be mainly blood pressure control, mainly lipids, or?

C5: Well, there would be some lipid cases but it would be primarily for blood pressure. But I think there would be a role with lipid control as well but the majority of problems we see in the clinic are blood pressure related.

In: Would patient history have anything to do with you referring a patient?

C5: What do you mean patient history?

In: If a patient has family history of cardiovascular disease, higher risk of cardiovascular disease?

C5: Yes, I think that would come in to your overall calculation for cardiovascular risk.

In: Are you aware of the referral form?

C5: Yes.

In: Do you use it?

C5: Ehm, I'd like to say yes, but I'm not sure that I'd use the form, I think I may send a copy of the clinic letter rather than the form.

In: Why is that?

C5: That is just because, ehm, probably laziness to be honest. Yes, it's just a lot more convenient whenever you're dictating a letter that you copy to the pharmacist with a couple of sentences of the reasons for referral.

In: But what do you think of the referral criteria?

C5: The referral criteria, ehm, macrovascular disease, well, in some people you're trying to prevent macrovascular disease, as primary prevention, so nephropathy yes, macrovascular disease, I think that that maybe needs to be looked at.

In: Do you think they should be different?

C5: Well, I think that the referral criteria, I would personally say that some patients you want to prevent macrovascular disease so it's almost the case if ticking that box is like shoving the stable door after the horse is gone. I would definitely put blood pressure up here, yes, that would be a good referral criterion, because one of the reasons, well, I would I guess, after reading this, I would prefer if that we put people who didn't have macrovascular disease.

In: OK?

C5: Well, say that someone got microalbuminuria so they don't have nephropathy but micoralbuminuria in the context of primary prevention is a very significant part of cardiovascular risk. And I guess they're, going back to that first question, they're the people I guess I would be looking at. You know, they probably don't meet the criteria of macrovascular disease or nephropathy but they're 5 year risk, they're calculated 5 year risk is actually very very high. So, nephropathy to me would indicate that we're missing maybe people who've got microalbuminuria with high cardiovascular risk.

In: An option would be to maybe remove the referral criteria and move the reasons for referral up, make the reasons for referral the actual referral criteria.

C5: Yes, referral criteria you could say were microalbuminuria or nephropathy but I think that they're an important subgroup that that we potentially undertreat to be honest.

In: Which ones?

C5: The microalbuminuria.

In: Ok. Ehm, do you think that, well, you've probably answered that question, if you find the referral criteria specific enough or if the criteria are easy to use. Anything else you would like to say about that?

C5: Well, the referral form is very straight forward.

In: Is the reason for referral section detailed on the current referral form specific enough?

C5: They're very specific.

In: Ok, is there any changes you would like to do? Anything you would add, or remove maybe?

C5: I'm not sure I would refer for smoking cessation advice, because I think that is something there are other ways of doing that. Ehm, anti-platelet therapy, I think that the two main reasons for referral would be blood pressure control and lipid lowering therapy... The pragmatist in me says that resources are tight and I think that we've got more to gain from the clinic focusing mainly on these two issues, and not worrying about, well unless you have the time for smoking cessation or anti-platelet therapy would have thought we'd be addressed in the clinic. General CVD advice... I would say to follow at least. I guess I would be keen to keep blood pressure control, lipid lowering therapy and general cardiovascular advice. I'm not sure anti-platelet therapy or smoking cessation advice are entirely necessary. Other, well I'm trying to think what other reasons I would refer for, I guess there might be the odd person that there might be something out with that so it's always good to tick an other-box.

In: Ok, in that case would cut-offs or scores be more useful, if the blood pressure were above a certain value you should refer?

C5: Yes, I think that, looking at cardiovascular risk overall is a sensible way of doing things, I think and, maybe not everybody that goes to the clinic is tuned in to the concept of cardiovascular risk, and that might be a better way of streamlining things, I don't think a scoring system would but we could work out percentage risk using one of the cardiovascular risk calculators I guess there is always going to be people that you want to optimize let's say the blood pressure even if the cardiovascular risk is maybe not that good to use on, particularly the young when the cardiovascular disease estimates are not that good to be honest. I guess it depends very much on where the clinic is with regards to numbers, you know, whether you're feeling that the number of referral you're getting is too much, you want to get a better way of stratifying it and that's probably the way to do it. So, yes, scoring system might be best.

In: We have two concerns, one of them is that clinicians don't refer patients to this clinic, and the other concern is that maybe the proper patients aren't referred. Do you have any comments on that?

C5: Ehm, the proper patients aren't referred...

In: We might think that it could be the form, that it's not specific enough.

C5: Ehm, I think with the referral criteria I guess yes, I suppose your concerns are the referral criteria, I mean, if you could broaden that if you don't feel that enough people are referred then you broaden that criteria, so you have difficult to control blood pressure, difficult to control lipids, take the macrovascular disease and because by addressing blood pressure and lipids you're addressing the chance of that happening, and split the nephropathy-box into microalbuminuria or nephropathy. But I think it is under estimation of cardiovascular risk if somebody's got microalbuminuria. I'd probably have an estimation in some people with nephropathy as well. You could broaden that out if you're not seeing enough people... really I'm surprised at that?

In: Well, maybe it's more like, a previous clinician said, he didn't have a clear answer, but he thought it was about, clinicians don't usually think about it when they sit with a patient, they think about following them through and not thinking that the clinic is a very good way to actually achieve what they want to follow through with the patient.

C5: Well, in that stage the clinic is actually very helpful because it can let you know, it can be very helpful in letting you know that if someone's has difficult to control blood pressure but they come to the clinic and the blood pressure is better controlled, and they come out of the clinic, and then blood pressure goes up again, that suggest to me that there's a problem with compliance. And the clinic is very very helpful for that, because where the clinic is actually very helpful at I think, is that you're asking, if we see somebody, we're going on the list of one-off meeting which generally speaking is very unhelpful because, you know, they're struggling to get the car parking, they've rushed in, their blood pressure might be high they might not have been taking their medication, if not inaccurate, not a good time to make an assessment. I'm surprised of the number of people that don't see their primary care physician, we see this a lot that people don't get integral blood pressure checks, this clinic is actually a very good way of doing that and get records of peoples blood pressure and

actually getting it sorted so I actually think that the clinic is very helpful. It might be a problem that people aren't referred, people aren't being identified and referred maybe we need to increase the awareness of it. How can we do that? Well, I think that's just another mailshot by emails and things, to increase everybody's awareness. I guess if you define the criteria people will maybe prefer a bit more.

In: Yes, and also that there's a turnover of clinicians here as well.

C5: Yes it is, that's right. I think that is part of the reason that there's permanent members of staff but the numbers of permanent members of staff are grossly outnumbered by the number of people moving through.

In: Would adherence be box to tick off at the form? Like for a reason for referral?

C5: Well, I guess... Do you mean like compliance to medication?

In: Yes.

C5: Well I think that would be more to put in the letter rather than you need to tick it on the form. Difficult to control blood pressure, I mean, one of the key things you have to think about then is lack of compliance anyway, this would always be taken in context I would imagine with the diabetes letter and the notes. I think that if you take out macrovascular disease because you're looking to prevent that in a lot of people, and you know, referral criteria whatever you think, blood pressure, lipid lowering should be the referral criteria, and adding microalbuminuria I think.

In: Previous clinicians has talked about an own comment field, where you can write your own thoughts, to broaden out your own thoughts?

C5: Yes, we use that in our referrals to our specialists we have a lot more free text. I mean again, the way I would work I guess you're having to tailor this for a lot of different individuals but, the way I would do it is that, all the permanent information would be on the letter from the clinic consultation. But I guess you need this for triage etc, I probably wouldn't add in much more on top of my letter, due to the duplication.

In: And that would probably be time consuming as well?

C5: Yes, I think so.

In: Do you have anything else you would like to say or add?

C5: No, I mean, I'm very supportive of the clinic, I think it's very very important, I think it provides us with a lot of help and information, and to achieve a number of things that we wouldn't be able to achieve in the clinic, I think, so.

In: Thank you for your time.

Interview with Clinician 6

Clinician number 6 (C6)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C6: Yes.

In: Do you refer patients to this clinic?

C6: On occasion, yes.

In: Why is that?

C6: I refer patient who have difficult to control hypertension in the main, and that's not very often. Generally patients are able to control and there is plenty of room in their antihypertensive therapy to control their hypertension, and we just titrate it up so, it is only when we are having real difficulties and there are more than one agent, that I tend to refer them.

In: What do you consider other than that when you refer the patient?

C6: Well, obviously it's important to have a lipid profile done and I'll always refer them for blood pressure monitoring so I can get an accurate blood pressure, and discuss other cardiovascular risk conflicts, smoking, family history, and all of these things will be taken into consideration.

In: What criteria do you use when referring the patient?

C6: I usually think if they're on two agents already with uncontrolled hypertension, that's the point when I generally refer.

In: When in the patient journey would you refer the patient?

C6: I usually refer them on the diabetes clinic, so at the meet point in their on-going management at the diabetes clinic with hypertension, that's uncontrolled I would generally refer them.

In: Ok, so it's not a general number, after two times or three times you've seen the patient?

C6: No.

In: Are aware of the referral form?

C6: No.

In: This is the referral form, which is used to refer the patients to the pharmacist-led clinic. Would you take a look at this form and tell me what are your thoughts about the referral criteria?

C6: I suppose, about the nephropathy, the patients, patients with nephropathy, well, the number with nephropathy, you can't refer them all. The number has macrovascular disease

as well and you can't refer them all. Most of these things we're able to manage anyway. Either by titrating up their ACE-inhibitor or ensuring they're on a beta-blocker, ACE-inhibitor, statin and aspirin for macrovascular disease. Anti-platelet therapy is something we're not, perhaps as good at, something I may think about in the future. Lipid lowering therapy, I've not generally referred them to that, for that reason before, I would generally email one of the consultant at the lipid clinic if I got a major issue with lipid lowering therapy, and ask them for advice. I didn't know that was something that the CVD clinic would do. But blood pressure control is really the only box that I would tick in that on, generally, yes.

In: Going back to the referral criteria a bit more, do you think anything could be changed about them? Do you think they're specific enough or?

C6: No, I think they're very very general. Like I said, you can't refer every patient with nephropathy. I would tend to say, I would say, to change it to say a specific range of nephropathy, and to what duration or despite goes through this sort of treatment. To split macrovascular disease I would say something like if they had reasons, if they had a recent coronary event that you don't think is being managed properly, or if you have got significant peripheral vascular disease that is painful, so more specific criteria would help me to refer patients, I think.

In: An option would be to switch the reasons for referral with the referral criteria?

C6: Yes, absolutely.

In: And then make it more specific?

C6: Absolutely, yes.

In: And also there's a turnover of clinicians here, and maybe for them it would be easier? Do you have any comments on that?

C6: Ehm, yes, it would be because most people are only here for 4 months, and aren't even introduced to this form at any point, so this is the first time I've seen this form. And generally I would just ask the pharmacist... Yes, having specific criteria would certainly help if you're a new doctor here.

In: Being a new doctor as well, could that be a reason why one of our concerns is that clinicians don't refer patients to this clinic?

C6: Absolutely, that could definitely be a reason to why we don't do that.

In: Do you have any other ideas why clinicians might not refer patients to the clinic?

C6: I think, maybe at the start of each attachment, if there could be just a very short introduction session for the new doctors to say this is what the cardiovascular risk clinic is for, and this is who you can refer, and also when the pharmacist is here on a weekly basis, just maybe to ask about any patients that they're worried about so continually you know, offering the clinic to the new doctors and make it sure they understand what it is for would be helpful too.

In: Another concern is that maybe not the proper patients get referred. Do you have any comments on that?

C6: Again, you just need a better form and better education of the clinical staff.

In: So, if I understand you correctly you think that this form should be more specific?

C6: Yes, absolutely.

In: Do you think more space to write your own thoughts would be a good idea?

C6: I think actually your own thoughts would probably be in the clinic letter, where you just dictate it. So, it wouldn't do any harm, but it would be easier seen from my point of view, I just dictate it from the previous letter.

In: Would cut-offs or scores be useful? For example, to the reason for referral?

C6: I don't know if there's a sort of predictive value of many of the scores, I suppose you could say somebody with a cardiovascular risk of x per cent but that might depend on the patient age entirely, so you know, when I'm 80 years old I might have a cardiovascular risk of 33 per cent in the next 10 years, so I don't think that would be particular helpful, maybe if you said somebody with cardiovascular risk of more than 20 per cent who's also under the age of 60, might be helpful.

In: So, maybe more of a recommendation of management, if the blood pressure is above a certain value you should refer, if the lipid level is above a certain value you should refer?

C6: Yes, certainly something like if the blood pressure remains above this despite, you know, cause you usually initiate first couple of, sort of, you know, interventions of blood pressure and lipids and anti-platelets. But if it's still uncontrolled and despite treatment, refer, that would be the easiest thing then you wouldn't get a flurry (...) then you would be seeing every patient with hyperlipidaemia that's a good idea that would be a specific reason for referral I would say.

In: Would you consider using a referral form?

C6: Yes, absolutely.

In: If it were more specific or?

C6: Yes, absolutely.

In: Do you have anything else you would like to say or add?

C6: No I don't think so. I do think it's probably an under used resource.

In: Thank you very much.

Interview with Clinician 7

Clinician number 7 (C7)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C7: Yes.

In: Do you refer patients to this clinic?

C7: Very rarely.

In: Ok, why do you refer patients rarely?

C7: I tend to forget and I suppose, I'm still not quite sure how the clinic fits in to the overall picture, of everything.

In: But if you were to refer a patient what criteria would you use?

C7: Somebody who's blood pressure was not well controlled, either because they were having difficulties in their medication or because their on a number of drugs already.

In: What are your thoughts when you're consulting a patient? Are there any specific thoughts about the patient's condition?

C7: Do you mean just in general a part from high blood pressure?

In: Yes.

C7: I suppose I tend to think of the three bloods: blood sugar, blood cholesterol and blood pressure. For the patient it's not smoking, exercise and diet, and that's my aid memoir, if you like, and I suppose it's a question of thinking what are the priorities from my perspective for diabetes and where is the patient.

In: So you would say that the three bloods you were talking about are your main priorities?

C7: Correct, yes.

In: When in the patient journey would you refer the patient? After seeing the patient three times or four times?

C7: It could be at any time, because it might be someone who has had high blood pressure for a long while but they might be new to the clinic, or it could be at any stage.

In: Are you aware of the referral form?

C7: No.

In: This is the referral form used to refer patients to the clinic. Would you take a look at the form and tell me what are your thoughts about the referral criteria?

C7: That's ok, if I think of cardiovascular I might just also include high blood pressure, so I suppose macrovascular is a little bit too vague, and, well, high blood pressure would be included in that, but as such they're slightly vague criteria for referral.

In: So making them more specific would be more helpful?

C7: You could, well, I'm not sure whether you could make them more... A brief sentence and then if I put my reason in writing, I mean, that's quite useful or if I have the chance to write by. So, let's say if it was yourself and you were struggling, well, slightly unambiguous in one set because it talks about macrovascular disease and then lipid low therapy, well, you could have a patient who had high cholesterol, blood pressure like normal, does that, you know, it's just a little bit vague.

In: An option would be to switch these to, make the reasons for referral the actual referral criteria?

C7: Yes, I think that's, yes, what you're saying is right, it's more practical, and what we would call pragmatic, cause its more useful because that's saying what it is I'm looking for. And I would be very happy, or would be happy with any referral where I might (X) but the person to whom I referring would say no.

In: What do you mean about that?

C7: Well, I might say, I want to send someone to yourself as a pharmacist to give them advice about x, but you might, you should not accept that referral if it wasn't appropriate. That's what I'm saying. So, you know, if I ticked those two (referral criteria) the pharmacist might say that that patient is not suitable. Somewhere if there is a bit more of a dialogue, is this referral appropriate.

In: Ok, I see. Would a comment field be helpful?

C7: Yes.

In: Maybe an own field or a field behind the reasons for referral?

C7: Just put any additional comments

In: Do you think more detailed information should be added? Like blood pressure levels, adherence, lifestyle management?

C7: Ehm, I think it's probably those questions which we ask again anyway about lifestyle and so forth. One of the interesting things is patients often say quite different things at different clinic appointments so I'm not sure that's very helpful.

In: Would cut-offs or scores be useful?

C7: Ehm, not particular no, because different people seem to have different scores and let's say for nephropathy or renal failure, what would be a score there?

In: So it would be difficult to make a general..?

C7: Well, specific things, I mean if you said: what would be the target blood pressure without kidney disease? There would be a little bit of fluctuation in each person.

In: What about recommendations for management, if the blood pressure was above a certain value, you should refer, if the lipid level were above a certain value, you should refer? More explanations to when you should refer?

C7: I think it's when you consider referral. Yes. What I mean is think about referral, if there is, you need an aide memoir "think about referral if...".

In: Yes, if the blood pressure were that value you should refer. But that would be useful?

C7: That's different from a referral form.

In: Yes, but if it was behind blood pressure control, that would be helpful?

C7: Yes.

In: More guidance?

C7: Yes, or just to think about it.

In: Would you consider using the referral form?

C7: I probably will following our talk today, yes.

In: Anything else you would like to comment or add?

C7: I think that just occasionally if there was some feedback from referrals or feedback about outcomes from the clinic, so has two people going to the clinic, does their blood pressure drop, is it maintained.

In: Yes, it has been shown that patients going to this clinic have reduced their blood pressure and it has been maintained for two years.

C7: But, if I've been told that, I've forgotten about it, but I'm not sure whether I've been told that or whether I've never known.

In: Making the referral form more specific would completing the form being time consuming be a concern?

C7: No, that wouldn't bother me too much, no.

In: Thank you very much.

Interview with Clinician 8

Clinician number 8 (C8)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C8: Yes.

In: Do you refer patients to this clinic?

C8: Sometimes.

In: Why would you refer patients to this clinic?

C8: If they have poorly controlled blood pressure and I want them to be seen more frequently than we can in our current NHS doctor delivered service.

In: What criteria do you use when you refer a patient?

C8: Ehm, I haven't referred too many people lately, maybe that's not a good thing, but criteria... when it comes to my head to refer them, ehm, someone who we look as though we put some work into improve their blood pressure control, but it just doesn't seem to be happening. So that would be when we would refer.

In: So mainly blood pressure control?

C8: It would be blood pressure more than anything, the lipid stuff, I think, if you give the drug you get the response. The blood pressure I think is more challenging parameter to treat.

In: When in the patient journey would you refer the patient? After seeing him two times or three times?

C8: We have seen many patient a lot of times, so it will be very variable. I think it would be unusual to send someone without them having been seen here two or three times in the general clinic first.

In: Is there any specific reason to why you haven't referred patients lately?

C8: I don't think I've spotted that many people to be referred.

In: As simple as that?

C8: Yes.

In: Are you aware of the referral form?

C8: Not immediately.

In: This is the referral form. So, you're not quite familiar with it?

C8: No, I have to say I would do a letter, or copy a letter.

In: Ok.

C8: So I would give a copy of my clinic letter to the pharmacist if I was referring.

In: Well, this is the referral form which is used to refer the patients to the pharmacist-led clinic. Would you take a look at this form and tell me what are your thoughts about the referral criteria?

C8: I think that it's reasonable to have macrovascular disease and nephropathy on it, that's fine. I think we have a separate smoking cessation advice service, so I'm not sure if that's where we should be with this service, but I'm prepared to be educated on that. I would say the main one that I would be dealing with when I refer would be the blood pressure. Antiplatelet therapy I decide that myself, lipid lowering therapy we can sort out, probably.

In: This is the referral criteria, and this is the reason for referral.

C8: Yes, the one I would use is the blood pressure.

In: Yes, and they're just a bit different, so you would tick the macrovascular disease and then tick the blood pressure control?

C8: Consider I don't really recognize this form, it's a bit hard to answer that.

In: Do you think the referral criteria are specific enough, or would you change them, are they fine as they are?

C8: There may be people who do not have macrovascular disease or nephropathy but they have difficult to control blood pressure, and, so, you could put in high cardiovascular risk or uncontrolled blood pressure but probably with that I think it would be easy enough.

In: Do you think more detailed information should be added, like blood pressure levels, adherence, lifestyle management?

C8: I think that that's all available in the clinical record and to create a form which requires more filling in will be a bigger a barrier to referral. I have to say this is added work to fill in a form, I tend to use a copy of my last letter, which should summarize what the thinking is at the time.

In: Making the referral form a bit more specific would that be more time consuming and thereby... ?

C8: Would that be for more information then it will be something that will be harder to do. At the same time, having this is, added value versus a copy of the clinic letter, perhaps limited.

In: Could you repeat that, what do you mean?

C8: I think that having the form, is reasonable, but my method of referring, I think would be a copy of my clinic letter rather than using the form.

In: Because it's time consuming?

C8: It's less time consuming, you just get a second copy of the letter and it will say why you are referring in more detail than this will, without having to fill in a second bit of documentation.

In: One of our concerns is that clinicians don't refer patients to the clinic. Do you have any comment on that, why that might be an issue?

C8: Yes, well, now that you've asked me, I will think of it more often. So, I think that there's an element of profile, there's an element possibly of feedback as well, somehow. So, if we refer someone, we don't see them for a year, and there may be some very good work that's going on, so how do we raise the profile of this clinic, within our service. So, I think that maybe there is something we should be doing about that, which is in the clinic referral form.

In: Another concern is that the proper patients don't get referred. Any comment on that?

C8: And what do you define as proper?

In: The patients that probably need it the most? Or who fits more with the profile of the clinic?

C8: Well, I think that's something that should be discussed in as we raise, if we decide to raise the profile that this is a reasonable idea, then I think we need to have some formal discussion about this. It should be something, if we started to have team-meetings more, then it's something we should be considering what do we do, and we're planning to try and look at redesigning some of the things we do here, and if we do then we need to look at further steps in.

In: Going back to the referral form a bit, there's a high turnover of clinicians here, well, not high, but it is a turnover.

C8: Absolutely.

In: Do you think making the referral form easier to use...

C8: I don't think the referral form is the issue, I think it's the thinking it's a good idea to refer. And, that reminding us all about the profile of the clinic.

In: Do you think any information should be removed on the referral form?

C8: No.

In: Do you think the form should include recommendations for managements, if the blood pressure is above a certain level, you should refer, if the lipids is above a certain value you should refer?

C8: On the form?

In: Yes.

C8: No, that's individual. Again, a general diabetes clinic is one where we deal with cardiovascular risk all the time. I think the added value of this clinic is frequent review, pharmacy expertise to educate the patient about the medications and to look at compliance and concordance issues. And I think that, that's the added value for patients. Can't remember your question now, but, so I think that's where it fits with us. It's a matter of having it high enough in our mindset to say "Ok, we're just not winning here, let's get this patient referred", and again, I do the combine renal diabetes clinic, and that's working sort of side by

side with the cardiovascular clinic, and there's a lot of overlap with that, and I think that's reasonable, but they are doing the same thing largely.

In: Anything else you would like to comment on or add?

C8: Well, I think we should be raising the profile of the clinic, again, it is a useful service. And if we're not using it, if it's not sufficiently busy, then we need to look at that and think about how we can use it better.

In: Thank you very much.

Interview with Clinician 9

Clinician 9 (C9)

Interviewer (In)

In: Are you aware of the pharmacist-led diabetes cardiovascular risk clinic?

C9: Yes.

In: Do you refer patients to this clinic?

C9: Occasionally. Yes, probably not very often, I just do the clinic here once a week, and I'm mostly based on another hospital, so I would probably see fewer patients than the other clinicians based here all of the time, but yes, I have referred some patients to the clinic in the past.

In: Why do you refer patients to the clinic?

C9: Usually it's the ones who I feel are going to need quite intensive management to their blood pressure so more frequent follow up than we can offer in the standard diabetes clinic, and patients who's gone beyond one or two agents for their blood pressure and where the GP perhaps might struggle with further choices of hypertensive agents. I suppose as well strictly patients who are high risk where we particularly want to get their blood pressure down for example patients with retinopathy or nephropathy, would be kind of people I would refer.

In: What do you consider when you are referring patients to the clinic?

C9: In terms of which kind of patients criteria?

In: Yes, your own criteria for referring the patient.

C9: somebody with difficulties to control blood pressure where we haven't managed to control their blood pressure on two or three agents, patients who've agreed to need frequent follow up to titrate up their medications, and patients with complications where good control of blood pressure would be beneficial for example patients with renal disease or retinopathy.

In: When in the patient journey would you refer the patient? After seeing him two times or three times, in general?

C9: It wouldn't particularly be after a set number of appointments with my self, for example I might be meeting a patient for the first time, but they've been in the clinic system for many years already. So it would really depend on what their blood pressure was like, how many hypertensive's they're on, if they have complications, rather than the number of times that I've met them. Cause even if I'm only meeting them the first time, I know that the reality is that I can't bring them back to the clinic sooner than three or four months to see me again, so when they going to need more frequent follow up than that for their blood pressure, that would be when I consider referring them to the blood pressure clinic.

In: Sop everything depends on you seeing the patient, what are your thoughts about the patient and you would consider referring or not.

C9: Yes.

In: Are you aware of the referral form?

C9: Yes, I think it sets in the folder at the clinic room.

In: Yes, I have one here if you would take a look. Do you use it?

C9: Yes, I mean, I've used it in the past when I've referred patients. I must admit I haven't used it at some time but I have done previously.

In: What are your thoughts about the referral criteria?

C9: I think they're both very reasonable referral criteria, the macrovascular disease and the nephropathy. To my mind, it probably would be good to add a third referral criteria which would be retinopathy, for you know, patients who have retinopathy, good control of blood pressure is beneficial and they would be another group that would, I think, benefit from access to the clinic, and technically they don't necessarily need to have either of those two criteria, although in fact very often patients with retinopathy also have nephropathy as well, but, you know, for the patients who only have retinal disease I think that would be a useful criteria to add in.

In: Do you find the referral criteria specific enough?

C9: I think so, I think you want the criteria to be broad enough in order to catch all of the people that you need. I mean I suppose with nephropathy you could argue that you don't want the clinic to be clotted up with people with very mild degrees of nephropathy but, so you know, I suppose perhaps you could specify nephropathy bracket CKD stage 3 or beyond. I think in reality the referral clinicians would have enough common sense to pick people that have a reasonable degree of complications so I don't think they necessarily need more specific than they are.

In: There's a turnover of clinicians here, junior doctors and new doctors, do you think they would have more, ehm, beneficial of the referral criteria being more specific?

C9: Possibly for them, actually. Again, I suppose we would see a lot of patient with type 2 diabetes who would have macrovascular disease of some form and a degree of nephropathy but you wouldn't refer the majority of them to the blood pressure clinic. So perhaps for them it might be useful to have something a little bit more specific, for example nephropathy, CKD stage 3 or beyond, for example. I guess it's difficult in a way for me to judge that because

I'm, I'm sort of funnelling people in to the clinic, but I'm not at the receiving end. So I imagine the pharmacist would have a better feel for whether the referrals that are coming through are appropriate or inappropriate.

In: One of our concerns is that clinicians don't refer patients to the clinic. Do you have any comments on that?

C9: Well, again, I suppose that some times, well, we would initially usually try and manage the patient between ourselves and the general practitioner, so in the early stages we would suggest to the general practitioner to initiate an ACE inhibitor, titrate up, recheck U&E's as such an interval, blood pressure target such and such. So, I suppose in the early stages I think it will be reasonable for us to do that and to save more complicated patients for here. But actually, I suppose if the clinic isn't getting enough referrals then maybe it's something we need to raise the awareness of, particularly amongst the junior trainees, as you say there is a turnover of staff and it may be that they are not specifically aware of the ability to refer in to the hypertension clinic. One of the difficulties that we have with the clinic that I do is that actually we don't get the blood pressure checked for us. I think in the other clinics the nurses do the blood pressure where with us we are the first ones to check the blood pressure. And I think that has to do with nursing staffing issues. I think where it comes useful to have the blood pressure done already is if someone has an initially high blood pressure and then you'll see them in the clinic and then you'll recheck it's perhaps a little bit lower, and you then got two blood pressure readings for that one clinic. So that's perhaps one way which we could, actually flag up awareness a little more because if somebody's coming in with you know, initially high blood pressure reading and then we get a slightly better but still not great blood pressure reading it gives you the impression of somebody who perhaps has not ideal blood pressure control whereas when we are only doing one measurement and we're getting one that's reasonably good will might perhaps miss the fact that the blood pressure was high on arrival. And I think that there is a reality that on busy clinic days, when the blood pressure isn't getting checked for you, I think that sometimes some of the junior doctors don't necessarily check the blood pressure on every clinic visit, so I suppose in terms of flagging up awareness of the importance of blood pressure that perhaps something that we need to look at across the clinic is getting the blood pressure done by the nursing staff so that it's always there, it's always something that we look at and have to respond to.

In: Another concern is that maybe the proper patients aren't referred, the patients who need it the most. Maybe that's a connection to the referral form. Do you have any comment on that?

C9: Within the nephropathy category I suppose that a lot of those patients would often get referred or perhaps only get referred to the joint diabetes renal clinic. I suppose the assumption would be to have referred them there and they will take on control the blood pressure. Now, whether again perhaps that clinic isn't able to see people frequently enough to get their blood pressure under control, and perhaps there needs to be closer links between the renal clinic and the hypertension clinic. Again, sometimes with the macrovascular disease patients that there's sometimes uncertainty about whether we're driving the change in blood pressure or whether it's the cardiologist who's seeing them who's driving change in blood pressure, and I suspect that sometimes there might be a delay in tightening up control because they're assuming that we're doing it, and we're assuming they're doing it. So, perhaps better communication is needed there.

In: Do you think the reasons for referral detailed on the current, are specific enough?

C9: I think so, yes. I have to confess here that, it's been a while since I've looked at the form because I haven't referred anybody for a while, but I have really only referred people for blood pressure control. I haven't referred them for lipid lowering therapy or smoking cessation advice or general cardiovascular disease advice or antiplatelet therapy. I mean, since antiplatelet therapy is often a decision we can make there and then in clinic, where things like lipid lowering and smoking cessation, I think that either require titration of treatment or multiple follow up visits. I think those would be too very appropriate reasons for referral, which I probably underused in the past. I would certainly, I think start referring more people on the basis of those criteria.

In: One option would be to switch the referral criteria and the reasons for referral to make the referral criteria more specific. Do you have any comment on that? To ensure that the proper patients get referred?

C9: So basically make referral criteria the reasons for referral.

In: Yes.

C9: I mean, that would probably be OK, because at the end of the day, the patients with nephropathy and the patients with macrovascular disease are being referred usually for blood pressure control or lipid lowering therapy, so I think the reasons for referral would cover all of the indications. Then, in terms of what we said earlier, that perhaps an additional referring criterion should be patients with retinopathy who have troublesome blood pressure that would come under the current reasons for referral, so I think that would certainly catch the at risk patients.

In: Just to make one thing a bit more clearly; why would you refer patients with only the retinopathy?

C9: Well, for blood pressure control. I mean if you've got retinopathy and currently excellent blood pressure I wouldn't refer them to the clinic, but it's really because in that context good blood pressure control reduces the risk of further haemorrhages or progression of the retinal disease. So, you know, although that's not really fitting in on the cardio-side of the cardiovascular clinic, it is a microvascular complication, and really nephropathy is a microvascular complication, so I think in those patients with nephropathy are eligible for the clinic for blood pressure control. I think patients with retinopathy probably should be considered as well, because they can benefit from having good blood pressure control as well.

In: Is there something else you would change on the current form?

C9: It might be useful to have, I mean there is a bit of space at the bottom of the form, but it might actually be useful just to insert a sort of a free text box for any comments. I mean, the comments would be in the previous letters, but for efficiency for the person who's been seeing this patient in the cardiovascular clinic, it would be useful to have something along the lines of "previously tried amlodipine, got peripheral oedema, developed cough on ACE inhibitor and hyperkalemia on ARB". Just to sort of note down perhaps some of the

challenges or difficulties in the past, it wouldn't necessarily mean to fill that in on every patient but it just save to the person in the cardiovascular risk clinic having to trawl through 4 or 5 letters. If I have to trawl through the same 4 or 5 letters in my clinic, I may as well summarize, the main points there, so I think that would be only thing, just a short free text area for any useful comments, you know, about the patient that could be added in there.

In: You don't think that would be more time consuming?

C9: I mean, literally it just would be a sort of 3 of 4 lines thing saying, you know, "oedema on calcium channel blocker, arrow up potassium on ACE inhibitor", you know, it would take 2 minutes, maximum, to write. I mean the alternative is just that the person who sees them in clinic sifts through all the past clinic letters, but I think it's not unreasonable when you're referring somebody to another service to have a quick summary of the main issues, for example when we refer patients to the diabetes specialist nurses there's a free text box for us to sort of really outline the reasons for referral. And while, you know, blood pressure control is the reason for referral it may go beyond that and it usually does. So it's usually blood pressure control in somebody who has already been intolerant of a number of medications or who's had side effects from a number of medications, so it just saves you from sort of reading through lots and lots of letters to glean that information again.

In: Would cut-offs or scores be more useful?

C9: Well, again you may get different impression speaking to the junior doctors in the clinic, but I think we're all pretty aware of the kinds of cut-offs and targets for blood pressure and lipids for our various patients so I'm not sure that that necessarily be helpful. I mean again, the kinds of patients who we're referring are usually the people who are miles away from those targets, or who are really close to the targets but are needing 4 or 5 antihypertensive agents for example to keep them there, so I don't think that would particularly be helpful. But as I say you might get a different the junior doctors.

In: Should there be any other additional actions requested?

C9: Again I mean, not wanting to make the form too cumbersome, but I suppose it wouldn't be unreasonable from your point of view to ask what their cholesterol was or what their last blood pressure was. Again when we refer to the diabetes nurses, you know, there's a space on the form to say what was their last HbA1c. If we're asking them to improve their glycaemic control, it's reasonable for us to put down what baseline we're starting from. So that might be actually some additional useful information from the clinics point of view rather than the referring clinician's point of view.

In: What about a box for adherence or lifestyle management?

C9: Yes. I mean again, that's sometimes is an issue with a lot of patients, it's really concordance with medication. So, yes, that would be a useful tick-box to have.

In: Do you think the form should include recommendations for management?

C9: It's difficult because often, again as I say, the patients we're tending to refer, tends to be the difficult patients or ones where we've tried the basics. My understanding is that there are

protocols that the cardiovascular clinic works to. In a sense to second guessing there are protocols and putting my own little mini protocol of what I'm expecting seems almost a bit counterproductive. So, I don't know that that would necessarily be helpful. There may be some patients where it's clear to us that we're never going to achieve the target that the guidelines state. But again, that's where the free text box for any other comments would be useful, because for example I might say, you know, "would be good to achieve a blood pressure of 150/85", I know we're never going to get down to target but at the moment we're sitting 200/110. So something like that might be useful, but I just wonder whether it might constrain and limit people in the clinic where actually what we're saying is that this is a difficult case, we think in the clinic you have the resources to manage it and we would like you to take this over, perhaps me imposing my recommendations actually just restrict the functions of the clinic, I think.

In: Do you have anything else you would like to say or add?

C9: No, I think that's probably covered all the aspects of the form.

In: Thank you very much.

Appendix 6: Analysis of interview

Analysis of interview with Clinician 1

Awareness of the clinic

- Aware of the clinic: yes.
- Referring patients: yes.
- Aware of referral form: yes.
- Using the referral form: yes, when referring someone who hasn't been referred before.
- Advantages/disadvantages about the clinic
 - o Obvious reason for attending the clinic: More frequent follow up about BP, monitor response to lipid lowering therapy and adjust it at a more regular interval than with the standard hospital clinic

Referral practice (own process)

- Reasons for referral
 - o Difficulties in controlling BP
 - o Patients on multiple agents
 - o Want to get to target
- Considerations
 - o Is the patient adherent to medication prescribed
 - o When the interval between clinical appointments, or referral back to GP isn't appropriate
 - o History of hypertension problems

When in the patient journey would you refer?

- New patients
- Also patients who's been on the system for a while where BP and/or renal function has become an issue
- Unusual to see a patient 2 or 3 times, patient see different doctor each time, so potentially anywhere in the patient journey

Referral criteria

- A lot of the information is already dictated in the clinical letter
- Cut-offs/scores: No, rather have it fairly open-ended than kind of one-size fits all approach

Referral form

- A fairly non-specific form is a good thing
- Easy to use, less time consuming

Recommendations for improvement

- Something on the form that states what the ideal target would be for an individual patient
- Space for you own comments
- Additional actions: the remit of the cardiovascular clinic is fairly clear
- Not sure how useful antiplatelet therapy is as a reason for referral to the risk clinic, something we can manage ourselves
- Recommendations for management: Doesn't feel this would add value as from a clinicians point of view you have a management plan following review if the patient

Analysis of interview with Clinician 2

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Yes
- Aware of the referral form: No
- Consider using the referral form: Yes, as long as there isn't too much to tick off, there is already mountains of paper work
- Advantages/disadvantages about the clinic

Referral practice (own process)

- Reasons for referral
 - o If someone has persistently high lipid profile, if they have a very high BP and secondary causes such as renal artery stenosis, family history of dialysis, polycystic kidney disease ruptured aneurism, stroke at young age has been out ruled.
 - o I would have a low threshold for investigating the patients for secondly hypertension
 - o High blood pressure which hasn't been controlled, after excluding secondary causes
 - o Lipids which are still suboptimal, having gone through maybe the spectrum of simvastatin, atorvastatin, rosuvastatin
- Considerations
 - o Because it's a pharmacist, the patients can also talk to a pharmacist, and they give a different perspective
 - o Give's an extra perspective about long term risk if they don't comply with their first medications
 - o Gives extra knowledge to the patient about diabetes, BP, lipids, and puts them all together

When in the patient journey would you refer?

- Suppose I wouldn't have a specific point at the moment

Referral criteria

- Macrovascular disease would be a very strong reason for referring
- When it comes to nephropathy I think we're getting the renal clinician involved, but I think the pharmacist would contribute a very additional important role here because of necessary changes in medication when the patient have a renal problem, such as the saxogliptin, sitagliptin and even antibiotics
- Blood pressure certainly would be another referral criteria, also general cardiovascular advice and lipid lowering therapy
- Not so much smoking cessation advice, cause there is a specific smoking cessation officer
- Mostly blood pressure control, general cardiovascular advice, lipid lowering therapy and referred macrovascular disease
- Recommendations of management: yes, that would probably be helpful

Referral form

- The macrovascular is quite vague
- If you use numbers for the nephropathy, the one concerns here would be you also include maybe creatinine or an eGFR maybe for renal referral

Recommendations for improvement

- Any information should be added: Blood pressure levels/readings
 - o Maybe a colour coding of red in the high zone and green, almost like a traffic light, green going into yellow going into red, in a big arrow
 - o It might be a picture that tells better the story, perhaps a series of columns or tick boxes
- Any information should be removed: I guess less is more, but this is quite simple
- An own comment field: Yes, that would be helpful, give a little of the patient's history, why you are concerned about them, and what you want to achieve by referring them

Analysis of interview with Clinician 3

Awareness of the clinic

- Aware of the clinic: No
- Referring patients: No
- Aware of the referral form: No
- Using the referral form: it probably was discussed with me when I first started, but I didn't realise that this was the precise form that I'd use
- Advantages/disadvantages about the clinic
- Didn't realise smoking cessation advice was available in-house

Referral practice (own process)

- Reasons for referral
- Considerations

When in the patient journey would you refer? ---

Referral criteria

- Would like more details
- For example BP control: would you like the patient to be referred or would you like confirmation of BP to be monitored first, before the referral was made?
- Otherwise; seem pretty straight forward
- The difference between the referral criteria and the reasons for referral is a bit unclear
- If it was just a BP issue, would I make the referral; not quite clear on that
- Easier if the boxes were another way around
- Cut-offs/scores: yes, just put in a couple of numbers, gives you a guidance, at least you know then which group of patient are of interest
- Also says "must tick at least on"; that kind of implies if there was just one issue you could make an appropriate referral

Referral form

- More detailed referral form, more time consuming: Don't think so
- More detailed information should be added: Yes

Recommendations for improvement

- Would add a few key points with the macrovascular and/or the nephropathy categories, the form won't change that much
- Once you've made a couple referrals the form should be familiar with you and shouldn't take more time
- Should be detailed how many ticks before an appropriate referral can be made
- Any information removed: No, most things here are relevant
- Comment field is a reasonable thought, could extend your reason for referral, add if there was something peculiar about the referral that didn't fit into any of the boxes.

Analysis of interview with Clinician 4

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Not very often, but have done in the past
- Aware of the referral form: Yes, haven't looked at it for a while
- Using the referral form: Yes, last time a year or so ago
- Advantages/disadvantages about the clinic
 - o Good way of passing them to someone who can see them quite frequently and make sequential adjustments in doses or choice of drugs

- Been tending to think of the cardiovascular clinic as targeted at patients with uncontrolled BP, or potentially lipids, who either have established or high risk of cardiovascular disease
- I need to see exactly what people are prepared to offer here
- A very useful service for patients where you yet somehow not quite winning and you can't see them all that often
- Haven't used the clinic that much, why: maybe I haven't seen that many patients where I felt I was really struggling, and just possibly cause I forget about it

Referral practice (own process)

- Reasons for referral
 - Patients where you're really struggling with BP
 - Patients who's been on a few antihypertensives and they haven't been effective
 - Ideally, if the BP is fine, they're not a person for the clinic
- Considerations
 - When it is quite difficult in the context of the diabetes clinic to see them often enough to titrate drugs, change drugs
 - When you've been referring back to the GP, or the practice nurse for measurements, but you just not really somehow getting there

When in the patient journey would you refer?

- Not after once, but probably after a couple of times

Referral criteria

- Feel that patients with macrovascular disease or very high risk of macrovascular disease will be targeted
- Was not aware of the smoking cessation advice box, might have forgotten about it
- Referral criteria are specific enough
- Not fully taken in that nephropathy was on the form
- Cut-offs/scores: I guess that would make it a bit more obvious, make it more clear who they want to see and don't want to see

Referral form

- Space enough to write on the form if you want to explain a little bit more
- Any other information needed: clinical letter
- Add a comment field: Wouldn't let that inhibit me, I just write on it

Recommendations for improvement

- Given the discussion, a little more space to write own thoughts would be useful
- The clinic letter will always be there and provide the information needed
- Recommendations of management: I think the trouble about that is if the BP or the lipids are above a certain value you will try something that you hope will succeed, first time off, so it's more about that your first line attempts haven't been successful
- Any information to be removed: No

Analysis of interview with Clinician 5

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Yes
- Aware of the referral form: Yes
- Using the referral form: Sending a copy of the clinic letter
 - o Just a lot more convenient
 - o Probably just laziness
- Advantages/disadvantages about the clinic
 - o The clinic is very very important, it provides us with a lot of help and information, and to achieve a number of things that we wouldn't be able to achieve in the clinic

Referral practice (own process)

- Reasons for referral
 - o Cardiovascular risk management
 - o Primarily blood pressure control
 - o Someone with fairly heavy proteinuria with poor blood pressure control
 - o Some lipid control
- Considerations
 - o The clinic is a good way of achieving repeated reviews
 - o Good way to achieve blood pressure target
 - o Difficult to control BP; one of the key things to think about then is lack of compliance

When in the patient journey would you refer? -----

Referral criteria

- Nephropathy is reasonable
- Macrovascular disease is a bit vague, you're trying to prevent macrovascular disease, primary prevention
- Would definitely put blood pressure as a referral criteria
- Would prefer that we put people who didn't have macrovascular
- Microalbuminuria in the context of primary prevention is a very significant part of cardiovascular risk – they're the people I would be looking at
- Nephropathy would indicate that we're missing people who've got microalbuminuria with high cardiovascular risk

Referral form

- The form is very straight forward
- Reasons for referral section: very specific
- Add compliance/adherence: that would be in the letter, rather than to tick on the form

Recommendations for improvement

- Not sure I would refer for smoking cessation advice – other ways of doing that
- Because resources are tight we've got more to gain from the clinic by looking at mainly blood pressure control and lipid lowering therapy
- Would keep blood pressure control, lipid lowering therapy and general CVD advice
- Not sure antiplatelet therapy or smoking cessation advice are necessary
- Good to have an other-box
- Don't think that cut-offs/scores would be a good way of streamlining things, but we could work out a percentage risk using the cardiovascular risk calculators
- A scoring system might be best
- You could broaden the referral criteria if you don't feel that enough people are referred, so you have difficult to control BP, difficult to control lipids, take the macrovascular disease and because by addressing BP and lipids you're addressing the chance of that happening
- Split the nephropathy-box into microalbuminuria or nephropathy
- It might be a problem that people aren't referred, people aren't being identified – maybe we need to increase the awareness of it
 - o A reason might be that there is a lot of staff moving through
- There's a lot of people that don't see their primary care physician, and they don't get integral blood pressure checks, this clinic is actually a very good way of doing that and get records of peoples blood pressure and actually getting it sorted so I actually think that the clinic is very helpful
- An own comment field: I would broaden out more in the clinic letter anyway, wouldn't add too much more due to the duplication, would also be more time consuming

Analysis of interview with Clinician 6

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: On occasion, yes
- Aware of the referral form: No
- Consider using the referral form: yes, absolutely
- Advantages/disadvantages about the clinic
 - o Didn't know that the clinic would help with lipid lowering therapy
 - o This is the first time I've seen the form
 - o Think it's an under-used resource

Referral practice (own process)

- Reasons for referral
 - o Mainly patients with real difficulties to control BP and there are more than one agent
 - o Always refer them BP monitoring so I can get an accurate BP value
- Considerations
 - o Important to have the lipid profile done
 - o Cardiovascular risk conflicts
 - o Smoking
 - o Family history

When in the patient journey would you refer?

- In the meet point in their on-going management at the diabetes clinic with uncontrolled hypertension
- Not a general number

Referral criteria

- You can't refer all the patients with macrovascular disease or nephropathy
- Most of these things we are able to manage anyway
- Antiplatelet therapy is something we're not as good at, will be thinking a bit more about that in the future
- Haven't referred anyone for lipid lowering therapy, would call one of the consultants at the lipid clinic if I got a major lipid issue and ask them for advice
- BP box is generally the one I would tick
- They are very general, more specific criteria would help me to refer patients, I think
- Switch the reason for referral with the referral criteria: absolutely, yes
- Cut-offs/scores: don't think you could say there's a predictive value, it might depend on the age, so don't think that would be very helpful
 - o Maybe if you said somebody with cardiovascular risk of more than 20 per cent who's also under the age of 60, that might be helpful

Referral form

- An own comment field: I think your own thoughts would be in the clinic letter, but wouldn't do any harm

Recommendations for improvement

- Would say to make a specific range of nephropathy, and to what duration or despite goes through this sort of treatment
- Split macrovascular disease into recent coronary event that you don't think is being managed properly or peripheral vascular disease that is painful
- Having more specific criteria would help if you're a new doctor here
- At the start of each attachment there should be a short introduction session for the new doctors to tell them about the clinic and what it does and can help with and what kind of patients you can refer
- Offering the clinic to the new doctors
- Need a better form and better education of staff
- Recommendations of management: yes, something like "if the BP remains above this value despite..."

Analysis of interview with Clinician 7

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Very rarely
- Aware of the referral form: No
- Consider using the referral form: Yes

- Advantages/disadvantages about the clinic
 - o Tend to forget, not sure how the clinic fits in to the overall picture of everything

Referral practice (own process)

- Reasons for referral
 - o Not well controlled BP, either because they were having difficulties in their medication or they're on a number of drugs already
- Considerations
 - o The patient's diet and exercise
 - o Not smoking
 - o The three bloods: blood pressure, blood glucose and blood cholesterol

When in the patient journey would you refer?

- Any stage, it could be someone who's had high BP for a long time but are new to the clinic

Referral criteria

- If I think of cardiovascular I might just also include BP
- Maybe the macrovascular is a bit too vague for referral criteria
- Switching the reasons for referral with referral criteria: Yes, that's more practical, that's more useful because it would say what I'm looking for
- Cut-offs/scores: No, because different people seem to have different scores, there would be a little bit of fluctuation in each person

Referral form

- An own comment field: yes, that would be helpful, just to put any additional comments
- Any other detailed information should be added: we ask about lifestyle and such anyway, and patients might say different things each time, so don't think that would be helpful
- More specific referral form, more time consuming: That wouldn't bother me too much, no

Recommendations for improvement

- More dialogue with the pharmacist about the appropriateness of the referral
- Would like some kind of feedback from referrals or feedback about the outcomes of the clinic

Analysis of interview with Clinician 8

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Sometimes

- Aware of the referral form: Not immediately, no, I would send a letter
- Consider using the referral form: -
- Advantages/disadvantages about the clinic
 - o Haven't referred too many patient lately, maybe that's not a good thing
 - o Having the form is reasonable, but my practice of referral is copying the clinic letter
 - Less time consuming, more detailed information about the referral
 - o Advantage: frequent review
 - o Advantage: pharmacy expertise to educate the patient about the medications and to look at compliance and concordance issues
 - o That is also an added value for the patients
- Don't recognise the form, difficult to see the difference between the referral criteria and the reasons for referral

Referral practice (own process)

- Reasons for referral
 - o Poorly controlled BP
 - o The patients we put some work trying to improve their BP but it just doesn't seem to be happening
 - o It would be the BP more than anything
- Considerations
 - o I want them to be seen more frequently
 - o Not so much lipids, I think BP is a more challenging parameter to treat

When in the patient journey would you refer?

- It would be unusual to send someone without having seen them in the general clinic 2 or 3 times
- In general it will be very variable

Referral criteria

- Reasonable to have macrovascular disease and nephropathy on it
- We already have a smoking cessation advice service, so not sure about that being there
- The main one I would be dealing with is BP
- I think we can sort out both antiplatelet therapy and lipid lowering therapy ourselves
- There may be patients without macrovascular disease or nephropathy but who has difficult to control BP

Referral form

- Creating a form which requires more filling in would be a bigger barrier to referral
- Information should be removed: No
- Recommendations of management: No, that's individual

Recommendations for improvement

- More detailed information added: I think that's all available in the clinic letter

- Clinicians don't refer patients: think we need to raise the profile of the clinic within our service
 - o Don't think the form is the issue
 - o It's the thinking that this is a good idea
 - o Must be reminded about the profile of the clinic
- It is a useful service, and if we're not using it, then we need to look at that and think about how we can use it better.

Analysis of interview with Clinician 9

Awareness of the clinic

- Aware of the clinic: Yes
- Referring patients: Yes, have referred some patients in the past
- Aware of the referral form: Yes
- Using the referral form: Used it in the past when referring someone
- Advantages/disadvantages about the clinic
 - o Need to raise the awareness of the clinic, particularly amongst the junior trainees and it may be that they are not specifically aware of the ability to refer in to the hypertension clinic

Referral practice (own process)

- Reasons for referral
 - o If someone needs quite intensive management to their BP
 - o Need more frequent follow up
 - o Patients who have gone beyond 1 or 2 agents and the GP might be struggling with further choices of hypertensive agents
 - o Patients with either nephropathy or retinopathy who are at high risk and we can't get the BP down
 - o Referring patients with retinopathy because of better blood pressure control
- Considerations
 - o Somebody with difficulties to control blood pressure where we haven't managed to control their blood pressure on two or three agents
 - o Patients who need more follow up to titrate up their medication
 - o Would in the early stages suggest to the general practitioner to initiate an ACE inhibitor, titrate up, recheck U&E's as such an interval, blood pressure target such and such – and save more complicated patients for later
 - o Good BP control reduces risk of further haemorrhages or progression of the retinopathy

When in the patient journey would you refer?

- Not any particular, for example; might see a patient for the first time but the patient has been in the system for a very long time
- Would depend on what their BP like, how many drugs they're on
- If they have complications
- Can't bring them back to the clinic for another 3 or 4 months, and it's someone who needs more frequent follow up than that for their BP

Referral criteria

- They are both very reasonable criterion, the macrovascular disease and the nephropathy
- Would be good to add a third criteria – retinopathy, because for patients with retinopathy, good BP is beneficial and they would benefit from access to the clinic
- They don't necessarily need to have either of the 2 current referral criteria
- Think the referral criteria are specific enough, they need to be broad enough in order to catch all of the people that you need
- Reasons for referral: they are specific enough, really only refer people for BP control
 - o Haven't referred them for lipid lowering control or smoking cessation advice or general CVD or antiplatelet therapy
 - o Antiplatelet therapy is a decision we often make in the clinic
 - o Lipid lowering and smoking cessation either require titration of treatment or multiple follow up visits, but they are 2 very appropriate reasons for referral which I've probably underused in the past

Referral form

- Cut-offs/scores: think we're already aware of the kind of cut-offs and targets for BP and lipids for the various patients so not sure that that's necessarily helpful
 - o The kind of patients we're referring are those who are miles away from those targets or really close to those targets but need 4 or 5 antihypertensives to be close to the target
- Adherence/compliance: that's an issue with a lot of patients so think that would be helpful
- Include recommendations for management: the patients we're tending to refer, tends to be the difficult patients or ones where we've tried the basics, so don't know that that would necessarily be helpful
 - o May be some patients where it's clear that we're never going to achieve the target stated in the guidelines
 - o Perhaps me imposing my recommendations actually just restrict the functions of the clinic

Recommendations for improvement

- Could specify nephropathy bracket CKD stage 3 or beyond because you don't want the clinic to be clogged up with people with very mild degrees of nephropathy
- In reality the referral clinicians would have enough common sense to pick people that have a reasonable degree of complications so don't think they necessarily need to be more specific than they are
- Might be more beneficial for the junior doctors or the new doctors to have the referral criteria a bit more specific
- It would be useful to have the blood pressure done already if someone has an initially high blood pressure and then you'll see them in the clinic and when you recheck, it's perhaps a little bit lower, and you then got two blood pressure readings for that one clinic
- It is a reality that on busy clinic days the blood pressure isn't getting checked for you
 - o Some of the junior doctors don't necessarily check the blood pressure on every clinic visit
 - o Need to flag up the awareness of the importance of blood pressure

- Need to look at across the clinic is getting the blood pressure done by the nursing staff so that it's always there, it's always something that we look at and have to respond to
- The proper patients aren't referred: Within the nephropathy category I suppose that a lot of those patients would often get referred or perhaps only get referred to the joint diabetes renal clinic
- Perhaps there needs to be closer links between the renal clinic and the hypertension clinic
- Whether we're driving the change in blood pressure or whether it's the cardiologist who's seeing them who's driving change in blood pressure; suspect that sometimes there might be a delay in tightening up control because they're assuming that we're doing it, and we're assuming they're doing it - perhaps better communication is needed there
- Think that making the reasons for referral the referral criteria is OK
 - Think the reasons for referral would cover all of the indications
 - An additional criteria should be added – patients with retinopathy who also have troublesome BP
- Would be useful to add some space at the bottom, like a free text box for any comments
 - The comments would be in the clinic letter but it would be more efficient for the person who's seeing the patient at the clinic
 - Just to say what you've previously used or tried
 - Just to note down some of the challenges or difficulties in the past
 - Not unreasonable when you're referring somebody to another service to have a quick summary of the main issues
- Additional actions added: wouldn't be unreasonable from your point of view to ask what their cholesterol was or what the BP was
 - It might sometimes be reasonable to say what the baseline we're starting from

Appendix 7: Diabetes Liaison Nurse Referral Form

DIABETES LIAISON NURSE REFERRAL SHEET

PATIENT DETAILS/ADDRESSOGRAPH	TELEPHONE NUMBER

HbA1C RESULT AND DATE:

ACTION REQUIRED

- | | |
|--|--|
| <input type="checkbox"/> RE-EDUCATION | <input type="checkbox"/> PRE-PREGNANCY |
| <input type="checkbox"/> TYPE 2 CONVERSION | <input type="checkbox"/> TRAVEL ADVICE |
| <input type="checkbox"/> CHANGE OF INSULIN | <input type="checkbox"/> GLUCAGON ADMINISTRATION |
| <input type="checkbox"/> IMPROVE CONTROL | <input type="checkbox"/> COMMENCEMENT OF HBGM |
| <input type="checkbox"/> COMMUNITY FOLLOW-UP | <input type="checkbox"/> OTHER |

COMMENTS:

HBGM: PLEASE SPECIFY:
TIME(S) OF DAY _____
NUMBER OF DAYS PER WEEK _____
TARGET BGM _____

INSULIN PRESCRIPTION WITH STARTING DOSES:

MISCELLANEOUS:

DOCTOR'S SIGNATURE: _____ DATE: _____

C:\Documents and Settings\kathleen.gough\Local Settings\Temporary Internet Files\OLK15\DIABETES LIAISON NURSE REFERRAL SHEET.doc

DIABETES LIAISON NURSE ACTION

DATE: _____

[Large empty rectangular box for notes or action items]

NAME: _____
SIGNATURE: _____

Appendix 8: The Diabetes Dietician Referral Form

DIABETES DIETITIAN REFERRAL SHEET

PATIENT DETAILS/ADDRESSOGRAPH	TELEPHONE NUMBER

HbA1c RESULT:

WEIGHT:

BMI:

DIETARY ADVICE REQUIRED BECAUSE OF

- | | |
|--|--|
| <input type="checkbox"/> WEIGHT GAIN | <input type="checkbox"/> RAISED HBA1C |
| <input type="checkbox"/> UNEXPLAINED WEIGHT LOSS | <input type="checkbox"/> RAISED LIPIDS |
| <input type="checkbox"/> GENERAL UPDATE ON DIET | <input type="checkbox"/> OTHER:..... |

PRESENT TREATMENT

- | |
|----------------------------------|
| <input type="checkbox"/> DIET |
| <input type="checkbox"/> OHA'S |
| <input type="checkbox"/> INSULIN |

COMMENTS

DOCTOR'S SIGNATURE:..... DATE:.....

Appendix 9: The Rheumatology Nurse Specialist Referral Form



RHEUMATOLOGY NURSE SPECIALIST REFERRAL

URGENT
2 – 4 days

NON URGENT
4 – 14 days

CNS REVIEW
3month

PATIENT TELEPHONE

PATIENT DETAILS:	CONSULTANT: DIAGNOSIS:
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ERA & SERA REFERRAL

CXR taken?	YES	NO	SERA PI provided?	YES	NO	DAS28 taken?	YES	NO
Hands/feetXray taken?	YES	NO	MTX/steroid PIL provided?	YES	NO	Patient asked to see GP 10 days hence	YES	NO
Bloods completed?	YES	NO	DEXA ordered?	YES	NO		YES	NO

VISUAL ACUITY	AMSLER	SCHIRMERS	SHORT SYNACTHEN	SALIVA TEST	DISEASE EDUCATION Issue ARC leaflet/ website information	DRUG COUNSELLING SWITCH to Subcut	PLEASE PRINT CLEARLY DRUG: DOSE:
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PRESCRIPTION KARDEX REQUIRED AS APPROPRIATE PLEASE

SAB LT RT	GHJ LT RT	ELBOW LT RT	WRIST RT LT	KNEE LT RT	ANKLE LT RT
--------------	--------------	----------------	----------------	---------------	----------------

ADDITIONAL INFORMATION:
PLEASE PRINT CLEARLY

DATE:	DOCTORS SIGNATURE:
-------	--------------------

ABOVE REQUEST COMPLETED

VISUAL ACUITY	R	L	Disease / Drug Information given.	CNS SIGN: DATE:	
AMSLER	R	L		Drug counselling Check list to be issued to patient please.	TELEPHONE COUNSELLING
SCHIRMERS	R	L			
SHORT SYNACTHEN					
SALIVA TEST					

JOINT ASPIRATED / INJECTED	AMOUNT RT	AMOUNT LT	CNS SIGN: DATE:	
AS PER PROTOCOL & PRESCRIPTION	COLOUR RT	COLOUR LT	PATIENT SIGN: DATE:	

PLEASE FILE IN MEDICAL RECORDS ON COMPLETION VERSION2FEB11 AMC REV 2/12

Appendix 10: Diabetes Cardiovascular Risk Reduction Clinic Referral form

<i>Patient details</i>	
(Addressograph) Name	Date of referral
Address	Referring doctor (Capital letters)
DOB: _____ Chi-number: _____	
<i>Referral criteria</i>	
Systolic BP > 130 mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Diastolic BP > 75 mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Cholesterol > 4 mmol/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
Microalbumin > 2.5 mg/mmol	<input type="checkbox"/> Yes <input type="checkbox"/> No
Signs of retinopathy	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>Additional information</i>	
Unsuccessful treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Suspected poor compliance	<input type="checkbox"/> Yes <input type="checkbox"/> No
Smoking cessation	<input type="checkbox"/> Yes <input type="checkbox"/> No
HbA1c: _____ mmol/L	
BMI: _____ kg/m ²	
Other: _____	
<i>Relevant past medical history</i>	
Angina <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Stroke <input type="checkbox"/> Renal artery stenosis <input type="checkbox"/>	
<i>Comments</i>	
Doctor's signature:	

Version date 20.03.12

Appendix 11: Table 5.3.5

Table 5.3.5 Calculations of number of patients identified from combinations with other criteria with the combination systolic BP >135 mmHg and/or microalbumin and/or retinopathy as initial combination

Criterion	Total numbers of patients meeting at least one criterion in each combination	Proportion of total study sample (%) (n=944)	Total number of patients referred meeting at least one criterion in each combination	Proportion of patients referred (%) (n=48)
SPB ¹ >135 mmHg +/- DBP ² >75 mmHg +/- Cholesterol ³ +/- Microalbumin ⁵	746	79.0	42	87.5
SPB>135 mmHg +/- DBP>80 mmHg +/- Cholesterol ³ +/- Microalbumin	658	69.7	41	85.4
SPB>135 mmHg +/- DBP>80 mmHg +/- Microalbumin +/- Retinopathy ⁶	662	70.1	42	87.5
SPB>135 mmHg +/- DBP>75 mmHg +/- Microalbumin +/- Retinopathy	746	79.0	42	87.5
SPB>135 mmHg +/- Retinopathy +/- Cholesterol ⁴ +/- Microalbumin	797	84.4	42	87.5
SPB>135 mmHg +/- Retinopathy +/- Cholesterol ³ +/- Microalbumin	682	72.2	42	87.5
SPB>135 mmHg +/- DBP>80 mmHg +/- Cholesterol ⁴ +/- Microalbumin	783	82.9	42	87.5
SPB>135 mmHg +/- DBP>75 mmHg +/- Cholesterol ⁴ +/- Retinopathy	817	86.5	37	77.1
SPB>135 mmHg +/- DBP>75 mmHg +/- Cholesterol ³ +/- Retinopathy	732	77.5	33	68.8
SPB>135 mmHg +/- DBP>80 mmHg +/- Cholesterol ³ +/- Retinopathy	654	69.3	33	68.8
SPB>135 mmHg +/- DBP>75 mmHg +/- Cholesterol ⁴ +/- Microalbumin	829	87.8	42	87.5
SPB>135 mmHg +/- DBP>80 mmHg +/- Microalbumin +/- Retinopathy	662	70.1	42	87.5
SPB>135 mmHg +/- DBP>75 mmHg +/- Microalbumin +/- Retinopathy	746	79.0	42	87.5

¹Systolic Blood Pressure, ²Diastolic Blood Pressure, ³Cholesterol above new target (>5mmol/L), ⁴Cholesterol above target (>4mmol/L), ⁵Microalbumin above target (>2.5 mg/mmol), ⁶Positive for retinopathy.

Appendix 12: Diabetes Cardiovascular Risk Reduction Clinic Referral form

Patient details	
(Addressograph) Name	Date of referral
Address	Referring doctor (Capital letters)
DOB: _____ Chi-number: _____	
Referral criteria (Tick at least two yes)	
Systolic BP > 130 mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Diastolic BP > 80 mmHg	<input type="checkbox"/> Yes <input type="checkbox"/> No
Cholesterol > 5 mmol/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
Microalbumin > 2.5 mg/mmol	<input type="checkbox"/> Yes <input type="checkbox"/> No
Additional information	
Signs of retinopathy	<input type="checkbox"/> Yes <input type="checkbox"/> No
Unsuccessful treatment	<input type="checkbox"/> Yes <input type="checkbox"/> No
Suspected poor compliance	<input type="checkbox"/> Yes <input type="checkbox"/> No
Smoking cessation	<input type="checkbox"/> Yes <input type="checkbox"/> No
HbA1c: _____ mmol/L	
BMI: _____ kg/m ²	
Other: _____	
Relevant past medical history	
Angina <input type="checkbox"/> Myocardial infarction <input type="checkbox"/> Stroke <input type="checkbox"/> Renal artery stenosis <input type="checkbox"/>	
Comments	
Doctor's signature:	

Version date 18.05.12

Appendix 13: Project Protocol

Project protocol

Review and development of referral criteria used to identify patients with diabetes who would benefit from attending a pharmacist-led cardiovascular risk out-patient clinic at the Western General Hospital, Edinburgh

Investigator

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Introduction

Diabetes mellitus is a worldwide problem because of the chronic features and its economic impact, and it is becoming an international healthcare crisis. Because of its complexity there is an enormous need for more pharmacists who are specialised in this field¹. Macrovascular complications (e.g. cardiovascular diseases, cerebrovascular disease and peripheral vascular disease) are counting for 50 % of deaths in patients with type 2 diabetes mellitus². Cardiovascular disease is responsible for over a quarter of deaths in Scotland³, and in the whole of UK cardiovascular diseases count for about 80 % of deaths in patients with type 2 diabetes mellitus⁴.

A study performed on patients with type diabetes mellitus to evaluate pharmaceutical care found that patients managed by a clinical pharmacist were associated with higher rate of patient satisfaction to their treatment and an improvement in control of blood glucose and blood pressure. During follow-up patients had less concerns and anxieties in relation to their disease and future complications¹. In a study performed to determine the efficacy of the Pharmacist-led Diabetes Cardiovascular Risk Clinic (DCVR) the researches set up a pharmacist-led clinic where a pharmacist would monitor blood pressure, total cholesterol and follow up the patients. This study showed that the patients had a decrease in blood pressure with an average of 13/9 mmHg after attending the clinic. Total cholesterol also decreased and remained low at follow-up, which was approximately every six weeks. Increased patient compliance was considered a contributing factor to these outcomes⁵. A study evaluating pharmaceutical care on patients with diabetes mellitus at the DCVR found 51 pharmaceutical care issues resulting in changes in patients medications. The study concluded that the pharmacists ensure safety and effectiveness in the treatment of diabetic patients⁶.

Clinicians refer patients with hypertension, hyperlipidaemia and/or hyperglycaemia to the DCVR and complete a referral form. It is known that not all suitable patients are referred to the clinic. Some suitable patients might never be referred at all, while unsuitable patients do get referred. The origin of this situation might have something to do with the specificity, usability, and availability of the referral form and medical team awareness of the DCVR. It is also known that there are limited pharmaceutical resources to manage all patients. Therefore it is very important that the proper patients get referred to the clinic.

This study will explore perceptions of clinicians about referring patients and try to develop more specific referral criteria.

Aim

To develop new referral criteria used to refer patients to the DCVR by the clinicians. To test the sensitivity and specificity of the new referral criteria.

Objectives

1. To identify obstacles in referring patients to the pharmacist-led clinic by gathering perceptions of hospital clinicians about the current referral form and its use.
2. To develop and propose new referral criteria from the results of objective 1, and to discuss them with the lead consultant diabetologist and lead pharmacist for the Pharmacist-led Diabetes Cardiovascular Risk Clinic.
3. To test the sensitivity and specificity of various cut-off measures/scores to inform reliability of new referral criteria.

Subjects and setting

Clinicians from the Western General Hospital, Edinburgh, whom may refer patients to the Pharmacist-led Diabetes Cardiovascular Risk Clinic will be identified and invited to take part in the project.

Advice will be sought from the scientific officer for the South East Scotland Research Ethics Service as to whether or not application for research ethics approval is necessary. If necessary an IRAS application will be made. If not, a clinical governance project proposal form will be completed and submitted through the Pharmacy Quality Improvement team (QIT) for approval. Additional clinical governance project approval was obtained from the QIT. All data collected from the clinicians will be anonymised and handled confidentially.

Methods

- 1.1 In co-operation with the lead pharmacist at the clinic an invitation letter to participate in a one-to-one semi-structured interview will be written and sent out via email to 10-12 clinicians. The invitation letter will ask them to respond with a possible appointment time to perform the interview. It is considered that this sample size will provide saturation of data. If new data is emerging the sample size will be extended.
- 1.2 Semi-structured interview questions will be written and agreed by the project team. Interview themes will be pre-decided by the project team to allow for thematic coding during analysis.
- 1.3 Once clinicians have responded positively to participation in the study, a convenient time and venue will be agreed. During the on-to-one semi-structured interviews, clinicians will be asked questions about using the referral form and their opinions of the current referral criteria.
- 1.4 Each interview will be recorded and anonymised. Each clinician will be allocated an identification number. The interviews will be transcribed verbatim. Each clinician will be given the opportunity to review the transcription of the interview and provide feedback. Recordings will be destroyed after transcription has been undertaken and agreed as accurate.
- 1.5 The interviews will be analysed by thematic coding analysis. A proportion of analysis will be reliability checked by a member of the project team.
- 1.6 Key-statements will be identified to fit pre-decided themes by the project team. During analysis of the transcripts, new themes might be generated.
- 1.7 Themes will be analysed to generate new referral criteria.

- 2.1 New referral criteria will be reviewed and agreed by the project team including the lead pharmacist for the DCVR and the lead consultant diabetologist.
- 2.2 The agreed referral criteria will be incorporated into the design of a new referral form.

- 3.1 The new referral form will be tested retrospectively on patients previously referred to see if the same patients would be referred using the new referral form.

3.2 New outcomes will be defined as continuous variables (e.g. blood pressure and/or microalbuminuria). Scores will be applied to combinations of variables. Options for referral will be agreed – whether patients meet only a single criterion or combination of criteria. Scores will be applied to each criterion to enable combinations of criteria to be given a score can be varied for application to the retrospective sample to calculate sensitivity and specificity of the different combinations.

3.3 The Receiver Operator Characteristic (ROC) curve will be used to determine the scores of single variables, combinations of variables or cut-off measures for patients referred against those previously referred.

3.4 The ROC curve will show sensitivity and specificity values for the new criteria.

Analysis of findings

1.1 Semi-structured interviews.

1.2 Thematic coding analysis will be used to code transcripts to enable interpretation of opinions about future referral criteria.

2.1 Interpretation of the interviews together with discussion with the project team will lead to design of new referral criteria which will be validated using sensitivity and specificity analysis.

3.1 Sensitivity and specificity will be expressed as a percentage using the different combination of criteria to allow judgement to be made in terms of the optimum sensitivity and specificity.

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