Impact of Care Pathways on the Care of People with Diabetes Mellitus

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor in Philosophy by

Sarah Victoria O'Brien, BA (Hons.), RN / Diploma Health.

September 2006

CONTENTS

DEDICATION

This thesis is dedicated to my family, my husband Martin, my son Jack and my parents Rosemary and Michael.

DECLARATION

This thesis is the result of my own work, performed whilst registered as a candidate for the Degree of Doctor in Philosophy at the University of Liverpool. None of the original work presented in this thesis has been submitted in support of an application for another degree or qualification.

The research was carried out in the Department of Diabetes and on the general medical wards at Whiston Hospital (St Helens & Knowsley NHS Hospital Trust).

Candidate:

Sarah Victoria O'Brien

Supervisor 1:

Dr Geoffrey Gill

Supervisor 2:

Dr Kevin Hardy

ACKNOWLEDGEMENTS

I wish to thank Dr Kevin Hardy for encouraging and inspiring me to undertake this work and for his constant support and mentorship during this research. I am indebted to him and all the staff at the Diabetes Centre, Whiston Hospital, for their contribution to the development of the diabetes care pathways and their perseverance and enthusiasm whilst undergoing such a radical change to service delivery. I would like to thank Sue Michaels and Jan Cardwell for their help with the RCT and Dr Shirley Hulme for her assistance with the Nephropathy studies and Dr Niall Furlong for his guidance on the literature review and practical tips on the writing up of this thesis. I would like to thank Dr Caroline Watkins for her guidance on developing the nurse knowledge questionnaire and all those who participated in interviews and studies during the development of this tool. I would also like to thank Dr Geoffrey Gill for his support as supervisor and all the patients with diabetes who took part in the studies. Lastly, and most importantly, I would like to thank my husband Martin for his support especially during the writing up of this thesis when I had to spend many evenings sat in front of the computer.

For the first two years of this research I received a Research and Development Fellowship Award from the North West NHS Executive.

LIST OF ABBREVIATIONS

ACR	Albumin Creatinine Ratio
AER	Albumin Excretion Rate
BMI	Body Mass Index
BP	Blood Pressure
CKD	Chronic Kidney Disease
DKA	Diabetic Ketoacidosis
DKD	Diabetic Kidney Disease
eGFR	Estimated Glomerular Filtration Rate
ESRD	End Stage Renal Disease
ESRF	End Stage Renal Failure
GFR	Glomerular Filtration Rate
CGWT	Care Group Workforce Team
GKI	Glucose Potassium Insulin infusion
HHS	Hyperglycaemic Hyperosmolar States
LDL-C	Low Density Lipoprotein Cholesterol
LDSAG	Local Diabetes Services Advisory Group
LOS	Length of Stay
MDRD	Modification of Diet in Renal Disease
NICE	National Institute for Clinical Excellence
NPA	National Pathway Association
NSF	National Service Framework
PCT	Primary Care Trust
RAAS	Renin Angiotensin Aldosterone System
RCT	Randomised Controlled Trial
SD	Standard Deviation
SHA	Strategic Health Authority

ABSTRACT

This thesis aimed to develop care pathways for the management of in-patients and outpatients with diabetes in an acute NHS Trust, to review the evidence-base for existing care pathways and to evaluate the impact of care pathways on the management of in-patients with diabetes and patients with Diabetic Nephropathy.

A comprehensive literature review (using the principles of a systematic review) was completed to determine whether care pathways improved the management and or outcome of hospital in-patients with a medical or surgical condition. From this review it appears that the main potential benefits associated with the introduction of a care pathway are a reduction in length of stay, reduced costs and possible improvements in the quality of patient care. However, these findings are limited because of the poor methodology used in all of the papers reviewed and there is a need for more robust research concerning care pathways.

This work has provided a systematic process for developing diabetes care pathways and examples of diabetes care pathways that could be used and adapted by other clinicians managing patients with diabetes.

A randomised controlled trial examined the impact of the in-patient diabetes care pathway on HbA1c, length of stay, re-admissions within 12 months, nurse knowledge and the quality of in-patient care. In terms of the primary endpoint of HbA1c, the null hypothesis cannot be rejected as there was no difference between the study groups. In the main, secondary endpoints improved, but limitations in the design and execution of the study preclude excessive weight being attached to these findings. Furthermore, completion of the care pathway was poor and sustaining its ongoing use outside of a research study may be difficult, further work is needed to assess the cost of wider implementation of this care pathway.

A care pathway-driven Diabetic Nephropathy service was developed, implemented and evaluated to examine whether it resulted in improvements in

the management of Diabetic Kidney Disease (DKD). The results demonstrated successful implementation of six key evidence-based interventions for DKD and more importantly both surrogate and hard endpoints were comparable to those achieved in recent large clinical trials, in particular, the rate of doubling of serum creatinine, progression to End Stage Renal Failure and Death.

This thesis demonstrates that in some circumstances care pathways can improve implementation of evidence-based diabetes care and lead to improvements in patient outcomes. Care pathways appear to be particularly useful when used by a dedicated, appropriately trained team dealing primarily with one condition, and can be an effective tool for the implementation of evidence-based diabetes care.

Further work examining the impact of care pathways in all areas of health care would be useful.

CHAPTER 1

DIABETES AND THE CASE FOR CARE PATHWAYS

1.1 INTRODUCTION

Diabetes is a common chronic disorder affecting approximately 3% of the UK population. It is a major public health problem and a massive burden to the individual and to the NHS. Knowledge of the disease has increased exponentially since the discovery of insulin in 1922. There is no cure for the disease but there is an abundance of robust evidence on effective measures to prevent, or treat the complications of diabetes and to reduce or prevent associated morbidity and premature mortality.

People expect to receive high quality, evidence-based diabetes care and have an expectation of living full and healthy lives. Why then do people with diabetes continue to suffer blindness, kidney failure, amputation, the many other complications of diabetes and premature death? In part, the answer is because modern treatments remain far from perfect, but arguably the main reason is an inability to deliver effectively evidence-based treatments to patients in an over-stretched, complex and multifaceted health care system.

It is essential that clinical scientists continue to work to develop and refine treatments to prevent and control diabetes and its complications, but it is equally crucial that clinicians (all health or social care professionals involved in diabetes management), health service managers and politicians work together to develop and refine systems to ensure that evidence-based treatments are delivered to all the patients who need them in a timely and effective manner. As part of this process all professionals involved in diabetes management will need to involve and engage with patients with diabetes, the Department of Health (2004) has set a clear agenda for ensuring patients have greater choice regarding health care and receive more personalised and responsive health care.

For clinical teams, getting the right care to the right patient, in the right place and at the right time must be a priority.

Care pathways have been promoted as a tool to enable clinicians to meet this challenge. Care pathways are said to promote a uniform standard of care delivery in a wide variety of clinical settings. The NHS Plan (Department of Health, 2000), the National Institute for Clinical Excellence (NICE) (NICE, 2000) and recent National Service Frameworks (NSFs), including Diabetes (Department of Health, 2001), all suggest the importance of care pathways in realising national goals for better health care and delivery of evidence-based practice.

The purpose of these studies is to evaluate the effectiveness of care pathways in delivering evidence-based diabetes care. This chapter briefly outlines the nature and scope of diabetes and its complications by way of an introduction to the scale and magnitude of the challenge facing clinicians before discussing the definition and origin of care pathways and how they might help clinicians meet the challenge of diabetes.

1.2 DIABETES

Diabetes is a complex disease characterised by problems with carbohydrate, protein and lipid metabolism (Pickup & Williams, 1991) but the most common manifestation is hyperglycaemia. There are two main types of diabetes: Type 1 and Type 2. Type 2 diabetes is more common and accounts for approximately 85% of people with diabetes in England (Department of Health, 2001).

Type 1 diabetes is predominantly a problem of insulin deficiency caused by autoimmune destruction of β-cells in the pancreas (Atkinson & MacLaren, 1994). It can occur at any age but typically arises in childhood. At presentation, people with Type 1 typically have polyuria, thirst, weight loss and tiredness. Because they have almost ceased to produce insulin, it is imperative that they receive insulin treatment quickly: they are *insulin dependent*. Prior to the discovery of insulin in 1922, the prognosis in Type 1 diabetes was grim. With the advent of insulin therapy, people with Type 1 diabetes survive many decades and the chronic complications of the disease: retinopathy, nephropathy,

neuropathy and cardiovascular disease have emerged. New and relatively effective strategies to prevent / control these complications have been developed - now the challenge is largely implementation!

Type 2 diabetes is characterised by relative insulin deficiency or insulin resistance or usually a combination of both. Type 2 diabetes typically occurs in those aged over 40 years and the incidence rises with age. However, it too can occur at any age and with rising obesity is increasingly recognised in those less than 40 years of age. At diagnosis, Type 2 patients may present with acute symptoms as in Type 1 diabetes but usually they are less severe and many people with Type 2 diabetes are relatively asymptomatic, accounting for the large number of people in the population with undiagnosed diabetes. As with Type 1 diabetes, knowledge of Type 2 diabetes has grown exponentially in recent years and there is much evidence of how to reduce the burden of the disease. Nevertheless, people continue to develop complications and die prematurely as a result of Type 2 diabetes.

1.2.1 Epidemiology of Diabetes

Diabetes is common, approximately 1.8 million people in the United Kingdom are known to have diabetes and it is estimated that a further one million have the disease but are undiagnosed (Diabetes UK, 2004a). More significantly the numbers are rising rapidly and diabetes is increasingly being described as a global epidemic. It is anticipated that the number of people with diabetes in the UK will have doubled by 2010 to over 3 million (Audit Commission, 2000) and world wide it is estimated that 221 million will have diabetes compared to 124 million in 1997 (Amos *et al.*, 1997). This growing population of people with diabetes is a major part of the challenge to ensure effective implementation of emerging and existing evidence-based interventions.

However, ensuring people with diabetes receive evidence-based interventions is made even more difficult because of the uneven distribution of the disease across the population.

Diabetes is more common in the elderly, ten percent of people over 65 years develop the disease (rises to a quarter in the Asian population) and the prevalence is higher again in those over the age of eighty five years (Audit Commission, 2000). It is widely recognised that the elderly, especially those in nursing or residential homes, are particularly vulnerable and often don't receive evidence-based management of their diabetes. Diabetes is also more common in other vulnerable groups in the population including ethnic minorities and those in lower socio-economic groups. As well as the prevalence of Type 2 diabetes being more common in Asian, African and African-Caribbean groups, the mortality rates from diabetes-related complications, especially cardiovascular and renal disease are significantly higher in these groups. People in social class V are three and half times more likely to experience problems associated with diabetes complications than those in social class I. (Department of Health, 2001a).

The major challenge facing clinicians and mangers to implement evidence-based interventions to a growing number of people with diabetes is compounded by this uneven distribution of the disease across some of the most vulnerable and hard to reach sections of the population.

1.2.2 Burden of Diabetes

The burden of diabetes impacts on both the individual and society and is a major drain on NHS resources. Much of the burden is from the chronic complications associated with the disease, but these can be prevented with good glycaemic control (as measured by HbA1c). There is robust evidence that the longer the duration of the disease especially when associated with poor glycaemic control, the greater the risk of developing complications (Diabetes Control & Complications Trial Research Group, 1993; UKPDS Study Group, 1998a, UKPDS Study Group, 1998b; Stratton *et al.*, 2000). Achievement of tight glycaemic control, however, needs well organised, timely, targeted and fairly labour-intensive care. In addition it typically requires considerable effort from the individual including significant lifestyle changes to balance diet, exercise, medications, and leisure pursuits. Studies examining the impact of diabetes on

quality of life have demonstrated the negative impact the disease can have on psychological well being.

As well as the day to day management of the disease placing a burden on the individual the potential acute and chronic complications associated with diabetes may increase the negative impact on quality of life.

The purpose of this section is to discuss the acute and chronic complications of diabetes as a means of examining the burden to the individual and the NHS and exploring why they remain such a huge problem.

1.2.2.1 Acute Complications of Diabetes

The acute complications of diabetes include hypoglycaemia (low blood sugars), Diabetic Ketoacidosis (DKA), and Hyperglycaemic Hyperosmolar States (HHS).

Hypoglycaemia

Patients receiving insulin therapy, or sulphonylurea with Type 2 diabetes, are at risk of hypoglycaemia (hypos) which may result from a mismatch between medication and diet or exercise / activity. The symptoms of hypoglycaemia vary for individuals but if not treated promptly they can be debilitating and may result in coma or in extreme (rare) cases death. People at risk of hypos often fear them and consequently will resist steps to achieve tight glycaemic control because of the fear of hypos. Some people with Type 1 diabetes develop hypoglycaemic unawareness where they lose warning of an impending hypo, this can be potentially dangerous for them and others. Hypoglycaemia can place a huge burden on those who suffer regular severe episodes and may adversely affect quality of life.

DKA and HHS

DKA is a metabolic crisis characterised by hyperglycaemia, hyperketonaemia and acidosis. It predominantly occurs in people with Type 1 diabetes but may

occur in Type 2 diabetes and is caused by a relative lack of insulin and an increase in catabolic hormones resulting in hyperglycaemia and the production of ketone bodies. Individuals are at risk if they are ill (common illnesses like infection, common cold, viruses etc), don't know they have diabetes or they mismanage their diabetes and DKA places a huge burden on the individual and the NHS. Treatment of DKA typically requires hospital admission, often to an Intensive Care or High Dependency Unit and if not treated promptly may result in death. It remains a major problem and is the most common cause of death in individuals with diabetes under the age of twenty years (British Diabetic Association, 1995).

HHS occurs in Type 2 diabetes, it is a metabolic crisis like DKA but without hyperketonaemia and is characterised by severe hyperglycaemia (blood glucose typically >40 mmol/L) and dehydration. Like DKA individuals are at risk if they have undiagnosed diabetes or are ill. It is not as common as DKA but when it does occur it causes severe morbidity and has an extremely high mortality rate.

Both DKA and HHS can be prevented if individuals are aware of the danger signs and know how to treat hyperglycaemia but they need to receive effective education regarding prevention. Education programmes for people with diabetes vary across the country (Audit Commission, 2000) but there is recognition that structured education is a necessary aspect of effective diabetes management and NICE (2003) recommend the establishment of structured education for all diabetes services. The challenge for clinicians will be incorporating such programmes into routine clinical care, but the work from these studies indicates that care pathways may be a tool to facilitate this.

There are national guidelines for the treatment of DKA and HHS but these are not successfully implemented into practice. Delays in diagnosis and a failure by clinicians to follow the guidelines contributes to the high morbidity and mortality associated with the conditions. Care pathways might address the problem of clinicians not following guidelines during an intervention with a patient and could be useful in improving the management of DKA and HHS.

1.2.2.2 Chronic complications

There are two main types of chronic complication: *microvascular* and *macrovascular,* associated with both types of the disease. Microvascular complications include: Diabetic Retinopathy, Diabetic Nephropathy and Diabetic Neuropathy. People with diabetes are more at risk of macrovascular disease such as angina, myocardial infarction, stroke and peripheral vascular disease.

Diabetic Retinopathy

Damage can occur to the small vessels in the eyes resulting in Diabetic Retinopathy. It develops progressively over time and can be treated with laser photocoagulation and other treatment modalities, which reduces the risk of visual loss. There is conclusive evidence that tight glycaemic control reduces the risk of developing retinopathy, and will prevent progression of the disease. Additionally, there are proven interventions to treat retinopathy and stop the damage to the eye, yet people still develop retinopathy and still go blind as a consequence. It remains a huge burden to the individual and the NHS and is the commonest cause of blindness in those of working age (Diabetes UK, 2004b). A major factor contributing to this ongoing burden may be a failure to deliver evidence-based interventions (in particular screening) to prevent and treat those at risk and it has been suggested that much of the blindness associated with diabetic retinopathy could be prevented if the disease was diagnosed earlier (Department of Health, 2005). To address this, clear targets were identified in the National Service Framework to facilitate improved screening for diabetic retinopathy and explicit standards for retinopathy screening have been identified by the UK National Screening Committee (National Diabetes Support Team, 2005).

Diabetic Nephropathy

Damage can occur to the vessels in the kidney resulting in Diabetic Nephropathy. It can go undetected for years and whilst in the early stages it causes no symptoms, if untreated it will progress to End Stage Renal Failure (ESRF),

requiring dialysis or causing premature death. As with Retinopathy, robust evidence suggests that tight glycaemic control can prevent development or delay progression of the disease. Yet it remains a major complication of diabetes, it has being estimated (Bloomgarden, 2005) that worldwide 42% of people with diabetes have microalbuminuria (early Nephropathy). This figure is huge and indicates that a significant number of people are not receiving appropriate, evidence-based interventions to prevent complications. Additionally, in recent years, our understanding of how to treat Nephropathy and prevent ESRF has grown substantially. People with microalbuminuria need not progress to overt Nephropathy or ESRF. Diabetic Nephropathy is a main cause of morbidity and mortality in people with diabetes and is the main cause of ESRF in Europe and America (Copper, 1998). There is scope for much better management of Diabetic Nephropathy and a failure to deliver appropriate, timely, interventions, to those who need them is a major problem (Mogensun and Cooper, 2004).

Diabetic Neuropathy

Diabetes can cause nerve damage resulting in Diabetic Neuropathy, it can affect peripheral nerves and the sympathetic and autonomic nervous system. Symptoms vary but include loss of sensation (in particular in the feet), pain, muscle weakness or wasting and loss of some autonomic functions including BP control and control of the bladder and bowel. Painful and Autonomic Diabetic Neuropathy are very difficult to treat and the impact on the individual's quality of life can be severe. Diabetic Neuropathy is one cause of foot problems in individuals with the disease and diabetes remains the commonest cause of non-traumatic lower limb amputations (Fox and Mackinnon, 1999) which places a huge burden on both the individual and the NHS. As with Retinopathy and Nephropathy, we know that tight glycaemic control helps prevent the onset of Neuropathy. Moreover, for those with Neuropathy eg Painful Neuropathy there are interventions to manage the symptoms if no effective cures. It is essential that we improve the management of Neuropathy by ensuring delivery of evidence-based interventions to improve glycaemic control.

Cardiovascular Disease

People with diabetes (especially Type 2 diabetes) are at increased risk of developing macrovascular disease, such as angina, myocardial infarction, stroke and peripheral vascular disease. Cardiovascular disease is a major cause of morbidity and premature mortality in the UK. People with diabetes have a two to threefold increased risk of coronary heart disease and stroke (Yudkin *et al.*, 1996) and cardiovascular disease is the main cause of death in people with Type 2 diabetes. There is strong evidence that treatment of BP, lipids, weight and other risk factors will reduce mortality but again a main problem is ensuring the right people receive appropriate intervention (Health and Social Care Information Centre, 2005).

It is evident that diabetes related complications are a significant cause of morbidity and mortality despite an abundance of robust evidence regarding effective interventions. A key factor appears to be failure to deliver appropriate, timely interventions to those who need them. The potential advantages of care pathways (see below), indicate that they could be an important tool in facilitating more appropriate management of diabetes, if this is the case they will be invaluable to the NHS.

1.2.3 Costs of Diabetes

The purpose of this section is to examine the financial burden of diabetes on the individual and on the NHS. Effective interventions leading to improved management of the disease could result in huge savings to the NHS, leaving money to be spent elsewhere for the good of others using health services.

There are direct costs and indirect costs associated with the disease and whilst it is hard to accurately assess these, studies have been able to highlight the huge financial burden of the disease. It was estimated that the average cost to the individual of managing Type 2 diabetes in 1999 was £802, this would be three times higher if they had any complications and they would be much more likely to need a carer if they had complications (Department of Health, 2001). The direct cost of Type 1 diabetes to the NHS was estimated in 2004 to be £212 million in 2001 prices (National Collaborating Centre for Chronic Conditions,

2004). This figure included costs of thirty eight million for renal replacement therapy, outpatient clinic costs of fifty million and hospitalisation costs of sixty five million. People with diabetes are more likely to require input from social services, in particular nursing or residential care (Department of Health, 2001). Indirect costs such as loss of earnings because of absenteeism from work are hard to calculate but will further add to financial burden on the individual and society.

People with diabetes are more likely to be admitted to hospital and have a longer length of stay than those without diabetes and hospital costs are six times greater for people with diabetes (Audit Commission, 2000). Up to 10% of in-patient resources are used by people with diabetes (Department of Health, 2001) and it has been estimated that this cost will continue to rise disproportionately over time (Currie *et al.*, 1997a). Admission to hospital for complications associated with diabetes such as lower limb amputation or coronary heart disease are much more expensive when compared to the same problem in non-diabetics. One study found that patients with diabetes accounted for 17% of coronary heart disease related admissions and were up to four times more likely to require a cardiac procedure (Currie *et al.*, 1997b). Another study found that 15% of primary admissions for lower limb problems were in people with diabetes and their length of stay was nearly double that of non-diabetics (Currie *et al.*, 1998).

With the estimated increase in the number of people with diabetes the financial burden of diabetes could reach problematic proportions, yet there is sound evidence for the prevention and treatment of the disease. Diabetes accounts for 5-10% of the NHS budget, savings will not be made without more effective care of people with diabetes. Care pathways have been recognised as a tool that may reduce the cost of healthcare and this is another reason for exploring their use in diabetes management.

1.3 DIABETES AND THE POLITICAL AGENDA

It is evident that more needs to be done to ensure people with diabetes receive effective interventions, but this will not happen unless clinicians and health

service mangers make diabetes a priority. The purpose of this section is to examine diabetes in the context of local and national agendas for health services and to explore whether it is likely that implementation of evidence-based treatments will improve in the near future.

1.3.1 Is Diabetes a National Priority?

In recent years, it has been recognised that diabetes is a growing public health problem because of the rising numbers and the burden and costs associated with the disease. It is also evident that diabetes services across the country are not equitable, the Audit Commission Report in 2000 clearly demonstrated that access to services and the standard of those services was variable. In response to the growing problems associated with diabetes, in particular the failure to deliver evidence-based care, it has become a national priority and the Department of Health developed a National Service Framework (NSF) for Diabetes with the purpose of ensuring accessible high quality diabetes care across the country.

1.3.2 Diabetes National Service Framework

NSF Standards

The NSF was published in two parts. The standards (Table 1.1) were published in December 2001 and outline 12 key areas of intervention to be implemented by all health authorities by 2013 with the aim of raising the quality of diabetes care and consequently reducing the burden to the individual and the NHS. The 12 standards cover all aspects of diabetes and if implemented would address many of the problems discussed above, but the challenge remains one of implementation. Prior to publication of the NSF there were evidence-based guidelines on managing diabetes, but we failed to use them, this suggests that implementation of the standards without incentives to mangers and clinicians may be problematic. The second part of the NSF, the Delivery Strategy was published in 2002 and aims to address the problem of implementation.

Delivery Strategy

The Delivery Strategy sets out a framework for local diabetes services to enable them to deliver the NSF standards and meet national targets. Implicit in the delivery strategy is a shift in responsibility for local diabetes services from the specialist team (typically secondary care based) in conjunction with primary care (traditionally through a LDSAG (Local Diabetes Services Advisory Group)) to the PCT (Primary Care Trust). This marks a huge change in the delivery of diabetes care and there is now clear responsibility for diabetes management at local level and 12 standards that PCTs have to meet by 2013. PCTs are expected to deliver on the NSF and they will be monitored by the Strategic Health Authority. In addition the Healthcare Commission will review progress made by PCTs on meeting the diabetes NSF. As PCTs are accountable to the SHA for the NSF, this may improve implementation of the standards and achieve more effective diabetes care than was in place previously. A cause for concern with the NSF is that the standards are very broad and could be interpreted differently by different PCTs, this may result in a continuation of the current problem of inequitable services across the country. However, there were four key areas of development in the Delivery Strategy that each PCT is expected to meet and success in these areas may ensure equitable and effective implementation of the standards.

Delivery Strategy – Key Targets for a PCT

1. Establishing a local diabetes network. Networks should be appropriate to the geography of the local area and local health service provision and may span more than one PCT and acute hospital trust. The PCT(s) involved are expected to appoint a network manager and identify a clinical champion(s) and people with diabetes to lead changes. The aim behind the diabetes networks is that they will integrate care, improve clinical outcomes and patient experience and lead to more cost-effective, equitable diabetes services (Department of Health, 2002). The network will oversee implementation of the standards and be accountable to the SHA, this should lead to improvements in services.

2. PCTs should undertake a baseline assessment of services to identify areas where implementation of the standards may be problematic and develop an action plan for meeting the standards. Part of the baseline assessment will be a profile of the local workforce and education and training programmes should be developed accordingly. Again this process should facilitate implementation of the standards and address local problems which will be to the benefit of local diabetes services.

3. PCTs will be expected to participate in local and national audit, a national dataset is being devised and comparisons will be made between PCTs. Whilst some of the standards are not specific, national comparisons of outcome data enable PCTs to indentify where they are struggling locally and the areas that need prioritising.

4. There were two specific targets for the first 3 years. The first was for PCTs to ensure that at least 80% of people with diabetes were offered screening (of a national standard) for diabetic retinopathy by 2006 and this rises to 100% by the end of 2007. Secondly, by 2006, in primary care there should be practice-based registers and systematic treatment regimens to ensure people receive treatment as stated in the NSF standards. As part of this people with diabetes should have a personal diabetes record and care plan and a named contact from the healthcare team.

These specific targets have to be met by PCTs, this should lead to improvements in local services and with the NSF there is an incentive that didn't exist previously, to address problems with diabetes services, this should lead to an improvement in the implementation of evidence-based care.

Other National Initiatives to Support Implementation of the NSF

It remains a huge challenge to implement the NSF and evidence-based care, because of the scope of the problems associated with diabetes and the growing numbers. Additionally, there was no specific ring-fenced money to support the diabetes NSF, extra resources for the NHS have been identified in the budgets and PCTs are expected to fund the NSF from their general allocation. However this could be problematic as other priorities will compete for the resources. To

facilitate implementation of the NSF other national initiatives were introduced. These include:

1. The appointment of a National Clinical Director for Diabetes in 2003. Her role is to provide national leadership and work with the SHAs to ensure there is local commitment to delivering the NSF.

2. NICE have developed various guidelines relating to the management of Type 2 and Type 1 diabetes to support clinicians and support the NSF standards.

3. The NHS Modernisation Agency is available to provide support to diabetes networks.

4. The CGWT (Long-Term Conditions Care Group Workforce Team) aim to support PCTs in terms of staff training, education and deployment and in ensuring these needs are incorporated into local and national plans (Department of Health, 2002).

5. There is a Diabetes Information Strategy (Department of Health, 2003) to ensure that IT infrastructures are in place to support delivery of the diabetes NSF and meet the needs of people with diabetes.

6. To encourage GPs to meet the diabetes NSF targets, the new GMS (General Medical Services) contract (came into effect in 2004) included a Quality and Outcomes Framework (QOF), this is a voluntary scheme for GP practices but there is a strong incentive to join as they are awarded financially for meeting targets. There are up to 1000 points that a practice can achieve and these include organizational factors, clinical factors and patient experiences. There are more points available for diabetes management (93 in total) than for any other condition, these include things such as; percentage of patients with record of retinal screening, record of HbA1c, neuropathy test etc (National Diabetes Support Team, 2006) and it is highly likely that because practices are financially awarded for achieving each point that this will drive up the overall quality of care in general practice.

Summary

The NSF places the problem of diabetes on the national agenda and aims for more equitable, high quality, national diabetes services. There is explicit responsibility and accountability for the delivery of the NSF and this should result in improvements in diabetes care.

Successful implementation of the NSF will require commitment from healthcare professionals on the frontline of diabetes services. Traditionally a significant proportion of service delivery has been the remit of specialist teams but with the changes outlined above, the emphasis has shifted to non-specialists in primary care who have multiple other conditions to manage as well as diabetes. Whilst the standards are there to guide them, they are not specific and clinicians will still need to keep abreast of evidence-based guidelines. Even when the responsibility for diabetes care lay predominantly with specialist teams, we were failing to deliver consistent, evidence-based care, this will be an even greater challenge for non-specialists who may find it more difficult to keep abreast of latest evidence and guidance. The QOF framework may result in more GP practices measuring key diabetes parameters, but, they will still need to be up to date with the latest evidence to know what to do with the results. Other tools will be needed to facilitate high quality diabetes services in line with the NSF and care pathways may be the answer. They are cited on the NSF web site as a tool to facilitate implementation of the NSF, but no pathways for diabetes have been developed nationally and there are very few diabetes care pathways published.

Table 1.1 Diabetes NSF Standards (Department of Health, 2001)

Standard	Summary
Standard 1: Prevention of Type 2 diabetes	The NHS will develop, implement and monitor strategies to reduce the risk of developing Type 2 diabetes in the population as a whole and to reduce the inequalities in the risk of developing Type 2 diabetes.
Standard 2: Identification of people with diabetes	The NHS will develop, implement and monitor strategies to identify people who do not know they have diabetes
Standard 3: Empowering people with diabetes	All children, young people and adults with diabetes will receive a service which encourages partnership in decision-making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle. This will be reflected in an agreed and shared care plan in an appropriate format and language. Where appropriate, parents and carers should be fully engaged in the process.
Standard 4: Clinical care of adults with diabetes	All adults with diabetes will receive high-quality care throughout their lifetime, including support to optimise the control of their blood glucose, blood pressure and other risk factors for developing complications.
Standard 5&6: Clinical care of children and young people with diabetes	All children and young people with diabetes will receive consistently high-quality care and they, with their families and others involved in their day-to-day care, will be supported to optimise the control of their blood glucose and their physical, psychological, intellectual, educational and social development. All young people with diabetes will experience a smooth transition of care from paediatric diabetes services to adult diabetes services, whether hospital or community-based, either directly or via a young people's clinic. The transition will be organised in partnership with each individual and at an age appropriate to and agreed with them.
Standard 7: Management of diabetic emergencies	The NHS will develop, implement and monitor agreed protocols for rapid and effective treatment of diabetic emergencies by appropriately trained health care professionals. Protocols will include the management of acute complications and procedures to minimise the risk of recurrence.
Standard 8: Care of people with diabetes during admission to hospital	All children, young people and adults with diabetes admitted to hospital, for whatever reason will receive effective care of their diabetes. Wherever possible, they will continue to be involved in decisions concerning the management of their diabetes.
Standard 9: Diabetes and pregnancy	The NHS will develop, implement and monitor policies that seek to empower and support women with pre-existing diabetes and those who develop diabetes during pregnancy to optimise the outcomes of their pregnancy.
Standard 10, 11 & 12: Detection and management of long-term complications	All young people and adults with diabetes will receive regular surveillance for the long-term complications of diabetes. The NHS will develop, implement and monitor agreed protocols and systems of care to ensure that all people who develop long-term complications of diabetes receive timely, appropriate and effective investigation and treatment to reduce their risk of disability and premature death. All people with diabetes requiring multi-agency support will receive integrated health and social care.

1.4 CARE PATHWAYS

1.4.1 Introduction

Different terms have been used to denote care pathways including: integrated care pathways, care maps, anticipated recovery paths, clinical pathways and multidisciplinary pathways of care. For the purpose of this thesis the term *care pathway* will be used.

The aim of this section is firstly to examine the difference between care pathways and clinical guidelines. Secondly, to define core features and origins of care pathways and the potential advantages and disadvantages will be explored as a means of examining why care pathways may be useful in implementing evidence-based diabetes care. Finally, the availability of existing diabetes care pathways will be examined.

1.4.2 Care Pathways and Clinical Guidelines – What's the Difference?

Characteristics of Clinical Guidelines

A formal definition of a clinical guideline is 'a systematically developed statement to assist both practitioner and patient decisions in specific circumstances' (Eccles and Mason, 2001). Increasingly there is an expectation within the NHS that clinical guidelines should be evidence-based and where possible this evidence should be robust, typically the result of high quality randomised controlled trials (RCTs). Where there is a lack of such evidence, clinical guidelines may be based on a consensus opinion regarding best practice agreed by relevant experts in the field.

In order to assist clinicians to make a judgement about the quality of the evidence used in clinical guidelines, many guidelines (especially those developed by NICE) grade the evidence, with meta-analyses of RCTs being the highest grade in the table and consensus opinions being the lowest grade (Table 1.2). Recommendations made in the guideline will also be graded to reflect the level of evidence on which these were based (Table 1.2).

Ideally recommendations for clinical practice would all be based on grade 1a evidence but this is unrealistic. It is important to recognise that this level of evidence is not always available and recommendations based on lower levels of evidence can still be clinically valuable. The establishment of NICE has endorsed the expectation that clinicians should be able to defend their practice against national, international or locally developed clinical guidelines. The problem with clinical guidelines is that they are typically large documents and it may not be easy to access the appropriate section regarding management of a disease during a patient consultation. For many clinicians their caseload requires them to keep abreast of a large number of clinical guidelines for a variety of conditions and in practice this is a difficult task. Consequently many clinical guidelines end up on the shelf and are not routinely referred to when making clinical decisions.

This is the challenge in diabetes, there are many facets to the disease and numerous guidelines on the most appropriate intervention. It is impossible for clinicians to keep abreast and use the relevant guideline(s) during a patient consultation, consequently they fail to deliver the evidence, consistently, to the right people.

Table 1.2 Grading of Evidence and Recommendations

(National Collaborating Centre for Chronic Conditions, 2004)

Hierarchy of evidence		Typical grading of recommendations	
1a	Evidence from meta-analysis of randomised controlled trials	**A**	Based on category 1 evidence
1b	Evidence from at least one randomised controlled trial	**B**	Based on category 11 evidence or extrapolated from category 1
11a	Evidence from at least one controlled study without randomization	**C**	Based on category 111 evidence or extrapolated from category 1 or 11
11b	Evidence from at least one other type of quasi-experimental study	**D**	Directly based on category 1V evidence or extrapolated from category 1, 11 or 111
111	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies	**DS**	Evidence from diagnostic studies
1V	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities	**NICE**	Evidence from NICE guidelines or health technology appraisal programme
DS	Evidence from diagnostic studies		
NICE	Evidence from NICE guidelines or health technology appraisal programme		

Characteristics of Care Pathways

Care pathways may address problems associated with clinical guidelines. A key goal of care pathways is to facilitate evidence-based practice and many care pathways are based on clinical guidelines.

There are many definitions of care pathways and no nationally agreed format, hence the format may vary within and between NHS Trusts. However, it is evident from the literature that there are core features attributable to care pathways distinguishing them from standard care plans and guidelines.

A care pathway specifies the expected route of care for a patient with a given condition or medical problem in a specified setting. Timeframes are often explicit and interventions are specified in chronological order. Care pathways

are usually multidisciplinary and developed locally (De Luc and Currie, 1999; Middleton and Roberts, 1998; Johnson and Burall, 1996; VFM Unit, 1996; National Assembly for Wales, 1999). Unlike guidelines, they form part or all of the medical records and it is this feature which may allow care pathways to more effectively facilitate evidence-based practice than clinical guidelines. The care pathway specifies what should happen and the clinician has to complete it to state whether they have followed the guidance or not.

Variance Analysis

Another core feature of a care pathway distinguishing it from other guidelines and care plans is variance analysis (Gottlieb *et al.*, 1996; Kitchiner *et al.*, 1996; Campbell *et al.*, 1998). It is not intended that care pathways replace clinical judgement, therefore if a clinician does not want to follow the care pathway they can deviate from it. Variance analysis is a record of deviations from the care pathway, with an explanation of the deviation.

Analysis of variations from care pathways can be undertaken to inform and (improve) care, and facilitate audit and continuous quality improvement. A variance from a care pathway may be positive (pathway not followed because of individual needs of a patient) or negative (pathway not followed because of a problem in the system). Variance analysis enables clinicians to individualise care, record shortfalls in the system that are preventing optimum care, and record situations where the clinical judgement dictates a different pattern of care from the norm.

Some care pathways define variances (Middleton and Roberts, 1998; Wigfield and Boon, 1996). *Systems variances* would include organisational problems or barriers to care such as nursing shortages, waiting times for procedures etc. *Clinician variances*, would include deviations because of an individual's clinical judgement to either omit an intervention specified on the care pathway or add an extra one. *Patient variances*, may include something unpredictable about the individual such as complications with co-existing morbidities.

1.4.3 Definition of Care Pathways

The National Pathways Association (NPA) has been in existence in the UK for a number of years, its members include clinicians from a variety of clinical settings involved in the use of care pathways, and they are recognised as the main body of knowledge on care pathways. The NPA define a care pathway as:

'*An integrated care pathway determines locally agreed, multidisciplinary practice based on guidelines and evidence where available, for specific patient / client group. It forms all or part of the clinical record, documents the care given and facilitates the evaluation of outcomes for continuous quality improvement.*'

Cited in De Luc and Currie, 1999.

Essential features of a care pathway as defined by the National Pathway Association:

1 Forms all or part of the patient record / documentation

2 For an identified patient or client group

3 Set within an agreed time frame

4 Locally agreed

5 Based on locally agreed or national guidelines

6 Has variance tracking

7 Is goal / outcome oriented

8 Multidisciplinary in development

The NPA definition of a care pathway and the eight features are concordant with the literature regarding pathways and succinctly draws the various definitions together, therefore it will be accepted as the definitive definition for the purpose of this thesis. It was used as the criteria for developing care pathways for the purpose of these studies and for judging (where possible) relevant studies to be included in the review in chapter 2.

1.4.4 Origin of Care Pathways

This concept is not unique to healthcare, the development of the care pathway method can be traced back to the Second World War and the United States Navy when it was used as a tool to facilitate planning. The method was developed further in the 1950s when the Navy developed the PERT (Programme Evaluation and Review Technique) system to manage a missile development programme. This programme (like care pathways) broke down the large task of developing the missile into smaller tasks in chronological order with specified time frames for completion. This method was used by many construction agencies throughout the 1950s and 1960s (Bragato and Jacobs, 2003; Olds, 1997).

Care pathways were first developed and used in healthcare in the 1980s in the USA and they are very closely linked to the concept of Managed Care / Case Management. The first care pathway to be developed for healthcare is attributed to Karen Zander at the Centre for Case Management in Boston (Laxade and Hale, 1995).

Managed Care / Case Management - USA

Hospital costs in the USA in the 1980s were increasing by 19% per year (Currie and Harvey, 1998), in an attempt to contain them the government introduced a new system of reimbursement based on diagnostic related groups (DRG). Hospitals no longer received payment for all costs entailed but a single payment for a patient based on their diagnosis. This new system provided an incentive for hospitals to contain costs and try and improve the efficiency of patient services and this concept of curbing costs and improving quality became known as managed care / case management. Managed care has been adopted widely in the USA since the 1980s and there has been a growing interest in the concept in the UK in recent years because of the advantages associated with the concept which include:

- Better patient outcomes
- Reduced costs

- Improved quality
- Efficient use of resources
- Seamless care
- Improved collaboration and communication
- Increased patient and staff satisfaction

Fairfield, *et al.*, 1997

Care pathways emerged from the concept of Managed Care, the theory being that as they specified the process of care in chronological order within specific timeframes they would ensure not only that patients received the necessary care but that it occurred promptly thereby improving efficiency and reducing costs.

Managed Care - UK

The concept of managed care has never been explicitly used in the UK but there are key features of the concept evident in the NHS. The NHS Care in the Community Act 1990 reflected the government of the time belief that competition and the internal market would improve efficiency in the NHS. 'Managed Competition' was a term used to describe regulation of the internal market whilst ensuring the NHS maintained its commitment to quality (Appleby *et al.*, 1994).

Features of the concept can be identified in current reforms of the NHS. The White paper 'The New NHS' (Department of Health, 1997) initiated the government's drive to improve efficiency, quality and performance. This has been reinforced by other key documents including; the NHS Plan (Department of Health, 2000), various National Service Frameworks and NICE guidelines. Key goals of the modernisation agenda are to improve the efficiency of services through re-engineering, performance management of both clinicians and managers within the NHS and a drive for high quality evidence-based care with ease and equity of access.

More recently, there has been a more explicit shift towards the concept of 'case management' in the governments approach to the management of older people and people with long-term chronic conditions. The Single Assessment Process is very similar to case management and was first introduced in the Older Persons NSF (Department of Health, 2001b) the NSF for Long-term Conditions (Department of Health, 2005a) identifies 'case management' as being central to the care of those with long-term conditions. Furthermore, the relatively new role of Community Matron is designed to provide support to those with the most complex needs and a key element of their role is the co-ordination and 'case management' of the individuals needs (Department of Health, 2005b).

Clinical governance is the umbrella term used to embrace most of the quality targets NHS Trusts have to meet and care pathways and the principles of managed care that underpin them, are viewed by many as a key vehicle to enable clinicians and managers to achieve these goals.

Care Pathways in the UK – Current Situation

There has been a significant increase in the number of care pathways in use over the last few years. One web site pertaining to care pathways within the NHS has more than 2,000 different care pathways registered and 200 NHS organisations listed as using care pathways (Bragato and Jacobs, 2003) and there are likely to be many more unregistered care pathways in use. Furthermore, care pathways were originally developed and used for predictable surgical conditions (eg fractured neck of femur) but they have increasingly been developed for more complex medical problems. This move towards using care pathways for a wide variety of conditions may reflect the pressure on clinicians and NHS organisations to meet modernisation targets and implement efficient evidence-based care.

This would account for the reason why care pathways have been proposed as a useful tool for diabetes management. However, of concern is the fact that this vast increase in the use of care pathways within the NHS does not appear to be underpinned by robust evidence of their effectiveness. They are being used as a

vehicle to implement evidence-based practice yet their effectiveness at doing this has not been rigorously tested (see chapter 2). Many of the potential advantages and disadvantages of care pathways presented below are based on theory and anecdotal reports of the impact of using a care pathway, as this comprises the bulk of the literature on the subject.

1.4.5 Advantages of Care Pathways and Why They May be Useful in Diabetes

This section outlines the potential advantages and disadvantages of care pathways and discusses them in relation to diabetes care. Table 1.3 synthesises the key points.

Improved Quality of Patient Care

This is one of the key advantages associated with care pathways. Care pathways should be developed locally by the multidisciplinary team, the process of reflecting and evaluating current practice and agreeing best practice in line with research evidence (where available) results in a plan of care that is of a high standard.

As a care pathway is typically based on clinical guidelines and research, it facilitates implementation of evidence which should improve the quality of care and improve clinical effectiveness (Campbell *et al.*, 1998; Fox *et al.*, 2003; Hannigan, 1998; Currie and Harvey, 1998; VFM Unit, 1996; Taylor, 1997). Quality of care may also improve with care pathways because they encourage continuous clinical audit and evaluation of practice (VFM Unit, 1996; Middleton and Roberts, 1998).

These are key reasons why care pathways may improve the management of patients with diabetes, if they are evidence-based and clinicians using them continuously evaluate services they should address failures in current services. The variance allows clinicians to record deviations from the anticipated norm and there should be regular evaluation of these deviations, this will enable

identification of problems in the system, the opportunity to address them and consequently improve care. The care pathway enables the recording of patient process and outcome measures on one record, this makes clinical audit easier and further facilitates ongoing evaluation of care and the potential to address issues and further improve services.

Improve Communication and Collaboration in Multidisciplinary Team

The process involved in developing a care pathway requires different professionals to work together and agree processes of care and they gain insight into different roles. Often for the first time, teams collaborate and agree a suitable system for managing a given condition and team working is improved. Services are streamlined as a consequence of improved collaboration and team working, there is less duplication because of the greater understanding of different roles and this may improve efficiency as well as quality. Furthermore, once the pathway is implemented all members of the multidisciplinary team record their interventions on the pathway, this improves ongoing communication, joint working and consistency of care (Middleton and Roberts, 1998; De Luc and Currie, 1999; Taylor, 1997; Parsley, 1998; Fox *et al.*, 2003; Ignatavicus and Hausman, 1995). Diabetes is a condition managed by a number of different professionals, if care pathways improve collaboration between these clinicians, they should improve services.

Improve Resource Management

Care with a care pathway should be cost effective as there is less duplication of intervention and therefore better time management by those involved. Collaborative working and the reflection on current practice should result in a reduction of wasted medical tests and procedures (Lowe, 1998; Taylor, 1997; De Luc and Currie, 1999; National Assembly for Wales, 1999). Many of those using care pathways anticipate and report a reduction in length of hospital stay that further reduces cost (Zander, 1988). In theory this would be expected because a care pathway will reduce duplication and defines the process to be followed within set time frames. Although, studies contradict this theory, and

not all papers report reduced length of stay and costs with a care pathway. The burden and costs associated with diabetes have already been stated, if care pathways can reduce these this would be another important reason for adopting them.

Reduction in Documentation

The care pathway should form all or part of the medical record, consequently there is the potential to reduce documentation especially where it is used as a single unified record. Many care pathways require clinicians only to tick a box or sign their initials to indicate an aspect of care was given, hence for those using them care pathways can be much quicker to complete than traditional records of care.

Improved Risk Management

Care Pathways increase the accountability of those using them because expected interventions are explicit, if someone doesn't follow them without a clear variance record they can be held to account for the omission, therefore, the number of potential errors should be minimised. Additionally, if care pathways facilitate better, more concise documentation this will also be useful for effective risk management within an organisation. Further, care pathways should make it easier to identify patients who are not following the anticipated course of events and initiate appropriate action to minimise any risks (Middleton and Roberts, 1998). It should be possible with a care pathway to plan ahead and ensure all appropriate interventions and services are in place for discharge and because the pathway prompts clinicians on what to do next there should be less omissions and negligence with a care pathway. A care pathway specifies what care to expect and provides standards to audit against, this will be useful in malpractice and negligence claims (VFM Unit, 1996).

Diabetes is potentially a high risk condition and the mismanagement of DKA has previously resulted in cases of litigation and in one case an Ombudsman review (Parliamentary and Health Service Ombudsman, 2000). If care pathways can

reduce this potential risk, it would be another important reason for clinicians to use them.

Education Tool

A further potential benefit of care pathways is that they can be used as an education and orientation tool for new staff and students. New staff can see clearly from the care pathway how to manage a certain condition within that setting, and they can be more confident that they are following locally agreed best practice.

Increased Staff and Patient Satisfaction

Many reports on care pathways suggest that they are associated with increased staff and patient satisfaction (National Assembly for Wales, 1999; Riddle *et al.*, 1996; Goode, 1995). A lot of care pathways are designed to be kept at the patient bedside therefore patients have access to information about their care and can feel more informed and involved. If a care pathway improves efficiency and quality of care then it is reasonable to anticipate increased patient satisfaction. Likewise if there is better communication and collaboration between staff and reduced documentation it is likely that a care pathway will improve staff satisfaction.

1.4.6 Disadvantages of Care Pathways

Paradoxically, some of the potential advantages of care pathways are also cited as possible disadvantages by critics of the method.

Inflexible

By specifying the predetermined pathway of care and defining what course clinicians should take, care pathways may be viewed as being less holistic and task oriented. In addition, they could curb an individual's clinical judgement and

initiative and may not encourage clinicians to be flexible if a patient's condition deteriorates or deviates from that anticipated on the care pathway (VFM Unit, 1996; Hotchkiss, 1997; Campbell *et al.*, 1998; Fox *et al.*, 2003). However, whilst this is a potential problem of care pathways it shouldn't arise if they are used properly. The variance is intended to allow clinicians to deviate from the pathway and record what they have done, care pathways can and should be used flexibly and the variance section allows clinicians to individualise care and deviate from the care pathway.

Increase Risk of Litigation

A further criticism is that they may lead to increased litigation against the individual and the organisation (Ignatavicus and Hausman, 1995). The expected standard of care is specified on the care pathway and patients typically have access to the document, therefore if care is not delivered to the standard set, patients may have a clearer case for complaint or legal action. However, there has been no evidence of increased litigation associated with the use of care pathways in America (Hotchkiss, 1997). Furthermore, many complaints in the NHS are associated with poor communication and a lack of understanding of the plan of care, care pathways should address this if used properly.

Increases Paperwork and Documentation

If care pathways don't replace the existing documentation but are used in addition they may result in more paperwork and documentation for clinicians. This may be a particular problem when they are first introduced if the organisation needs to use them alongside existing methods. The potential for extra paperwork may be more of a problem in more complex patients with co-existing diseases where not all aspects of care can be included on one care pathway. This is one reason why it has been suggested that care pathways are inappropriate for complex medical conditions (Kitchener *et al.*, 1996; Campbell *et al.*, 1998; Hunt, 1996). They were initially designed for predictable surgical procedures such as fractured neck of femur and eye surgery where the course of action was very predictable. Patients with conditions like diabetes and heart

disease often have multiple problems and it may be very difficult to predict the course of action needed for such conditions during a particular episode of care. However, in recent years care pathways have increasingly being used for medical conditions and whilst development and implementation in these areas may be more difficult, because of the complexity of these conditions, there may be more benefits from using a care pathway.

For example, diabetes is a high cost, high volume condition for which there are many evidence-based guidelines for clinicians to decipher. A care pathway facilitating joint planning and implementation of care, based on the available evidence and most appropriate course of action could significantly improve standards and outcomes for patients.

Difficult to Implement

A further criticism of care pathways is that they are hard to implement and in particular gaining medical compliance can be problematic and there are reports in the literature of poor use of care pathways by doctors (Ignatavicus and Hausman, 1995). Implementing new initiatives is very difficult and this problem is not unique to care pathways. If representatives of all the multidisciplinary team concerned with a particular condition are involved and committed to the development and use of a care pathway it should contribute to effective implementation. In addition, strategies for successful implementation of change will have to be adopted if care pathways are going to be implemented effectively and used by all the professional groups involved. Successful implementation of care pathways will require strong leadership, effective communication and motivation.

Costs

Another disadvantage of care pathways is the cost involved with development and implementation (VFM Unit, 1996; Fox *et al.*, 2003). Clinicians will have to invest a lot of time initially in meetings to review current services, the evidence base and agree best practice. There needs to be a firm commitment to the use of

care pathways from both the clinicians involved and the organisation otherwise implementation will be difficult. In addition to the cost of developing care pathways there are ongoing costs such as paper and printing and a system will be needed for reviewing and collating information from the variance analyses. For many teams involved in using care pathways these costs are in addition to current workload and this could pose a potential threat to the success of a care pathway. Some NHS organisations employ a specific co-ordinator to facilitate the use of care pathways but this is a further ongoing cost in addition to the extra input required of the clinicians involved. If an organisation hasn't adequately allowed for the resources needed to develop, implement and maintain care pathways then successful implementation will be problematic and unsustainable.

Evidence Base?

Lastly, there is a lack of good evidence that care pathways work. Yet care pathways have been implemented in both the USA and UK without this evidence base. There is a lot of pressure on NHS organisations to improve the quality and efficiency of services, especially in conditions like diabetes with huge mortality, morbidity and rising costs. Care pathways appear to be a good tool to facilitate this, but as discussed above, the resources needed to develop and implement care pathways are not insignificant, therefore it could be argued that they shouldn't be used without evidence that they work.

Table 1.3 Possible Advantages and Disadvantages of Care Pathways

Advantages	Disadvantages
Improved Quality of Patient Care • Developed by MDT team, agree best practice • Underpinned by research-based evidence • Continuous clinical audit & evaluation (facilitated by variance analysis)	**Inflexible** • Less holistic & task orientated • Inhibit clinical judgement
Improve Communication & Collaboration • Multidisciplinary team have to work together to agree care pathway • Better understanding of roles • Improved team working because use same documentation	**Difficult to Implement** • Staff compliance may be a problem especially from medics • Need strong leadership, effective communication & motivation for successful implementation
Improve Resource Management • Less duplication • Reduction in number tests and procedures • Better time management • Possible reduced length of stay (reduce costs)	**Increases Paperwork and Documentation** • If don't replace existing paperwork it may increase documentation • May be more problematic for complex multi-faceted conditions
Reduced documentation • Where it is all / part of medical record • Less writing (tick boxes common feature)	**Increase Risk of Litigation** • Expected standard of care explicit, if not met greater risk of complaint
Improved Risk Management • Increased accountability • Easier to identify patients not receiving appropriate management • Explicit audit standards	**Costs** • Require significant clinician time to develop and implement • Costs of printing & administration • Costs of monitoring variance
Education Tool • Clear guidance for new staff & students	**Evidence Base** • Lack of robust evidence that care pathways are effective
Increased Staff and Patient Satisfaction • Reports of better satisfaction because more efficient care & better communication	

1.4.7 Diabetes Care Pathways

The aim of this section is to examine the availability of published care pathways for diabetes.

Prior to the start of these studies the use of care pathways in diabetes was limited. A search of the literature using electronic databases (MEDLINE, CINAHL, EMBASE) revealed only one reference to a care pathway for diabetes (Price and McDaniel, 1995). This was an anecdotal report of the development of a care pathway for managing an insulin-dependent patient at home. The pathway had not been tested and there was no report of its impact on patient outcomes.

With the publication of the Diabetes NSF and the increasing number of guidelines available for the management of diabetes, more specialist diabetes units have started to consider and work towards developing care pathways for the management of diabetes. This has been evident from reports at national diabetes conferences and from the number of units across the UK requesting copies of the diabetes care pathways presented and described in this thesis.

A further search of the literature in December 2004 found eight papers (Ilag *et al.*, 2003; Crane and Werber, 1999; Price and McDaniel, 1995; Holland *et al.*, 2000; Fox *et al.*, 2004; Courtney *et al.*, 1997; Katon *et al.*, 2003; Bernstein, 1997) concerning care pathways for diabetes. Two of these were from the UK the rest were concerning care pathways used in the USA.

Only two of the eight papers reported an evaluation (the rest described development of the pathway and its intended purpose) of the care pathway concerned, and both of these were American papers. Crane and Werber (1999) report the use of a care pathway for the management of diabetes foot infections in an in-patient setting. They retrospectively compared patients on the care pathway to non-pathway patients and found that those on the care pathway had a reduced length of stay, reduced costs and less morbidity compared to patients not on the care pathway. Ilag *et al.* (2003) assessed the impact of a care pathway on the management of DKA (Diabetic Ketoacidosis). The study was a pre and post

comparison of patients admitted to hospital with DKA. They concluded that the critical pathway reduced variations in practice and was associated with reduced length of stay but not all the processes of care improved with the critical pathway.

On closer examination, of the two papers concerning diabetes care pathways in the UK, the one by Holland *et al.* (2000) doesn't describe a care pathway as defined by the NPA. It describes a 'referral pathway' for patients with diabetes foot problems not a care pathway for the management of these patients. The paper by Fox *et al.* (2004) presents a care pathway for pregnant patients with diabetes, but doesn't describe how it was developed and doesn't report any evaluation of the effectiveness of the care pathway.

It is evident from the literature that the use of care pathways in diabetes is limited and there has been no robust evaluation to date of the effectiveness of care pathways on the management of diabetes.

1.5 SUMMARY OF CHAPTER AND AIMS OF STUDIES

Diabetes is a major public health problem. There is robust evidence for the prevention and treatment of diabetes related complications, yet morbidity and mortality remain high. A key factor is a failure to implement evidence-based guidelines in a systematic and timely manner to the appropriate people. People with diabetes are cared for by a variety of health professionals in different settings and most of their routine management will not be by clinicians with a specialist training in diabetes. For the professionals involved, diabetes can be complex and trying to decipher the vast number of national and international guidelines on the disease may be daunting.

The Diabetes NSF has set a precedent that diabetes services should be standardised, of a high quality and readily accessible to people with diabetes. There is pressure on healthcare providers to deliver the NSF and ensure people with diabetes receive high quality evidence-based care. However, this is a major

challenge because of the growing numbers, inequity of current services, scope of the complications and associated burden and costs and limited resources.

Care pathways are a tool that may facilitate implementation of evidence-based care and improve communication and collaboration between multidisciplinary teams. In theory care pathways appear to be a useful tool which may facilitate better management of diabetes in specified settings and could be particularly useful to non-specialists managing patients with diabetes. However, the use of care pathways for diabetes is limited and evidence that care pathways in general are effective is lacking.

Care pathways are increasingly being used within the NHS in diabetes and other areas but the cost of development and implementation can be significant, and more evidence as to the effectiveness of care pathways should be gained before they are routinely implemented. The aim of this study was to determine whether care pathways would be effective in the management of patients with diabetes.

1.5.1 AIM OF THE STUDIES

The overall aim of the work described in this thesis was to develop and evaluate care pathways for the management of in-patients and out patients with diabetes in an acute NHS Trust. To this end, the secondary objectives included:

1 A literature review of the impact of care pathways on the management of in-patients with a surgical or medical condition.

2 Developing diabetes care pathways for in-patients and out patients.

3 Developing evaluation tools for the studies, in particular a staff knowledge questionnaire.

4 Conducting a RCT of the diabetes in-patient care pathway.

5 Examine the impact of a care pathway on patients with Diabetic Nephropathy.

The results of the studies presented may:

(A) Inform use of evidence-based diabetes care pathways in other Trusts within the NHS, and

(B) Clarify some of the present uncertainty concerning the effectiveness of care pathways, in particular, the hypothesis that care pathways might improve implementation of evidence-based medicine.

CHAPTER 2

LITERATURE REVIEW OF CARE PATHWAYS

2.1 INTRODUCTION

With the emergence of evidence-based medicine it is expected that clinicians make clinical decisions and decisions about the organisation of services based on available evidence, but, with the vast array of peer-reviewed journals and electronic databases this can be a daunting task. Systematic reviews have evolved as a key tool to facilitate collation and evaluation of the evidence by clinicians.

Systematic reviews are different to traditional literature reviews in that they follow a strict scientific protocol that minimises bias and increases reliability. A systematic review will:

'*locate, appraise and synthesise evidence from scientific studies in order to provide informative empirical answers to scientific research questions.*'

(NHS Centre for Reviews and Dissemination, 1996).

With the emergence of systematic reviews there has been a shift from healthcare based on anecdote and experience to services and interventions based on research evidence (Appleby *et al.*, 1995). The Cochrane Collaboration and the NHS Centre for Reviews and Dissemination undertake systematic reviews based on high quality research with rigorous methodology, such as randomised controlled trials (RCTs) or controlled 'before and after' studies. Such reviews are widely regarded as the 'gold standard' and their conclusions are a valid resource for clinicians to make decisions regarding the delivery of healthcare.

The aim was to undertake a systematic review to ascertain if there was a reliable evidence-base for the use of care pathways in healthcare in the UK. From preliminary work, it was clear that there are too few well designed and conducted studies to undertake a meaningful systematic review of care pathway use at this time, so the process was adapted to take this into account.

The purpose of this chapter is to describe the approach taken for the systematic review in the first instance, and the methods subsequently used to complete the literature review. It will explain the question being addressed by the review, the search strategy, the number of papers located and subsequently included in the review, results and overall conclusions.

2.2 OBJECTIVES

Care pathways have been advocated as an important tool for implementing evidence-based medicine and the purpose of this work was to examine their use in the delivery of diabetes care. Preliminary literature searches revealed a lack of existing diabetes care pathways but a plethora of papers relating to care pathway use in other conditions. The aim was to establish the existing evidence-base for the use of care pathways as a rationale for developing and using them in diabetes.

The objective was to assess the impact of care pathways compared to usual care, on the management of in-patients with either a medical or surgical condition. The primary outcome measures were length of stay (LOS), recovery rate, complications of disease or surgery / intervention, patient satisfaction, staff satisfaction and re-admission rate. A secondary outcome measure was the quality of care patients received.

2.3 METHODOLOGY

2.3.1 Introduction

This section will describe the methodology used to undertake a systematic review to answer the question 'Do care pathways improve the management and or outcome of hospital in-patients with a medical or surgical condition?' The protocol for the systematic review is presented in Appendix 1 and the sections below will discuss the rationale for this protocol and explain why the methodology was adapted following the results of the literature search.

2.3.2 Population and Intervention

When conducting a systematic review it is usual to define the population to be included in the study. The population for this review was to be in-patients with a medical or surgical condition and the mode of admission could be either an emergency or a planned admission. Paediatrics and mental health were excluded from the review because these patients are very different to medical patients with diabetes in whom the diabetes care pathways would be used. Surgical patients were included because if the in-patient diabetes care pathway proved to be effective on medical wards, it would be implemented across the surgical wards.

The primary intervention in the studies to be included in the review had to be a care pathway. The National Pathway Association (NPA) definition of a care pathway (chapter 1) was used to determine if the intervention described was a care pathway; if the core features (guidelines for a given condition in a specified setting, with time frames and a variance analysis) were present the study could be included. Also included were studies using different terms to describe a care pathway, such as Integrated Care Pathway, Anticipated Recovery Map and Critical Pathway, if they fitted the above definition of a care pathway.

2.3.3 Outcomes and Inclusion / Exclusion Criteria for Studies to be Included

The preliminary search of the literature indicated that papers relating to care pathways reported a variety of outcome measures, therefore, as many as possible were included in order to capture all the potential benefits of a care pathway. The aim was to include papers in the review reporting at least one of the following primary outcomes:

- Length of stay
- Recovery rate
- Complications of the disease or surgery
- Patient satisfaction

- Staff satisfaction
- Re-admission rate

A secondary outcome was quality of care, but studies describing only this outcome measure would not be included because it is not a hard endpoint and it has been suggested that surrogate endpoints can be misleading and studies based on them may be less reliable (Gotzsche *et al.*, 1996).

Types of Study

Ideally, the aim was to include unconfounded randomised controlled trials comparing a care pathway to usual care. However, it was expected that there would be a limited number of such studies and that studies of weaker research design would be included in the review and allow for the potential for bias. The types of study to be included were, RCTs (assessed using a quality criteria from NHS Centre for Reviews and Dissemination, 1996), quasi-experimental studies describing a control and intervention group but no randomisation, controlled and uncontrolled before and after studies and systematic reviews. Anecdotal reports, retrospective studies, descriptive studies and studies where there was an inadequate description of the methodology, would be excluded because the potential for bias would be too great and the validity of such studies questionable.

Data Extraction

Two data extraction forms (Appendix 1) were used, one was developed for non-randomised controlled studies and one for RCTs based on guidance from the NHS Centre for Reviews and Dissemination (1996), including their quality criteria for RCTs, which was used for assessing randomised controlled studies. The data extraction forms were to be used to assess the suitability and validity of each study and the information to be recorded on them included:

- General information: title, authors, reference, country of origin, published or unpublished

- Study characteristics: study design, randomisation, duration, concealment, intervention, outcomes
- Subjects: inclusion / exclusion criteria, mean age & sex, number in each group, matched at baseline, loss to follow up
- Results: Overall findings, results for each outcome

The aim was to identify potential studies to be included in the review and two reviewers would use the data extraction form(s) to determine if a study was suitable for inclusion.

2.3.4 Search Strategy

The search was originally conducted in February 2000 and was redone in October 2004 to capture new studies. The following electronic databases were searched with no language restrictions:

1. Embase (1974-2004)
2. Medline (1951-2004)
3. Cinahl (1951-2004)
4. Allied & Complementary medicine (1985-2004)
5. British Nursing Index (2000-2004)
6. DH-DATA (2000-2004)

In addition, the Journal of Integrated Care Pathways (2001 to 2004) was hand searched, reference lists of papers retrieved from the search were checked and the NPA was contacted to ascertain if any of the members knew of ongoing studies pertaining to care pathways.

The following search strategy was used initially for MEDLINE and adapted for the other databases.

1. Care pathways* (Mesh, all subheadings included)
2. Inpatients

3. 1 and 2
4. Medical
5. 3 and 4
6. Surgical
7. 3 and 6
8. Clinical path
9. Critical pathway
10. Care map
11. Managed care
12. Case management
13. Randomised controlled trial
14. 1 and 13

Results of the Search

The search generated 1496 citations, all the titles, abstracts and keywords provided by the electronic database were screened, following which 1406 citations were eliminated. Those eliminated were duplicates or did not fit the review protocol (Appendix 1), most of those excluded either did not describe a care pathway or were not a study but a descriptive account of developing and implementing a care pathway.

This left 90 papers that either appeared to fit the protocol or it was not clear from the summary information provided by the database whether they were relevant. All of these papers were retrieved. The aim was to exclude those which clearly did not fit the study protocol and for the author and a second reviewer to review the remaining papers, record information on the data extraction sheet(s) and agree which studies to include and exclude. However, it was clear when the 90 papers were reviewed that many were either descriptive accounts of a care pathway or did not meet the protocol, of those left the quality of the research methodology was not rigorous. There were only four references that described a randomised controlled trial and three of these described the same study (Sulch *et al.*, 2000; Sulch *et al.*, 2002a; Sulch *et al.*, 2002b) but were reporting different outcomes, this left potentially only two RCTs to include in the systematic review.

The reviewers agreed that it was not possible to proceed with a systematic review of care pathways because of a lack of studies describing high quality research relating to this topic.

However, whilst a systematic review as conducted by the Cochrane Collaboration or NHS Centre for Reviews and Dissemination should be viewed as a 'gold standard' because they focus on high quality research using only rigorous methodologies, there are many areas in healthcare where such research is not available. The dilemma in areas where there is a lack of robust research, either because the studies haven't been done or because the nature of the topic lends itself towards qualitative studies, is, do we ignore the literature that is available? It has been recognised that only to rely on systematic reviews of robust quantitative research may be restrictive and that other types of evidence may also be important in shaping decisions about healthcare and policy (Mulrow and Oxman, 1997). Therefore, it would still be useful to consider the findings from studies relating to care pathways despite the weaknesses of many of the studies identified. At the start of this literature review there was a lack of published, standardised guidance for conducting a systematic review of less rigorous studies, but it seemed reasonable to conduct a review of the literature on care pathways using as much as possible, the same methods as for a systematic review. In the last few years there have been a number of publications highlighting the importance of including qualitative studies in systematic reviews (Thomas *et al.*, 2004; Cooper *et al.*, 2000; MacEachen *et al.*, 2004) and criteria for scoring qualitative papers have been published (Weston *et al.*, 1999; Bromley *et al.*, 2002; HCPRDU, 2003). If these publications had been available at the start of this review each study not describing a randomised controlled trial could have been assessed against a quality criteria.

Revised Protocol

As a result of the lack of high quality research relating to care pathways it was not possible to conduct a systematic review but a review of the literature on care pathways was undertaken using the principles of a systematic review to guide the process.

The review question of the original protocol (Appendix 1) would remain the same as would the population, intervention and outcomes. The search strategy remained the same and the search already conducted would be used for the literature review. The main revision to the original protocol was to the inclusion / exclusion criteria. Retrospective studies and any studies that attempted to measure the impact of a care pathway by comparing patients on a care pathway to those not, irrespective of the timeframe for the control group, lack of matching and lack of control or randomisation, would be included.

Anecdotal reports, descriptive studies and studies with inadequate description of the methods used, would still be excluded.

It was agreed by the reviewers that all studies that met the revised criteria would be included. Moreover, it was agreed that because those studies now being excluded were easy to identify, and those to be included had less rigorous methodology, the potential for disagreement would be at a minimum and a second reviewer would not be necessary. However, if a quality criterion had been identified at the start of the review this could have been used independently by two reviewers to assess the quality of each paper and this would have strengthened the findings.

A meta-analysis or statistical pooling of the results of the studies would not be possible with the papers identified, therefore, a summary of the nature of the studies included would be provided in table format and a descriptive summary of the findings would be presented.

2.4 RESULTS

2.4.1 Introduction

This section will discuss the papers included and excluded from the review. For those included, an overview of the method used in each study, the population and

outcome measures will be provided and a summary of the findings from all the studies will be presented.

2.4.2 Excluded Studies

As described above 90 papers were identified from the original search as being potentially relevant, each one was reviewed against the revised study protocol and 67 papers were excluded from the review. Of those excluded, 49 papers were not describing a study but were descriptive accounts of developing or implementing a care pathway. Five papers were not related to an in-patient setting, 8 papers did not have the right population but described either paediatrics or mental health and in 5 papers a care pathway was not the main intervention being described.

2.4.3 Included Studies

Twenty-three studies were included in the review. Of these there were 4 RCTs (3 described the same study), 19 were before and after studies but with varying methods, some were retrospective, some prospective and some a combination of both. One paper described a retrospective comparison of care pathway to non-pathway patients being treated in a similar time frame. All the studies were single centre studies, some gave more details than others regarding characteristics of subjects and there were very few exclusion criteria for subjects. Table 2.1 provides an overview of each of the papers including study design, subjects and number in each group, intervention and outcomes reported in the paper.

The methodological quality of all the studies was poor, including the RCTs when assessed against a quality criterion. The majority of the studies were retrospective case note comparisons of outcomes before and after introduction of a care pathway with no randomisation of subjects, the potential for bias and confounding in such studies is high and the results of all the papers should be interpreted with caution.

This conclusion regarding the methodological quality of the papers was strengthened after the review was completed when the author re-reviewed each paper against one of the published quality criterion for qualitative studies (Weston *et al.*, 1999). This particular quality score states that qualitative research should demonstrate:

1. An explicit account of the theoretical framework and inclusion of literature review if appropriate
2. Stated clear aims and objectives
3. A clear description of context
4. A clear description of sample
5. A clear description of fieldwork methods
6. An analysis of data by more than one researcher – systematic data collection
7. Sufficient original evidence to mediate between evidence and interpretation

Based on the authors assessment of each paper none of the studies would have scored more than 5 using the above criterion, indicating poor methodological quality.

Paper	Study Design	Subjects (Number included)	Intervention	Outcomes
Dowsey *et al,* 1999	Single centre, RCT, not clear if randomisation was blinded, minimum 3 months follow-up	Patients undergoing hip or knee joint arthroplasty, recruited for 12 months (92 pathway vs. 71 control)	Clinical pathway for hip & knee arthroplasty versus usual care	Length of stay, time to sitting out of bed & ambulation, post op complications, readmission & discharge matching (did they return to pre-admission address)
Sulch *et al.* 2000 Sulch *et al.* 2002a Sulch *et al.* 2002b *	Single centre, RCT (allocation concealed), unblinded, Follow up to 26 weeks	Patients transferred to a stroke rehabilitation unit within 2 weeks of an acute stroke. (Excluded if severe premorbid disability) (76 pathway vs. 76 control)	Integrated care pathway for stroke rehabilitation versus conventional care Subjects were on same unit but in 2 separate bed areas with little cross over of staff	**Sulch et al, 2000** – Length of stay, mortality, rate of institutionalisation, anxiety & depression, quality of life **Sulch et al, 2002a**- processes of care **Sulch et al, 2002b**- Quality of life
Velasco *et al.* 1996	Single centre, pre & post intervention comparison – data collected prospectively for intervention & compared to historic controls	Patients undergoing Coronary Bypass Surgery, consecutive patients over 6 month period compared to historic controls (114 pathway vs. 382 pre-pathway)	Critical pathway for coronary bypass surgery	Length of stay Cost Quality of care (post-op mortality, re-admission rate)
Dzwierzynski *et al.* 1998	Single centre, retrospective case note review, pre & post intervention comparison.	Patients undergoing surgical reconstruction of a pressure ulcer (43 pathway vs. 54 pre-pathway)	Clinical pathway for surgical reconstruction of pressure ulcers	Length of stay Total charges Re-admission rate

*** 3 papers reporting same study but different outcomes**

Table 2.1 Characteristics of Included Studies

Paper	Study Design	Subjects (Number included)	Intervention	Outcomes
Gheiler *et al.* 1998	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing radical prostatectomy (under either an academic or private physician) (522 pathway vs. 607 pre-pathway	Clinical care pathway for radical prostatectomy	Length of stay Morbidity Mortality Cost Re-admission rate
Iireson 1997	Single centre, prospective, pre & post intervention comparison	Patients undergoing total hip or knee replacement. 3 lost to follow up (64 pathway vs. 64 pre-pathway)	Critical pathway for patients having total hip or knee replacement	Length of stay Quality of care Cost
Stanley *et al.* 1998	Single centre, pre & post intervention comparison, data collection prospective for intervention group but retrospective controls used	Patients undergoing Infrainguinal bypass surgery (planned or emergency) (69 pathway vs. 67 pre-pathway)	Critical pathway for Infrainguinal bypass surgery	Length of stay Re-admission Mortality Complication rates
Cushing & Stratta 1997	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing simultaneous pancreas-kidney transplant (10 pathway vs. 10 pre-pathway)	Critical pathway for simultaneous pancreas-kidney transplant	Length of stay Hospital charges
Archer *et al.* 1997	Single centre, prospective, pre & post intervention comparison	Patients undergoing total colectomy and ileal pouch / anal anastomosis (14 pathway vs. 10 pre-pathway)	Clinical pathway for elective total colectomy and ileal pouch / anal anastomosis	Length of stay Hospital charges
Noedel *et al.* 1996	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing cardiac transplant (23 pathway vs. 51 pre-pathway)	Critical pathway for thoracic surgery patients (including cardiac transplant)	Length of stay Clinical management Hospital charges

Table 2.1 Characteristics of Included Studies

Paper	Study Design	Subjects (Number included)	Intervention	Outcomes
Schaldach 1997	Single centre, retrospective case note review, compared 3 groups consecutive patients – 1) NO care pathway, 2) consultation with rehabilitation services in postoperative period, 3) rehabilitation-focussed care pathway	Patients with arterial occlusive disease for above or below knee amputation (46 pathway vs. 104 no pathway & 34 rehab consultation)	Care pathway for above or below knee amputation	Length of stay Costs Number discharged home
Chang *et al.* 1999	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing urological surgery (1382 pathway vs. 1279 pre-pathway)	18 clinical pathways for various urological surgery	Length of stay Costs Quality of care (7 clinical indicators)
Gregor *et al.* 1996	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing total knee or hip arthroplasty. Excluded patients requiring ITU or additional surgery. (122 pathway vs. 152 pre-pathway)	Care pathway for knee and hip arthroplasty	Length of stay Quality of intervention (appropriate use of tests)
Dardik 1997	Single centre, retrospective case note review, pre & post intervention comparison	Patients undergoing elective Carotid Endarterectomy procedures (134 pathway vs. 67 pre-pathway)	Carotid Endarterectomy critical pathway	Length of stay Cost Re-admission Post-op complications
Liao *et al.* 1998	Single centre, retrospective case note review, pre & post intervention comparison	Patients with prostate hyperplasia undergoing TURP. Excluded acute pyelonephritis or a final diagnosis of prostatic carcinoma. (61 pathway vs. 65 pre-pathway)	Clinical pathway for TURP	Length of stay Cost Quality of care

Table 2.1 Characteristics of Included Studies

Paper	Study Design	Subjects (Number included)	Intervention	Outcomes
Ranjan *et al.* 2003	Single centre, retrospective case note review, compared pathway to non-pathway patients.	Patients with discharge diagnosis of congestive heart failure (174 pathway vs. 197 non-pathway)	Clinical pathway for congestive heart failure	Length of stay Hospital charges
Roberts *et al.* 2004	Single centre, prospective pre & post intervention comparison. Used audit data from nearby hospitals (same time period to control secular trends)	Femoral neck fracture >65 years Excluded multiple fractures, malignancy, total hip replacement, re-fracture, operation done elsewhere (369 pathway vs. 395 pre-pathway)	Care pathway for older hip fracture patients	Length of stay Quality of care Discharge destination 30-day mortality
Kowal & Delaney 1996	Single centre, pre & post intervention comparison. Retrospective case note review for pre group & prospective review for post intervention group.	Patients undergoing surgery for mastectomy (convenience sample) (31 pathway vs. 31 pre-pathway)	Care pathway for mastectomy	Length of stay Cost
Rumble *et al.* 1996	Single centre, retrospective case note review, pre & post intervention comparison	Patients admitted for CABG (401 pathway vs. 379 pre-pathway)	Critical pathway for CABG	Re-admission within 365 days Length of stay
Ilag *et al.* 2003	Single centre, prospective, pre & post intervention comparison	Non-pregnant adults admitted with a primary or secondary diagnosis of DKA (77 pathway vs. 72 pre-pathway)	Care pathway for DKA (focussed on 7 key areas for management)	Length of stay Cost
Pearson *et al* 2001	Single centre, study of intervention (prospective) compared to 2 year baseline & length of stay in 4 neighbouring hospitals	Patients undergoing CABG, total knee replacement, colectomy, thoracic surgery or hysterectomy	Critical pathways for CABG, colectomy, knee replacement, thoracic surgery & hysterectomy	Length of stay

Table 2.1 Characteristics of Included Studies

2.4.4 Results

The papers measured similar outcomes and the combined results will be summarised below under outcome headings.

Length of Stay

All of the included studies had length of hospital stay as a primary outcome measure. Nine papers (Velasco *et al.*, 1996; Gheiler *et al.*, 1998; Ireson, 1997; Archer *et al.*, 1997; Chang *et al.*, 1999; Gregor *et al.*, 1996; Liao *et al.*, 1998; Kowal & Delaney, 1996; Rumble *et al.*, 1996) report a statistically significant reduction in length of stay following introduction of a care pathway. Nine papers (Dowsey *et al.*, 1999; Dzwierzynski, 1998; Stanley *et al.*, 1998; Cushing & Stratta, 1997; Schaldach, 1997; Noedel *et al.*, 1996; Ranjan *et al.*, 2003; Ilag *et al.*, 2003) reported a reduction in length of stay with a care pathway but with no measure / report of statistical significance. Three papers (Pearson *et al.*, 2001; Sulch *et al.*, 2000; Dardik *et al.*, 1997) reported no difference in length of stay between the care pathway and non-pathway group. One paper (Roberts *et al.*, 2004) reported an increase in length of stay with a care pathway but suggested this was because patients received better quality care.

Recovery Rate

Only one paper (Sulch *et al.*, 2000) examined the impact of a care pathway on recovery rate and they found there to be no difference between a care pathway and conventional care.

Complications of Disease / Surgery

Seven papers (Gheiler *et al.*, 1998; Stanley *et al.*, 1998; Archer *et al.*, 1997; Noedel *et al.*, 1996; Gregor *et al.*, 1996; Dardik *et al.*, 1997; Liao *et al.*, 1998) found no difference to complications of the disease or surgery (eg morbidity or

mortality) with a care pathway. One paper (Roberts *et al.*, 2004) reported better clinical outcomes (in particular ambulation on discharge) with a care pathway.

Quality of Life

Only one paper (Sulch *et al.*, 2002b) reported the impact of a care pathway on Quality of Life, and found this to be better in the control group not the care pathway group.

Re-admission Rate

Only one paper (Dowsey *et al.*, 1999) reported a reduction in re-admission rate following introduction of a care pathway. Five other papers (Dzwierzynski, 1998; Stanley *et al.*, 1998; Chang *et al.*, 1999; Gregor *et al.*, 1996; Rumble *et al.*, 1996) examined the impact of a care pathway on re-admission rate and all reported no difference with a care pathway.

Discharge Matching

One paper (Dowsey *et al.*, 1999) considered the impact of a care pathway on 'discharge matching' that is were patients discharged to their admission address / anticipated discharge destination, and found this to better in the care pathway group.

Quality of Care

The quality of care (eg appropriateness of intervention, tests ordered, use of drugs) was assessed in nine of the papers, seven papers (Ireson, 1997; Cushing & Stratta, 1997; Chang *et al.*, 1999; Gregor *et al.*, 1996; Ranjan *et al.*, 2003; Roberts *et al.*, 2004; Ilag *et al.*, 2003) reported an improvement in the quality of care with a care pathway. Improvements included a reduction in the number of tests (with no adverse impact on outcome), better use of some drugs and improved documentation. Two papers (Sulch *et al.*, 2002a, Velasco *et al.*, 1996)

reported no difference in quality of care indicators between the care pathway and non-pathway groups.

Costs

Thirteen papers (Velasco *et al.*, 1996; Dzwierzynski *et al.*, 1998; Gheiler *et al.*, 1998; Ireson, 1997; Cushing & Stratta, 1997; Archer *et al.*, 1997; Schaldach, 1997; Noedel *et al.*, 1996; Chang *et al.*, 1999; Liao *et al.*, 1998; Ranjan *et al.*, 2003; Kowal & Delaney, 1996; Ilag *et al.*, 2003) examined the impact of a care pathway on resource utilisation / cost of care. All reported a reduction in costs with a care pathway.

2.5 SUMMARY

The aim of this literature review was to determine whether care pathways improved the management and or outcome of hospital in-patients with a medical or surgical condition. The primary outcome measures were length of stay, recovery rate, complications of the condition, re-admission rate and staff and patient satisfaction. A secondary outcome measure was the quality of care patients received.

It was not possible to complete a systematic review as initially intended, because of the poor methodological quality of all of the papers identified in the literature search. However, a literature review based on the principles of a systematic review was completed in an attempt to ascertain the quality and content of existing evidence relating to care pathways. Recent publications regarding the use of qualitative studies in systematic reviews and guidance on quality criteria would improve the robustness of similar reviews to this one in the future.

Twenty-three papers met the revised inclusion criteria, all were of a poor methodological quality, including the RCTs. The majority of the studies were retrospective case note comparisons of outcomes before and after introduction of a care pathway, there was no randomisation of subjects or any attempt to control for confounding factors. Consequently, the results from all the studies should be

interpreted with caution and it would not be reasonable to change practice based on the overall findings of this literature review.

Length of stay was measured in all the studies and 19 of them reported a reduction in length of stay with a care pathway and only one study reported a longer length of stay with a care pathway. There was no evidence of an improvement to recovery rates with a care pathway and as only one paper reported an improvement in complications of the disease / surgery there was no evidence for this as a better outcome with care pathways. Seven studies reported an improvement in the quality of care received and one found better 'discharge matching' with a care pathway. There was no strong evidence that care pathways improved re-admission rate, of the six studies that examined this only one reported an improvement and the one paper to measure quality of life found it to be better in the control group. No studies measured patient or staff satisfaction as an outcome measure. Cost of care was not an outcome measure for this review, however, thirteen of the included studies examined the impact of a care pathway on costs and all found there to be a reduction in the cost of care with a care pathway.

From this review of the literature regarding in-patient care pathways it appears that the main potential benefits following introduction of a care pathway are on length of hospital stay and costs with possible improvements to the quality of care patients receive.

2.6 CONCLUSIONS

The main aim of this literature review was to ascertain whether there was sufficient evidence to justify the development and implementation of care pathways for in-patients with diabetes. As discussed in chapter one, patients with diabetes are known to stay in hospital longer than patients with a similar admission diagnosis without diabetes and they consume more resources. Therefore if a care pathway for diabetes reduced length of stay and cost (especially if also improving the quality of care) it would be a valuable tool. The findings from this review suggest that reduced length of stay, lower costs and

potentially better quality of care, could be a benefit of in-patient care pathways, but other factors such as re-admission rate, complication and quality of life are not improved by care pathways. However, these conclusions are severely limited by the poor quality of the evidence and it is debatable whether existing evidence is adequate to justify development and implementation of in-patient care pathways.

Moreover, since this review was completed, a systematic review of care pathways for acute stroke / stoke rehabilitation has been completed by the Cochrane Collaboration (Kwan and Sandercock, 2005). They found that care pathways appear to have both positive and negative effects and also concluded that the quality of the evidence was poor. The overall conclusion from this review was that there was not enough evidence to justify routine implementation of care pathways for stroke management.

It seems ironic that care pathways are advocated as a useful tool for implementing evidence-based medicine, yet, there is no robust evidence of their effectiveness! Despite this many areas continue to develop and implement care pathways, it seems imperative that either more conclusive research is conducted in this area to justify the continued use of care pathways or that NHS managers and clinicians review the appropriateness and effectiveness of care pathways.

Despite the findings from the literature review, the development of in-patient and outpatient diabetes care pathways continued for three reasons: firstly, development of the care pathways started simultaneously to the literature review. Therefore, by the time it was apparent that the available evidence was poor most of the care pathways had been developed and studies to assess their impact were underway so it seemed reasonable to conclude the studies. Secondly, the problem with the existing evidence was the poor methodological quality, it may be perhaps, that care pathways are effective but have not been tested properly, the aim was to conduct a more robust study to measure the effectiveness of an in-patient care pathway. Lastly, initial experiences with the outpatient diabetes care pathways were overwhelmingly positive, they appeared to be facilitating significant improvements to the diabetes service and it was important to continue

with their development. However, if following the studies there was no conclusive evidence for the continued use of any of the care pathways they would not continue to be used for the management of patients with diabetes.

CHAPTER 3

DEVELOPING DIABETES CARE PATHWAYS

3.1 INTRODUCTION

As discussed in Chapter 1, it is evident from the literature that very little has been published on care pathway use in the context of diabetes; an 'off-the-peg' solution was not available for this work. This may have been fortuitous because there is considerable evidence that successful implementation of a care pathway is strongly linked to the development process, including early and significant engagement by key stakeholders, especially senior clinicians within the service (Ibarra *et al.*, 1996).

The aim of this chapter is to discuss the rationale for and development of care pathways within a diabetes service. The need for care pathways locally will be presented and the literature regarding best practice in care pathway development will be summarised. The care pathways used in these studies were developed by following an explicit, systematic process and this will be outlined along with key success, difficulties and lessons learned.

3.2 THE CASE FOR LOCAL CARE PATHWAYS

Systematic external analysis (see below), local (informal) internal services review and ad hoc patient feedback identified shortfalls in some aspects of local diabetes service provision. In particular, some aspects of service organisation and the effective implementation of local clinical care guidelines were imperfect. The challenge was to better organise diabetes services to try to ensure that patients consistently received high quality, evidence-based care. It was hypothesised that care pathways might prove to be a useful tool to achieve these goals.

3.2.1 Shortfalls in Diabetes In-patient Care

It is well documented that hospital admission rates and length of stay are substantially greater for people with diabetes, even when admission diagnosis is similar. Indeed, people with diabetes stay in hospital up to twice as long as their

non-diabetic counterparts (Mackinnon, 1993). At any one time, up to one in ten acute hospital beds is occupied by someone with diabetes; they use more services than those without diabetes and account for 9% of hospital costs (Department of Health, 2001; Pickup and Williams, 1991; Koproski *et al.*, 1997; Kennedy *et al.*, 1999). The reason for this costly difference in length of stay may, in part, be inherent to the condition itself. People with diabetes have more extensive myocardial damage and more complications such as systolic heart failure following myocardial infarction, for example, (Savage *et al.*, 1998; Abbot *et al.*, 1988), but it is widely believed that suboptimal management of diabetes on general wards may also be a contributing factor. Furthermore, delays in discharge are regularly caused by problems with diabetes when diabetes was not the primary cause of admission (Driskill, 1996; Callaghan and Williams, 1994, Kyne-Grzebalski, 1999; McDermott, 1995; Department of Health, 2001).

Thus, the management of in-patients with diabetes in the local acute Trust was a cause for concern. Indeed, in-patients regularly reported a lack of confidence in ward staff and problems with the management of their diabetes. Feedback from patients and staff experience of the management of in-patients with diabetes highlighted the following problems:

- Inappropriate timing of medication (especially insulin therapy)
- Patients not receiving the right diet and having meals at inappropriate times
- Inappropriate monitoring of blood glucose levels (patients either had too many or too few tests and results were not acted on)
- Poor knowledge of diabetes amongst ward staff
- A failure by staff to act on blood results such as HbA1c, lipids and investigations for proteinuria (a sign of diabetes-related kidney disease).

There were comprehensive, local, evidence-based guidelines (Hardy, 1998) for the management of in-patients with diabetes but it was evident that they were not used consistently. In addition, there was a nurse specialist dedicated to in-patient care, but she was unable to see all in-patients with diabetes and relied on ward based staff to follow the guidelines.

Many of the problems facing in-patients with diabetes in the local Trust appeared to be the result of poor organisation and a failure to use guidelines. It was proposed that a care pathway might facilitate better use of guidelines and lead to more consistent, higher quality care.

3.2.2 Shortfalls in Diabetes Outpatient Care

In 1997, there was a Regional Accreditation visit of the District's Diabetes Services, which included a survey of patients' views (NHS Executive Northwest, 1997). Overall the feedback was very positive but several areas of concern with the existing outpatient services were identified:

1. There was no system in place to ensure that patients received consistent medical management and advice. Treatment sometimes varied between doctors and advice and education could differ between nurses and doctors within the hospital clinic and between staff at the hospital and in primary care. Patients who responded to the survey highlighted inconsistent advice as a particular source of frustration. They wanted more consistency within the hospital clinic and between the hospital and their GP.
2. There was no formal programme of patient education. Education was delivered in busy clinics with constant interruptions, or as one-off sessions to unacceptably large groups. The service wasn't streamlined: patients tended to be seen in one of two large diabetes clinics irrespective of the nature of their diabetes problems and were often seen by a junior doctor with no specific experience managing complications of diabetes. It was evident from the surveys that patients wanted more personal contact and education tailored to their individual needs.
3. There were few means of measuring the effectiveness of education and other interventions and no systematic ongoing review of patient process and outcome measures.
4. No measures of patient satisfaction or quality of life were being undertaken.

5. Documentation was ad hoc, incomplete and non-centralised. Nurse specialists often recorded interventions separately from doctors, dietitians and podiatrists, and advice given to patients was not clearly documented.
6. Following the weekly consultant-led diabetes clinics, the staff involved would meet to review the patients seen in clinic and to give junior doctors the opportunity to present patients to the consultant but there was no regular forum for the multidisciplinary team to review the service and address problems.

In summary, it was evident that changes were needed to improve consistency of patient care, to standardise and improve documentation of patient education, to promote more efficient use of resources, to develop and improve tools for measuring effectiveness of clinical care and patient satisfaction, and to facilitate better audit and evaluation.

Again it was hypothesised that care pathways for outpatients with diabetes might facilitate the necessary changes to service provision. As there were no existing care pathways available, care pathways for general referrals to the service and for patients with specific problems, such as Diabetic Nephropathy had to be developed, implemented and evaluated.

3.3 HOW TO SUCCESSFULLY DEVELOP & IMPLEMENT CARE PATHWAYS

3.3.1 Introduction

Care pathways define an expected pathway of care for a given condition in a specified setting. Typically, each anticipated intervention is specified in chronological order. Deviations from the pathway of care are acceptable but should be recorded on a 'variance'. The variance explains why care deviated from the pathway and these deviations should be analysed to:

1. Understand an individual patient's care
2. Learn lessons to improve clinical management and or organisation of care

Care as defined on a care pathway is usually very structured as illustrated in figure 3.1, and in order to devise a care pathway, clinical teams need to review existing services and agree the most appropriate organisation of services and specify the 'journey' patients' should follow. There are explicit recommendations in the literature for care pathways as to the best methods to adopt when developing and implementing a care pathway. It is suggested that if these 'best practice' methods are not adopted then a care pathway may not be successfully used by clinicians. The review of services by a multidisciplinary team is invaluable and a key reason why the process of developing a care pathway may be as important an influence on care as the final document.

The aim of this section is to summarise 'best practice' in care pathway development and implementation, as described in the literature, and evaluate the diabetes care pathways against these standards. The key points are summarised in Table 3.1.

Figure 3.1 Example of Care Being Specified on a Care Pathway

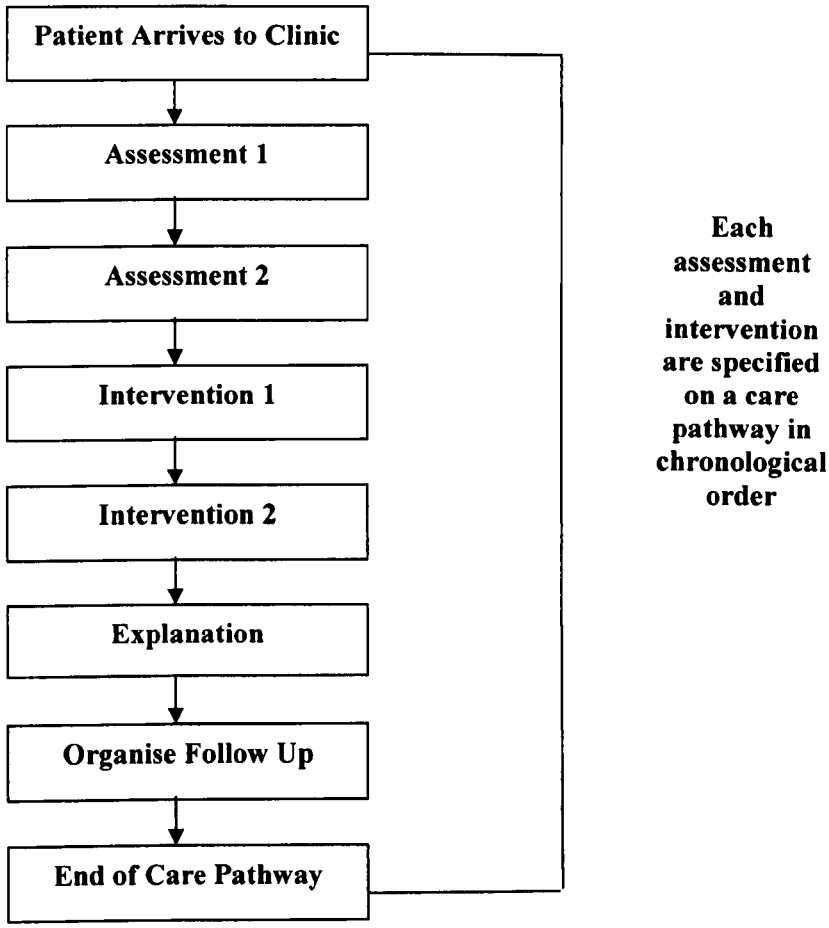


Table 3.1 Best Practice in Care Pathway Development

Best Practice Feature	Did it Apply to Diabetes?
1. Choose an Appropriate Condition It is important that the condition to be managed is amenable to care pathway-driven care and that the expectations of a care pathway are realistic (Danish *et al.*, 1995).	Some users of care pathways may argue that diabetes is not suited to care pathway-driven care because it is unpredictable. The rationale for developing diabetes care pathways was that the disease is a high volume, high cost condition with local, comprehensive evidence-based guidelines that were not being implemented effectively. The purpose of the diabetes care pathways was to implement existing evidence-based guidelines and to standardise delivery of diabetes care. This was an innovative project, but it was reasonable in light of the theoretical advantages of care pathways to improve implementation of evidence-based care.
2. Commitment from the Clinical Team and Strong Leadership It is important that involved clinicians are enthusiastic and committed. It is also important to have a 'champion' amongst the clinical team (Danish *et al.*, 1995; Wooster and Thane Forthman, 1996; Ibarra *et al.*, 1996).	Within the diabetes team there was considerable enthusiasm, commitment and support for care pathways championed by the author and strongly supported by the lead consultant.
3. Medical Involvement Doctors play a pivotal role in many / most clinical teams. Not infrequently care pathways have foundered because of a lack of medical engagement. Controversially, perhaps, it has been suggested that development and implementation of a successful care pathway should be led by a doctor or at least have a doctor as one of the main leaders (Horne, 1996; Ibarra *et al.*, 1996; Bing *et al.*, 1997).	There was a strong commitment from the doctors within the diabetes service for the development of care pathways and they were closely involved in their development from the outset. Interestingly, perhaps, on the wards it was more difficult to engage doctors and the use of diabetes care pathways in this setting proved more problematic.

4. Multidisciplinary Team Involvement As well as strong leadership and a clinical champion, it is vital to the successful development and implementation of care pathways to also establish (and maintain) strong stakeholder engagement (Newman, 1995; Burns *et al.*, 1995; Wietlispach Claussen and Pickering, 1995; Bultema *et al.*, 1996; Elizondo, 1995). One of the potential key advantages of care pathways is that they bring multidisciplinary team members together in the development and ongoing use of the care pathway. This may improve communication and collaboration and should be fostered from the beginning. This process typically involves considerable background work before the team start to write the care pathway (Lee, 1996). It is important that care pathways are designed to meet local needs and that team members feel they have ownership of the plan. Care pathways should not be imposed upon unsuspecting clinicians (Johnson and Smith, 2000).	The specialist diabetes team were engaged in the development of the outpatient diabetes care pathways at each stage but it proved more difficult to engage staff on the wards. Those diabetes care pathways that from the outset were associated with most involvement of the multidisciplinary team were easiest to develop and implement. By contrast, those with lesser degrees of involvement proved more difficult to establish.
5. Organisational Support Available organisational support is also considered by many to be important for the successful development and subsequent use of care pathways. Proponents of care pathways suggest that availability of resources to support the development of care pathways is essential. It is suggested that this should include clinical time, secretarial and administration support, paper costs etc (Danish *et al.*, 1995). In addition many argue that a designated care	Within the Trust there was organisational agreement for the development of diabetes care pathways but no dedicated resources to support the process. It was possible to overcome this difficultly for the outpatient diabetes care pathways because of the author's commitment and willingness to invest time over and above normal clinical commitments and because of the support of the lead clinician. The paper costs were

pathways co-ordinator is also necessary, to provide specialist expertise, education and support for staff (Turley *et al.*, 1995; Martich, 1993; National Assembly for Wales, 1999).	absorbed in the specialist team budget and it proved possible to sustain these commitments over time. However, a lack of dedicated resources proved to be problematic in the development and sustained use of in-patient diabetes care pathways.
6. Ease of Use A user friendly format greatly increases the likelihood of successful adoption of a care pathway (Crummer and Carter, 1993). Additionally, the status of existing documentation is also an important factor, if that was problematic then a change to using a care pathway may be more successful but if existing documentation is working well it may prove more difficult to implement a care pathway.	There was agreement that documentation of diabetes care in outpatients and on the wards needed improvement. The diabetes care pathways have two key elements: a set of evidence-based standards, underpinning the care pathway, and the care pathway itself. This format worked well.

3.3.2 Summary

To summarise, the success of a care pathway depends on a variety of factors including: commitment from staff and the organisation, adequate resources, clearly identified problems that are suited to the development of a care pathway and effective co-ordination and facilitation of the process. All of these factors existed to some degree for the development of the diabetes care pathways.

3.4 THE DEVELOPMENT PROCESS

3.4.1 Introduction

For all the care pathways, the development process was long and involved repeated meetings with the relevant clinicians and multiple revisions of each of the care pathways. The same process was followed when developing each of the care pathways; the process is outlined below and could be used by others wishing

to develop care pathways. The purpose of this section is to summarise the key stages in the development process and to highlight the successes and difficulties encountered.

3.4.2 Developmental History

The development process was devised following an extensive review of the literature on care pathways, including the studies used in the systematic review discussed in chapter 2 (although none of these outlined in any great detail the development process of a care pathway as they were predominantly describing an evaluation of the impact of a care pathway on patient care) and the papers summarised in Table 3.1. In addition guidance from the National Care Pathways Association (De Luc and Currie, 1999) and from national conferences on care pathways was incorporated. Each stage of this process is outlined in section 3.4.3 and Table 3.2 illustrates how the process worked in practice by summarising the development of the in-patient diabetes care pathway and education clinic care pathway used in outpatients. The latest version of the in-patient care pathway and core outpatient care pathways (New Patient Clinic, Education Clinic and Discharge Assessment Clinic) are in Appendix 2.

3.4.3 Stages of the Development Process

Stage 1 – Identify a gap in current services

The first stage is to identify problems in existing services that appear amenable to care pathway development. As discussed in section 3.2 there were shortfalls in local in-patient and outpatient diabetes services and because these appeared to predominantly reflect poor organisation of care delivery and a failure to implement evidence-based guidelines it was hypothesised by the author that care pathways may be a solution. Another task at this stage is to conduct preliminary literature searches to identify existing care pathways that could be used. There were no existing diabetes care pathways identified at the start of this work

Stage 2 – Involve Multi-disciplinary Team from the Start

It is crucial that the co-operation of the multi-disciplinary team is gained at the beginning of the development process; there is a clear consensus in the literature that engaging the multi-disciplinary team at the beginning is a key factor in the successful development of care pathways (Kowal and Delaney, 1996; Burns *et al.*, 1995; Johnson and Smith, 2000). At this early stage it is important to gain agreement regarding the need for a care pathway, some members of the team may not recognise gaps within the service and could regard such suggestions as a criticism of their work if not handled sensitively.

Meetings were held from the start with the specialist diabetes team to discuss the problems with existing diabetes services and to propose the need for care pathways. Generally there was agreement regarding the problems discussed in section 3.2 and a willingness to try care pathways. However, members of the ward staff were not consulted at this early stage to agree the need for improvements in in-patient care or the need for a care pathway and this may be a contributing factor to subsequent poor compliance with the in-patient care pathway. A difficulty when developing care pathways for general wards with a large number of staff and regular staff turnover is identifying the key stakeholders to work with.

Stage 3 – Identify Leaders and a Working Party

It is important to identify one or two members of the team to co-ordinate the process and maintain commitment. As summarised in table 3.1 if one of these leaders can be a medic there is even more chance that the care pathway will be successfully developed (Horne, 1996; Bing *et al.*, 1997). Where the team is large, a working party should be established to oversee the rest of the stages in the development and to ensure representation of all professions (Pearson *et al.*, 2001). This wasn't necessary with the outpatient diabetes care pathways as there were only ten members of the team at the start of the development process and a weekly team meeting was established to work through each stage and evaluate

progress. However, another limitation in the development of the in-patient care pathway was a failure to involve staff from the ward(s) in a 'working party' at this early stage. Furthermore, whilst the author and lead consultant were effective leaders in the process for the specialist team it may have been more appropriate to identify a key person (perhaps another consultant) to work with them in developing the in-patient care pathway as this may have secured more acceptance amongst ward staff for the care pathway. At this time there was no care pathway co-ordinator in post within the Trust, if there had been this person may have been an effective leader of the process.

Another factor to be considered at this stage is the experience and or training of those identified as leaders or members of a working group. There are regular national conferences on the subject of care pathways and there are companies offering training programmes for people wanting to develop care pathways (Venture Training and Consulting, 2006). Where there is a care pathway co-ordinator in post within an organisation with experience of care pathway development, the clinical staff may not need specific training as they can be guided in the process by this person, otherwise some training or knowledge of development is important but it is hard to be specific about how much as there no explicit guidelines. The leaders of the diabetes care pathways attending national conferences, joined the National Care Pathways Association and reviewed the literature to guide them in the process.

An agreement of how often the key people will meet should be made at this stage, experience from this work suggests this should initially be at least monthly. We discussed the progress of the care pathways at the weekly team meeting.

Stage 4 – Agree Remit and Content of the Care Pathway

The preliminary meetings of the working party should be used to agree the remit and content of the proposed care pathway. If it was an audit or accreditation visit which first identified gaps in the service then it may be very obvious what the care pathway needs to address but this should be discussed and agreed by those

involved in the care pathway development. For example both internal audits and the regional accreditation visit identified the gaps in the diabetes service but discussions were still held with the multidisciplinary team to determine the exact remit and content of the care pathways to be developed.

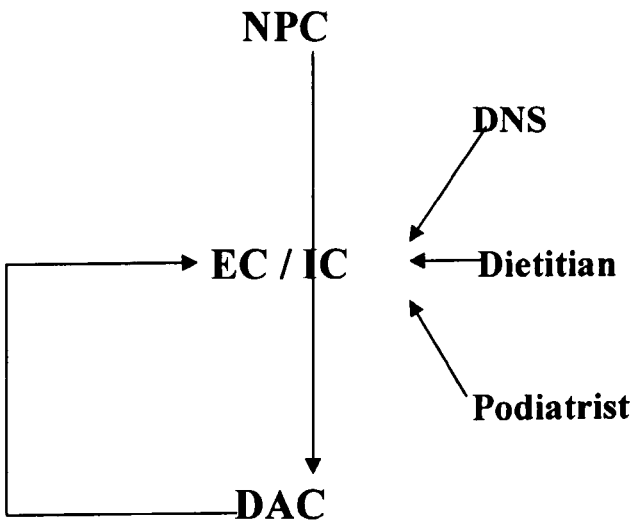
After a couple of team meetings, the following areas of in-patient care were identified as requiring improvements in management:

1. *Routine Investigations for Diabetes* – including; HbA1c, BP, urinalysis for protein, cholesterol and creatinine.
2. *Patient Education* – The intention was for ward staff (in particular nurses) to 'educate' patients about their diabetes. This section was removed from the final version because it didn't work.
3. *Blood Glucose Monitoring*
4. *Management of GKI & Patients undergoing Surgery* – It was evident that the GKI regimen and preparation of patients for surgery was poorly managed in the hospital, despite clear guidelines, and we hypothesised that a care pathway would address this, but this section proved to be problematic.
5. *Referrals to the Diabetes Team and Follow up after Discharge* – We anticipated that the care pathway would facilitate more appropriate referral and appropriate follow up after discharge.

Similarly with the outpatient care pathways, multidisciplinary (consultants, specialist registrars, diabetes nurse specialists, dietitian, podiatrist) team meetings were held to determine the remit of the care pathway and to review the current system and agree which aspects required changing. The main problem identified was a lack of structured education, and there was no means of ensuring patients received an appropriate review following New Patient Clinic, especially if seen by a junior doctor at their next appointment. Therefore, it was agreed by the team that the outpatient care pathway should map the patient journey from their first appointment (NPC), through a structured education programme (EC) to a second, consultant-led appointment 12 weeks after NPC (Discharge Assessment Clinic (DAC)), as illustrated in figure 3.2.

Once the remit has been agreed the evidence-base for the care pathway needs establishing, this is much easier where evidence-based guidelines already exist (as with the diabetes care pathways), otherwise a search for the latest evidence needs to be completed and further meetings with the key stakeholders will need to thrash out and agree the evidence base. If there is little evidence available a consensus opinion will need to be reached (Roberts *et al.*, 2004).

Figure 3.2 Outpatient Care Pathway Programme



Key:

NPC New Patient Clinic
EC Education Clinic
IC Insulin Clinic
DAC Discharge Assessment clinic

Stage 5 – Establish Working Methods

Once the remit and content of the care pathways have been agreed the working party need to agree a project plan and decide how they will develop the care pathways. The project will need to identify and outline the following factors in the development process:

1. **Care Pathway format** – how will the care pathway look, is there a Trust specific format, will an existing model be used? If as with the diabetes care pathways there was no existing pre-established Trust format then the group will need to discuss ideas and nominate someone to produce a first draft based on the ideas raised by the group.
2. **Set time frames and goals** – It is important to agree a time scale for production of first draft through to pilot studies and implementation of final version.
3. **Staff training** – If staff have never used a care pathway before they will need training / support, how this will occur and who will deliver it should be established at this early stage.
4. **Pilot studies** – The care pathway will need testing once a first drat is produced, the working group will need to decide where this will be, how long for, how it will be evaluated etc. If as with the in-patient care pathway the area it is intended for have not been included on the working group, this is the time to approach them and gain support and input. The purpose of pilot studies at this stage is to determine if the format of the care pathway works in practice and whether the content appears appropriate and valid. The most appropriate way to asses this is through interviews with the staff using it and audits of the pathways to assess compliance with completion.
5. **Implementation and Evaluation** – A plan for implementation once the pathway is finalised is required as is a plan of how to evaluate the care pathway. Evaluation will include two dimensions, firstly whether the format of the care pathway is practical and this will be assessed through feedback from staff and documentation audits. Secondly, there should be some measure of how effective the care pathway is at addressing the initial problems. For the majority of work on care pathways to date this has involved a semi-quantitative or qualitative evaluation of a care pathway as described in the systematic review, typically a before and after evaluation of changes in care following introduction of a care pathway. This evaluation should be planned at this stage.

Stage 6 – Produce first draft and pilot

Once the working methods have been identified in a project plan the first draft should be produced and brought back to the group for review and revisions. A number of revisions and redrafts will then be produced, how long this stage takes is dependent on the group and how frequently it meets, but this can be a lengthy process. Once everyone is happy with the first draft the pilot study will begin. How this is conducted and how long it takes will vary for different pathways but it is reasonable to suggest that there should be a system for regular review with the staff using the care pathway and the nominated lead during the process and a system of audit of the care pathways. Table 3.2 summarises how the pilot studies were completed for this work.

Amendments will be made during the pilot study, but once it appears the care pathway is working in practice it is ready for widespread implementation.

Stage 7 – Ongoing evaluation and revision

There needs to be a clear system in place for ongoing review and evaluation of the care pathway and nominated leads to take responsibility for this. Regular ongoing review of the variances from care pathways is an important component of this process (Kitchiner *et al.*, 1996; Campbell *et al.*, 1998) but may be difficult in practice. The outpatient diabetes care pathways developed in this work have changed numerous times (following internal audit and discussions at team meetings), mainly in terms of format or because evidence-based targets have changed. In particular the length has changed and they are now very concise, an ongoing difficulty has been maintaining regular analysis of variances and this will remain problematic until the care pathways can be adopted into an electronic format.

The seven stages outlined above were followed for both the development of the in-patient and outpatient diabetes care pathways and the practicalities of how these stages were followed is summarised in table 3.2.

3.4.4 Successes and Difficulties

It is evident from the seven stages of care pathway development outlined above that it can be a lengthy and difficult process to develop care pathways, and whilst others can follow the stages to guide them there will be variations according to the condition and care setting. Table 3.2 summarised the stages in practice for this work and illustrates that the main methodology used to evaluate the care pathways in development was one of regular meetings with key staff and regular audits of the care pathways. Through these evaluations it was possible to identify which aspects of the care pathways worked well and which didn't and to recognise which stages of the process were conducted effectively and to see areas that could have been improved.

Table 3.3 summarises successes and difficulties in developing the diabetes care pathways. Overall, the key lesson to learn is to keep the format as concise as possible and to engage key members of the multidisciplinary team from the outset, especially in a context like the in-patient diabetes care pathway where there isn't a dedicated team and the environment is less predictable. Others have cited difficulties engaging staff to use care pathways in an acute environment (Bragato and Jacobs, 2003).

Table 3.2 Development of In-patient and Education Clinic Care Pathways

Stage of Development	In-patient Care Pathway	Education Care Pathway
1. Identify Gap in Service	Feedback from patients and diabetes ward liaison nurse highlighted problems (section 3.2.1), local audits of in-patient diabetes care confirmed the issues	Regional accreditation visit identified lack of structured education, patients and diabetes team dissatisfied with existing system for education
2. Involve multidisciplinary team	Preliminary discussions held with specialist diabetes team (nurses, doctors, dietitians) to secure agreement for idea of in-patient care pathway. Representatives of ward staff should have been included in these discussions but they were not involved until the first draft was completed, this is a limitation in the development of the in-patient care pathway.	The original idea for a care pathway-driven structured education programme was formulated by the author and lead consultant. A meeting was held with the specialist diabetes team (specialist registrars, diabetes nurse specialists, dietitian and podiatrists) to ascertain their ideas and secure agreement for the proposed changes. Introduction of a weekly structured education programme signified a huge change in practice and there were some early reservations from the team, maintaining regular communication and involvement facilitated acceptance of the proposed changes.
3.Identify leaders & working party	The author and lead consultant led the development of the in-patient care pathway and provided feedback (including the opportunity for comment and input) at the weekly diabetes team meeting.	The weekly diabetes team meeting (lasting 2-3hours) was established to facilitate development and implementation of the care pathways, in particular the outpatient care pathways. The author and lead consultant took a lead but brought each draft back to the team meeting for discussion and approval.
4. Agree remit and content	At the preliminary diabetes team meeting the remit of the care pathway was agreed and would include: routine investigations for diabetes, patient education, blood glucose monitoring, management of GKI (Glucose Potassium and Insulin Infusion), management of DKA, management of patients	There were local evidence-based guidelines for outpatient management, but, these did not include education. One of the issues highlighted by patients was a lack of consistent advice within the unit. This was discussed by the team and it was agreed that there should be an

	undergoing surgery, referrals to Diabetes Liaison Nurse and follow up on discharge. (ward staff should have been involved more at this stage). Local evidence-based guidelines were in existence and the content of each section of the care pathway would be based on these.	explicit 'Education Pack' to outline various teaching topics and agree the content of each session. Each member of the team took an agreed topic and produced a detailed outline of the information to be included in the session, each topic was discussed by the whole team and agreed. The pack is used to underpin each session in the care pathway, the topics for each week were agreed by the whole team. The pack has subsequently being developed into a Patient Education Book to be used in the education programme and 20,000 copies printed for the district.
5. Establish working methods	**Format** – No Trust format of care pathways at this time, the leads agreed to draft a format and ask for feedback from the team. They drafted a format of A4 size, with all the prompts in the pathway and predominantly tick boxes. **Time frames** – The work started in January 1999, the aim was to have a first draft ready within 4 months and to start a pilot study within 6 months (July 1999), these targets were met. It took the leads about two months to have a first draft to take to the team and a further 2 months to get feedback and make amendments. **Training** – The specialist diabetes team had a two day 'away time' so that the care pathway leads could explain how all the pathways worked and this was classed as training. Sessions were provided for ward staff to explain how to use the care pathway,, these were held at varying times of the day to capture staff from all shifts. It was also agreed that the ward staff would require ongoing input about how to use the care pathway during the pilot study, and this would be provided by the author.	**Format** – The care pathway was A4 because this was concordant with the diabetes records in the department. The model for the in-patient care pathway was used and there were two parts to the care pathway, a set of evidence-based standards and the care pathway itself. The original draft was 7 pages long and consisted of mainly tick boxes with the variance on the back. **Time frames** – The work started in January 1999, this care pathway didn't take as long to develop as the in-patient one because it only involved the specialist diabetes team. The first draft was introduced in April 1999, evaluation and revision was ongoing and the care pathway has changed at least yearly since it was introduced based mainly on feedback from the diabetes nurses regarding the format. **Training** – Similar as for the in-patient care pathway. During the first 12 months of use the author provided daily support to members of the team regarding how to use the care pathways. **Pilot Study** – As the care

	Pilot study – It was agreed to pilot the care pathway on one ward (main medical diabetic ward), this was the lead consultant's ward which meant he could reinforce the need to complete it with the junior doctors, at this time the author was based in an office on this ward so she would be able to offer ongoing training and support in using care pathways. The staff on the ward were approached at this stage to discuss the care pathway and ask permission to do the pilot study	pathway was intended for use in the department it was not possible to hold a separate pilot study elsewhere. However, it was agreed that the first three months of use would be classed as a 'pilot' and during this time the variance analysis was not used in order to allow people time to adjust to the new education programme and paperwork. During this time staff received intense support from the author and after three months they started to use the variance analysis.
6.First draft and pilot	The first version consisted of 26 pages. At this stage there were a lot of explanations in the care pathway, e.g. why certain tests were required and how to get the results. Each section had a flow chart on the front page providing an overview of what to do with time scales. There was a section for patient education including a knowledge questionnaire and how to act on scores, staff would use this to decide which patients required further education. There were sections covering diabetes treatment options, blood glucose monitoring, referral to team and discharge. Each action in each section had an identifier code for recording on the variance and the variance section in this first version divided into two sections. The pilot study started in August 1999, once most of the nursing staff had been educated on using the pathway it was tested and the author reminded staff daily how to use it, & held weekly discussions with nursing staff and audited completion of the care pathways once patients went home. The lead consultant was tasked with teaching junior medical staff how to use the care pathway.	During the pilot period staff found they had to keep the clinical standards with them to remember what to cover in each session, this was cumbersome and added to the volume of paperwork required in clinic. As the staff gained more confidence they felt less need to have the standards with them. Further, case note audits at this time identified a problem with only having tick boxes on the care pathway, once filed in the notes away from the standards they were meaningless and posed a risk management issue. Later versions of the care pathway have a summary by the tick box to identify which topic has been covered (Appendix 2).

7. – Ongoing evaluation and revision	Evaluation of how well the care pathway format worked occurred in two main ways, firstly staff feedback to the author and consultant was recorded and staff had the option to leave anonymous comments in a notebook on the ward, secondly compliance with the completion of the care pathway was monitored through documentation audits. The care pathway was revised extensively three times (each time it went back to staff on the pilot ward for comment and was tested by them) and the final version was ready for use in the RCT (chapter 5) by September 2000, it had changed radically from the first version.	Evaluation involved weekly feedback from the specialist team, documentation audits and analysis of variance. The main revisions to the education care pathway have involved reducing the length (it is now one page long), abandoning the variance codes because they were reported as confusing and reducing the length of the programme to 4 weeks as patients fed back that this was more acceptable. It has proved difficult to maintain regular analysis of the variances and this may only be possible once an electronic version of the care pathway is possible. The education care pathway is currently under significant review following publication of recent guidance regarding diabetes patient education (Diabetes UK and Department of Health, 2005).

Table 3.3 Developing Diabetes Care Pathways – Successes and Difficulties

Care Pathway	Key Points	Successes	Difficulties
In-patient Diabetes Care Pathway (Appendix 2)	• Initial draft was too long (26 pages) and variance codes confused staff. • Pilot study from August 1999 for 12 months, on one ward. There was regular education of staff & team meetings. The care pathway was revised repeatedly and the Patient Education and Surgery sections were removed because they were not used by ward staff.	• Separating the standards from the care pathway made it easier to use. • The pathway evolved into an easy to use format using charts rather than lots of text, staff found this much easier to follow & complete, a key lesson was the simpler the better!	• The initial version included the standards but this was not easy to use. • Initially too much was included and there were unrealistic expectations of ward staff. • There were ongoing problems with poor completion of the care pathway & sub-optimal documentation. • Involving ward staff was difficult.
Outpatient Diabetes Care Pathway (Appendix 2)	• Establishing structured education programme was the biggest challenge and most significant change in practice. • Evidence-based standards to underpin care pathways were developed and tools such as a Staff and Patient Education book were introduced. • Numerous changes to format & detail over last 6 years & all are now 1 page & an integral part of diabetes service.	• Weekly team meeting was invaluable & essential part of process. • Care pathways are very simple to use – this has evolved over time & is a key factor in their success. • Strong leadership and dedicated time for the process was essential • Outpatient care pathways have been most successful	• Variance codes were initially confusing, we made them simpler which made a difference. • Engaging all staff groups is hard work and requires perseverance! • Regular review of variances is a key factor in using care pathways and we have found it difficult to maintain routine evaluation of care pathway variances.

3.5 SUMMARY

It was hypothesised that shortfalls in local in-patient and out patient diabetes services could be addressed with care pathways. During the development of the care pathways, the aim was to follow a systematic process to ensure successful implementation and use of the care pathways. There were clear leaders for the process in the specialist diabetes team but this was more problematic for the in-patient care pathways. It was more difficult to maintain effective leadership with ward-based staff, and this contributed to the difficulties experienced with the inpatient care pathways.

Organisational support is key and in particular sustainable resources are vital, there were no dedicated resources for the development and implementation of any of the care pathways. It was possible to manage this problem for the outpatient care pathways, but for the inpatient care pathways, a lack of resources was a major problem. For those developing care pathways a budget should be identified as part of the development process. The literature review reported in chapter 2 suggested that potential benefits of care pathways include reduced length of stay and reduced costs these savings could be offset against the development costs associated with care pathways.

One of the key difficulties with the in-patient care pathway during the pilot phase was getting staff to complete the care pathway. Poor documentation in both medical and nursing records is a recognised problem within healthcare (Schott, 2003; Lowson, 2004) despite the fact that both the Nursing and Midwifery Council (2005) and General Medical Council (2001) have clear standards for documentation. The care pathway should have made documentation easier for staff as most of it consisted of ticking a box or completing a chart. But poor completion of the document was a consistent problem throughout the pilot phase and has been recognised by others using care pathways (Luther and Crofts, 1997; Gottlieb *et al.*, 1996). Nurses were better at completion than the doctors, for both groups, it was observed that if they were being prompted on a regular basis by a

member of the diabetes team, then completion was significantly better but such input may not be practical outside of a research study.

Care pathways should be concise, simple to use and evolve with changes in practice. The outpatient care pathways were viewed by the specialist team as being an important tool that significantly facilitated an improvement in patient management, they were introduced in 1999 and have been used across all outpatient clinics since the year 2000.

The in-patient care pathways proved more difficult to develop and use than the outpatient care pathways, predominantly because they were being used by staff with many other conditions to deal with and because it was much harder to influence and drive their use on a regular basis. However, they were developed successfully and it was felt that they could be useful at improving the management of in-patients with diabetes, hence they were implemented and tested as described in chapter 5.

CHAPTER 4

DEVELOPMENT OF ASSESSMENT TOOLS

4.1 INTRODUCTION

The aim of this chapter is to discuss the tools used to assess the impact of the diabetes care pathways.

Two of the tools were developed in-house for these studies; the staff knowledge and audit tool. The methodology used to develop these tools will be discussed. The Barthel Index (Mahoney and Barthel, 1965) is a published tool and use of this tool in the in-patient care pathway study will also be discussed.

4.2 STAFF KNOWLEDGE QUESTIONNAIRE

4.2.1 Aims

As outlined in chapter 3, the management of in-patients with diabetes is problematic (Kennedy *et al.*, 1999; Callaghan and Williams, 1994) and a lack of knowledge amongst non-specialist staff on in-patient wards appears to be a key factor (Firth *et al.*, 1999; Wallymahmed *et al.*, 2004; Audit Commission, 2000). There were problems with the management of in-patients in the local trust similar to the issues highlighted in the literature, and inadequate knowledge amongst ward staff appeared to be a key factor but had not been measured because of a lack of tools with which to measure it. Knowledge is only one factor to impact on patient management, others such as staff attitudes and skills will also have a bearing, but, an underlying sound knowledge base is essential and it was hypothesised that the introduction of an in-patient diabetes care pathway would improve staff knowledge and therefore may improve care. A secondary objective of the study was to measure the impact of the care pathway on staff knowledge, and whilst it was recognised that other factors may also influence care it was deemed outside the remit of the randomised controlled trial to measure these, but, factors such as staff attitudes and skills could be explored in future studies.

The original aim was to find and use an existing knowledge questionnaire but when it was evident there wasn't a suitable tool, one was developed for the purpose of these studies.

The aim of this section is to discuss the existing knowledge questionnaires reported in the literature and to explain why they were unsuitable for this study, before detailing the methodology used to develop a new tool.

4.2.2 Existing Knowledge Questionnaires

A literature search of the MEDLINE, CINHAL and PSYCLIT databases revealed few diabetes-specific knowledge questionnaires, and none from the UK. Although it was apparent from UK conference material that such tools were in existence, they were either unpublished or had not been validated.

Initially, it appeared as if there were a number of American tools, but, on closer examination it was evident that most of the references to knowledge tools developed in America described the same tool by Drass *et al.* (1989), which is a modification of an earlier tool produced by Scheiderich (1983), permission was obtained to use the version described by Drass *et al.* (1989). The tool was reviewed with a panel of four diabetes nurses based in the UK to ascertain its validity for the study, and the consensus opinion was that the questionnaire would need significant modification because of differences between American and British practice and consequently it would be easier to develop a new tool for the study.

Other tools, also from America, were of very limited relevance to British practice because of the terminology they used and because the validation conducted in America was not transferable to British practice. Moreover, there were significant methodological weaknesses in all of the tools reviewed.

When using a tool that has been validated elsewhere, it is essential to re-evaluate it to ensure it is transferable to a different study population and therefore produces reliable results. This was the main failing in the American tools

reviewed. One study by Baxley *et al.* (1997) used the Drass questionnaire in their study and re-examined validity and reliability for their subjects, but, Gossain *et al.* (1993) and Jayne and Rankin (1993) both used the Drass questionnaire and failed to re-examine validity and reliability for their study population. Leggett –Frazier *et al.* (1994) developed a knowledge questionnaire but did not examine the reliability of her tool and Moriarty and Stephens (1989) used an existing tool but did not re-examine reliability and validity.

None of the studies reviewed tested test re-test reliability of the questionnaires used. Test re-test reliability is a measure of the stability of the questionnaire, that is will it produce similar results when administered at different time points to the same people. This is essential if the tool is going to be used before and after an intervention designed to improve knowledge. With no measure of test re-test reliability results showing improved knowledge after a teaching programme would be unreliable.

All of the tools had been developed specifically for nurses and none had been tested in doctors, the original aim for this study was to test knowledge in junior doctors and nurses and therefore the tools did not meet the study's requirement.

In view of the methodological problems with the existing tools and the lack of published tools developed in the UK a new knowledge questionnaire was developed for the purpose of these studies.

4.2.3 Methods

4.2.3.1 Item Generation

The first stage in the development process was to generate items for the questionnaire. This is an essential aspect of questionnaire design, because if relevant topics are not included or questions are poorly worded or ambiguous, the questionnaire will not be an accurate measure of knowledge. There are various methods for generating items for a questionnaire: from the subjects (patients or clinicians), observation, theory, and expert opinion (Streiner and

Norman, 1995). The items for the staff knowledge questionnaire were generated by: interviewing diabetes professionals and ward nurses, from the literature, including the existing knowledge questionnaires discussed above and through feedback from the diabetes specialist team.

Interviews

Seven professionals (five specialist nurses, a diabetes liaison nurse and diabetologist) from various hospitals across the North West, were interviewed to ascertain their views on the level of knowledge ward based staff should have about diabetes. Advice was sort from the local university on how to approach the interviews, consequently they were semi-structured, taped and typed immediately afterwards, the questions were similar for each interview and were based on aspects of diabetes management relevant to the wards as identified from the literature and personal clinical experience. It is possible that by using the authors experience to produce the interview questions this may have biased the outcomes. However, the literature was also used as a guide to the relevant areas that should be included and because the interviews were semi-structured the interviewees were able to raise issues they judged to be relevant, these two facts should have minimised the impact of any potential bias, although it is important to be aware of it as a possible limitation of the questionnaire. The interview tool is in Appendix 3.

Core themes were highlighted from each transcript following the interviews. Subsequently, core themes were collated to identify the topics to include in the questionnaire. After five interviews the same themes were emerging, these were repeated in the last two interviews and it was evident that no further interviews were necessary. Two general staff nurses were also interviewed to determine what they knew about diabetes and their expectations of what they should and shouldn't do when managing in-patients with diabetes.

The themes to emerge were similar to those covered in the existing knowledge questionnaires and concordant with the areas the specialist team knew to be problematic on the wards.

Refining the Items

An initial draft of the questionnaire containing 11 sections (Physiology, Blood Glucose Monitoring, Medications, Hypoglycaemia, Insulin, Hyperglycaemia, Complications, Diet, Screening/prevention, Surgery, General) each with six items was developed. At this stage the response to each item differed, some had a true / false / don't know response and others were a multiple-choice answer. The lead consultant and some other members of the team and two ward staff nurses, reviewed the questionnaire to determine the appropriateness of the wording.

When forming items for questionnaires it is essential to ensure they are clear and unambiguous. It is recommended that the reading level be no higher than 12 years and that double-barrelled (asks two questions at the same time) questions are not used. Other features of good questionnaire design include avoiding jargon and negatively worded items, keeping items as short as possible and testing them on a sample similar to the intended study population (Streiner and Norman, 1995; Oppenheim, 1966; Simpson, 1984; Reynolds *et al.*, 1990; Hunt *et al.*, 1982; Dunning and Martin, 1996).

A published list of 1000 common words (Payne, 1954) was used to judge the suitability of the items, the list indicates whether each word is unambiguous or has different meanings. Much useful feedback from those reviewing the questionnaire and several revisions added clarity to the wording. It was agreed that the answer format should be consistent and all the questions were changed to a Yes / No / Don't know response. Following the changes to the wording the questionnaire still consisted of 11 sections with a total of 66 items.

4.2.3.2 Face and Content Validity

Face and content validity establish whether the tool is appropriate for its intended use (Streiner and Norman, 1995). *Face Validity* refers to whether a tool appears to measure what it should be measuring and *Content Validity* refers to whether

the questionnaire has covered all relevant topics. The usual method in questionnaire design for establishing validity, is to submit the tool to a small group of experts in the field for their comments on its appropriateness (Stager, 1993; Dunning and Martin, 1996; Recker and O'Brien, 1995).

To establish validity, the questionnaire was sent to four specialists – two Diabetologists and two Diabetes Nurse Specialists, and to two general nurses from three hospitals, who were asked to consider its clarity, content and readability.

Comments were received from all reviewers and they agreed the content was appropriate. Most of their suggestions related to the readability of some of the items. Despite efforts to ensure the wording was simple, it was apparent from the feedback that there was still ambiguity in some of the items and jargon such as 'HONK'. The items were amended and the questionnaire was re-assessed by two of the specialists.

Following their further feedback only 3 questions were amended slightly. The questionnaire was given to three ward nurses who were asked to complete it, and the author subsequently went through each question with them to determine what they thought the question was asking, as it has been suggested that this is the best way to ensure subjects understand the questions (Streiner and Norman, 1995). Only one question caused confusion and this was subsequently changed. The final version (version 6) of the questionnaire still contained the 11 sections with 6 items per section.

4.2.3.3 Reliability

Definition

Reliability refers to how reproducible a test is (Oppenheim, 1966), measurement at different times or by different people or with similar tests should produce the same results (Streiner and Norman, 1995).

There are different types of reliability. Most previous studies had used *internal reliability*, which can be measured on the basis of a single administration of a tool. It is therefore relatively easy to obtain. Internal reliability measures how items on the questionnaire relate to other items on the questionnaire, for example if measuring a single trait such as knowledge, then each item should reflect different aspects of the trait but not reflect a different trait and the scores should correlate. The correlation can be calculated in several ways, but *Cronbach's alpha co-efficient* (Cronbach, 1951), is typically used. It produces a correlation coefficient between 0 and 1, 0 indicating no reliability and 1 indicating perfect reliability. (Litwin, 1995; Steiner & Norman, 1995). A coefficient of greater than 0.7 and less than 0.90 is generally regarded as acceptable (Steiner & Norman, 1995). If internal reliability is low, it can be improved by adding more items or by reviewing and changing the existing ones. The limitation of this measure of reliability is that it doesn't allow for diurnal variations or intra-observer variations in the test and therefore can overestimate the reliability of the test.

Test re-test reliability examines the stability of the test. If a questionnaire is to be used to measure a domain before and after an intervention, it is essential that there is some indication of the stability of the test (Steiner & Norman, 1995). The usual method for measuring this is to administer the questionnaire twice in a short time frame to the same group of people. The time frame is important, too short and they may remember their first response, too long and factors may have influenced the trait being measured, opinion varies, but a retest interval of 2 to 14 days is typical (Streiner and Norman, 1995). *Cohen's kappa coefficient* (Cohen, 1960) can be used to measure the internal reliability of a test, it is a measure of agreement between two raters, or the same one at different time periods. The kappa coefficient can be interpreted using Table 4.1 (Brennan and Silman, 1992).

Table 4.1 Interpretation of Kappa Coefficient

Kappa Value	Strength of Agreement
<0.21	Poor
0.21-0.40	Fair
0.41-0.60	Moderate
0.61-0.80	Good
0.81-1.00	Very Good

Measuring Reliability

For this study, both internal reliability using *Cronbach's alpha* and test re-test reliability using *Kappa statistic* were measured.

Internal Reliability

Internal reliability was measured by distributing the questionnaire to all the nurses (147) on the medical unit (Whiston Hospital) and testing the results using Cronbach's Alpha. Subjects scored 1 if they got the answer right and 0 if it was wrong or they marked don't know. The questionnaire was also distributed to a convenience sample of 27 Pre-Registration House Officers (PRHOs), to examine internal reliability when used to measure doctor's knowledge.

105 nurses responded (73%) and all of the PRHOs (100%). Internal reliability was measured separately for the nurses and doctors. Cronbach's Alpha was measured using the SPSS statistical package and was 0.81for the nurses' and 0.72.for the doctors, demonstrating good internal reliability.

Test Re-Test Reliability

Test re-test reliability was measured by administering the questionnaire to a sample of twenty nurses working on the medical unit, who were subsequently asked to re-do the questionnaire 2-4 weeks after they first completed it. This time frame was chosen for logistical reasons, because of changes in shift patterns two to four weeks seemed reasonable for meeting with the nurses a second time to re-administer the questionnaire. They received no intervention about diabetes

in this period, therefore, if the questionnaire was a good measure of knowledge, their scores should have been similar both times they completed it.

After the second administration of the questionnaire, the nurses were interviewed to determine why they answered some questions differently the second time and to further examine the readability of the questions. The main reason reported for differences in answers was that they did not know the answer, for a few of the items the wording was a problem for the nurses, such questions were subsequently amended and when re-tested on a group of four nurses the readability was found to be acceptable. The Kappa statistic was used to analyse the differences between the answers from first to second administration of the questionnaire.

Of the 20 nurses involved in examining test re-test reliability 16 (80%) completed the questionnaire twice. The kappa coefficient was 0.689, indicating that the questionnaire has good stability and would be a reliable measure of changes in knowledge following an intervention.

4.2.4 Summary

It was hypothesised that the in-patient diabetes care pathway would improve nurse knowledge of diabetes and measuring this was a secondary objective of the in-patient study (chapter 5). There were some existing knowledge questionnaires available but because they had been developed in America and because of weaknesses in the methodology used in their development, they were not appropriate for this study. A knowledge questionnaire with 11 sections was developed and tested (using nurses similar to those in the intended study population) for readability, validity and reliability. The final version of the questionnaire (Appendix 3) proved to have good validity and reliability on formal evaluation and was a key evaluation tool used in the RCT of in-patient care pathways.

4.3 AUDIT TOOL

4.3.1 Aims

The studies included in the review (chapter 2) indicated that care pathways may improve the quality of care patients receive (Ireson, 1997; Cushing and Stratta, 1997; Chang *et al.*, 1999; Gregor *et al.*, 1996; Ranjan *et al.*, 2003; Roberts *et al.*, 2004; Ilag *et al.*, 2003). It was hypothesised that the in-patient diabetes care pathway would improve the quality of diabetes care patients received. An improvement in staff knowledge alone, would not be indicative of an improvement in patient care. To measure the impact of the care pathway on diabetes management, the aim was to audit diabetes care before and after introduction of the care pathway. To do this, an audit tool to measure the quality of diabetes care was developed.

The aim of this section is to present the audit tool.

4.3.2 Audit Tool

Clinical audit has been defined by NICE (2002), page 1 as:

'*Clinical audit is a quality improvement process that seeks to improve patient care...Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria.*'

Typically, when conducting clinical audit an area of care to audit is identified, evidence-based standards as to how that care should be delivered (e.g. NICE guidelines) are also identified and an audit tool based on these standards is developed. Care is then measured against these standards (usually by going through the clinical records for a sample of patients) and recorded on the audit tool, the primary aim is to assess whether care has been delivered as specified in the audit criteria (evidence-based standards / guidelines).

To devise an audit tool to evaluate the quality of the management of in-patients with diabetes it was necessary to determine the most appropriate parameters and processes of care to measure. For this study, the process of identifying explicit criteria against which to audit care was simplified because of the work already undertaken. Development of the in-patient diabetes care pathway (chapter 3) had already identified the key areas where care needed improving and the care pathway was aimed at addressing these. Consequently, it was logical that an audit of the quality of in-patient diabetes care would use the care pathway parameters and standards as its criteria.

The following parameters (taken from the care pathway) were included in the audit tool to measure the quality of diabetes care:

1. Blood glucose monitoring – was the frequency appropriate.
2. GKI – were bloods taken and recorded according to the care pathway standards.
3. HbA1c – was it checked and was the result acted on appropriately.
4. Urinalysis for protein – was there a record in the notes and was the result acted on.
5. Were creatinine and cholesterol measured and appropriate action taken.
6. Referral to Diabetes Liaison Nurse – was it appropriate

For this study the hospital IT department identified a sample of patients (see chapter 5) with diabetes who had been in hospital before introduction of the care pathway and their hospital case notes were collected and audited using the audit tool. The aim was to audit all the case notes of the participants in the study. For each parameter the process of care was audited, that is had the parameter been checked, and the subsequent action taken was audited against the criteria specified in the in-patient standards using the audit tool.

Audit should be an objective systematic process, as the audit tool specifies clear criteria against which to measure care, but, to ensure the audit tool in this study was generating reliable results as to the processes of care delivered, a sample of the audits undertaken before implementation of the care pathway were audited by

the author and a colleague to ensure the audit tool was generating similar findings irrespective of the person conducting the audit. There were consistent results (Table 4.2) and the audit tool (Appendix 3) was used to audit diabetes management before and after implementation of the in-patient diabetes care pathway.

Table 4.2 Audit of a Sample of 10 Case Notes by Two Auditors

Parameter	Auditor 1 N=10	Auditor 2 N=10
Was blood glucose monitoring appropriate?	3 (30%)	3 (30%)
Was patient on a GKI?	0	0
Was HbA1c recorded?	2 (20%)	2 (20%)
Was there urinalysis for protein?	1 (10%)	1 (10%)
Was creatinine checked?	10 (100%)	10 (100%)
Was BP checked?	8 (80%)	8 (80%)
Was cholesterol checked?	6 (60%)	6 (60%)
Any record of foot exam?	0	0
Appropriate referral to Diabetes Liaison Nurse?	2 (20%)	2 (20%)

4.4 BARTHEL INDEX

4.4.1 Definition

The Barthel Index (Appendix 3) was developed in the USA in the 1950s (Mahoney and Barthel, 1965) and is a measure of independence which was originally used in patients with neuromuscular or musculoskeletal disorders to assess their ability to perform daily tasks such as dressing and washing. In the USA the scores for each parameter on the index are either 0 (unable), 5 (needs help) or 10 (independent) and a total score of 100 is attainable. The Barthel Index is used widely in the UK as an indicator of independence in the activities of daily living, here the scoring is typically changed to 1,2, and 3 and a maximum score of 20 is attainable (Wade and Colin, 1988).

The Barthel index is relatively simple to use and studies have demonstrated its validity and reliability as an indicator of independence in patients (van der Putten *et al.*, 2006; Colin *et al.*, 1988; Gresham *et al.*, 1980) and it is commonly used in the UK as a marker of independence / dependence in relation to the activities of daily living.

4.4.2 Interpretation and Use in This Study

The higher the score the greater the degree of independence in a given patient. A score of 20 indicates complete independence, generally, a score of 14 indicates a degree of disability that may require ongoing support (GP Notebook, 2005).

The aim in this study was to use the Barthel Index in the RCT of the in-patient diabetes care pathway as an indicator of independence at baseline. It was hypothesised that if there were significant differences between independence levels of the two groups at baseline this may confound outcome measures such as length of stay and re-admission rates, by measuring the Barthel score for each participant at baseline it would indicate if such confounding variables were present.

CHAPTER 5

IMPACT OF CARE PATHWAYS ON THE MANAGEMENT OF IN-PATIENTS WITH DIABETES

5.1 INTRODUCTION

Chapter 3 detailed the process of development of a care pathway for the management of in-patients with diabetes. This chapter describes a study to evaluate its effectiveness. It was evident from the literature search described in chapter 2, that there was a lack of robust studies of care pathways, in particular there were very few quantitative studies and the aim of this work was to evaluate the in-patient diabetes care pathway using a quantitative research process.

The aim of this chapter is to discuss the chosen scientific framework for the study and describe the research undertaken including methodology, results, limitations and implications for future work regarding care pathways and for the future management of in-patients with diabetes.

5.2 SELECTING THE RESEARCH PROCESS

Traditionally, research design underpinning therapeutic intervention in healthcare delivery has been arguably arbitrarily subdivided into qualitative research methodologies and those employing a more quantitative approach, in particular, the Randomised Controlled Trial (RCT). The latter and the RCT in particular have often being hailed as the 'Gold Standard' in clinical research because of their "more scientific" approach (Medical Research Council, 2002). Critical examination of this issue, however, clearly demonstrates that quantitative research also has its limitations, particularly where studies are not conducted rigorously either because of poor research design or when clinical circumstances preclude the use of such methodologies. There is increasing recognition that there are many areas of clinical care where a qualitative approach is more apposite. Moreover, from a more pragmatic perspective, it is useful to recognise that the scientific framework underpinning studies may not be purely qualitative or quantitative, but that a continuum exists between the two methodologies (Neuman, 2000; Bhopal, 2002) and many studies describe a Triangulation of methods (Polit et al, 2001).

Furthermore, there is a danger that excessive focus on a particular methodological approach may undermine the underlying philosophical and theoretical issues (Crossan, 2003). It has been suggested (Crotty, 1998) that when designing a research project there are four key questions to be asked: what epistemology (theory of knowledge) informs the research; what theoretical perspective (philosophical stance) underlies the methodology; what methodology (action plan or strategy) governs the choice and use of methods; and what methods (techniques and procedures) are used. Creswell (2003) took this model and simplified it into three key questions underpinning the research process:

1. What are the underlying knowledge claims of the researcher
2. What strategies (e.g. quantitative, qualitative or mixed) will guide the process
3. What methods of data collection and analysis will be used

For the evaluation of the in-patient diabetes care pathway a *positivist* approach was the chosen epistemology. Positivism has been defined in various ways, Smith (1998) describes it as; 'Positivist approaches to the social sciences....assume things can be studied as hard facts and the relationship between these facts can be established as scientific laws.' Positivism is concordant with the scientific or quantitative approach to research, it assumes that there is a cause and effect between two phenomena and research underpinned by this epistemology is typically objective and aims to measure outcomes quantitatively (Crossan, 2003).

As a positivist approach was used to underpin this work it was logical to adopt a quantitative strategy to guide the research process. There were very few randomised controlled trials (RCTs) of care pathways reported in the literature (as discussed in chapter 2), so it seemed reasonable and logical to aspire to this 'gold standard' methodology to test a cause and effect relationship between the in-patient diabetes care pathway and certain processes and outcomes of in-patient diabetes care.

Whilst in theory RCTs are a robust scientific framework for research there are many potential errors in the way RCTs are conducted and analysed that may undermine the validity of this research methodology - and consequently the reported outcomes in a given study. Evidence suggests that the quality of reporting of RCTs is often suboptimal and that this is associated with the introduction of bias and systematic error, that may undermine the scientific framework of RCT (Altman *et al.*, 2001). In response to this problem, a checklist has been developed to guide authors on the reporting of RCTs. This CONSORT (Consolidated Standards of Reporting Trials) checklist and flow chart is available on a dedicated website (www.consort-statement.org) and is used by editors of leading journals.

The CONSORT checklist does not specify how RCTs should be conducted but guides researchers on how they should be reported (Altman *et al.*, 2004), it will be used to structure this report of the RCT of the in-patient diabetes care pathway.

5.3 RANDOMISED CONTROLLED TRIAL OF A DIABETES IN-PATIENT CARE PATHWAY

5.3.1 Introduction

The aim of this study was to examine the impact of a care pathway on the management of in-patients with diabetes. There was no existing work examining the use of care pathways in the management of in-patients with diabetes, but many studies examining care pathways for other conditions. As discussed in chapter 2, much of this work was inconclusive about the effectiveness of care pathways, and the aim here was to try to establish a more definitive answer to the question of the effectiveness of a care pathway on inpatient care. A positivist approach underpinned this work: it was assumed that an explicit relationship between the diabetes in-patient care pathway and patient outcomes could be determined by adopting a traditional scientific approach to the research process. A RCT was the chosen methodology because there were only three existing RCTs of care pathways and it was anticipated that this method would be more

likely to provide more convincing evidence of the effectiveness (or otherwise) of care pathways than another methodology.

5.3.2 Methods

The study was a single-centre, unblinded, randomised controlled trial conducted on the medical wards of a District General Hospital on Merseyside between December 2000 and November 2001. The protocol was approved by the Local Research Ethics Committee (LREC), and all subjects gave written informed consent prior to participation in the study (information sheets and consent forms in Appendix 4). The data were collected from the participants at baseline, from the hospital case notes following discharge, in questionnaire form from the nurses in the study and following discharge, data were collected directly from the patient (follow up visit), from the GP and from the hospital patient information system.

5.3.2.1 Participants

There were two main groups of participants in the trial; patients with diabetes and the staff managing their care on the ward.

Inclusion and Exclusion Criteria

It was hypothesised that if the care pathway proved to be effective it would be used to guide the management of all patients with diabetes admitted to the hospital irrespective of the reason for admission, therefore there were very few exclusion criteria to allow the care pathway to be tested on the wide range of patients intended for its final use.

All male and female patients over 18 years of age with Type 1 or Type 2 diabetes, admitted to the Medical Admissions Unit with either a diabetes-related problem or another medical complaint were invited to participate. Children were excluded because they are managed differently, because of practical issues over

informed consent and because this was designed a priori as an adult diabetes in-patient care pathway.

Patients unable to give informed consent were excluded for obvious ethical reasons and those that had been on the admissions ward for more than 24 hours were excluded because a care plan would have been initiated by then and this might have biased the end results.

There is a tension in any research study between narrow inclusion/exclusion criteria (which facilitate the design and execution of the study by limiting confounding variables) and adequate representation of the subsequent target population (which reduces the need for subsequent extrapolation of results to groups not represented in the original study). Confounding occurs when it is not possible to ascertain a true cause and effect relationship between the variables under study because variables not of interest to the study (extraneous) variables are impacting on the results (Moore, 1991). One reason for choosing a RCT as the methodology in this study was that by randomly assigning groups to interventions the possibility of confounding is reduced. As in all RCTs, it was anticipated that randomisation would reduce the likelihood of bias by producing two equivalent study groups, matched for extraneous variables; of course, this is governed by chance and may not always occur. Therefore, pre-existing co-morbidities for the groups are recorded at baseline and reported so that this information is available to those appraising the effects of the intervention.

Ward Staff

The impact of the care pathway on ward staff was examined in two ways. Firstly, one hypothesis was that a care pathway would improve patient management (that is staff would initiate management in line with the evidence-based guidelines underpinning the care pathway) and this was measured by auditing case notes before and after the study. The audit examined performance by both ward doctors (including all grades involved in the management of a patient with diabetes) and nurses involved in the management of patients with diabetes. In addition, to examine any changes in the knowledge-base

underpinning any actions by ward staff, ward nurses' knowledge of diabetes was measured before and after the study. The nurses included in the analyses were of varying grades (ranging from grade D to G) and had been qualified for varying lengths of time.

5.3.2.2 Interventions

The primary intervention in this study was the diabetes in-patient care pathway (Appendix 2). The aim was that those participants randomised to the intervention group would be started on the care pathway at baseline by staff on the Medical Admissions Unit and that the care pathway would be used throughout their hospital stay irrespective of the ward(s) to which they were transferred. The care pathway guided staff on; monitoring blood glucose levels, initiating and acting on investigations, using a GKI and information to give patients on discharge. For those participants in the control group it was expected that they would receive 'usual care', typically a nursing care plan for the management of diabetes. There were no core care plans in this organisation so that content would vary between wards, all staff had available to them the local in-patient diabetes guidelines (Hardy, 1998).

A secondary intervention was for some wards to receive ongoing support in the use of the care pathway. The medical wards were divided into two groups; wards in group one received ongoing support in use of the care pathway, they were visited regularly by the author or a colleague and reminded how to use the care pathway. Wards in group two received no ongoing support in the use of the care pathway.

5.3.2.3 Objectives

The primary objective of this study was to examine whether the care pathway improved the management of in-patients with diabetes. A secondary objective of the study was to examine whether ongoing support and education for staff using the care pathway improved its use.

The scientific framework underpinning this study assumed that a cause and effect could be established between two variables, namely: use of the care pathway and aspects of diabetes inpatient management (see below for details).

The null hypothesis is a statement of 'no difference,' in specified outcome(s) between interventions and the *alternative hypothesis* assumes the effectiveness of the intervention (Moore, 1991). In this study, the null hypothesis was that care pathways would make no difference to in-patient management of diabetes and the alternative hypothesis was that they would improve it (or make it worse).

Statistical tests are used to test the statistical significance of any difference in outcomes attributed to the intervention i.e. the likelihood that any difference in outcome was the result of the intervention and not merely a result of chance. Conventionally, a likelihood of less than 1 in 20 (5% or $p < 0.05$) is considered to be unlikely to be as a result of chance (see also below).

Tests for statistical significance are many and varied. The most robust and commonly used (parametric) test for comparing a variable in two groups in normally distributed data is Student's *t* test. In a one-tailed test, the hypothesis assumes that the intervention will either have no effect or will produce a positive effect; in a two-tailed test, the hypothesis allows that the intervention may produce no change, a positive effect or a negative effect. If the test examines the difference in a variable in two groups of similar variance (i.e. assumed to be drawn from a single population), then an unpaired test is typically appropriate; if the test examines a change in a variable in a single group of subjects (i.e. before and after intervention) then a paired test is performed. If data are non-normally distributed, then non-parametric testing must be employed; thus, testing for normality is essential if the correct (parametric or non-parametric) test is to be selected. Comparison of the distribution of a discrete variable in sample with the distribution of the same discrete variable in another sample is typically most simply and effectively tested by a Chi squared test (it should be noted that actual numbers and not percentages must be used in this test). When numbers are relatively small, the test is more robust if it is subjected to Yates' correction for continuity.

5.3.2.4 Outcomes

The primary endpoint in the study was HbA1c at three months following discharge. HbA1c was chosen as the primary endpoint because it is currently the best measure of diabetes control (Kinshuck, 2005) and is clearly linked to the development and progression of complications as discussed in chapter 1. HbA1c measures the proportion of glucose bound to the red blood cells before they are renewed (every 8-12 weeks) and therefore provides a measure of glucose over the last 8 to 12 weeks. It is common practice for the HbA1c to be measured three months following any changes in diabetes treatments as this is the approximate lifespan of the erythrocyte that carries the haemoglobin underpinning the test. The rationale for using HbA1c at three months as the primary endpoint was that if changes had been made to diabetes treatments whilst the patient was in hospital these would be evident at three months; a longer time frame would be more likely to be a result of confounding treatments implemented post-hospital discharge.

Secondary objectives were:

1. Length of stay – this was chosen because the papers in chapter 2 indicated that care pathways reduced length of stay. In addition, there is evidence that people with diabetes stay in hospital longer and if care pathways can reduce this it would have significant implications for the NHS.

2. Number of re-admissions in the 12 months following discharge – the papers in the review reported in chapter 2 indicated that this may be a further benefit of care pathways and the aim was to examine this for the diabetes care pathway.

3. Nurse knowledge of diabetes – it was hypothesised that nurse knowledge of diabetes would improve through using a care pathway.

4. Quality of diabetes care – it was hypothesised that the care pathway would improve the overall quality of the care patients received.

HbA1c was measured using a using a high performance liquid chromatography assay (Menarini Diagnostics, Wokingham, UK) or a latex immunoagglutination inhibition methodology (Bayer Diagnostics, Newbury, UK) with both assays internally and DCCT (Diabetes Control and Complications Trial) aligned, reference range 4.6-6.2% (DCCT, 1993) and quality assured weekly to ensure reproducible standardised accuracy. The baseline value was a laboratory measurement at or within 4 weeks of admission (since the laboratory will not repeat the test if a figure from the last four weeks is available). Three months post-discharge HbA1c testing was undertaken either by the GP or from the Diabetes Centre, using the same aligned assays.

Length of stay data was attained from the hospital case notes. Data on re-admissions within twelve months was gained from either the hospital case notes or the hospital patient information system.

Nurse knowledge was measured prior to starting the study (using the validated questionnaire described in chapter 4) and at the end of the study. It took approximately 6 weeks prior to starting the study to receive all completed questionnaires back. Once the trial was completed, the nurses who had completed the knowledge questionnaire before the RCT were invited to complete the questionnaire again: it took approximately 8 weeks to receive all the questionnaires back. Comparisons were made between their first and second answers and between staff located on wards in group one (support in use of care pathway) and group two (no support in use of care pathway).

Following discharge, the patients' case notes were audited against a structured proforma, to assess the quality of diabetes care received and compliance with the care pathway. Ten sets of notes were audited twice by different assessors (by the author and a colleague) to ensure the objectivity (and lack of subjectivity) of proforma-use (see chapter 4).

To measure the quality of diabetes care four parameters were identified a priori where it was hypothesised the care pathway would have a positive impact on patient management, namely, HbA1c (proportion tested), urinalysis for protein (proportion tested), cholesterol levels (proportion tested), and appropriate referral to the diabetes team (proportion appropriately referred). A summary measure, based on the four parameters was used as an overall measure of quality of care and this was compared in those whose care was determined by a care pathway and those receiving usual care.

In addition to comparing patients on a care pathway to those receiving usual care, a retrospective, case note audit of diabetes management on the wards before (August 1999 to May 2000) and after (December 2000 to November 2001) the study was conducted. The aim was to ascertain if there had been any general changes in the management of diabetes during the study period that might confound interpretation of the study. The in-patient care pathway and local in-patient guidelines were used as the audit standard.

5.3.2.5 Sample Size

When conducting a study it is essential to use an adequate sample size in order to reduce the risk of errors that can arise from the statistical tests used. There are two types of error that can occur in an intervention study such as a RCT. A *Type 1 error* (denoted by α) occurs when there is no relationship between the independent and dependent variable in a study but a conclusion is made that there is (the null hypothesis is rejected when it is true). As discussed above, the *significance level* of the test used is the probability of a type 1 error occurring, for most studies a 5% significance level is used, which indicates that there is a 5% chance of a type 1 error occurring (Bruce and Cleave, 1999).

A *Type 2 error* (denoted by β) occurs when there is a real effect between two variables but a conclusion is made that this doesn't exist (Bruce and Cleave, 1999). A type 2 error is more likely to occur if the study is too small, to avoid

this it is important to ensure the study has enough *statistical power*, typically studies have power between 80% and 90%.

To calculate an adequate sample size for a study the significance level and statistical power are decided first. In addition, a decision has to be made as to whether a *one-sided* or *two-sided* test will be used (see above). A larger sample size is typically needed for a two-sided test.

The power calculations in this study were based on a local pilot study some years ago to determine the distribution (mean and variance) of HbA1c in local patients; the estimates used have been re-tested over the years and have proved to be consistent and robust and to produce sample sizes consistent with those produced by other researchers working with similar patient populations. Specifying 90% power at a 5% level of statistical significance to detect a 1% difference in HbA1c between the intervention and control group, it was calculated (GB-Stat, dynamic Microsystems, Inc. Silver Spring, MD, USA) that 36 subjects were needed in each group. A 10% drop out rate was assumed and the aim was to recruit 40 participants to each group.

5.3.2.6 Randomization

A key strength underpinning RCTs is the randomisation procedure. The aim of randomisation is to minimise potential bias by distributing confounding variables between groups and increasing the comparability of the groups under study (Moore, 1991; Bruce and Cleave, 1999). However, the robustness of this process is dependent on how well the randomisation process was undertaken and on the sample size. This relates to the randomisation procedure itself (generation of random numbers and how they were concealed) and blinding. The extent of *blinding* in a RCT is important as it has been shown that bias is reduced the more blinding there is (Department of Public Health Sciences, 2006) and where possible double-blind trials are favoured because researchers have been shown to be influenced by knowledge of the interventions (Moore, 1991).

If following randomisation there are clear differences between the groups under investigation, it is possible the randomisation procedure has failed to minimise confounding variables and this will need accounting for in the analysis. This is more likely in smaller studies or where procedures were not followed rigorously.

Sequence Generation

As the numbers needed in each group was relatively small a *Simple Random Sample* was deemed acceptable for this study. For the purpose of randomisation, random numbers were generated on a computer package (EXCEL). It was decided that odd numbers would indicate the control group (non-pathway) and even numbers the intervention group (care pathway).

Allocation Concealment

The numbers were placed in a sealed envelop prior to the start of the study and were concealed from the investigators until the moment of randomisation.

Randomisation Implementation

The random numbers were sealed in envelopes (care pathway or usual care was written next to each number depending on whether it was an odd or even number), the envelopes were numbered from 1-100 (aiming to recruit a minimum of 40 in each group and it was assumed that by approaching 100 patients this number would be achieved) by the author (primary investigator) in order of where the random number was on the computer generated list. The participants were recruited to the trial by one of two investigators (author and another diabetes nurse) and the envelopes were used in sequential order. The investigator recruiting the participant would open the envelope and allocate the subject to either a care pathway (intervention) or usual care (control) depending on what was inside the envelope.

5.3.2.7 Blinding

This was an open study because it was impossible to conceal the intervention (care pathway) from either the investigators or the participants.

5.3.2.8 Statistical Methods

Analysis was on an intention-to-treat basis. The primary endpoint (HbA1c) and length of stay in the intervention and control groups were compared at baseline and 3 months post discharge using Student's (unpaired), 2-tailed *t* test, after Shapiro-Wilks testing for normality of distribution. The proportion of patients readmitted within 12 months and the proportion receiving better quality care (see above) in the intervention and control groups were compared using Yates-corrected Chi squared tests.

Nurse knowledge questionnaire results before and after introduction of the pathways (and control) were compared using two-tailed paired *t* tests.

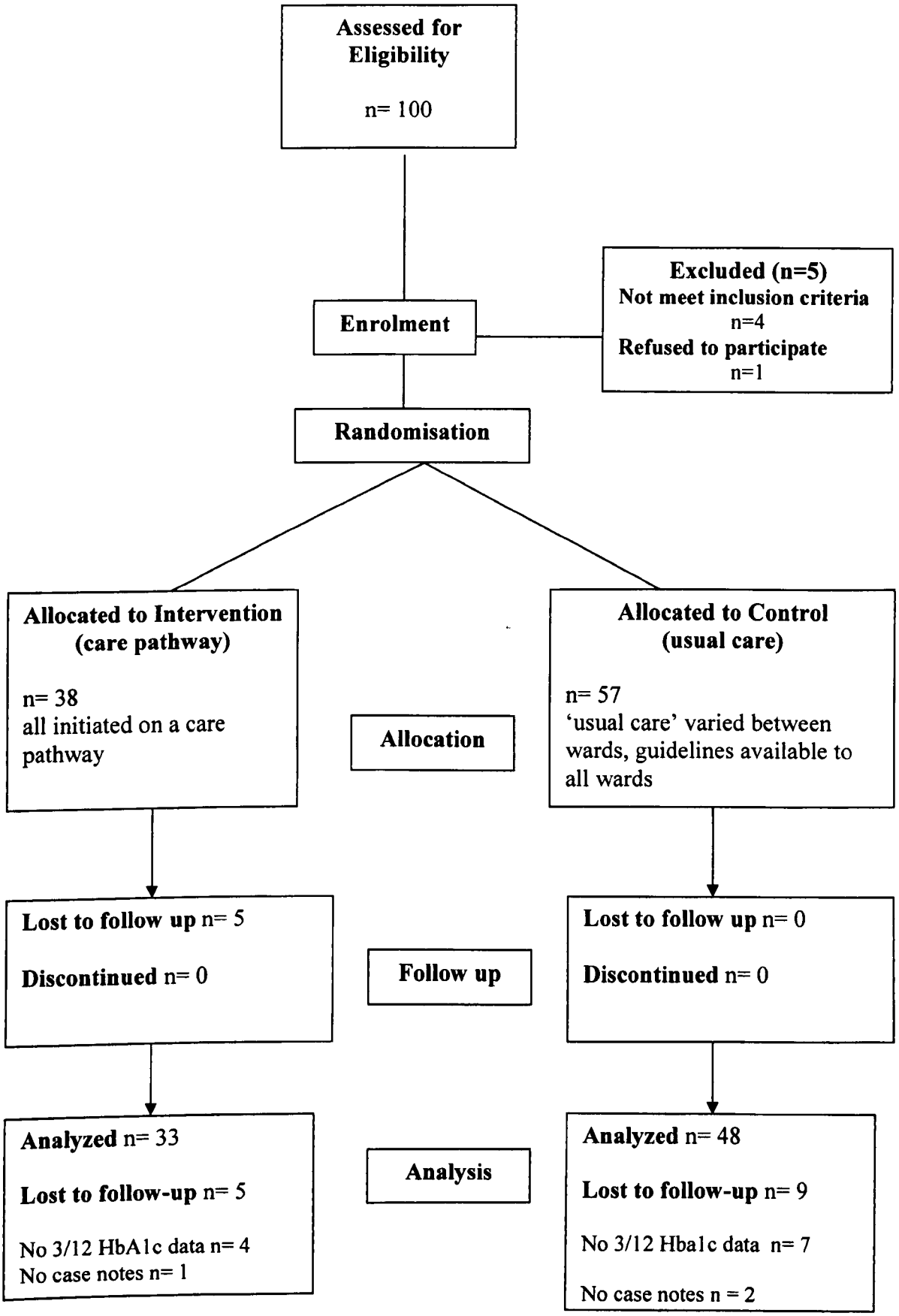
5.3.3 Results

5.3.3.1 Participant Flow

Figure 5.1 illustrates the allocation of participants to study groups and how they progressed through the study.

One hundred patients were approached and invited to participate in the study, four did not meet the inclusion criteria (not medically fit enough to consent) and one refused. Ninety-five patients were recruited to the study: 38 to a care pathway (CP) and 57 to usual care (NP). Eighty-one were included in the final analyses of which 33 were randomised to CP, and 48 to NP. The reasons for exclusion from the analyses were either missing three-month HbA1c data (11 patients) because patients failed to attend for a repeat HbA1c, or missing hospital case notes (3 patients), therefore diabetes management could not be evaluated.

Figure 5.1 Participant Flow through the Study



5.3.3.2 Recruitment

Participants were recruited from the Medical Admissions Unit between December 2000 and November 2001. The length of the intervention period varied for each participant because it was determined by their length of hospital stay. Once discharged, each participant had HbA1c data collected at three months and re-admission data at 12 months. Therefore the recruitment period lasted for 11 months but the trial lasted for a total of 23 months as it finished twelve months after recruitment of the last participant (November 2002).

5.3.3.3 Baseline Data

As discussed above there were only three exclusion criteria for this study because the intended population in which the care pathway would be used was diverse. However, this increased the possibility of confounding variables clouding the results and because of this it was deemed necessary to record a wide range of data at baseline on each participant which could be reviewed in light of any significant differences in the results. The data to be collected were agreed by the author and two local Diabetologists and viewed to be inclusive of the key factors potentially affecting the primary endpoint of HbA1c.

Once subjects had given written, informed consent, the following information was recorded:

- Type and duration of diabetes
- Current diabetes therapy and other medications
- Co-morbidity
- Reason for admission and number of hospital admissions in the last 12 months
- Body habitus (slim, normal, large, obese)
- Diabetes complications
- Barthel score (see chapter 4)
- HbA1c (Diabetes Control and Complications Trial-aligned assay, normal range 4.6-6.2%) (DCCT, 1993).

Table 5.1 shows the baseline demographics of the two groups.

Table 5.1 Baseline Demographics

Demographic	CP (n=33)	NP (n=48)
Age (mean ± SD)	66 ± 13 years	65 ± 13 years
Diabetes Duration (mean ± SD)	10 ± 11 years	10 ± 9 years
Sex	Male: 16 (48%) Female: 17 (52%)	Male: 33 (69%) Female: 15 (31%)
Type 2 diabetes	28 (85%)	42 (88%)
HbA1c (mean ± SD)	7.8 ± 1.8	8.0 ± 1.8
Number on insulin	10 (30%)	20 (42%)
Number on Oral Diabetic Therapy	18 (55%)	24 (50%)
Number other medications (mean ± SD)	6.9 ± 3	7.8 ± 3.4
Number patients with admission last 12 months	21 (64%) Mean number admissions = 1.2 ± 1.6	26 (54%) Mean number admissions = 1.0 ± 1.5
Number existing diabetes complications (retinopathy, nephropathy, neuropathy)	13 (39%)	12 (36%)
Pre-existing IHD	22 (67%)	40 (83%)
Pre-existing Asthma / COPD	8 (24%)	14 (29%)
Pre-existing CVD	7 (21%)	9 (19%)
Barthel Score (mean ± SD)	18 ± 2.9	18 ± 2.5

5.3.3.4 Outcomes

HbA1c, Length of Stay and Re-admission Rate

Patients randomised to CP had a significantly lower re-admission rate than those in the NP group, length of stay was also shorter for the CP group, although this was not statistically significant and HbA1c at 3 months was 0.6% lower in both groups (Table 5.2).

Table 5.2 HbA1c, Length of Stay and Re-admission Rate

	CP (n=33)	NP (n=48)	P value
HbA1c	7.2 ± 1.6	7.4 ± 1.3	NS
Length of Stay (days)	8 ± 7	9.2 ± 10	0.5
Number patients re-admitted in 12 months	12	33	0.008

Quality of Diabetes Care

The care pathway was associated with a significantly better quality of diabetes care (measurement of HbA1c, cholesterol, urinalysis for protein and referrals to the diabetes team), CP 26/33 (79%) people versus NP 24/48 (50%) people (p=0.02)

In addition to an improvement in management in these areas, it was evident from the case notes that the frequency of blood glucose monitoring was more appropriate in the CP group. Twenty-three out of 33 people in the CP group (70%) compared to 8/48 people (17%) in the NP group had an appropriate number of blood glucose tests recorded when judged against the standard

specified in the care pathway document, this standard was also specified in the Hospital Guidelines published some years earlier and available on every ward. It was also much easier to recognise a pattern in patients' blood glucose readings from the care pathway chart compared to the existing blood glucose chart making treatment adjustments easier.

Almost all of the patients in both groups (33 (100%) CP and 45 (94%) NP) had their blood pressure and creatinine measured, as these are done routinely on admission.

Nurse Knowledge

We compared the change in knowledge of nurses working on wards in group 1 (received ongoing support in the use of the care pathway) to nurses working on wards in group 2 (no ongoing support in care pathway use). The questionnaire had 66 questions and total knowledge scores improved more for nurses on wards in group one than for those in group 2 ($p=0.04$), although there were no significant differences between the two groups for individual questions.

Documentation

The standard of documentation in both the CP and NP groups was sub-optimal. In the NP group 22/48 (46%) patients did not have a nursing care plan and in those that did (26/48 (54%) many were not fully completed. Similarly in the CP group many sections of the pathway were not completed, in particular the doctors' sections were often blank. The two parts of the care pathway where documentation was poorest were the GKI section and patient-held care pathway. The GKI section was not completed on any of the pathways, although patients were on a GKI regimen, and the patient-held section was filed in many of the notes, indicating that it had not been completed and given to patients. Table 5.3 summarises compliance with each section of the care pathway for all those on a care pathway and according to whether the patient was on a ward in group 1 (support in using a care pathway) or group 2 (no ongoing support).

Sub Group Analyses

We were unable to recruit enough patients to conduct an adequate sub group analyses of whether wards receiving ongoing support in the use of a care pathway did better than those receiving no support and the reasons for this will be discussed under limitations below. The only notable difference when comparing wards in group one to wards in group two was that the blood glucose monitoring and investigations charts were filled in better on wards in group one (Table 5.3). 81% of the nurses' section on the blood glucose monitoring chart were completed accurately on wards in group one versus 58% on wards in group two and similarly the doctors section was completed more accurately on wards in group one (33%) versus wards in group two (8%). Similarly, the nurses' section of the investigation chart was used better on wards in group one compared to wards in group two (86% versus 58%) although there was no difference in the use of the doctors section of the investigations chart.

There were no other obvious differences in the management of diabetes between wards in group one versus wards in group two for either the care pathway or usual care group.

Table 5.3 Documentation – Compliance With Care Pathway

Number of care Pathways completed Accurately	All Care Pathways (n=33)	Care Pathways, Group 1 (n=21)	Care Pathways, Group 2 (n=12)
Blood Glucose Monitoring (nurses section)	24 (73%)	17 (81%)	7 (58%)
Blood Glucose Monitoring (doctors section)	8 (24%)	7 (33%)	1 (8%)
Investigations Chart (nurses section)	25 (76%)	18 (86%)	7 (58%)
Investigations Chart (doctors section)	6 (18%)	4 (19%)	2 (17%)
GKI Chart	0	0	0

Audit

There was an audit of management of diabetes in 97 patients before the care pathway study and the 93 patients recruited into the study. The findings are presented in Table 5.4. Of those in the pre-study group (PSG) only 53/97 (55%) had a nursing care plan for diabetes, this was similar for the study group (SG), 36 were on a care pathway, and of the other 57, only 32 (56%) had a nursing care plan for diabetes. Documentation was poor in both the PSG and SG.

The appropriateness of blood glucose monitoring (BGM) (number of tests recorded) was audited. In the PSG, BGM was only appropriate in 12/97 (12%) patients. It was better in the SG for those on a care pathway where it was

appropriate in 24/36 (67%), but not for those with no care pathway, when it was only appropriate in 9/57 (16%).

In the PSG, HbA1c was measured in 40/97 (41%) and in the SG, it was measured in 30/36 (83%) of the care pathway group and 18/57 (32%) of the non-pathway group. Urinalysis for protein didn't improve in the second audit for those not on a care pathway. In the PSG, 24/97 (25%) had a recorded urinalysis for protein, 21/36 (58%) of those on a care pathway in the SG had a urinalysis for protein but only 10/57 (18%) of those not on a care pathway had a recorded urinalysis for protein.

There appeared to be an improvement in the measuring of cholesterol in the SG for those on a pathway (26/36 (72%)) compared to the PSG (46/97 (47%) and those in the SG not on a pathway (28/57 (49%)).

Table 5.4 Audit Results

	Pre-Study Group (PSG) (n=97)	Study Group (SG)	
		Care Pathway (n=36)	No care Pathway (n=57)
Was there a care plan?	53 (55%)	NA	32 (56%)
Was BGM appropriate?	12 (12%)	24 (67%)	9 (16%)
Was HbA1c measured?	40 (41%)	30 (83%)	18 (32%)
Urinalysis for protein?	24 (25%)	21 (58%)	10 (18%)
Was Cholesterol measured?	46 (47%)	26 (72%)	28 (49%)

5.3.4 DISCUSSION

Interpretation

The aim of this study was to determine whether a diabetes in-patient care pathway improved the management of diabetes on acute medical wards. The primary outcome measure was change in HbA1c, and secondary measures were Length of stay, re-admissions within 12 months, nurse knowledge and the quality of diabetes in-patient care.

The results indicate that although care pathway use was associated with a significant improvement in the quality of diabetes care and a significant reduction in readmissions within 12 months, there was no significant difference in the primary endpoint (HbA1c 3-months post-discharge) between care pathway and non-care pathway driven care (HbA1c improved equally in both groups by 0.6%). Length of stay also did not differ significantly between the two groups.

The study was powered on a difference in HbA1c between the care pathway and control groups and although there were a small number of patients lost to follow-up, it is unlikely that this lack of a difference in the primary outcome measure with care pathway use was the result of a type 2 error. Thus, in terms of the primary outcome measure, this was a negative study: blood glucose control as measured by 3-month post-discharge HbA1c did not improve more with care pathway driven care than with conventional care.

It is possible that there may have been general changes to care, unrelated to the study intervention, over the timescale of the study that might confound the results of the study. To address this, a planned case note audit of diabetes management before and after the study was undertaken. In this regard, the key comparison is between the pre-study group (PSG) with that in the control (non care pathway group) during the study. No systematic, changes in care were evident on the basis of this audit.

Consistent with the findings in the interventional study, however, the audit suggested that care pathway use improved certain aspects of diabetes care, namely: more appropriate blood glucose monitoring and measurement of HbA1c, proteinuria and cholesterol.

Completion of the care pathway by both medical and nursing staff was generally poor and the GKI section and the patient held care pathway were rarely used. Nevertheless, the results indicate that the Blood Glucose Monitoring and Investigations sections of the care pathway were effective and associated with an improvement in these aspects of diabetes management.

Thus, at least in terms of the primary endpoint, the null hypothesis cannot be rejected. In the main, secondary endpoints improved, but limitations in the design and execution of the study preclude excessive weight being attached to these findings.

Limitations

A sub-study aimed to determine whether care pathway use with ongoing support was any different to care pathway use without ongoing support as some studies in the literature (Laxade and Hale, 1995; Martich, 1993) suggest ongoing support may be necessary to realise the full benefits of care pathway use. Thus, some wards received ongoing support in the use of the care pathway whilst others received no further education on the care pathway. This turned out to be a design flaw because it was not possible to recruit sufficient subjects to examine this sub-study with statistical confidence (30 patients in each subgroup, i.e. 240 patients overall) and it confounded interpretation of the main intervention (pathway versus non pathway) because it was not then possible to separate out changes that resulted from care pathway use from changes that resulted from the additional support. Indeed, other studies have found improvements in the management of inpatients with diabetes associated with intense support of a diabetes nurse specialist (Firth and Jones, 1999; Waldon *et al.*, 2004).

Why was it not possible to continue recruitment until adequate numbers of subjects were enrolled? Imminent changes to the structure and staffing of the medical unit meant that this was not possible; these changes were so extensive that they would have completely undermined the design of the study.

It is very difficult to maintain a 'controlled' environment within an acute care setting and it was evident during the course of this study that there are many variables such as the movement of staff between wards which threaten to confound effective execution of such a RCT in this environment. This may be one reason why there are so few RCTs of care pathways.

Arguably, a surprising finding of the study was the highly statistically significantly lower re-admission rate for patients on a care pathway. It is entirely plausible that improved diabetes care (as has been demonstrated) reduced the need for hospital readmission, but it is also possible that some other confounding factor or chance led to this result. The two groups were similar at baseline in terms of age, diabetes duration, HbA1c, number of previous admissions and

diabetes complications, but, there were more men in the NP group, more people on insulin therapy and more with pre-existing IHD (83% NP group versus 67% of CP group).

These apparent differences between the two groups may account for the difference in the re-admission rate but it is beyond the scope of this study to explore this further. As discussed above, the reason for not excluding participants with co-existing morbidities was that the care pathway was intended for use in all people with diabetes irrespective of other conditions, and it was anticipated that randomisation would reduce the risk of confounding and minimise bias - small numbers reduce the benefits from randomisation in this regard. With hindsight, in view of the small numbers recruited to the trial it might have been more appropriate to try and minimise potential bias by having more stringent exclusion criteria and by attempting to more formally match the groups under comparison.

Generalizability

The limitations of this study, discussed above, undermine any attempts to generalise its conclusions to the wider use of care pathways or the use of this diabetes inpatient care pathway in the wider NHS. It was hoped that by using a positivist approach to studying care pathways this study would provide robust answers as to their effectiveness. Whilst some of the weaknesses are in the study design such as not controlling adequately for confounding variables, it was also very difficult to sustain a 'controlled' environment within an acute NHS Trust and therefore difficult to prevent confounding and recruit adequate numbers and these factors make it difficult to undertake a RCT of care pathways. A key message from this study is that a RCT may not be the most appropriate methodology and that a triangulation of research methods (combining both quantitative and qualitative methods) may be a more appropriate approach to examining care pathways in future studies.

5.3.5 IMPLICATIONS FOR THE FUTURE MANAGEMENT OF INPATIENTS WITH DIABETES

As with other studies of care pathways (chapter 2) the results from this study indicate that the in-patient diabetes care pathway improved aspects of the quality of care patients received. In particular, improved blood glucose monitoring and investigations for diabetes, improved nurse knowledge, shorter length of stay, better diabetes control and significantly fewer re-admissions after one year. However, the findings are limited by the study design and therefore it is not possible to reliably conclude that care pathways should be used for the in-patient management of diabetes.

Nonetheless, it was evident from the study that some sections of the care pathway (Blood Glucose Monitoring and Investigations) worked better than other sections (GKI and Patient Held Pathway). However, it also appeared that sustainable, Trust-wide implementation of the care pathway, would probably require significant ongoing support and education for the staff involved. The resource implications of this additional support are beyond the scope of this study, but would require careful assessment before any recommendation to broaden the use of care pathways in this regard could be made. Following the study, a decision was made not to implement the care pathway Trust wide but to take the two sections that worked well and adapt and implement them across the Trust. Additionally, the study provided insight into the importance of ongoing support by the specialist team to ward staff and plans are underway to change the current system for reviewing inpatients to address these findings.

CHAPTER 6

A CARE PATHWAY-DRIVEN DIABETIC NEPHROPATHY SERVICE

6.1 INTRODUCTION

Diabetic Nephropathy remains the leading cause of renal failure in Europe (and worldwide), yet, in the last 10-15 years, much high quality (Level 1) evidence has emerged to inform the management of Diabetic Kidney Disease (DKD). The outcome for patients should have been transformed, but, relatively little attention has been paid to effective implementation of this new evidence. Outcomes are improved in tightly controlled clinical trials, typically performed in centres of excellence by leading experts in the field, but are these improved outcomes achievable in routine clinical care, by relative non-experts, in potentially less well-resourced departments.

The aim of this initiative was to examine whether outcomes from current best international research can be realised, relatively quickly and inexpensively in a routine care setting by use of a care pathway-driven Diabetic Nephropathy Management Programme.

6.2 DIABETIC NEPHROPATHY

6.2.1 Definition

Diabetic nephropathy can be defined as the presence of proteinuria, declining glomerular filtration rate (GFR) and rising blood pressure (Pickup and Williams, 1991). It can be arbitrarily divided into two stages based on the degree of urinary albumin: Microalbuminuria or Incipient Nephropathy and Macroalbuminuria or Overt Nephropathy.

Albuminuria can be measured in several different ways (ADA, 2004) as shown in Table 6.1. Increasingly, ACR is the internationally preferred methodology.

Table 6.1 Measuring Albuminuria

	24 hour urinary albumin	24 hour urinary protein	Timed albumin excretion ratio (AER)	Albumin Creatinine Ratio (ACR)
Normal	≤ 30mg / 24hr	≤ 50mg / 24hr	< 20microg / minute	<2.5mg / mmol (men) <3.5mg / mmol (women)
Microalbuminuria	30-299mg / 24hr	50-499mg / 24hr	20-199microg / minute	>2.5<30mg / mmol (men) >3.5<30mg / mmol (women)
Nephropathy	≥ 300mg / 24hr	≥ 500mg / 24hr	≥200microg / minute	> 30mg / mmol

Albuminuria is a marker of kidney damage and of more generalised vascular damage, overt nephropathy is associated with a highly significant increased risk of premature morbidity and premature mortality from cardiovascular disease (Valmadrid *et al.*, 2000; Anderson *et al.*, 1983).

6.2.2 The Size of the Problem

Diabetic nephropathy is the leading cause of end-stage renal failure necessitating renal replacement therapy worldwide, and affects up to 40% of patients with Type 1 and up to 25% of those with Type 2 diabetes (Gross *et al.*, 2005). It is associated with significantly higher mortality rates than for non-proteinuric patients with diabetes. In one 12-year study (Wang *et al.*, 1996) of 4714 patients, diabetic nephropathy was associated with a 5-8 fold increased mortality (for men and women respectively) compared with those with diabetes and no proteinuria.

Diabetic nephropathy is more prevalent amongst certain ethnic groups such as Asians, African Americans and Native Americans (Young, *et al.*, 2003). Recently, the incidence of Diabetic Nephropathy has declined (Rossing, 1998;

Gross *et al.*, 2005). This may reflect improved intervention in those at risk of overt nephropathy and it is unclear whether nephropathy has been prevented or postponed to a later age of onset. Despite this reduced incidence, diabetes remains the leading cause of renal failure, suggesting a possible failure to implement evidence-based interventions. Mogensen and Cooper (2004), suggest that there is a lack of good patient management worldwide for those at high risk or with nephropathy, in particular they state that glycaemic control and blood pressure (2 key risk factors) are not managed appropriately. This problem has to be addressed, the importance of early identification and treatment of those at risk is emphasised in many key studies of DKD.

6.2.3 Evidence-based Interventions

The first major study to emphasise the renoprotective effect of Ace Inhibitors (Lewis *et al.*, 1993) was in Type 1 diabetes, but in recent years major studies (Parving *et al.*, 2001; Lewis *et al.*, 2001; Brenner *et al.*, 2001) examining similar interventions in Type 2 diabetes have also been published, with similar conclusions. There is now a plethora of evidence on how to delay or prevent progression of DKD and a clear international consensus on key interventions, reflected in national and international guidelines.

The purpose of this section is to summarise the main interventions recommended in these national (NICE (National Institute for Clinical Excellence)) and international (ADA (American Diabetes Association)) guidelines for the management of DKD. Individual guidelines differ slightly in precise targets or wording of a recommendation but the six key interventions for DKD are shown in table 6.2.

Table 6.2 Six Key Recommendations for Diabetic Kidney Disease, summarised and merged from ADA Guidelines (2004) and NICE Guidelines (2002a)

	Recommendation	Level of Evidence-Based Recommendation (Cochrane Graded) The evidence is graded I-IV and recommendations A-D.
1.	Blood glucose control. Target HbA1c 6.5-7.5%	Level A
2.	Blood Pressure control Target 125/75 – 130/80	Level A
3.	Renin-angiotensin-aldosterone-system (RAAS) blockade	Level A
4.	Aspirin: use 75-162 mg daily	Level A
5.	Cholesterol lowering with HMG CoA Reductase Inhibitors (Statins)	Level A
6.	Smoking cessation	No level given

6.3 SHORTFALLS IN THE MANAGEMENT OF DIABETIC NEPHROPATHY IN ST HELENS & KNOWLSEY

Some years ago, it was recognised that the management of diabetic nephropathy in the district was sub-optimal, including a failure to implement promptly, and consistently key interventions for diabetic nephropathy. The purpose of this section is to outline the key shortfalls in the management of diabetic nephropathy in the local area as a background to the development and implementation of a care pathway-driven nephropathy service.

6.3.1 Inadequate Screening & Intervention (Primary Care)

Screening for diabetic nephropathy is simple, and cheap. It involves a urinalysis (dipstick) for proteinuria and a measure of Albumin: Creatinine Ratio (ACR) in the laboratory. People with persistent dipstick positive proteinuria will have

diabetic nephropathy or microalbuminuria, the ACR enhances diagnostic accuracy and qualification of proteinuria.

In 1999 an audit was completed with the St Helens Multidisciplinary Audit Advisory Group (MAAG) to assess the prevalence of diagnosed and undiagnosed proteinuria in the district (O'Brien *et al.*, 1999a) and to determine how well these patients were being managed (O'Brien *et al.*, 1999b). The audit studied 22 GP practices, total practice population was 114,335, representing 34% of the district population. There were 2232 patients with diabetes (Type 1 and Type 2), representing a prevalence of 1.95%.

Inadequate Screening & Diagnosis

The audit found 57 (2.6%) patients who were already known to have diabetic nephropathy. Only 1539 (69%) patients had had a urinalysis for protein (to screen for nephropathy) in the last 12 months, of whom, 80 had isolated proteinuria which hadn't been investigated further and 52 had persistent proteinuria recorded but had not been diagnosed (or managed) as having nephropathy. Thus, whilst the prevalence of known nephropathy was 2.6%, 2.4% (52/2232) had undiagnosed nephropathy and a further 3.7% (80/2232) had isolated proteinuria but had not had nephropathy confirmed. Furthermore, 31% (693/2232) of patients had not had a urinalysis for protein in the last 12 months and so the estimates of undiagnosed nephropathy were likely to be substantial underestimates. The results showed that screening for diabetic nephropathy was inadequate and that much nephropathy was undiagnosed. If people with DKD were not being diagnosed there is little prospect of them receiving vital interventions to improve their outcomes.

Inadequate Intervention

The audit also found sub-optimal management of the 57 patients known to have diabetic nephropathy. 31% (18/57) were not on any blood pressure treatment and 40% (23/57) were eligible for RAAS (Renin Angiotensin Aldosterone System) blockade but were not receiving it. Despite a wealth of evidence

regarding the best management of nephropathy, substantial numbers of patients were not receiving the most appropriate interventions.

The results demonstrated that there was much scope for improving the diagnosis, management and outcomes of diabetic nephropathy in the district.

6.3.2 Inadequate Intervention (Specialist Care)

Before the care pathway-driven nephropathy service, patients with microalbuminuria and nephropathy were seen in general diabetes clinic, where they were reviewed by a consultant, registrar or senior house officer, typically a different person at each visit. There was some awareness of recommendations for managing nephropathy but there were no specific guidelines and few patients were followed up in these clinics. Some of those with overt nephropathy and significant renal impairment (unspecified) were referred to a nephrologist at a neighbouring hospital (there is no nephrologist in our Trust).

In 1999, a retrospective case note audit of 102 patients attending the general diabetes clinic was conducted to assess management of patients with microalbuminuria and nephropathy. Only 17% of the patients had a blood pressure (BP) in target and the mean treated BP was 151 / 90. It was clear from the notes that BP medication was not being increased adequately. Only 5% of patients were on maximum dose RAAS blockade and mean HbA1c was 8.6%. Neither Aspirin, or Statin therapy were being routinely initiated.

Thus, it was clear that in specialist care as well as primary care there was a failure to implement evidence-based practice for DKD.

6.4 A CARE PATHWAY-DRIVEN DIABETIC NEPHROPATHY SERVICE

This section outlines the steps taken to improve the management of DKD in the district.

6.4.1 Improving Screening, Diagnosis and Management in Primary Care

A major problem in primary care was a lack of awareness of how to screen and diagnose DKD. Local guidelines for the management of diabetes in primary care were developed, including detailed recommendations for screening for microalbuminuria. These guidelines were distributed to all GP practices and were the subject of much publicity.

Also, it was anticipated that implementation of the nephropathy care pathway in specialist care (see below) would result in consistent evidence-based management and reinforce the primary care guidelines.

6.4.2 Improving the Management of Diabetic Kidney Disease in Specialist Care

There were three key actions to address the shortfalls in the management of DKD in specialist care:

1. **Development of Local Guidelines for Microalbuminuria and Nephropathy**

International guidelines and the results from the large clinical trials were used to develop simple, local guidelines for the management of microalbuminuria and nephropathy. These were publicised extensively in primary and secondary care to increase awareness of best practice in DKD and formed the basis of the evidence-based standards underpinning the nephropathy care pathway.

2. **Establishment of a Care Pathway-Driven Nephropathy Service**

In developing the care pathway, a structured 'nephropathy service' was established. Patients with DKD are reviewed in dedicated 'Nephropathy Clinics' and the care pathway states each intervention the patient should receive to ensure delivery of evidence-based interventions. A structured clinic sheet records results and medication at each visit, this is copied to the patient and their GP with

the clinic letter to ensure effective communication, patients receive information leaflets about DKD and any drugs initiated in clinic.

The service started in 1999. Over the last 5 years it has evolved and presently there are three Diabetic Nephropathy Clinics each week. Originally the aim was to follow up (indefinitely) all patients with microalbuminuria and nephropathy referred to the service, but, the number of referrals proved unmanageable and the criteria were revised. Presently, patients with microalbuminuria are reviewed and educated about the complication and treatment goals, but, those who are stable and with normal renal function, are discharged back to primary care. Patients with overt nephropathy and impaired renal function are kept under review in the clinic.

The targets have evolved over the years with emergence of new evidence NICE, 2002a; Lewis *et al.*, 2001; Parving *et al.*, 2001; Brenner *et al.*, 2001). There are six factors reviewed with the patient at every appointment. All targets are individualised, but the default levels were adapted from the International Targets (table 7.1) to 6 key interventions (NICE, 2002a; ADA, 2004):

1. Tight glucose control, target HbA1c <7.0% (recently reduced to 6.5%)
2. Tight blood pressure control, target BP <125/75
3. Maximum single-agent RAAS blockade
4. Statin treatment, target LDL-cholesterol <2.6mmol/L (recently reduced to <2.0mmol/L)
5. Smoking cessation
6. Use of Aspirin 75mg daily.

The clinician reviewing the patient has to complete the care pathway which prompts them to review each of these interventions, thus ensuring implementation of best practice. The latest version of the care pathway, clinic sheet and patient leaflet are presented in Appendix 5.

In addition to the six interventions outlined above, the clinic has evolved further in the last few years and there are clear standards for managing other aspects of

DKD such as anaemia, and disturbances of phosphate, calcium, bicarb and PTH levels. The policy regarding these areas of management can be found in the care pathway standards in Appendix 5. To illustrate how the care pathway-driven service works in practice, two case studies are presented in table 6.3.

3. Named Staff to Deliver the Nephropathy Service

Feedback (from Regional Accreditation Visit) indicated that consistency of staff was an important factor for patients. Three named staff (Diabetologist, Diabetes Nurse, Senior Clinical Fellow) took responsibility for the nephropathy service; patients only see one of these three, to allow continuity and consistency in care. They have access to the diabetes nurse in between appointments either by phone or if necessary in person to allow further support and continuity. Over the last five years, these named staff have developed an 'expertise' in the management of diabetic nephropathy which has further enhanced the service.

Additionally, links were forged with a nephrologist from the tertiary centre to agree a joint approach to managing patients with diabetic nephropathy. Liaison with a named nephrologist has resulted in improvements in communication and increased consistency for those patients who attend both clinics.

Table 6.3 Case Studies To Illustrate Intervention with Nephropathy Clinic Care Pathway

	Patient Characteristics at baseline	Intervention per care pathway	Follow up
Case 1 Mr Smith, 54 years Microalbumiuria eGFR = 98 ml/min/1.73m^2	Type 2 diabetes for 4 years BP = 158/89 HbA1c = 7.2% (on Metformin 500mgs tds) LDL-C = 2.1 mM Smokes 20 per day	Started on Irbesartan & GP asked to increase to maximum dose (300mgs od) GP advised to add further BP tablets & aim for target of <125/75 Metformin increased to reduce HbA1c (target <6.2%) Started on Simvastain 40mgs od GP advised to start Aspirin 75mgs od once systolic BP <145 Advised abut smoking cessation Microalbuminuria would be explained and an information leaflet provided	Discharged from clinic & GP advised about six key interventions Patient advised about importance of achieving & maintaining targets
Case 2 Miss Roberts, 30 years Nephropathy eGFR = 34 ml/min/1.73m^2	Type 1 diabetes 15 years BP = 110 / 65 HbA1c = 9.6% on twice daily insulin LDL-C = 2.6mM on Simvastain 40mgs od Non-smoker	Started on Ramipril & GP asked to titrate to 10mgs od (advised about pregnancy risk) Receive advice & support to improve HbA1c – insulin changed if patient wanted, reviewed as much as patient & nurse feel is necessary Simvastatin changed to Atorvastain 80mgs od 24 hour urine for protein measured & serum creatinine, phosphate, bicarb, PTH & ferritin measured. If any of results are out of target medication is initiated and levels monitored until stable and then at each visit	Reviewed in Nephropathy clinic as often as is necessary (frequency of visits is determined by blood results) May be referred to nephrologist for shared care if eGFR deteriorates

6.5 HAS THE MANAGEMENT OF DIABETIC KIDNEY DISEASE IMPROVED?

6.5.1 Introduction

The aim in establishing the care pathway-driven nephropathy service was to ensure implementation of the six, key, evidence-based interventions and to improve outcomes for patients with DKD. Just prior to the evaluation of the service, three large clinical trials reported on the impact of Renin-Angiotensin-Aldosterone-System (RAAS) Blockade in patients with Type 2 diabetes and microalbuminuria (Parving *et al.*, 2001) or nephropathy (Lewis *et al.*, 2001; Brenner *et al.*, 2001), the hard endpoints they examined were progression to nephropathy (Parving *et al.*, 2001), doubling of serum creatinine, death and End Stage Renal Disease (Lewis *et al.*, 2001; Brenner *et al.*, 2001). These studies were highly significant for the management of DKD as previously most of the hard evidence related to Type 1 diabetes and whilst it had always been suspected that the interventions were as important for Type 2 diabetes, there was now robust evidence. However, the favourable outcomes reported in these studies were achieved in a tightly controlled clinical trial, could they be replicated in routine clinical care?

It was hypothesised that a care pathway-driven nephropathy service would be effective at ensuring implementation of the key interventions for DKD and evaluated this by examining management and outcomes in 465 patients with Type 2 diabetes attending the clinics. The same outcomes as reported in the studies highlighted above (progression to nephropathy, doubling of serum creatinine, death and ESRD (End Stage Renal Disease)) were examined and compared the results to those achieved in the clinical trials.

The purpose of this section is to describe the methods and results and to discuss whether the care pathway-driven nephropathy service has improved the management of patients with DKD.

6.5.2 Methods

The processes of care, surrogate endpoints and hard endpoints were examined.

Processes of Care

A retrospective case note audit was completed to examine whether patients had received the six key interventions specified in the care pathway. The evidence base for the interventions is continuously evolving and the care pathway standards have evolved to reflect this, for the purpose of this study the targets specified below (figure 6.1) were used as the audit standard, because they were in use for the majority of the follow up time of those patients included in the analyses.

Figure 6.1 Six Interventions Audited

1. Aggressive blood pressure control – target 125/75
2. Maximum dose RAAS blockade: Ace inhibitor (Ramipril 10mgs o.d) or Angiotensin-II receptor antagonist (Irbesartan 300mgs o.d).
3. Aggressive use of statins (typically starting with Simvastatin 40mg nocte) – target LDL-cholesterol <2.6mmol/L
4. Aspirin 75mgs o.d unless contraindicated
5. Smoking cessation
6. Tight glycaemic control – individualised target, typically HbA1c <7%

Surrogate Endpoints

Secondary outcome measures were changes in HbA1c, BP, creatinine, lipids and weight, from baseline (first appointment in the clinic), to their last appointment at the time of the study.

Hard Endpoints

The primary outcome measures was death, but, also examined were: the number of patients with a doubling of serum creatinine and new ESRF (we defined this as starting renal replacement therapy). This data was collected from one of three sources; the diabetes notes, Hospital Patient Information System or the patient's GP.

The outcomes for patients with microalbuminuria (defined as albumin:creatinine ratio (ACR) >2.5 (men) or >3.5 (women) and <30 mmol/micromol on two separate occasions) were compared to the results from IRMA2 study (Parving *et al.*, 2001). The outcomes for patients with nephropathy (defined as ACR > 30 mmol/micromol on two separate occasions) were compared to the results of two studies, IDNT (Lewis *et al.*, 2001) and RENAAL (Brenner *et al.*, 2001).

Patients

The study involved Type 2 diabetes patients attending a care pathway-driven nephropathy clinic with a diagnosis of either microalbuminuria or nephropathy. The inclusion criteria specified they should have had at least two clinic appointments (to allow opportunity for intervention to have taken place) and both baseline and follow up data had to be available.

Statistical Analysis

Mean HbA1c, BP, LDL-C and serum creatinine were calculated at baseline and at the latest follow up visit and compared using two-tailed paired t-tests calculated in Microsoft Excel (2003). Smoking rates at baseline were compared to follow up and eGFR (see section below) was calculated for baseline and follow up and the rate of change of eGFR calculated using Microsoft Excel.

eGFR

Traditionally, serum creatinine has been widely used as a marker of kidney function, however, this is problematic because it can be influenced by factors such as age, diet and body mass and Glomerular Filtration Rate (GFR) is regarded as the best measure of kidney function (Cameron and Gregor, 1998; Jones, 2005). However, in practice, GFR is not routinely measured because it is timely and expensive (Rigalleau *et al.*, 2005; Jones, 2005; Mahajan *et al.*, 2005), consequently the use of prediction equations for estimating GFR has become accepted practice in the management of patients with Chronic Kidney Disease (CKD) and these equations are recommended by the National Kidney Foundation (Levey *et al.*, 2003) and the K/DOQI (2002) guidelines. Both these guidelines recommend using eGFR equation to classify patients according to their degree of CKD using the stages outlined in Table 6.4.

There are various prediction equations available for calculating eGFR but the two most commonly used are the Cockcroft-Gault formula (Cockcroft and Gault, 1976) and the Modification of Diet in Renal Disease (MDRD) formula (Levey *et al.*, 1999).

The Cockcroft-Gault formula (figure 6.2) uses age, body weight and serum creatinine to estimate eGFR and was developed by examining the relationship between age and 24-hour creatinine excretion in 249 patients aged 18-92, results for creatinine clearance were predicted by five methods including the formula and compared to the means of two 24-hour creatinine clearances. The Cockcroft-Gault formula had a correlation coefficient of 0.83 and was found to give a good prediction of GFR (Cockcroft and Gault, 1976).

Figure 6.2 Cockcroft-Gault Formula

Men: ((140-Age) x Body weight) / (0.792 x serum creatinine)

Women: ((140-Age) x Body weight) / (0.792 x serum creatinine) x 0.85

The MDRD formula (figure 6.3) was developed in a large study (Levey *et al.*, 1999) involving 1628 patients (derived from results of 1070 patients and validated in the other 558), stepwise regression was used to derive the equation and it was compared and validated against other prediction equations.

Figure 6.3 MDRD Equation

Men: $186 \times ((\text{serum creatinine} \times 0.0113)^{-1.154}) \times (\text{age}^{-0.203}) \times 1$

Women: $186 \times ((\text{serum creatinine} \times 0.0113)^{-1.154}) \times (\text{age}^{-0.203}) \times 0.742$

A problem with both formulae is that they may not be as accurate in populations different from those in which they were developed. For example, different ethnic groups, people with diabetes or people with normal renal function. Further studies are underway to establish validity in different populations.

Despite limitations of using prediction equations it is recommended as good practice in the management of CKD (K/DOQI guidelines, 2002), and the MDRD equation appears to be most reliable estimate of eGFR (Mahajan *et al.*, 2005; UK CKD eguide, 2005; Poggio *et al.*, 2005), especially in diabetes (Rigalleau *et al.*, 2005).

For the purpose of this study, eGFR was calculated (in Microsoft Excel) using both formulae in order to compare differences (if any) between the results. Also, comparisons were made between median values for MDRD in those < 70 years of age to those > 70 years of age as the formula may be less reliable in those > 70 years.

Table 6.4 Stages of Chronic Kidney Disease (K/DOQI Clinical Practice Guidelines, 2002)

Stage	Description	GFR (ml/min/1.73m$^{2)}$
1	Kidney damage with normal or ↑ GFR	≥ 90
2	Kidney damage with mild ↓ GFR	60-89
3	Moderate ↓ GFR	30-59
4	Severe ↓ GFR	15-29
5	Kidney failure	<15 (or dialysis)

6.5.3 Results

Microalbuminuria

338 study patients had microalbuminuria, mean (± standard deviation) follow up time in the care pathway-driven service was 22 ±11 months. The baseline demographics and parameters for these patients are shown in Table 6.5, with the baseline demographics for patients in the three groups reported in the IRMA2 study (Parving *et al.*, 2001).

Process Measures and Surrogate Endpoints

324/338 (96%) were on maximum dose RAAS blockade, hyperkalaemia was the main contraindication in all of those not on it. In addition to RAAS blockade, patients were on a mean of 2 ± 1 other antihypertensive agents and this resulted in a mean fall in BP of -11/6, from 141/78 at baseline to 130/72 at follow up ($p<0.0001$), 33% of patients achieved the BP target specified on the care pathway of <125/75.

All patients with no contraindications received Aspirin 75mgs daily.

During the study period, proteinuria fell in 64% (216/338) of patients, incidence of nephropathy was 6.1 per 100-Pt-yr and the incidence of new cardiovascular disease (MI, stroke, TIA or new PVD) was 7.7% which is comparable to that seen in IRMA2 (8.7% and 4.5% placebo and 300mg groups respectively, p=0.11). Mean HbA1c fell from 7.6 ± 1.4% at baseline to 7.3 ± 1.2% at follow up (p=0.0004) and 46% (115/338) achieved individual HbA1c targets. LDL-Cholesterol fell from 2.6 ± 0.8 mmol/l at baseline to 2.1 ± 0.8mmol/l at follow up (p= <0.0001), 77% (260/338) of patients achieved the LDL-Cholesterol target of <2.6mmol/l.

There was a 17% reduction in the number of patients smoking from baseline to follow up.

Table 6.6 shows patients with microalbuminuria stratified by stages of CKD at baseline and follow up. It was noted in the literature pertaining to the MDRD formula that it was most reliable for people over 18 and below 70 years of age, in order to examine the significance of this we compared creatinine clearance in those <70 years to those ≥70 years and the results are presented in Table 6.7.

Table 6.8 shows median eGFR at baseline and follow up, the absolute reduction in eGFR and the annual rate of change. The same data from IRMA2 is presented (for the placebo and Irbesartan 300mg group) by way of comparing our results to those in the trial. Study patients' eGFR is presented for both the Cockcroft-Gault and MDRD equations but the data from IRMA 2 was calculated using only the Cockcroft-Gault formula.

Hard Endpoints

The primary endpoint in IRMA2 was progression from microalbuminuria to nephropathy, during the study follow up period, 10% (38/338) of our patients progressed from microalbuminuria to nephropathy. Lastly, during the follow up period, 4 (1%) of patients had doubling of serum creatinine, 2 (1%) required dialysis and 13 (4%) died.

Table 6.5 Microalbuminuria Baseline Demographics

	THIS STUDY	IRMA2		
	Care Pathway Clinic	Control Group	Irbesartan 150mg	Irbesartan 300mg
Number subjects	338	201	195	194
Age (yrs)	62 ± 11	58 ± 8.7	58 ± 8	57 ± 7.9
M:F	223:115	138: 63	129: 66	137 : 57
Duration Diabetes (yrs)	7.4 ± 7.1	10.4 ± 8.6	9.5 ± 6.9	9.2 ± 6.9
BMI (kg/m^2)	31 ± 6.2	30.3 ± 4.4	29.9 ± 3.8	30.0 ± 4.3
Cardiovascular disease (%)	47	23	30	26
Smoking (%)	18.9	17.9	21.5	16.5
HbA1c (%)	7.6 ± 1.4	7.1 ± 1.6	7.3 ± 1.7	7.1 ± 1.7
Systolic BP (mmHg)	141 ± 21	153 ± 15	153 ± 14	153 ± 14
Diastolic BP (mmHg)	78 ± 11	90 ± 9	90 ± 9	91 ± 10
Serum creatinine (µmol/l)	112 ± 37	M: 97 ± 9 F: 80 ± 9	M: 97 ± 18 F: 80 ± 9	M: 97 ± 18 F: 88 ± 18
LDL-Cholesterol (mmol/l)	2.6 ± 0.8	3.7 ± 1.0	3.7 ± 1.2	3.5 ± 1.0
ACR (mmol/µmol)	9.82	-	-	-
AER (µg/min)	-	55	58	53

Table 6.6 Microalbuminuria Stages of CKD at Baseline and Follow Up (n=338)

CKD Stage		Baseline (Number (%))	Follow Up (Number (%))
Stage 1	**(GFR ≥90)**	13 (4)	12 (3)
Stage 2	**(GFR 60-89)**	181 (53)	165 (49)
Stage 3	**(GFR 30-59)**	126 (37)	136 (40)
Stage 4	**(GFR15-29)**	16 (5)	20 (6)
Stage 5	**(GFR <15)**	2 (1)	5 (2)

Table 6.7 Median eGFR (MDRD Formula) in Patients with Microalbuminuria Under and Over 70 years of age

Age Group	Baseline eGFR	Follow Up eGFR
Under 70 years of Age (n=248)	67.1 ml/min/1.73m^2	64.3 ml/min/1.73m^2
70 years and above (n=90)	50.6 ml/min/1.73m^2	48.2 ml/min/1.73m^2

Table 6.8 eGFR

Group	eGFR Baseline ml/min/1.73m^2	eGFR End ml/min/1.73m^2	Absolute reduction ml/min/1.73m^2	Annual rate of decline ml/min/yr
Care Pathway Cockcroft-Gault (MDRD)	79 (63.3)	75.8 (60.6)	3.2 (2.7)	0.78 (1.56)
Placebo (IRMA2) Cockcroft-Gault	109	106	3	1.5
Irbesartan 300mg (IRMA2) Cockcroft-Gault	108	101	7	3.5

Nephropathy

127 patients had nephropathy and the mean (± standard deviation) follow up time in the care pathway-driven service was 26 ± 10 months. Baseline demographics and parameters for these patients are shown in Table 6.9 with the baseline

demographics for patients in the two groups reported in the RENAAL study (Brenner *et al.*, 2001) and two of the groups reported in the IDNT study (Lewis *et al.*, 2001).

Process Measures and Surrogate Endpoints

98% (124/127) were on maximum dose RAAS blockade, and a mean of 2 ± 1 other antihypertensive agents, this resulted in a mean -11/7 fall in BP from 148/80 at baseline to 137/73 at latest follow up appointment ($p<0.001$), 33% of patients achieved the BP target of 125/75 (39% achieved the systolic BP target of <125 and 59% the diastolic BP target of <75).

During the study period, proteinuria fell in 66% (84/127) of patients and incidence of new onset cardiovascular disease (MI, stroke, TIA or new PVD) was 3.2 per 100-Pt-yr. All patients without contraindications received Aspirin 75mgs daily and smoking fell from 16% (20/127) to 13% (17/127). Mean HbA1c fell from 7.7 ± 1.7 at baseline to 7.4 ± 1.3 at follow up ($p=0.03$), and 44% (56/127) achieved a HbA1c <7%. LDL-C fell from 2.8 ± 1 at baseline to 2.1 ± 0.8 ($p<0.001$) at last follow up visit and 81% (103/127) achieved the LDL-C target specified on the care pathway of <2.6.

Table 6.10 shows patients with nephropathy stratified by stages of CKD at baseline and follow up, and Table 6.11 shows eGFR (MDRD formula) in those < 70 years and those ≥70 years.

Table 6.12 shows median eGFR at baseline and follow up, the absolute reduction in eGFR and the annual rate of change.

The rate of change in eGFR (using Cockcroft Gault) was calculated and how many nephropathy patients fell into different rates of change of eGFR, the results are presented in Table 6.13. We examined whether there were any differences between those whose eGFR improved versus those whose eGFR had fallen the most (>-10ml/min/yr). There was no difference in HbA1c, but systolic BP was

lower (138) in those whose eGFR had improved compared to those (147) whose rate of change of eGFR was >-10ml/min/yr ($p<0.02$). Diastolic BP was lower (72) in the improvers versus the rapid fallers in eGFR (75) but this was not statistically significant. None of the improvers progressed to ESRD but 20% of the rapid fallers did, and mortality was higher in the rapid fallers (20%) compared to the improvers (6%).

Hard Endpoints

Table 6.14 presents the number of patients experiencing a doubling of serum creatinine, ESRD or death for the care pathway-driven service, RENAAL and IDNT.

Table 6.9 Nephropathy Baseline Demographics

	THIS STUDY	RENAAL		IDNT	
	Care Pathway Clinic	Placebo Group	Losartan Group	Placebo Group	Irbesartan Group
Number subjects	127	762	751	567	579
Age (yrs)	63 ± 9	60 ± 7	60 ± 7	58.3 ± 8.2	59.3 ± 7.1
M:F	89: 38	494:268	462:289	403:164	378:201
Duration diabetes (yrs)	8.1 ± 7	-	-	-	-
BMI (kg/m^2)	32 ± 6	29 ± 6	30 ± 6	30.5 ± 5.9	31.0 ± 5.6
Cardiovascular disease (%)	41%	31%	27%	29%	27%
Smoking (%)	16%	17.1%	19.6%	-	-
HbA1c (%)	7.7 ± 1.7	8.4 ± 1.6	8.5 ± 1.7	8.2 ± 1.7	8.1 ± 1.7
Systolic BP (mmHg)	148 ± 19	153 ± 20	152 ± 19	158 ± 20	160 ± 20
Diastolic BP (mmHg)	80 ± 12	82 ± 11	82 ± 10	87 ± 11	87 ± 11
Serum creatinine (µmol/l)	131 ± 56	168 ± 44	168 ± 44	149 ± 50	148 ± 47
LDL-C (mmol/l)	2.8 ± 1	3.7 ± 1	3.7 ± 1	-	-

Table 6.10 Nephropathy Stages CKD at Baseline and Follow Up (n=127)

CKD Stage		Baseline (Number (%))	Follow Up (Number (%))
Stage 1	(GFR ≥90)	7 (6%)	4 (3%)
Stage 2	(GFR 60-89)	42 (33%)	39 (31%)
Stage 3	(GFR 30-59)	64 (50%)	58 (45%)
Stage 4	(GFR15-29)	12 (9%)	15 (12%)
Stage 5	(GFR <15)	2 (2%)	11 (9%)

Table 6.11 Median eGFR (MDRD Formula) in Patients with Nephropathy Under and Over 70 years of age

Age Group	Baseline eGFR	Follow Up eGFR
Under 70 years of Age (n=104)	53.8 ml/min/1.73m^2	51.9 ml/min/1.73m^2
70 years and above (n=23)	43.6 ml/min/1.73m^2	42.5 ml/min/1.73m^2

Table 6.12 eGFR (Nephropathy Patients)

CrCl Formula	eGFR Baseline ml/min/1.73m^2	eGFR End ml/min/1.73 m^2	Absolute reduction ml/min/1.73m^2	Annual rate of decline ml/min/yr
Cockcroft-Gault	71.7	63.4	8.3	-1.56
MDRD	52.8	49.1	3.7	-1.95

Table 6.13 Nephropathy Patients rate of Change of eGFR (Cockcroft-Gault)

Change eGFR (ml/min/yr)	Number of patients (%) N=127
Better	50 (39%)
0-0.99	9 (7%)
¯1-¯1.99	8 (6%)
¯2 - ¯2.99	9 (7%)
¯3 - ¯3.99	5 (4%)
¯4- ¯4.99	8 (6%)
¯5 - ¯10	16 (13%)
>¯10	22 (18%)

Table 6.14 Doubling Serum Creatinine, Progression to ESRD and Death (Events expressed per 100-patient-years for comparisons)

	THIS STUDY	RENAAL		IDNT	
	Care Pathway Clinic	Placebo Group	Losartan Group	Placebo Group	Irbesartan Group
Doubling of Serum Creatinine	1.4	10	7.9	8.9	3.9
ESRD *	1.1	9.1	6.8	4.3	5.4
Total Mortality	2.2	6.6	6.8	6.5	5.8

***Note:** ESRD was defined as patients requiring renal replacement therapy, in RENAAL it was also defined as the need for long term dialysis or transplant and in IDNT it was defined as initiation of dialysis, transplant or serum creatinine of 530 μmol/l.

6.5.4 Discussion

This study shows that the care pathway-driven nephropathy service has improved the management of microalbuminuria and nephropathy and resulted in effective implementation of six key, evidence-based, interventions for DKD, critically with improved hard endpoints.

Microalbuminuria

Previously, the use of RAAS blockade was sub-optimal whereas now, only 4% of patients with microalbuminuria are not on maximum dose RAAS blockade and in all of these hyperkalaemia was the primary contraindication. All patients with microalbuminuria eligible for Aspirin, received it, and there was a significant improvement in smoking cessation. Mean LDL-C fell significantly, and more importantly, 77% achieved the LDL-C target of <2.6mM, the LDL-C target changed recently to <2mM with a more aggressive use of statins and other

drugs to reduce lipids, and it is probable that if re-examined, more patients would now be in target.

There was a highly significant (P<0.00001) drop in BP and the mean BP at last follow up visit of 130/72, was lower than the BP achieved in the Irbesartan 300mg group in IRMA2 (Parving *et al.*, 2001), however, only 33% of patients with microalbuniuria achieved a BP <125/75 and the mean number of antihypertensive drugs was 2. The care pathway prompts a review of BP at each visit, however, sometimes a BP close to target isn't treated, but, the GP is asked to monitor BP and treat if it remains above target; this does not consistently happen. The findings from this study suggest there is scope to improve BP management within the service, there is a need to be more aggressive with BP intervention in order to achieve a BP <125/75 in more patients with microalbuminuria. Similarly, whilst there was a significant fall in HbA1c (p=0.0004), 54% of patients did not achieve target HbA1c and this needs improving in the future.

The results demonstrate that patient outcomes in the care pathway-driven nephropathy service are comparable to those achieved in a large clinical trial.

The incidence of new cardiovascular disease was relatively low and comparable to that in IRMA2. A key goal in managing DKD is to reduce the rate of decline of creatinine clearance, and a commentary with the latest ADA position statements suggests the goal should be a decline in GFR <2ml/min/yr (Gross *et al.*, 2005). This rate of decline of eGFR was achieved in patients with microalbuminuria, using the MDRD formula (which is the most appropriate for diabetes) the rate of decline was -1.56 ml/min/yr which was better than the Irbesartan 300mg group in IRMA2, although the authors (Parving *et al.*, 2001) report an initial rapid decline in eGFR during the first 3 months in the treatment groups and suggest this may be caused by the functional (haemodynamic) effects of antihypertensive therapy, after the first 3 months the rate of decline slows and levels out. Furthermore, the initial rapid decline didn't adversely affect their primary outcome measure of progression to nephropathy and they report that only 5.2% (10/194) of the patients in the 300mg Irbesatran group and 9.7%

(19/195) of those in the 150mg Irbesartan group versus 14.9% (30/201) of the placebo group progressed to nephropathy, 10% of our patients progressed to nephropathy which is comparable to the 150mg Irbesartan group. Consequently, if you consider patients stratified according to the stages of CKD (table 6.6) there are no significant difference between baseline and the end of the study and the majority of patients have either stage 2 or stage 3 CKD at baseline (90%) and follow up (89%).

Nephropathy

Similar to the microalbuminuria group, all those in whom it was not contraindicated, received Aspirin and only 2% did not receive maximum dose RAAS blockade. There was a reduction in smoking rates and a significant ($p<0.0001$) fall in LDL-C to 2.1, 81% of the patients with nephropathy achieved a LDL-C target of <2.6. The onset of new cardiovascular disease was low, and the rate is comparable to that achieved in the MICROHOPE Study (HOPE Study Investigators, 2000), which demonstrated that Ramipril 10mgs daily provided cardiovascular benefits (reduction in stroke, MI and all cause mortality) independent of a lowering of BP, a further indication that the outcomes of large clinical trials are achievable in routine clinical care.

Again, BP improved significantly but only 33% achieved the <125/75 target and this needs addressing in the future with more aggressive use of antihypertensive agents. It is evident from all the large trials pertaining to DKD that tight BP control is essential and when we compared those whose eGFR had improved to those with the greatest decline, the only significant difference between them was the systolic BP, further indicating that it is important to be aggressive with BP treatment in this group of patients.

Similarly, only 44% achieved a HbA1c <7% and this could be improved, many in this group have individualised HbA1c targets to allow for problems such as hypoglycaemic unawareness and it is not clear from our data how many achieved their individual target, therefore, in addition to aiming to get more people to a

HbA1c <7% we need to improve our recording and monitoring of individual targets.

Similar to the microalbuminuria group, patient outcomes are comparable to those achieved in recent clinical trials. The annual rate of decline of eGFR (table 7.11) in the nephropathy group was -1.95 (MDRD formula) which is within the target suggested by Gross *et al.* (2005). The most significant result in the nephropathy patients was that the rate of doubling of serum creatinine (1.4 per 100-patient-years), progression to ESRD (1.1 per 100-patient-years) and mortality rate (2.2 per 100-patient-years) were as good (if not better) than the rates achieved in IDNT and RENAAL. Even allowing for some differences between these study patients and those in the trials, the key message is that the outcomes reported in large, controlled studies, can be achieved in routine clinical care.

Cockcroft-Gault and MDRD Formula

EGFR was examined using Cockcroft-Gault and MDRD, in all the patients to examine differences between the two formulae and to consider the implications of this for clinical practice.

The MDRD formula has not been validated for patients over 70 years of age. In both the microalbuminuria and nephropathy groups when patients were separated into those <70 years and those ≥70 years, it was found that the eGFR in both groups, for those >70 years, was lower than the median eGFR for the whole group. However, this is not an unusual finding, as you might expect the older patients in the clinic to have a lower eGFR and it is known that kidney function deteriorates with age independent of other causes of declining kidney function (Rowe, 1976). The main consideration when using the MDRD formula in clinical practice is to be aware that it hasn't been validated in those >70 years and to interpret eGFR more cautiously in this group.

The eGFR (using MDRD) in those < 70 years was closer to the median for the whole group in the nephropathy patients (53.8 ml/min/1.73m^2 versus 52.8 ml/min/1.73m^2 respectively) compared to the microalbuminuria group where

eGFR for those <70 years was 67.1 ml/min/1.73m^2 versus 63.3 ml/min/1.73m^2 for the whole group. This may reflect that MDRD has not been validated for normal renal function and it may be prudent in clinical practice to interpret the results in those with normal renal function more cautiously.

Lastly, it was interesting to note in both groups that there are significant differences in the eGFR values obtained depending on which formula is used and it is clear from our results that the MDRD formula gives a lower eGFR than the Cockcroft-Gault formula. The implication for clinical practice is that it is important to be aware that the formulae provide only an estimate of GFR and that they do not have perfect sensitivity and specificity and should be used with some caution and as part of the overall clinical picture, they should not be the only factor determining intervention in CKD patients. The MDRD equation will be adopted in the care pathway-driven nephropathy service because it is has been tested and validated in patients with diabetes and is the most applicable to the population.

6.5.5 Conclusions

There is an abundance of robust evidence for the management of DKD and in essence there are six key interventions but *the* challenge is achieving consistent *implementation* of this evidence. It was hypothesised that a care pathway-driven nephropathy service would achieve successful implementation of the six key interventions for DKD and the aim was to examine implementation of the interventions and the impact on patient outcomes and to assess whether patient outcomes in this service were as good as those achieved in recent large trials concerning type 2 diabetes.

In conclusion, the care pathway-driven nephropathy service has achieved implementation of the six key interventions for DKD. More importantly, patient outcomes are comparable to those achieved in recent clinical trials. This is a key finding, often the outcomes of studies conducted in centres of clinical excellence, in a tightly controlled environment, are not achievable in routine clinical care but this study demonstrates that using a care pathway to ensure better organisation,

dedicated staff and appropriate paperwork, the results from recent trials in type 2 diabetes and CKD are transferable to routine care anywhere!

6.6 SUMMARY

Diabetic Kidney Disease is a major cause of morbidity and premature mortality and places a significant financial burden on healthcare. There is an abundance of robust evidence and clear recommendations for the management of DKD which could significantly improve outcomes for patients but *implementation* remains a problem and *the* challenge for clinicians is finding ways to ensure patients receive key interventions for DKD.

Prior to the development and implementation of the care pathway-driven nephropathy service, the management of DKD in this service and the district was poor, but, this has been addressed by the development of a dedicated nephropathy service. The results show that the care pathway-driven service ensures patients receive six key interventions for DKD and that patient outcomes have improved, and, impressively, our results are comparable to those achieved in recent large clinical studies.

A key area for future research is the management of DKD in primary care. It is suspect, from the referrals to the service, that it has improved since the 1998 audit, but, this needs formally reassessing and additionally, there is a need to follow up those patients discharged from the service and examine their management since discharge.

CHAPTER 7

DISCUSSION

7.1 INTRODUCTION

Diabetes is a major public health problem and a massive burden to those with the disease. It consumes 5-10% of the NHS budget and with the estimated doubling in numbers by 2010, the burden of diabetes could reach epidemic proportions. There is no cure for diabetes, but, there is an abundance of evidence-based recommendations on how best to treat it to reduce the burden of associated complications. Morbidity and premature mortality rates associated with diabetes are high, indicating a failure to implement appropriate evidence-based interventions, and the challenge for clinicians is getting the right care to the right people, at the right time.

The aim of the work presented in this thesis was to examine whether care pathways would facilitate implementation of evidence-based management in diabetes and improve patient outcomes.

The purpose of this chapter is to summarise the findings from the work and to discuss the implications for the use of diabetes care pathways in the NHS

7.2 SUMMARY

The Case for Care Pathways (chapter 1)

A care pathway specifies the expected route of care for a patient with a given condition and typically forms part of the medical record. There has been a significant increase in the use of care pathways across the NHS and they are regarded by many as an important vehicle for the implementation of evidence-based practice. It has been suggested that the potential advantages of care pathways include: improvements in the quality of patient care, better communication and collaboration in multidisciplinary teams, improved resource management, reduced documentation, improved risk management. Potential disadvantages of care pathways include: they may prevent holistic care, increased risk of litigation, increased paperwork and documentation,

implementation difficulties, development and implementation costs and a lack of robust evidence regarding effectiveness.

At the start of these studies, the use of care pathways in diabetes was limited, and this thesis aimed to answer questions about the use of care pathways in diabetes by:

1. Conducting a literature review (using principles of a systematic review) of published studies concerning care pathways to determine their impact on the management of patients with a surgical or medical condition.
2. Developing diabetes care pathways for the management of in-patients and outpatients with diabetes.
3. Developing evaluation tools (in particular a staff knowledge questionnaire) to be used in the studies.
4. Conducting a RCT of the diabetes in-patient care pathway.
5. Examining the impact of a care pathway on outpatient management of patients with Diabetic Nephropathy.

Literature Review of Care Pathways (chapter 2)

It is something of a paradox, perhaps, that at the start of these studies, care pathways were advocated as a key tool for ensuring implementation of evidence-based medicine, but, there appeared to be no robust evidence demonstrating that care pathways worked!

A rigorous literature review (using the principles of a systematic review) was undertaken to examine the evidence-base for care pathways. The findings from the review should be interpreted with caution because of the poor methodological quality of the studies examined.

The findings from the twenty-three papers included in the review were heterogeneous, the main potential benefits associated with a care pathway were:

1. Reduction in length of stay. Nine studies reported a statistically significant reduction and ten papers reported a reduction but no measure of significance. Only one paper reported an increase and three no difference in length of stay.
2. Reduced costs. Thirteen of the studies included examined the impact of a care pathway on costs and all reported a reduction.
3. Improved quality of care. Nine studies examined the impact of a care pathway on the quality of care, seven reported an improvement and the other two no difference.

The literature review raised more questions than it answered. It was evident, that at present, there is not a robust evidence-base to justify the use of care pathways and of those studies reporting positive outcomes following introduction of a care pathway, the findings are limited because of the poor methodological quality. A recent systematic review of stroke care pathways (Kwan and Sandercock, 2005), also concluded that there was not enough evidence to justify the routine use of care pathways.

Developing Diabetes Care Pathways (chapter 3)

Previously, there were shortfalls in in-patient and outpatient diabetes services such as: poor implementation of local evidence-based guidelines, inconsistent advice, lack of structured education, inconsistent documentation and poor multidisciplinary collaboration. It was hypothesised that diabetes care pathways might address these problems. As there were no existing diabetes care pathways, diabetes care pathways were developed following the best practice principles suggested in the literature and using the following systematic process:

1. Identify a gap in current services
2. Involve Multi-disciplinary team from start
3. Identify leaders and a working party
4. Agree remit and content of care pathway(s)
5. Establish working methods
6. Produce first draft and pilot

7. Ongoing evaluation and revision

The development process was particularly time-consuming. The experience from this work suggests that it takes a *minimum* of 6 months and more realistically one year to develop a new care pathway from start to first draft. Nonetheless, it is essential that those wanting to develop and implement care pathways adopt a systematic and staged approach to the task, because many of the potential benefits to be realised from care pathways are gained during the development and implementation phase.

There were more difficulties developing and implementing the in-patient care pathway compared to the outpatient care pathways and these studies suggest that care pathways are more suited to an environment where their content is the primary condition being managed and where you have a dedicated, highly specialist team with minimal staff turnover.

Impact of Care Pathways on the Management of In-Patients with Diabetes (chapter 5)

A RCT was conducted to examine the impact of the diabetes in-patient care pathway on the primary endpoint of glycaemic control (HbA1c), and secondary endpoints of length of stay, re-admissions within 12 months, nurse knowledge and the quality of diabetes in-patient care.

The results indicated that the care pathway was associated with significant improvement in the quality of diabetes care and a significant reduction in readmissions within 12 months, but, there was no significant difference in the primary endpoint of HbA1c 3-months post discharge. There was an improvement in nurse knowledge on those wards receiving ongoing support in the use of the care pathway, but, there were design flaws in this study such as not adequately controlling for confounding variables and it is possible that the improvement in knowledge may have been associated with the extra input from the diabetes team as much as the care pathway, further studies are necessary to address this question.

A significant limitation was the small numbers of patients recruited to the study, preventing sub-group analysis to determine which aspects of the care pathway had the most impact. There was considerable movement of staff between wards during the study period making it difficult to maintain a controlled environment for the RCT, which threatened to further confound the results. Overall this was a negative study because the null hypothesis that HbA1c would not improve with an in-patient diabetes care pathway could not be rejected and problems with the study design limit the validity and generalisability of the positive outcomes from the study.

A Care Pathway-driven Diabetic Nephropathy Service (chapter 6)

There is extensive evidence regarding the management of Diabetic Kidney Disease (DKD), which can be synthesised into six, relatively simple, key interventions, despite this, DKD remains the leading cause of end stage renal disease worldwide and is associated with significant premature morbidity and mortality.

The aim was to examine whether a care pathway for diabetic kidney disease would improve management and the findings demonstrate that the Diabetic Nephropathy care pathway had a significant impact on the management of DKD. There were significant improvements in the processes of care and study patients consistently received the six key interventions for DKD. More importantly, there were improvements in both surrogate and hard endpoints. The rate of: doubling of serum creatinine, progression to End Stage Renal Failure and death, in this study, were as good (if not better) than recent international clinical trials for DKD in type 2 diabetes.

The Diabetic Nephropathy care pathway has transformed local management of DKD and might be a useful tool for other diabetes services.

7.3 DISCUSSION

Strengths and Limitations

The rationale for this work was that despite having a vast, robust evidence-base for the management of diabetes, mortality and morbidity rates for those with the disease remain unacceptably high, and a contributing factor may be a failure to implement evidence-base care. Care pathways are cited in the Diabetes NSF (Department of Health, 2001) as an important tool for facilitating implementation of the 12 NSF standards and they are used in many areas of health care, therefore the outcomes of these studies are of potential benefit to the wider NHS and in particular to those involved in diabetes care.

The main strengths of this work were the literature review, development of the care pathways and the evaluation of the Nephropathy care pathway. The main limitation was the RCT of the in-patient care pathway.

The literature review of care pathways was limited because it was not possible to conduct a systematic review as initially intended, because there were no rigorous RCTs of care pathways. Despite this, the review was undertaken using a systematic process and the findings are valid and provide useful insight into the potential benefits of care pathways whilst highlighting the limitations of the research to date on care pathways. Moreover, at the time of conducting the review a scoring system for undertaking reviews of qualitative studies was not used but when considered retrospectively it is unlikely such a system would have changed the outcome of the review, further strengthening the validity of the literature review findings.

The key finding from the literature review was that whilst care pathways appear to offer some benefit, this is not a reliable conclusion because of weaknesses in the studies on care pathways and further studies are required to justify widespread use of care pathways across the NHS. As the review focused on a wide range of care pathways this finding is important for anyone wishing to use

care pathways for either a surgical or medical condition and careful consideration should be given as to whether this is justified.

Prior to this work there were no existing diabetes care pathways available and this study has provided a systematic staged process (chapter 3) for the development of diabetes care pathways. This process was developed following an extensive review of the literature and takes into account best practice guidance from a wide range of sources including the National Pathway Association. The care pathways presented in this thesis were developed using the process and the outpatient care pathways in particular have been used and revised for over 5 years and provide other clinicians wishing to use diabetes care pathways with a useful model to follow. Furthermore, the evaluation of the Nephropathy care pathway in chapter 6 provides evidence that the outpatient format works in practice, and is a key strength of this work as it demonstrates that care pathways can not only improve the process of care but improve patient outcomes. The study demonstrated that this care pathway was an effective tool for facilitating evidence-based management of diabetic nephropathy, this is an important finding in light of both the Diabetes and Renal NSF and the care pathway could be used by others in the NHS to improve the management of diabetic kidney disease.

The major limitation of this work was the RCT used to evaluate the in-patient diabetes care pathway. The study design was flawed and this undermines the validity of the findings and limits the generalisability of the results for others in the NHS. The inclusion and exclusion criteria were not very stringent, consequently there were differences between the intervention and control group which may have confounded the results. In addition, the attempt to distinguish between the impact of the care pathway versus support to the wards by a specialist nurse, further biased the results because the small numbers recruited meant that a valid comparison could not be made. Furthermore, the trial was negative in that there was no significant difference in the primary endpoint (HbA1c) between the intervention and control group. Overall, the findings from this study of care pathways was similar as in the studies reviewed in chapter 2, it appeared that a care pathway for in-patients with diabetes improved the quality of diabetes care and possibly re-admission rates, but, these findings are not

reliable because of weaknesses in the study design and therefore not generalisable to the wider NHS.

Furthermore, the author found it difficult to sustain enthusiasm and motivation for the use of the in-patient care pathway compared to the outpatient care pathways. A possible explanation is that staff on the general wards have multiple problems to deal with and there is a high turnover of staff making it more difficult to sustain education and training in both diabetes and care pathways. Consequently, it could be suggested that care pathways are more appropriate and more successful in a predictable environment (Diabetes Outpatients) with dedicated staff, rather than in an acute environment with a high turnover of staff and patients. Bragato and Jacobs (2003) report similar findings in their study of care pathways on a trauma unit versus an elective unit. However, whilst this is suggested from this work, because of the limitations with the RCT it is not a reliable conclusion and further studies of the use of care pathways (including diabetes) in an acute in-patient setting need to explore this further.

Implementing Evidenced-Based Medicine

Since the late 1990s, the importance of evidence-based medicine in the NHS has been transparent in key government documents (Department of Health, 1997; Department of Health, 1998) including the NHS Plan (Department of Health, 2000). Furthermore, the establishment of NICE and the development of National Service Frameworks reinforced the importance of evidence-based medicine and the expectation that both primary and secondary care NHS Trusts would ensure they were implementing evidence-based practice. Diabetes is a prime example of a condition for which there is a NSF and numerous NICE technology appraisals and clinical guidelines for clinicians to follow. Whilst NICE and the NSFs set the standards to be achieved, they do not specify how this should be realised locally and the responsibility for implementing national guidance and evidence-based medicine, lies with NHS Trusts and individual clinicians. Consequently, those responsible are looking for tools to ensure implementation of evidence-based care and care pathways are being promulgated by many for this purpose, but, do they work?

A primary goal of these studies was to examine whether care pathways were *the* tool to ensure implementation of evidence-based diabetes care and the findings suggest that in some circumstances they may be.

In these studies, diabetes care pathways were associated with significant improvements in the management of Diabetic Kidney Disease.

The in-patient diabetes care pathway was associated with improvements in the quality of diabetes in-patient care. But, implementation of the in-patient care pathway was problematic, it was not well used by ward staff (evident in the poor completion of the care pathway) and required much ongoing support of staff to achieve the level of use attained in the study, and the difficulties encountered in this study suggest that outside of a research project it would be difficult to achieve sustained use of the in-patient diabetes care pathway, therefore, even if the limitations of the study were addressed, it may not be an effective tool for ensuring implementation of evidence-based diabetes care.

In these studies, the outpatient diabetes care pathways appeared to be more successful than the in-patient diabetes care pathways as a tool for implementing evidence-based diabetes care, because they were used by a dedicated team with strong leadership and diabetes was the only condition being managed. By comparison, the in-patient care pathways were being used by staff who regularly changed wards and who were also managing numerous other conditions with overlapping paperwork and competing priorities. Medical in-patients typically have co-morbidities in addition to the admission diagnosis and it had previously been suggested in the care pathway literature that medical conditions may be too complex for care pathways (Fox *et al.*, 2003; Hotchkiss, 1997). The experience from the study suggests that it is not the complexity of the condition that is an issue, but, the *number* of complex conditions. Where a patient has multiple medical problems it may be too difficult for staff to follow numerous care pathways, because this can result in duplication and an increased volume of paperwork, and in these circumstances, care pathways might not effectively ensure implementation of evidence-based medicine.

At present care pathways may not be an effective tool for implementation of evidence-based medicine in settings where there are multiple conditions to manage, but, this may change in the future with the move towards electronic patient records across the NHS. Electronic patient records should address the problems of excessive paperwork, duplication and missing records (NHS Executive, 1998), and it may be easier for clinicians to follow care pathways for numerous conditions because the computer will prompt them to take action rather than relying on them to follow paper based instructions.

A further complication for the successful use of in-patient care pathways to implement evidence-based medicine is the recent emphasis in the NHS on achieving access targets, such as the "four hour waiting time target" in A&E departments. For many acute Trusts, this target increases the pressure to achieve a more efficient throughput of patients and this may make it more difficult for staff to follow a pre-specified care pathway if patient turnover rises. There is, perhaps, something of a conflict between the drive for evidence-based care on the one hand and the need to achieve access targets on the other and this may further impede the use of care pathways in the acute environment.

Clinical Governance

The concept of Clinical Governance also emerged at the end of the 1990s and it is the umbrella term used to describe the government's quality improvement strategy (Donaldson and Halligan, 2001). Implementation of evidence-based medicine is one component of clinical governance, others include; risk management, clinical audit, controls assurance, HR issues including training and monitoring of poor performance, management of clinical risk and research (National Audit Office, 2003). These studies have indicated that care pathways may be useful in implementing evidence-based medicine, but, they may also facilitate implementation of other components of clinical governance. The use of care pathways in the outpatient diabetes service in this study has led to improvements in documentation which has resulted in a reduction of clinical risk and has facilitated improvements in clinical audit because the care pathway

standards provide a clear evidence base against which to audit practice and they are an invaluable teaching tool for students and new staff working in the service. Moreover, development of the outpatient diabetes care pathways facilitated an extensive review of the service and enabled the establishment of a service that is structured and organised so that patients receive consistent, evidence-based, high quality care in line with the national clinical governance agenda, but, care pathways will only be a useful tool for implementing clinical governance where they are used properly. For example, during the RCT the in-patient diabetes care pathway was poorly completed and this problem potentially increased clinical risk issues because poor compliance with a care pathway may result in increased litigation, if a care pathway specifies a standard of care and this is not implemented, patients may be vindicated if they complain.

Care pathways may address clinical governance issues but this is more likely where they are used routinely and rigorously such as with the outpatient diabetes care pathways described in these studies.

Staff Training and Qualifications

In the current NHS there is much overlap of professional roles and previous boundaries are blurred. For example, nurses are now prescribing and running nurse-led clinics for conditions that were historically the domain of doctors. In diabetes some specialist nurses are now involved in initiating and adjusting antihypertensive therapy which would not have been the case five years ago. This may be viewed as a positive development or a necessity because of the shortage of trained doctors, and protocols or care pathways may assist them. A potential disadvantage of care pathways is that they are inflexible and unresponsive to individual needs, this may be more problematic in complex multifaceted conditions such as diabetes, but, this will depend on who is using the care pathway. If they are used by specialists with the appropriate expertise to manage the condition they can still be flexible by using variance analysis.

Care pathways should not be used as a vehicle for enabling less specialised and appropriately qualified staff (and therefore cheaper staff) to manage conditions

like diabetes. The current government agenda to move much of the management of diabetes to non-specialists in primary care suggests that this may become a problem, care pathways are cited on the Diabetes NSF website as a tool to facilitate evidence-based care, but, if they are used primarily by relative non-experts without the experience and skills to deviate from the care pathway as appropriate, they may not improve care and may even lead to a deterioration in the quality of diabetes care.

In the outpatient service in this study the diabetes care pathways are used by the specialist diabetes team with the appropriate knowledge and experience to know when to deviate from the care pathway, and a lack of flexibility or non-holistic care has not been a problem. It was evident from the in-patient diabetes care pathway study, however, that whilst nurse knowledge improved, the care pathway alone was not the answer to improving staff expertise in the management of diabetes; and care pathways should be used to *complement* and *assist* training of appropriate staff and not to replace it.

Patient Choice

There is a clear priority within the NHS to involve and engage patients in the planning and delivery of healthcare and to offer them more choice accessing services and greater input into consultations (Department of Health, 2002a). The introduction of care pathways to implement pre-specified standards and evidence-based medicine is perhaps, contradictory to this agenda and there may be tension for clinicians using care pathways between completing the care pathway and meeting an individual's perceived needs. To date, there have not had any problems in this regard, but, it will be interesting to see if this changes with the emergence of greater choice for patients in the NHS.

Implications for Further Research

As is often the case, this research raises many questions.

The literature search identifies a lack of robust evidence supporting the effectiveness of care pathways. In part, their nature and the dynamic and diverse nature of the healthcare environment in which care pathways may be used, doesn't lend itself to quantitative research, such as RCTs and this was apparent in this work when trying to conduct a RCT to test care pathways (chapter 5). Whilst some of the difficulties can be explained by design flaws, it was evident during this study that for multiple reasons a RCT of the in-patient diabetes care pathway posed a significant challenge and in future studies of care pathways there may be more appropriate research methodology. The key difficulties in conducting a RCT of care pathways in an in-patient setting include:

1. An unpredictable environment, movement of staff between wards and reallocation of wards can be a common occurrence in acute NHS trusts which threatens to confound a RCT.
2. Difficulties in recruiting adequate numbers of participants. A key issue in this study was the small numbers recruited. Multi-centre studies recruiting large numbers of participants are likely to be more robust (larger sample size reduces bias) but as care pathways are typically developed according to an organisation's needs it would be difficult to develop the same care pathway and test it in a RCT across multiple organisations.
3. Blinding in RCT is an important tool for further reducing bias and increasing the validity of the findings, it would be impossible to blind a study of care pathways because staff know they are using it, but this further reduces the rigor of a RCT.

Thus, although the lack of scientific rigor with which many care pathway studies have been conducted inevitably means that evidence from this literature must be interpreted with some caution, limitations constraining the design and execution of these studies must be borne in mind so that one does not dismiss out of hand a potentially useful vehicle for delivery of evidence-based care. However, because of these problems it is important that future studies of care pathways carefully select and design the research methodology. Future studies may wish to consider using a combination of qualitative and quantitative methods. A case control

study rather than a RCT may be more appropriate, in addition it may also be useful to focus more on the staff using the care pathway (rather than the patients) as a key question appears to be does a care pathway improve the quality of care received, that is does it change staff behaviour? It would be useful to conduct a study of staff behaviour regarding care pathway use and as part of this an assessment of staff attitudes and beliefs regarding the process of care would be useful. Methods such as focus group interviews and analysis with questionnaires may be useful.

The in-patient diabetes care pathway was associated with a significant reduction in re-admission rates - this requires further investigation where the study groups are better matched at baseline for confounding variables such as co-morbidities.

7.4 CONCLUSIONS

This work has provided a staged process for the development of diabetes care pathways and examples of diabetes care pathways that could be used / adapted by others.

The work in this thesis has demonstrated that use of care pathways for specific conditions in a carefully controlled environment by a stable and engaged team can greatly enhance effective implementation of evidence-based care.

Rigorous scientific evaluation of care pathways, for example, by RCT is challenging and different research methodologies may prove more effective in the assessment of this clinical tool.

Much work remains to be done before the widespread use of care pathways within the NHS can be justified.

REFERENCES

Abbot, R.D., Donahue, R.P., Kannel, W.B., Wilson, P.W.F. (1988) The Impact of Diabetes on Survival Following Myocardial Infarction in Men vs Women . The Framingham Study. *JAMA*, **260**, 3456-3460.

ADA (American Diabetes Association). (2004) Nephropathy in Diabetes (Position Statement). *Diabetes Care*, **27**, Suppl. 1, S79-S83.

Altman, D.G., Schulz, K.F., Moher, D., Egger, M., Davidoff, F., Elbourne, D., Gotzsche, P.C., Lang, T. (2001) The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration. *Annals of Internal Medicine,* **134**, 8, 663-694.

Altman, D.G., Schulz, K.J., Moher, D. (2004) Turning a blind eye. Testing the success of blinding and the CONSORT statement. *BMJ,* **328**, 1135.

Amos, A., McCarty, D., Zimmet, P. (1997) The Rising Global Burden of Diabetes and its Complications: Estimates and Projections to the year 2010. *Diabetic Medicine,* **14,** S5: S7-15.

Anderson, A.R., Sandahl, C., Anderson, J.K., Kreiner, S., Deckert, T. (1983) Diabetic Nephropathy in Type 1 (insulin dependent) diabetes: an epidemiological study. *Diabetologia,* **25**, 496-501.

Appleby, J., Smith, P., Ranade, W., Little, V., Robinson, R., cited in Robinson, R., Le Grand, J. (Editors). (1994) *Evaluating the NHS Reforms.* Kings Fund, London.

Appleby, J., Walshe, K., Ham, C. (1995) Given in Evidence. *The Health Service Journal*, **105**, 28, 9.

Archer, S.B., Burnett, R.J., Flesch, L.V., Hobler, S.C. *et al* (1997) Implementation of a clinical pathway decreases length of stay and hospital

charges for patients undergoing total colectomy and ileal pouch / anal anastomosis. *Surgery*, **122**, 4, 699-705.

Atkinson, M., MacLaren, N. (1994) The pathogenesis of insulin dependent diabetes. *New England Journal Medicine,* **331**, 1428-1436.

Audit Commission. (2000) *Testing Times a review of diabetes services in England and Wales.* Audit Commission, London.

Baxley, S.G., Brown, S.T., Pokorny, M.E., Swanson, M.S. (1997) Perceived Competence and Actual Level of Knowledge of Diabetes Mellitus Among Nurses. *Journal of Nursing Staff Development*, **13**, 2, 93-98.

BDA (British Diabetes Association) (1987) *Minimum Educational Requirements for the Care of Diabetes in the UK.* BDA, London.

Beeney, L.J., Dunn, S.M., Welch, G. (1994) Measurement of Diabetes Knowledge – The Development of The DKN Scales. Cited in Bradley, C. (editor) (1994) *Handbook of Psychology and Diabetes.* harwood academic publishers, Netherlands.

Bernstein, A. (1997) Critical Pathways. Developing guidelines for the evaluation and treatment of the pedal manifestations of diabetes mellitus. *Podiatry Management*, **9**, 25-29.

Bhopal, R.S. (2002) Concepts of Epidemiology. An integrated introduction to the ideas, theories, principles and methods of epidemiology. Oxford University Press, Oxford.

Bing, M., Abel, R.L., Sabharwal, K., McCauley, C., Zaldivar, K. (1997) Implementing a Clinical Pathway for the Treatment of Medicare Patients with Cardiac Chest Pain. *Best Practices and Benchmarking in Healthcare*, **2**, 3,118-122.

Bloomgarden, Z.T. (2005) Diabetic Nephropathy. *Diabetes Care,* **28**, 3, 745-751.

Bragato, L., Jacobs, K. (2003) Care pathways: the road to better health services? *Journal of Health Organisation and Management*, **17**, 3, 164-180.

Brennan, P., Silman, A. (1992) Statistical methods for assessing observer variability in clinical measures. *BMJ*, **304**, 1491-1494.

Brenner, B.M., Cooper, M.E., Zeeuw, D., Keane, W.F. (2001) Effects of Losartan on Renal and Cardiovascular Outcomes in patients with Type 2 Diabetes and Nephropathy. *New England Journal of Medicine*, **345**, 12, 861-869.

Bromley, H., Dockery, G., Fenton, C., Nhlema, B., Smith, H., Tolhurst, R., Theobald, S. (2002) *Criteria for evaluating qualitative studies.* University of Liverpool School of Tropical Medicine, Liverpool.

Bruce, N., Cleave, N. (1999) *Research Methods 2. Part 5 Case Control Studies.* University of Liverpool, Liverpool.

Bultema, J.K., Mailliard, L., Getzfrid, M.K., Lerner, R.D., Colone, M. (1996) Geriatric Patients with Depression. Improving Outcomes Using a Multidiscipinary Path Model. *JONA*, **26**, 1, 31-38.

Burns, J.M., Tierney, K., Long, G.D., Lambert, S.C., Carr, B.E. (1995) Critical Pathway for Administering High-Dose Chemotherapy Followed by Peripheral Blood Stem Cell Rescue in the Outpatient Setting. *BURNS*, **22**, 8, 1219-1224.

Callaghan, D., Williams, A. (1994) Living with diabetes: issues for nursing practice. *Journal of Advanced Nursing*, **20**,132-139.

Cameron, J.S., Gregor, R. (1998) Renal function and testing of function. Cited in Davison, A.M., Cameron, J.S., Grunfield, J.P., et al, eds. (1998) *Oxford Textbook of Clinical Nephrology*. New York, Oxford University Press. 36-39.

Campbell, H., Hotchkiss, R., Bradshaw, N., et al. (1998) Integrated care pathways. *British Medical Journal*, **316**,133-137.

Chang, P.L., Wang, T.M., Huang, S.T., Hsieh, M.L., Tsui, K.H., Lai, R.H. (1999) Effects of Implementation of 18 Clinical Pathways on Costs and Quality of care Among Patients Undergoing Urological Surgery. *The Journal of Urology*, **161**, 1858-1862.

Cockcroft, D.W., Gault, M.H. (1976) Prediction of Creatinine Clearance from serum creatinine. *Nephron*, **16**, 1, 31-41.

Cooney, R.N., Bryant, M.D., Haluck, R., Rodgers, R.D., Lowery, M. (2001) The Impact of a Clinical Pathway for Gastric Bypass Surgery on Resource Utilization. *Journal of Surgical Research*, **98**, 97-101.

Copper, M. (1998) Pathogenesis, prevention, and treatment of diabetic nephropathy. *The Lancet*, **352**, 213-219.

Crane, M., Werber, B. (1999) Critical Pathway Approach to Diabetic Pedal Infections in a Multidisciplinary Setting. *The Journal of Foot and Ankle Surgery*, **38**, 1, 30-33.

Creswell, J.W. (2003) *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches. Second Edition.* SAGE Publications, California.

Crossan, F. (2003) Research philosophy: towards an understanding. *Nurse Researcher*, **11**, 1, 46-55

Crotty, M. (1998) *The foundations of social research: Meaning and perspective in the research process.* Sage, London.

Cohen, J. (1960) A coefficient of agreement for nominal scales. *Educational and Psychological Measurement,* **20**, 37-46.

Colin, C., Wade, D.T., Davies, S., Horne, V.(1988) The Barthel ADL Index: a reliability study. *Int Disabil Stud.,* **10**, 2, 61-63.

Cooper, H., Carlisle, C., Watkins, C., Gibbs, T. (2000) Using qualitative methods for conducting a systematic review. *Nurse Researcher*, **8**, 1, 28-38.

Courtney, L., Gordon, M., Romer, L. (1997) A Clinical Path for Adult Diabetes. *The Diabetes Educator*, **23**, 6, 664-671.

Crummer, M.B., Carter, V. (1993) Critical pathways – the pivotal tool. *Journal of Cardiovascular Nursing*,**7**, 4, 30-37.

Cronbach, L.J. (1951) Coefficient alpha and the internal structure of tests. *Psychometrika,* **16**, 3, 297-334.

Currie, C.J., Kraus, D., Morgan, C.L.I., *et al.* (1997) NHS Acute Sector Expenditure for Diabetes: the Present, Future, and Excess In-patient Cost of Care. *Diabetic Medicine*, **14**, 686-692.

Currie, C.J., Morgan, C.L.I., Peters, J.R. (1997b) Patterns and Cost of Hospital Care for Coronary Heart Disease Related and Not Related to Diabetes. *Heart*, **78**; 6, 544-549.

Currie, C.J., Morgan, C.L.I., Peters, J.R. (1998) The epidemiology and Cost of Inpatient Care for Peripheral Vascular Disease, Infection, Neuropathy and Ulceration in Diabetes. *Diabetes Care*, **21**; 1, 42-48.

Currie, L., Harvey, J. (1998) *The Origins and Use of Care Pathways in the USA, Australia and the United Kingdom.* RCN Institute Report No. 15., Oxford.

Cushing, K.A., Stratta, R.J. (1997) Design, development and implementation of a critical pathway in simultaneous pancreas-kidney transplant recipients. *Journal of Transplant Coordination*, **7**, 4, 164-172.

Danish, A., Wynnewood, P.A., Mawr, B. (1995) Critical Care Pathways: the Basics of Development and Implementation. *Continuum: An Interdisciplinary Journal on Continuity of Care*, **15**, 2,1-9.

Dardik, A., Williams, M., Minken, S.L., Perler, B.A. (1997) Impact of a critical pathway on the results of carotid endarterectomy in a tertiary care university hospital: Effect of methods on outcome. *Journal of Vascular Surgery*, **26**, 2, 186-192.

De Luc, K., Currie, L. (1999) *Developing, Implementing and Evaluating Care Pathways in the UK: The Way to Go.* Health Services Management Centre Research Report 34, Oxford.

Department of Health. (1997) *The New NHS Modern and Dependable. Cm3807.* Department of Health, London.

Department of Health. (1998) *A First Class Service – Quality in the NHS.* Department of Health, London.

Department of Health. (2000) *The NHS Plan: a plan for investment, a plan for reform.* Department of Health, London.

Department of Health. (2001) *National Service Framework for Diabetes: Standards.* Department of Health, London.

Department of Health. (2001a) *Health Inequalities in Diabetes.* www.doh.gov.uk/nsf/diabetes.htm

Department of Health. (2001b) *National Service Framework for Older People.* Department of Health, London.

Department of Health. (2002) *National Service Framework for Diabetes : Delivery Strategy.* Department of Health, London.

Department of Health. (2002a) *Shifting the Balance of Power: The Next Steps.* Department of Health, London.

Department of Health. (2003) *Diabetes Information Strategy.* Department of Health, London.

Department of Health. (2004) *The NHS Improvement Plan. Putting People at the Heart of Public Services.* Department of Health, London.

Department of Health. (2005) *Improving Diabetes Services – The NSF Two Years On.* Department of Health, London.

Department of Health. (2005a) *The National Service Framework for Long-term Conditions.* Department of Health, London.

Department of Health. (2005b) *Supporting People with Long Term Conditions. An NHS and Social Care Model to support local innovation and integration.* Department of Health, London.

Department of Public Health Sciences. (2006) *Design of Randomised Controlled Trials.* www.phs.kcl.ac.uk/teaching/ClinEpid/DesignR.htm.

Diabetes Control and Complications Trial Research Group. (1993) The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long Term Complications in Insulin-Dependent Diabetes Mellitus. *The New England Journal of Medicine*, **329**, 14, 977-986.

Diabetes UK. (2004a) *Diabetes in the UK 2004. A report from Diabetes UK, October 2004.* Diabetes UK, London.

Diabetes UK (2004b) *What is Diabetes.* www.diabetes.org.uk

Diabetes UK., Department of Health. (2005) *Structured Patient Education in Diabetes. Report from the Patient Education Working Group.* Department of Health, London.

Donaldosn, L., Halligan, A. (2001) Implementing clinical governance: turning vision into reality. *BMJ*, **322**, 1413-1417.

Dowsey, M.M., Kilgour, M.L., Santamaria, N.M., Choong, P.F.M. (1999) Clinical Pathways in hip and knee arthroplasty: a prospective randomised controlled study. *MJA,* **170**, 59-63.

Drass, J.A., Muir-Nash, J., Boykin, P., Tyrek, J.M., Baker, K.L. (1989) Perceived and Actual Level of Knowledge of Diabetes Mellitus Among Nurses. *Diabetes Care*, **12**, 5, 351-356.

Driskill, W. (1996) Diabetes Education: What Every LPN Should Know. *The Journal of Practical Nursing*, **3**, 14-18.

Dunning, T., Martin, M. (1996) Developing a questionnaire: some methodological issues. *Australian Journal of Advanced Nursing*, **14**, 2, 31-39.

Dzwierzynski, W.W., Spitz, K., Hartz, A., Guse, C., Larson, D.L. (1998) Improvement in Resource Utilization after Development of a Clinical Pathway for Patients with Pressure Ulcers. *Plastic and Reconstructive Surgery,* **102**, 6, 2006-2011.

Eccles, M., Mason, J. (2001) How to develop cost-conscious guidelines. *Health Technology Assessment,* **5**, 1-69.

Elizondo, A.P. (1995) Nursing Case Management in the Neonatal Intensive Care Unit, Part 2: Developing Critical Pathways. *Neonatal Network*, **14**,11-19.

Fairfield, G., Hunter, D., Mechanic, D., Flemming, R. (1997) Implications of Managed Care for health systems. *British Medical Journal*, **314**,1805-1898.

Firth, A.J., Jones, G.R. (1999) Diabetes Education and Training for Ward Based Nurses. *Diabetic Medicine*, **16** (Suppl.1), 55.

Fox, C., Mackinnon, M. (1999) *Vital Diabetes*. Class Health, London.

Fox, R., Moran, S., MacCormick, A. (2003) Guidance for integrated care pathways: a reference document for an acute NHS trust. *Journal of Integrated Care Pathways*, **7**, 100-106.

Fox, R., Watson, J., Close, C., Evans, K., Moran, S. (2004) Integrated care pathway for diabetes in pregnancy. *Journal of Integrated Care Pathways*, **8**, 27-40.

General Medical Council. (2001) *Good Medical Practice*. GMC, London.

Gheiler, E.L., Lovisolo, J.A., Tiguert, R., Tefilli, M.V., Grayon, T., Oldford, G. (1998) Results of a Clincal Care Pathway for Radical Prostatectomy Patients in an Open Hospital – Multiphysician System. *European Urology*, **35**, 210-216.

Goode, J. (1995) Impact of a CareMap and Case Management on Patient Satisfaction Collaboration and Autonomy. *Nursing Economics*, **13**, 6, 337-361.

Gossain, V.V., Bowman, K.A., Rovner, D.R. (1993) The Actual and Self-Perceived Knowledge of Diabetes Among Staff Nurses. *The Diabetes Educator*, **19**, 3, 215-219.

Gottlieb, L.D., Roer, D., Jega, K., Darc St Pierre, J., Dobbin, J., Dwyer, M. (1996) Clinical pathway for pneumonia: development, implementation, and initial experience. *Best Practice an Benchmarking in Healthcare*, **1**, 262-265.

Gotzsche, P.C., Liberati, A., Toni, V., Rossetti, L., (1996) Beware Surrogate End Points. *International Journal Health Technology Assessment,* **12**, 238-246.

GP Notebook. (2005) *activities of daily living (Barthel index).* www.gpnotebook.co.uk.

Greenhalgh, J., Georgiou, A., Long, A.F., Williams, R., Dyas, J. (1997) *Measuring The Health Outcomes of Diabetes Care.* Nuffield Institute for Health, Leeds.

Gregor, C., Pope, S., Werry, D., Dodek, P. (1996) Reduced length of Stay and Improved Appropriateness of care with a Clinical Path for Total Knee or Hip Arthroplasty. *Journal of Quality Improvement,* **22**, 9, 617-629.

Gresham, G.E., Phillips, T.F., Labi, M.L. (1980) ADL status in stroke: relative merits of three standard indexes. *Arch Phys Med Rehabil.,* **61**, 8, 355-358.

Gross, J.L., De Azevedo, M.J., Silveiro, S.P., Canani, L.H., Caramori, M.L., Zelmanovitz, T. (2005) Diabetic Nephropathy: Diagnosis, Prevention, and Treatment. *Diabetes Care,* **28**, 1, 164-176.

Hardy, K.J. (1998) Diabetes: *A Handbook for St Helens and Knowsley Hospitals.* Department of Diabetes and Endocrinology Whiston Hospital, Merseyside.

Hannigan, B. (1998) Assessing the new public management: the case of the National Health Service. *Journal of Nursing Management,* **6**, 307-312.

Health Care Practice Research and Development Unit (HCPRDU). (2003) *Evaluation Tool for Qualitative Studies.* University of Salford, Salford.

Health and Social Care Information Centre. (2005) *National Diabetes Audit. Key Findings about the quality of care for people with diabetes in England.* National Clinical Audit Support Programme, Leeds.

Holland, E., Bradbury, R., Meeking, D. (2000) Using a team approach to set up a diabetic foot referral pathway. *The Diabetic Foot*, **3**, 106-108.

HOPE (Heart Outcomes Prevention Evaluation) Study Investigators. (2000) MICRO_HOPE Substudy. Effects of Ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus. *Lancet,* **355**, 253-59.

Horne, M. (1996) Involving Physicians in Clinical Pathways: An Example for Perioperative Knee Arthroplasty. *Journal on Quality Improvement*, **22**, 2, 115-124.

Hotchkiss, R. (1997) Integrated Care Pathways. *Ntresearch*, **2**, 1, 30-37.

Hunt, J. (1996) Development, Implementation, and Conclusions of Critical Pathways: Walk Don't Run. *Journal of Burn Care and Rehabilitation*, **17**, 6, S7-S9.

Hunt, S.D., Sparkman, J.R., Wilcox, J.B. (1982) The Pretest in Survey Research: Issues and Preliminary Findings. *Journal of Marketing Research,* **XIX**, 269-73.

Ibarra, V., Titler, M.G., Reiter, R.C. (1996) Issues in the Development and Implementation of Clinical Pathways. *AACN Clinical Issues*, **7**, 3, 436-447.

Ignatavicus, D.S, Hausman, K.A. (1995) *Clinical Pathways for Collaborative Practice*. WB Saunders, Philladelphia.

Ilag, L., Kronick, S., Ernst, R., Grondin, L., Alaniz, C., Liu, L., Herman, W. (2003) Impact of a critical pathway on inpatient management of diabetic ketoacidosis. *Diabetes Research and Clinical Practice*, **62**, 23-32.

Ireson, C.L. (1997) Critical pathways: Effectiveness in Achieving Patient Outcomes. *JONA*, **27**, 6, 16-23.

Jayne, R.L., Rankin, S.H. (1993) Revisiting Nurse Knowledge About Diabetes: An Update and Implications for Practice. *The Diabetes Educator*, **19**, 6, 497-503.

Johnson, S., Burall, K. (1996) Pathway to the heart. *Nursing Management*, **3**, 4, 24-25.

Johnson, S., Smith, J. (2000) Factors influencing the success of ICP projects. *Professional Nurse*, **15**, 12, 776-779.

Jones, G. (2005) GFR Estimate with the MDRD equation. *SydPath Information Sheet*, 10/5/05, www.sydpath.stvincents.com.

Katon, W., Von Korff, M., Lin, E., Simon, G., Ludman, E., Russo, J., Ciechanowski, P., Walker, E., Bush, T. (2003) Improving primary care treatment of depression among patients with diabetes mellitus: the design of the Pathways Study. *General Hospital Psychiatry*, **25**, 158-168.

K/DOQI (2002) Clinical practice guidelines for chronic kidney disease: evaluation, classification and stratification. Kidney Disease Outcome Quality Initiative. *American Journal Kidney Disease*, **39** (suppl. 2), S1:S246.

Kennedy, R., Pachipala, K., Abd Rabou, A.(1999) Emergency Medical Admissions in Patients with Diabetes: Increased Rate of Admission and Length of Stay. *Diabetic Medicine*, **16**, S1, 50.

Kinschuck, D. (2005) What is the HbA1c? *www.diabeticretinopathy.org.uk*

Kitchiner, D., Davidson, C., Bundred, P. (1996) Integrated care pathways: effective tools for continuous evaluation of clinical practice. *Journal of Evaluation in Clinical Practice*, **2**, 65-69.

Koproski, J., Pretto, Z., Poretsky, L. (1997) Effects of an Intervention by a Diabetes Team in Hospitalised Patients with Diabetes. *Diabetes Care*, **20**, 10,1553-1555.

Kowal, N.S., Delaney, M. (1996) The Economics of a Nurse-Developed Critical Pathway. *Nursing Economics*, **14**, 3, 156-161.

Kwan, J., Sandercock, P. (2005) *In-hospital care pathways for stroke (Review).* The Cochrane Collaboration Published by Wiley & Sons, UK.

Kyne-Grzebalski, D. (1999) Education, education and more education! *Practical Diabetes International*, **16**, 5, 149-151.

Lawrence, M., Williams, T. (1996) Managed care and Disease Management in the NHS. *British Medical Journal*, **313**,125-126.

Laxade, S., Hale, C. (1995) Managed Care 1: an opportunity for nursing. *British Journal of Nursing*, **4**, 5, 290-294.

Lee, S.S. (1996) Hospital-Home Care Critical Pathways in Disease Management: Improving Case Management and Patient Outcomes in Postoperative Cardiothoracic Surgical Patients. *The Journal of Care Management*, **2**, 3, 54.

Leggett-Frazier, N., Turner, M.S., Vincent, P.A. (1994) Measuring the Diabetes Knowledge of Nurses in Long-Term Care Facilities. *The Diabetes Educator*, **20**, 4, 307-310.

Levey, A.S., Bosch, J.P., Lewis, J.B., Greene, T., Rogers, N., Roth, D. (1999) A More Accurate Method to Estimate Glomerular Filtration rate from Serum Creatinine. A New Prediction Equation. *Annals of Internal Medicine*, **130**, 6, 461-470.

Levey, A.S., Coresh, J., Balk, E., *et al.* (2003) National Kidney Foundation Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. *Annals of Internal Medicine*, **139**, 137-147.

Lewis, E.J., Hunsicker, L.G., Bain, R.P., Rhode, R.D. (1993) The effect of angiotensin converting enzyme inhibition on diabetic nephropathy. *New England Journal Medicine*, **329**, 1456-1462.

Lewis, E.J., Hunsicker, L.G., Clarke, W.R., Berl, T., Pohl, M.A., Lewis, J.A., Ritz, E., Atkins, R.C., Rhode, R., Raz, I. (2001) Renoprotective effect of the Antagiotensin-Receptor Antagonist Irbesartan in Patients with Nephropathy due to Type 2 Diabetes. *New England Journal of Medicine*, **345**, 12, 851-860.

Lewis, K.S. (1994) *An Examination of the Health Belief Model When Applied to Diabetes Mellitus.* PhD Thesis, University of Sheffield, Sheffield.

Liao, S., Chu, S., Chen, Y., Chung, K., Lai, M. (1998) The impact of a Clinical Pathway for Transurethral Resection of The Prostate on Costs and Clinical Outcomes. *J Formos Med Assoc,* **97**, 5, 345-351.

Litwin, M.S. (1995) *How to Measure Survey Reliability and Validity.* Sage Publications, London.

Lowe, C. (1998) Care pathways: have they a place in 'the new national Health Service'? *Journal of Nursing Management*, **6**, 303-306.

Lowson, S. (2004) Getting the record straight: the need for accurate documentation. *Journal of Wound Care,* **13**, 10, 427.

Luther, T., Crofts, L. (1997) Managed care: Development of an integrated care pathway in neurosciences. *Ntresearch,* **2**, 4, 283-291.

McDermott, J. (1995) Communication and Education. Developing the role of the diabetes specialist nurse. *Professional Nurse*, **2**, 290-292.

MacEachen, E., Clarke, J., Franche, R., Cullen, K., Sinclair, S., Frank, J. (2004) *What systematic reviews gain when they include qualitative research: a*

systematic review of qualitative work on workplace-based return to work practices. www.cochrane.org/colloquia/abstracts/ottawa.

Mackinnon, M. (1993) *Providing Diabetes Care in General Practice.* Class Publishing, London.

Mahajan, S., Mukhiya, R., Singh, S.C., et al. (2005) Assessing glomerular filtration rate in healthy Indian adults: a comparison of various prediction equations. *Journal of Nephrology*, **18**, 257-261.

Mahoney, F.I., Barthel, D.W. (1965) Functional Evaluation: The Barthel Index. *Maryland State Medical Journal,* **14**, 56-61.

Martich, D. (1993) The Role of the Nurse Educator in the Development of Critical Pathways. *Journal of Nursing Staff Development*, **9**, 5, 227-229.

Medical Research Council. (2002) *Randomised controlled Trials and evidence based medicine.* www.mrc.ac.uk.

Middleton, S., Roberts, A. (1998) *Clinical Pathways Workbook.* Clinical Pathways Reference Centre, London.

Mogensen, C.E., Cooper, M.E. (2004) Diabetic renal disease: from recent studies to improved clinical practice. *Diabetic medicine,* **21**, 4-17.

Moore, D.S., (1991) *Statistics. Concepts and Controversies.* W.H. Freeman and Compnay, New York.

Moriarty, D.R., Stephens, L.A. (1989) Factors That Influence Diabetes patient Teaching Performed by Hospital Staff Nurses. *The Diabetes Educator*, **16**, 1, 31-35.

Mulrow, C. D., Oxman, A.D. (eds) (1997) *Cochrane Collaboration Handbook. In the Cochrane Library.* Update Software, Oxford.

National Diabetes Support Team. (2005) *Factsheet No.13. Hitting the Target for Retinal Screening.* NHS Clinical Governance Support Team, www.cgsupport.nhs.uk

National Diabetes Support Team. (2006) *Factsheet No. 15. Quality and Outcomes Framework Factsheet.* NHS Clinical Governance Support Team, www.cgsupport.nhs.uk

National Collaborating Centre for Chronic Conditions (2004) *Type 1 Diabetes in Adults. National Clinical Guideline for diagnosis and management in primary and secondary care.* Royal College of Physicians, London.

National Assembly for Wales. (1999) *An Introduction to Clinical Pathways.* NHS Wales, Cardiff.

National Audit Office. (2003) *Achieving Improvements through Clinical Governance. A Progress Report on Implementation by NHS Trusts.* NAO, London.

NHS Executive North West. (1997) *Diabetes Developmental Accreditation. Report of the Regional Group on Pilot Schemes and Recommendations for the Future.* Health Care Development Unit, Liverpool.

National Health Service Executive. (1998) *Using Electronic Patient Records in Hospitals: Legal Requirements and Good Practice.* Department of Health, Wetherby.

National Institute for Clinical Excellence. (2000) *search engine for care pathways.* www.nice.org.uk

National Institute for Clinical Excellence. (2002) *Principles for Best Practice in Clinical Audit.* Radcliffe Medical Press, Oxon.

National Institute for Clinical Excellence. (2002a) *Management of type 2 diabetes. Renal disease – prevention and early management. Inherited Clinical Guideline F.* NICE, London.

National Institute for Clinical Excellence. (2003) *Guidance on the use of patient-education models for diabetes. Technology Appraisal 60.* NICE, London.

Neuman, W. L. (2000) *Social research methods. Qualitative and quantitative approaches (4th ed.).* Allyn and Bacon, Boston.

Newman, B. (1995) Enhancing Patient Care: Case Management and Critical Pathways. *Australian Journal of Advanced Nursing*, **13**, 1,16-24.

NHS Centre for Reviews and Dissemination. (1996) *Undertaking Systematic Reviews of Research on Effectiveness. CRD Guidelines for Those Carrying Out or Commissioning Reviews. CRD Report Number 4 January 1996.* University of York, York.

Noedel, N. R., Osterloh, J.F., Brannan, J.A., Haselhorst, M.M., Ramage, L.J., Lambrechts, D. (1996) Critical pathways as an effective tool to reduce cardiac transplantation hospitalization and charges. *Journal of Transplant Coordination*, **6**, 1, 14-19.

Nursing and Midwifery Council. (2005) *Guidelines for records and record keeping.* Nursing and Midwifery Council, London.

O'Brien, S.V., Nicholson, J., Hardy, K.J. (1999a) Undiagnosed diabetic nephropathy in a UK health district. *Diabetes Update.*

O'Brien, S.V., Nicholson, J., Hardy, K.J. (1999b) Improved diagnosis and management of diabetic nephropathy in primary care. *Diabetes Update*

O'Brien, S.V., Michaels, S.E., Hardy, K.J. (2003) A comparison of general nurses' and junior doctors' diabetes knowledge. *Professional Nurse,* **18**, 5, 257-260.

Olds, S. (1997) Designing a Care pathway for a Maternity Support Service Program in a Rural Health Department. *Public Health Nursing*, **14**, 6, 332-338.

Oppenheim, A.N. (1966) *Questionnaire Design and Attitude Measurement.* Heinemann, London.

Parliamentary and Health Service Ombudsman. (2000) *Errors in the care and treatment of a young woman with diabetes. Presented to Parliament Pursuant to Section 14(4) of the Health Service Commissioners Act 1993.* Health Service Ombudsman, London.

Parsley, K. (1998) In Search of Pathways. *Nursing Times*, **94**, 32, 40-41.

Parving, H.H., Lehnert, H., Brochner-Mortenson, B., et al. (2001) The Effect of Irbesartan on the Development of Diabetic Nephropathy in patients with Type 2 Diabetes. *New England Journal of Medicine*, **345**, 12, 870-878.

Payne, S.L. (1954) *The art of asking questions.* Princeton University Press, Princeton NJ.

Pearson, S.D., Kleefield, S.F., Soukop, J.R., Cook, E.F., Lee, T.H. (2001) Critical Pathways Intervention to Reduce Length of Hospital Stay. *The American Journal of Medicine,* **110**, 175-180.

Pickup, J., Williams, G. (editors). (1991) *Text Book of Diabetes Volume 1.* Blackwell Science, Oxford.

Poggio, E.D., Wang, X., Greene, T., Van Lente, F., Hall, P.M. (2005) Performance of the modification of diet in renal disease and Cockcroft-Gault

equations in the estimation of GFR in health and in chronic kidney disease. *Am Soc Nephrol*, **16,** 2, 459-66.

Polit, C., Beck, C., Hungler, B. (2001) *Essentials of Nursing Research Methods, Appraisal Utilisation (fifth ed.).* Lippincott, Philadelphia.

Polonsky, W.H. (2000) Understanding and Assessing Diabetes-Specific Quality of life. *Diabetes Spectrum*, **13**, 1, 36-41.

Price, A., McDaniel, J. (1995) Critical Pathway. An Effective Way to Manage care of The Insulin-dependent Diabetic. *CARINGMagazine*, **2**, 24-27.

Ranjan, A., Tarigopula, L., Srivastava, R.K., Obasanjo, O.O., Obah, E. (2003) Effectiveness of the Clinical Pathway in the Management of Congestive Heart Failure. *Southern Medical Journal*, **96**, 7, 661-663.

Recker, D., O'Brien, C. (1995) Reliability and validity of Critical Care Orientation Tests. *The Journal of Continuing Education in Nursing,* **26**, 1, 21-27.

Reynolds, N., Diamantopoulos, A., Schlegelmilch, B. (1990) Pretesting in questionnaire design: A review of the literature and suggestions for further research. *Journal of Market Research Society*, **35,** 2, 171-181.

Riddle, M., Dunstan, J., Castanis, J. (1996) A Rapid Recovery Program For Cardiac Surgery Patients. *American Journal of Critical Care*, **5**, 2,152-159.

Rigalleau, M.D., Lasseur, C., Perlemoine, C., Barthe, N., Raffatin, C., Liu, C., Chauveau, P., Baillet-Blanco, L., Beauvieux, M., Combe, C., Gin, H. (2005) Estimation of Glomerular Filtration Rate in Diabetic Subjects. Cockcroft Gault or Modification of Diet in Renal Disease study Equation? *Diabetes Care*, **28**, 838-843.

Roberts, H.C., Pickering, R.M., Onslow, E., Clancy, M.(2004) The Effectiveness of implementing a care pathway for femoral neck fracture in older people: a prospective controlled before and after study. *Age and Ageing,* **33**, 178-184.

Rogers, E. M. (1995) *Diffusions of Innovations (4th Ed.),* Free Press, London.

Rossing, P. (1998) Promotion, Prediction and Prevention of Progression of Nephropathy in Type 1 Diabetes Mellitus. *Diabetic Medicine,* **15**, 900-919.

Rowe, J.W. (1976) The effect of age on creatinine clearance in men: a cross sectional and longitudinal study. *J Gerontol*, **31**, 55-63.

Rumble, S.J., Jernigan, M.H., Rudisill, P.T. (1996) Determining the Effectiveness of Critical pathways for Coronary Artery Bypass Graft Patients: Retrospective Comparison of Readmission Rates. *Journal Nursing Care Quality*, **11**, 2, 34-40.

Savage, M.P., Krolewski, A.S., Kenien, G.G. (1988) Acute Myocardial Infarction in Diabetes Mellitus and Significance of Congestive Heart Failure as a Prognostic Factor. *American Journal of Cardiology*, **62**, 665-669.

Schaldach, D.E. (1997) Measuring quality and cost of care: evaluation of an amputation clinical pathway. *Journal of Vascular Nursing*, **XV**, 1, 13-21.

Scheiderich, S.D., Freibaum, N., Peterson, M. (1983) Registered Nurses' Knowledge About Diabetes Mellitus. *Diabetes Care,* **6**, 1, 57-61.

Schott, S. (2003) How poor documentation does damage in the courtroom. *Journal of AHIMA,* **74**, 4, 20-24.

Simpson, M.A. (1984) Design and Use a Questionnaire in Evaluation and Educational Research. *Medical Teacher*, **6**, 4, 122-127.

Smith, M.J. (1998) *Social Science in Question.* Sage, London.

Stanley, A.C., Barry, M., Scott, T.E. *et al.* (1998) Impact of a critical pathway on postoperative length of stay and outcomes after infrainguinal bypass. *Journal of Vascular Surgery*, **27**, 6, 1056-1065.

Stratton, I.M., Adler, A.I., Neil, H.A.W., Matthews, D.R., Manley, S.E., Cull, C.A., Hadden, D., Turner, R.C., Holman, R.R. (2000) Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *British Medical Journal*, **231**, 404-411.

Streiner, D.L., Norman, G.R. (1995) *Health Measurement Scales. A Practical Guide to Their Development and Use.* Second Edition. Oxford Medical Publications, Oxford.

Stager, J.L. (1993) The comprehensive Breast Cancer Knowledge Test: validity and reliability. *Journal of Advanced Nursing*, **18**, 1133-1140.

Sulch, D., Perez, I., Melbourn, A., Kalra, L. (2000) Integrated care pathway based rehabilitation for acute stroke did not reduce length of hospital stay. *Stroke*, **31**, 1929-1934.

Sulch, D., Evans, A., Melbourn, A., Kalra, L. (2002a) Does an integrated care pathway improve processes of care in stroke rehabilitation? A randomised controlled trial. *Age and Ageing*, **31**, 175-179.

Sulch, D., Melbourn, A., Perez, I., Kalra, L. (2002b) Integrated Care Pathways and Quality of Life on a Stroke Rehabilitation Unit. *Stroke*, **33**, 1600-1608.

Taylor, J. (1997) *Seamless Care: Examining the Role of Integrated Care Pathways.* The Florence Nightingale Foundation, London.

Thomas, J., Harden, A., Oakley, A., Oliver, S., Sutcliffe, K., Rees, R., Brunton, G., Kavanagh, J. (2004) Integrating qualitative research with trials in systematic reviews. *BMJ*, **328**, 1010-1012.

Turley, K.M., Higgins, S.S., Archer-Duste, H., Cafferty, P. (1995) Role of the Clinical Nurse Co-ordinator in Successful Implementation of Critical Pathways in Pediatric Cardiovascular Surgery Patients. *Progress in Cardiovascular Nursing*, **10**, 1, 22-26.

UK CKD eguide (2005) Information about eGFR. www.renal.org/eGFR.

UKPDS Study Group (1998a) United Kingdom Prospective Diabetes Study 24: a 6 year randomized controlled trial comparing sulfonylurea, insulin and metformin therapy in patients with newly diagnosed type 2 diabetes that could not be controlled with diet therapy. *Annals of Internal Medicine*, **128**, 167-175.

UKPDS Study Group (1998b) Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. *Lancet*, **352**, 837-853.

Valmadrid, C.T., Klein, R., Moss, S.E., Klein, B.E. (2000) The risk of cardiovascular disease mortality associated with microalbuminuria and gross proteinuria in persons with older-onset diabetes mellitus. *Arch Intern Med,* **160**, 1093-1100.

VFM (Value for Money Unit). (1996) *Care Pathways Literature Review.* NHS Wales, Cardiff.

Van der Putten, J.J.M.F., Hobart, J.C., Freeman, J.A., Thompson, A.J. (2006) Measuring change in disability after inpatient rehabilitation: comparison of the responsiveness of the Barthel Index and the Functional Independence Measure. *Journal Neurosurg Psychiatry*, **66**, 480-484.

Velasco, F.T., Ko, W., Rosengart, T., Altorki, N., Lang, S., Gold, J.P., Krieger, K.H., Isom, O.W. (1996) Cost Containment in Cardiac Surgery: Results with a Critical Pathway for Coronary Bypass Surgery at the New York Hospital-Cornell Medical Center. *Best Practices and Benchmarking in Healthcare*, **1**, 1, 21-29.

Venture Training and Consulting. (2006) *Integrated Care Pathways.* www.venturetc.com

Wade, D.T., Collin, C. (1988) The Barthel ADL Index: a standard measure of disability? *International Disability Studies*, **10**, 64-67.

Waldon, E., Jones, C., Dozio, N., Heyburn, P., Greenwood, R., Sampson, M. (2004) Excess diabetes related bed occupancy in a large acute trust (1998-2003) and the impact of a dedicated inpatient diabetes nurse facilitator. *Diabetic Medicine,* **21** (Suppl. 2), 82.

Wallymahmed, M.E., Dawes, S., Clarke, G., Saunders, S., Younis, N., MacFarlane, I.A. (2004) Hospital in-patients with diabetes: increasing prevalence and management problems. *Diabetic Medicine,* **21** (Suppl. 2), 84.

Wang, S.L., Head, J., Stevens, L., Fuller, J.H. (1996) Excess mortality and its relation to hypertension and proteinuria in diabetic patients. The World Health Organisation Multinational Study of vascular Disease in Diabetes. *Diabetes Care*, **19**, 305-312.

Weston, R., Harden, A., Oakley, A. (1999) *A Systematic Analysis of Process Evaluations*. www.cochrane.org/colloquia/abstracts/rome.

Wietlispach Claussen, D., Pickering, P. (1995) A Clinical Pathway for Endoscopy. *Gastroenterology Nursing*, **18**, 5,182-185.

Wigfield, A., Boon, E. (1996) Critical care pathway development: the way forward. *British Journal of Nursing*, **5**, 12, 732-735.

Wooster, L.D., Thane Forthman, M. (1996) Clinical Pathways Before Implementing a Clinical Improvement Program. *Best Practices and Benchmarking in Healthcare*, **1**, 2, p84-88.

Young, B.A., Maynard, C., Boyko, E.J. (2003) Racial differences in diabetic nephropathy, cardiovascular disease, and mortality in a national population of veterans. *Diabetes Care*, **26**, 2392-2399.

Yudkin, J., *et al.* (1996) Prevention and Management of Cardiovascular Disease in Patients with Diabetes: An Evidence Base. *Diabetic Medicine*, **13**, S 4, S101-S121.

Zander, K. (1988) Nursing care management: strategic management of cost and quality outcomes. *Journal of Nursing Administration*, **18**, 23-30.

Zander, K. (1990) Differentiating managed care and case management. *Definition*, **5**, 2, 1.

APPENDIX 1

SYSTEMATIC REVIEW OF CARE PATHWAYS – PROTOCOL

1. REVIEW QUESTION:

"Do Care Pathways improve the management and or outcome of hospital in-patients with a medical or surgical condition?"

2. POPULATION

- Hospital in-patients
- Medical or surgical, acute or planned admission
- Adults (> 18 years of age)

3. INTERVENTION

Care pathway must be primary intervention. Definition of a care pathway for the purpose of the study: a set of guidelines, for a given condition in a given setting, with time frames and variance analysis. Other terms such as ICP, anticipated recovery map, critical pathway etc are all acceptable as long as the intervention described has recognised features of a care pathway.

4. PRIMARY OUTCOMES

Papers included must measure at least one of the following outcomes:

- LOS
- Recovery rate
- Complications of disease, state or surgery
- Patient satisfaction
- Staff satisfaction
- Re-admission rate

SECONDARY OUTCOME

- Quality of patient care

5. INCLUSION / EXCLUSION CRITERIA

INCLUDE:

- RCT (assessed according to quality criteria)
- Quasi-experimental studies (control vs. intervention group but not randomised)
- Controlled and uncontrolled before and after studies
- Systematic reviews

EXCLUDE:

- Anecdotal reports
- Retrospective studies
- Descriptive studies
- Studies with inadequate description of methodology

6. SEARCH STRATEGY

- Electronic databases (Cochrane Systematic Reviews Database, Cochrane controlled Trials Register, Medline, Cinahl, British Nursing Index, DH-DATA, Embase).
- Bibliographies of included studies
- Conference material
- Reference lists of retrieved articles
- Experts
- Hand search relevant journals
- Internet

7. VALIDITY OF INCLUDED STUDIES

Data extraction strategy – Data concerning study population, the intervention and outcomes will be extracted by one person & checked by a second. Any disagreements will be resolved through discussion.

Quality assessment strategy- Quality of included systematic reviews and RCTs will be assessed using NHS Centre for Reviews and Dissemination (University of York) criteria. Criteria will be applied by 1 reviewer & checked by a second, disagreements will be resolved via discussion.

8. METHODS FOR ANALYSIS

Clinical effectiveness will be synthesised by narrative review with tabulation of included studies. Data will only be combined statistically if of sufficient quantity or quality.

DATA EXTRACTION SHEET – Non-RCTs

AUTHOR:

TITLE:

JOURNAL:

SETTING:

POPN:

SAMPLE SIZE:

INTERVENTION:

METHODOLOGY:

OUTCOME MEASURES:

RESULTS:

DROP OUT:
(inc loss to fu)

CONC:

NOTES:

DATA EXTRACTION FORM - RCT

<table>
<tr><th>Reference & Design</th><th>Intervention (list all components)</th><th>Subjects</th><th>Outcome measures</th></tr>
<tr><td>Surname & Year:</td><td>Treatment intervention:</td><td>Eligible?</td><td>Primary outcomes used (eg. LOS, satisfaction etc)</td></tr>
<tr><td>Title:</td><td rowspan="3"></td><td>How chosen?</td><td>Secondary outcomes used:</td></tr>
<tr><td>Source: (published)</td><td>Numbers involved:</td><td>How outcomes assessed?</td></tr>
<tr><td>Setting:</td><td>Baseline measurements of outcome:</td><td>Validated?</td></tr>
<tr><td>Language:</td><td>Control Intervention:</td><td>Gender:</td><td>Timing outcomes same both groups?</td></tr>
<tr><td rowspan="3">Trial design:</td><td rowspan="2"></td><td>Age ranges:</td><td rowspan="3">Length follow up:</td></tr>
<tr><td>Duration Intervention:</td><td>Ethnic groups:</td></tr>
<tr><td></td><td>Losses to follow up</td></tr>
<tr><td colspan="4">Results:</td></tr>
<tr><td colspan="4">Methodological Comments:
Allocation to treatment groups (method of randomisation):

Blinding of outcome assessors:

Allocation concealment:</td></tr>
</table>

Analysis by intention to treat?

Comparability of treatment groups (any difference in baseline characteristics):

Method of data analysis (ITT, confidence intervals given?)

Sample size/power calculation given?

Attrition/drop out (percentages given)?

Quality assessment (of trial) are all quality criteria met?

General comments

Generalisability (inclusion exclusion criteria defined, are groups comparable to general population)

Conflict of interests (funding support mentioned)?

Other (duplicate publications, any other comments)

APPENDIX 2

DIABETES CARE PATHWAYS

Diabetes In-patient Care Pathways

Overall Guideline and Standards

1. All patients admitted with diabetes should be commenced on the pathway and given a patient held pathway.

2. The standards below detail the expected care of in-patients with diabetes. The objective is that patients will receive optimum diabetes care.

3. These standards underpin the care pathway and should be kept in a central place on the ward so that all staff can refer to them as necessary.

Standard 1 Blood Glucose Monitoring

- All patients should be started on the blood glucose monitoring chart (green) on admission to the ward. BMs should be recorded 6 hourly for the first 24hr (Target 4-7mM pre-meal & 6-10mM pre-bed).
- On admission, nurse to record usual treatment on BG monitoring chart & give patient an information leaflet (green).
- After the first 24hr BMs should be reviewed by a DR, it is important to always look for trends.
- **Stable BMs (most 4-10).** Monitor 2 days per week, 4 times a day pre-meal & pre-bed. Review patient status daily, if they become unstable monitor 6 hourly each day.
- **Unstable BMs.** Continue to monitor 6 hourly, there is no need to test any more frequently than this! Doctor to review BMs daily and adjust treatment accordingly (see standard 3). Check for ketones in type 1 patients if they are unwell with BMs > 16mM.
- BG monitoring should be performed only by those who have been trained. Anyone who needs formal training should contact DLN (bleep 1348).
- Patients who wish to do their own BG monitoring should be encouraged to do so. A RN should check their technique initially.

Standard 2 Investigations

1. **HbA1c.** Check in all patients on admission

Excellent control	<6.2%	Poor control	7.0-8.0%
Good control	<7.0%	Very poor control	>8.0%

Patients target HbA1c should be determined on an individual basis, but most patients should aim for <7% to reduce/retard complications of diabetes.

Action: If HbA1c >7% change treatment & arrange GP to repeat in 3 months.

2. **Creatinine.** Check on admission in all patients. Target <120μM.

Action: If >120μM refer to diabetes SpR (Specialist Registrar).

3. **Proteinuria.** Do urinalysis for protein in all patients on admission. Persistent proteinuria without infection signifies diabetic nephropathy.

Action: Positive proteinuria, send MSSU and refer to diabetes SPR.

4. **Cholesterol.** Check cholesterol on admission in all patients.

Action: If >5.0mM – start statin.

5. **Blood Pressure.** Check on admission in all patients. It is essential that patients with diabetes have their BP maintained within the targets below.

Action: Persistent elevation indicates need for treatment.

Diabetes alone	<140/80
Diabetes & nephropathy / microalbuminuria	<125/75

6. **Cardiovascular risk.** Dr to record IHD/CVD/PVD on investigations chart (pink), on admission.

Standard 3 Treatment

- Dr to assess patients treatment requirements within 12hr of admission.
- Dr should prescribe treatment on basis of patients status and BM results:
- **Unstable Diabetes:**
  - Eating – TDS Actrapid
  - Not eating –GKI pathway
  - DKA – as per hospital guidelines
- **Stable Diabetes:**
  - Continue usual treatment

- Dr should review patient status & BM results daily and adjust prescription on basis of these. Changes should be recorded clearly on prescription chart.
- If capable, patients on insulin will administer their own, under nurse supervision.
- The diabetes in-patient guidelines (green book on ward) provides further information on diabetes treatments.

Standard 4 Referrals

Diabetes Liaison Nurse (DLN)

The patients listed below should be referred to DLN. Record date & time referred on front page of pathway. DLN will review referrals within 1 working day.

- All newly diagnosed patients should be referred immediately.
- Patients admitted because of hypoglycaemia.
- Patients admitted with DKA or HONK.
- Patients requiring long term insulin therapy.

Note:

Patients with poor blood glucose control should be reviewed by the doctors on the ward. Patients with a raised creatinine or proteinuria should be referred to SPR as per pathway.

Dietitians

The patients listed below require review by a dietitian. Record date & time referred on front page of pathway. Referrals will be reviewed within 1 working day.

- Newly diagnosed patients.
- Patients admitted because of hypoglycaemia.
- Patients requiring long term insulin therapy.

Review By DLN

- DLN will review patients referred for all of reasons listed above. She will respond to referral within 1 working day.

- If a patient requires follow up by the diabetes team post discharge the DLN will organise a clinic appointment. She will record the appointment on her pathway and a copy of this will be filed with the in-patient pathway. Please make sure patients with follow up appointments are aware of the date before discharge.

Standard 5 GKI Infusion

- The following groups should receive a GKI:
  - Type 1 not eating
  - Type 2 not eating
  - Planned surgery / investigations (Type 1)
  - Major surgery / doubt Type 2 patients
  - Emergency surgery
  - DKA once stable (BG 5-11mM)

Initial GKI Infusion (Dr to prescribe):

- 500 ml 10% dextrose
- 16 units Actrapid / Humulin S (if on Pork insulin use Pork Actrapid)
- 10 mmol KCL
- Infuse at 80ml/hr

N.B: If initial BG is high you need more insulin in the bag, eg if initial BG 22mmol/l, use 24-unit GKI and switch to 16 unit GKI when BG 5-11mmol/l.

Monitoring:

- 4 hrly BG & U&E until stable
- When stable 12hrly BG & U&E
- If insulin dose is increased or decreased, repeat BG in 2hr & make up new bag as per chart below (Dr to prescribe)
- Continue GKI until able to eat

Changing Bags (Dr to prescribe new bags every 6hr as per chart below):

Plasma Glucose	Soluble Insulin	Plasma K	KCL
5-11	16 units	3.5 – 5.0	10mmol
<5	4 units less	<3.5	20mmol
>11	4 units more	>5.0	0mmol

- Record BG & U&E results on GKI chart (Blue)
- Contact DLN if problems

- **Restarting Treatment:**

  - **Insulin Treated Patients**

BD Insulin	*Basal Bolus*	*Insulin & Tablets*
Aim to restart normal insulin pre-breakfast or pre-tea. Otherwise Dr	Give usual insulin before first meal.	Start tablet with first meal & insulin when

to prescribe 8units Actrapid pre-lunch.

next due.

- **Patients on Tablets**

Once Daily Tablets	BD/TDS Tablets
Give usual AM tablet with first meal post-op.	Give AM tablet pre-lunch & usual tablet pre-tea.

Standard 6 Discharge

- Prior to discharge a nurse should record all diabetes investigations on the patients information sheet.
- A nurse should go through the information sheet with the patient / family and make sure they understand about Annual Review.
- If they are not already in the eye and foot screening programmes ensure they have a list of optometrists and podiatrists and recommend they have a screen within 2-4 weeks.
- If they have a follow up appointment with the diabetes team ensure they are aware of this, otherwise remind them to see their GP.
- Make sure the Doctor has completed all parts of the discharge summary.

DIABETES TEAM CONTACT NUMBERS

Jane Kennedy (DLN)	**bleep 1348**
SPR	**bleep 0065**
Diabetes Nurse Specialists	**ext. 1348**

Diabetes In-Patient Care Pathway

Patient details or sticky label

(1) Admission date & time:

_____

(2) Admitted with diabetes?

Y☐ N☐

(3) Newly diagnosed?

Y☐ N☐

(4) Referred Date

DLN ☐ _____

SpR ☐ _____

Dietitian ☐ _____

(5) Discharge date

_____

VARIANCE:

Record a variance if any part of the pathway not completed or any standard not met.

ON ADMISSION TO WARD

- Start BG monitoring pathway
- Start Investigatins pathway
- Give Pt Information Sheet
- If need GKI use GKI pathway

DAILY

- Get Dr to assess Pt & BM results & adjust treatment if necessary

ENSURE

- Investigations sheet completed & necessary action taken
- Referrals made if necessary

DISCHARGE

- Explain Pt Information sheet
- Ensure referrals completed
- Ensure all relevant people receive copy of D/C summary
- Record discharge date.

REFER TO DLN

- Newly diagnosed
- DKA or HONK
- Severe hypoglycaemia
- Need for long term insulin

REFER TO SPR

- Proteinuria
- Creatinine >120
- Foot ulceration
- Complex problems

REFER TO DIETITIAN

- Newly diagnosed
- Severe hypoglycaemia
- Need for long term insulin

If DLN/SpR/Dietitian don't review within 1 working day record a Variance.

SUMMARY

FRONT PAGE VARIANCE RECORD SHEET

BACK PAGE OF SUMMARY SHEET

VARIANCE CODES:

DH (Diabetes human)
DS (Diabetes system)
OP (Patient/carer)
OHP (Other health professional)
OS (Other system)

Standard not met	Date	Variance Code	Comment	Signature	Date evaluated diabetes team
Admission date & time not recorded					
Not record if reason for admission was diabetes					
Not record if newly diagnosed					
Referred to DLN but date not recorded on pathway					
Referred to DLN & not reviewed in 1 working day					
Referred to SPR but date not recorded on pathway					
Referred to SPR & not reviewed in 1 working day					
Referred to dietitian & date not recorded on pathway					
Referred to dietitian & not reviewed in 1 working day					
Discharge date not recorded on pathway					

BLOOD GLUCOSE MONITORING CHART

(SVO:Ver 12:1100)

Pt name & address or sticky label.

BOX 1: NURSE

What should Nurse do?		Day 1		Day 2		Day 3		Day 4		Day 5	
1. Give Pt (green) Info. Sheet. 2. Record pre-admission Rx here: Diet only ☐ Tablets ☐ Insulin & Tablets ☐ Insulin ☐ 3. Record BMs as per Guidelines & test urine for ketones if BM ≥ 16 (Type 1) 4. Ask doctor (& record) to review results daily or if problems **5. Record a variance (see sheet) if any section (incl. Box 2) of form not completed.**		Date: Do 6 hourly BMs		Date: Do ——— tests		Date: Do ——— tests		Date: Do ——— tests		Date: Do ——— tests	
		VALUE	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*
	Pre-breakfast										
	Pre-lunch										
	Pre-Tea										
	Pre-bed										
	Ketones if Bm ≥ 16 & ill (Type 1)										
	Dr asked to review Results (time)										

BOX 2: DOCTOR

What should doctor do?											
1. Review Pt status & BMs if done 2. Assess need to change Rx 3. Change Rx if needed, using guidelines to make appropriate change	1.BG profile/Pt status reviewed?	Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐	
	2. Does Rx need changing.	Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐	
	2. If yes, then has it been changed?	Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐		Y N ☐ ☐	

BGM CHART VARIANCE RECORD SHEET

BACK PAGE OF BGM CHART

Standard not met	Date	Comment	Signature	Date evaluated diabetes team
Not give Pt info sheet				
Admission Rx not recorded				
Day 1 – not 6 hourly BMs				
Day 1 – no Dr review				
Day 1- need Rx change & Not done				
Day 2 – tests not done as stated				
Day 2 – no Dr review				
Day 2- need Rx change & not done				
Day 3 – tests not done as stated				
Day 3 – no Dr review				
Day 3- need Rx change & not done				
Day 4 –tests not done as stated				
Day 4 – no Dr review				
Day 4 – need Rx change & not done				
Day 5 – tests not done as stated				
Day 5 – no Dr review				
Day 5 – need Rx change & not done				
Type 1 -BMs >16, ketones not checked				

DIABETES INVESTIGATIONS CHART

(SVO:Ver10:900)

NURSE					
What should NURSE do: 1. Organise test 2. Record result 3. Ask doctor to review results & record time Dr informed 4. Record variance if test not done or not reviewed	**HBA1C** Y N Order: ☐ ☐ Date : Initials:	**CREATININE** Y N Order: ☐ ☐ Date: Initials:	**URINALYSIS** (Protein) Y N Done: ☐ ☐ Date: Initials:	**CHOLESTEROL** Y N Order: ☐ ☐ Date: Initials:	**BP** Y N Done: ☐ ☐ Date: Initials:
Record Result					
Record name of doctor asked to review results & date					
DOCTOR					
What should DOCTOR do: 1. Record CVS risk: Y N IHD ☐ ☐ CVD ☐ ☐ PVD ☐ ☐ 2. Review results & take action. 3. Record variance if action not taken when should be. 4. Print initials & date in box at end of each column PRINT INITIALS / DATE →	Is result >7% Y☐ N☐ If yes, change Rx & ask GP to check in 3/12 DONE ☐ If not done, do Variance ☐	Is result >120μM Y☐ N☐ If yes, refer to Diabetes SpR DONE ☐ If not done, do Variance ☐	Proteinuria? Y☐ N☐ If yes, send MSSU & refer to Diabetes SpR DONE ☐ If not done, do Variance ☐	Is result >5mM? Y☐ N☐ If yes, statin started/increased & GP to check in 3/12 DONE ☐ If not done, do Variance ☐	BP > target Y☐ N☐ If persistent, start/increase Rx GP to monitor DONE ☐ If not done, do Variance ☐

INVESTIGATIONS CHART VARIANCE RECORD SHEET

BACK PAGE OF INVESTIGATIONS CHART

VARIANCE CODES:

DH (Diabetes human)
DS (Diabetes system)
OP (Patient/carer)
OHP (Other health professional)
OS (Other system)

Standard not met	Date	Variance Code	Comment	Signature	Date evaluated diabetes team
CVS risk not recorded					
HbA1c not done					
HbA1c no Dr review					
HbA1c >7% no Rx change					
Creatinine not done					
Creatinine no Dr review					
Creatinine >120, not refer SPR					
Urinalysis not done					
Proteinuria no Dr review					
No MSSU / no referral to SPR					
Cholesterol not done					
Cholesterol no Dr review					
Cholesterol >5mM & no statin					
BP not done					
BP no Dr review					
BP high, no Rx change					

Pt name & address or sticky label

GKI RECORD CHART

(SVO:Ver 4:06/00)

Reason For GKI:	Date	Time sample Taken & Initials	Time result back	Doctor Review: Time & Initials	Blood Results					How much K+ & insulin in the bag		Time GKI started & initials	Time next GKI due
					BG	Pot	Urea	Creat	Na	K+	Insulin		
Not eating ☐ Surgery ☐ DKA(stable) ☐ Other ☐ **Record Variance:** 1.No blood results 2.GKI not renewed 6 hourly 3.GKI not adjusted as per ICP 4.GKI stops before Pt restarts normal insulin 5. Chart not filled in													
Restarting treatment: Insulin Pts: Have they had s/c insulin before GKI stops? **Y ☐ N ☐** **If No, do variance** Tablet Pts: Have they had AM tablet with 1st meal post-op? **Y ☐ N ☐** **If No, do variance**													

GKI CHART VARIANCE RECORD SHEET

BACK PAGE OF GKI CHART

Standard not met	Date	Comment	Signature	Date evaluated diabetes team
Reason for GKI not recorded				
Day 1- No blood results				
Day 1- Not renewed 6hrly				
Day 1- No Dr review				
Day 2- No blood results				
Day 2- Not renewed 6hrly				
Day 2- No Dr review				
Day 3- No blood results				
Day 3- Not renewed 6hrly				
Day 3- No Dr review				
Day 4- No blood results				
Day 4 – Not renewed 6hrly				
Day 4 – No Dr review				
Insulin Pts – GKI stopped pre-s/c insulin				
Tablet Pts GKI stopped & no am tablet				

Hospitals Diabetes Team

SVO:Ver 2: 900

NAME:

Attach sticky label

In-Patient Pathway

PATIENT INFORMATION

WHAT TO EXPECT WHILST IN HOSPITAL

- **Doing it yourself.** You should have the opportunity to manage your own diabetes if this is well controlled and stable.
- **Monitoring.** Your blood sugars should be monitored and a doctor should discuss with you the need to change treatment if, allowing for your current circumstances, your sugars are too high or too low.
- **Investigations.** In addition to any tests relevant to your admission, you should have your blood pressure measured, your HbA1c, creatinine, and cholesterol measured (blood tests) and a urine test for protein. Ask for the results – they should be written in column 2.
- **Referrals.** If you were admitted with newly diagnosed diabetes, diabetic ketoacidosis (DKA), hyperosmolar non-ketotic coma (HONK) or hypoglycaemia (HYPO), then you should be referred to the diabetes liaison nurse. If your creatinine blood test is high or you have protein in your urine, or diabetic foot ulceration, then you should ask to be referred to the diabetes registrar. ASK.
- **Communication.** If you are attending diabetes clinic at another hospital or are known to have problems with your diabetes, then please let the ward staff know so that we let the right people know about your admission.

WHAT TO EXPECT AFTER DISCHARGE

- **Yearly checks.** All patients with diabetes should have an Annual Review to assess diabetes and nip problems in the bud. Make sure that you get one – ask your GP/Practice Nurse.
- **Blood/urine tests.** While in hospital some of the blood tests for your annual review have been done, make sure the nurse records the results below so that you can show them to your GP/Practice Nurse.
- **Eye checks.** Having your eyes checked yearly is VITAL. If you are not in the screening programme – ask the nurse for the list of opticians.
- **Foot checks.** Are also essential. If you are not in the screening programme – ask the nurse for a list of podiatrists (chiropodists).
- **Your results and targets.**

	Target	Result
HbA1c	**< 7.0%**	_____
BP	**< 140/80**	_____
Cholesterol	**< 5mM**	_____
Creatinine	**<120μM**	_____
Urine (protein)	**None**	_____

HOSPITAL DIABETES TEAM CONTACT NUMBERS

Diabetes Nurses	430 1348
Diabetes Dietitian	430 1360 9am-5pm
Emergency	**426 1600 &bleep emergency line**

Diabetes New Patient Clinic (NPC)

Overall Guideline and Standards

1. New patient clinic (NPC) will form part of the Hospital Diabetes Service. Most newly diagnosed patients who are referred will pass through this clinic.

Standard 1

GPs will be asked to provide an ACR, U&Es, Fasting Lipids, HbA1c and a full list of medications when referring patients. If this information isn't provided the referral form / letter will be sent back to the GP for completion and a letter will be sent to the patient informing them of the delay. Within three working days of receiving referrals with all the relevant information a letter will be sent to the patient asking them to ring the Centre (4301033) to book their NPC appointment, a copy of this letter will be sent to the GP.

NOTE: Current arrangements for making NPC appointments will change under the new 'Choose & Book' Scheme to be implemented in the near future, GPs will be able to book patients directly into clinic from the surgery.

Note: NHS Plan target – all patients to receive booked outpatient appointment by 2005.

Standard 2

Appointment date to be within 13 weeks of patient phoning for their appointment.

Note: we believe patients should be seen within 4 weeks of referral ideally. NHS Plan target is all patients to be seen within 13 weeks of outpatient referral by 2005. Responsibility will rest with PCT in Chose & Book.

Standard 3

All patients to be sent confirmation of the appointment and patient information pack and if phone number available to be phoned within 1 wk of appointment. If patient does not attend (DNA) they will be sent a DNA letter, with a copy to their GP and this will be recorded clearly in their case notes.

Note: DNA's reduced from 19% to 1% by this measure (Hardy KJ, Furlong NJ, O'Brien SV. Telling patients about their visit beforehand reduced outpatient non-attendance from 15% to 1%. **BMJ** 2001; 323: 1298-1300).

Standard 4

Patient to be greeted within 5 min of being seated and clinic nurse to run through Info. Pack with Pt and explain what will happen in the clinic. To supply a new pack if Pt. doesn't have one.

Standard 5

Carers to be given opportunity to join Pt in clinic if Pt happy with this.

Standard 6

All patients to have height measured <u>without shoes</u> and recorded on clinic sheet in <u>metres.</u> This includes Pts in wheelchairs unless they are totally unable to stand even with support.

Standard 7

All patients to have weight measured <u>without shoes and coat</u> and recorded on clinic sheet in kilograms. This includes Pts in wheelchairs unless they are totally unable to stand even with support. Patients must place their feet on the bar when being weighed.

Standard 8

Body mass index (BMI) to be calculated using electronic scales and recorded on clinic sheet (BMI= wt(kg) / Ht $(m)^2$).

Standard 9

Urine to be tested either visually with strip or by machine for glucose, ketones, nitrite, protein and blood in all patients and recorded on sheet. Negative results to be recorded as 'Neg'. If no specimen provided then this to be recorded on sheet as 'No specimen'.

Standard 10	**After enquiry by clinic nurse, this nurse to advise patients who have not had dilated funduscopy by either an ophthalmologist or an accredited optometrist to seek a screen within 2-4 weeks.**
Standard 11	**Patients not in Community Eye Programme to be given list of accredited optometrists with explanation of why we recommend using these particular optometrists - that they have been specifically trained and accredited to examine for diabetes properly and are part of a formal quality assurance scheme. Patients to be advised to see GP following eye test for result and to ensure they have been referred on if necessary.** ***Note: Annual eye examination recommended for all people with diabetes (NICE, grade D) with screening modality that has for STED (sight threatening eye disease) sensitivity ≥ 80% & specificity ≥ 95% (NICE, grade D). Local programme sensitivity = 87%, specificity = 91%.*** ***Note: NSC (National screening committee) have recommended digital screening for all people with diabetes but practicalities for this have not yet been resolved locally.***

Standard 12	**After enquiry by clinic nurse, this nurse to advise patients who have not had annual foot screen to be advised to seek a screen within 2-4 weeks and will be given self referral form for community podiatry.**
Standard 13	**Blood pressure to be recorded in all patients after they have been seated quietly for 5 min., by method described in British Hypertension Society Guidelines. BP to be repeated after a further 5 min in all those in whom first reading was > 130 / 80. If three readings made record all on clinic sheet.**
Standard 14	**Addressograph label to be entered on an MSSU form if there was any blood or nitrite in the urine and send MSSU. If there is no ACR result for patient or if there is one raised result, a second ACR will be undertaken in clinic using the DCA 2000 Analyser.**
Standard 15	**HbA1c to be measured and recorded on sheet and in HbA1c book. Record date of test, Pt. details expiry date & Lot number for HbA1c cartridge. Any machine errors to be recorded with code in book (log form).**
Standard 16	**Complete medical assessment as per clinic sheet to be performed and clinic sheet to be completed in full. Patients to be given explanation of diabetes appropriate to the individual and their diagnosis and reassured about any misconceptions they may have.**
Standard 17	**Record medications and targets (BP, HbA1c) and discuss targets. The usual target HbA1c should be <7.0% as this is proven to reduce risk of complications developing or progressing. However, >6.2% is still above normal range and the lower the HbA1c the better, patients with Type 2 diabetes, BMI >22, HbA1c <7% ≥ 6.2% and treated by diet alone should be offered Metformin 500mg tds (providing they can tolerate it and Creatinine is ok). You may need to negotiate a higher target in those at risk from hypoglycaemia and in other individual circumstances. The target for creatinine should be <120 μM. Don't use Metformin or a Fibrate when creatinine is above this. Obviously, when creatinine is raised it is rarely possible to lower it again. Target microalbumin: creatinine ratio is < 2.5 for men & < 3.5 for women. Target BP is <130/80 unless they have Nephropathy or Microalbumiuria when it is <**

125/75. SEE HOSPITAL GUIDE FOR DETAILED DISCUSSION.

Note: Level 1 evidence for tight blood glucose control in type1 & type 2 diabetes, NSF 2002.

Standard 18

Review HbA1c result, if above target or newly diagnosed Type 2 on diet only ask GP to prescribe more / new tablets for Type 2 patients (Metformin (1st line), Rosiglitazone (2nd line) or Gliglazide possibly 3rd line) or adjust insulin / arrange CSC for Type 1 and insulin treated Type 2 patients (if not doing EC). Consider ICE for Type 1 patients. Arrange Combo Clinic for Type 2 patients on maximum oral hypoglycaemic agents requiring insulin. Patients will be offered Glitazones if appropriate. If intolerant of Metformin consider MR preparation. Do not use Metformin if Gd III or Gd IV heart failure (NYHA) or if severe LV impairment (Echo) without symptoms.

Standard 19

Review creatinine result and stop Metformin or Fenofibrate if raised. If >120 μM do FBC and Ferritin. Ca^{2+}, PO_4^{3-}, HCO^{3-}, & PTH.

Standard 20

Review BP result, if above target ask GP to start BP treatment or arrange further monitoring (ask GP) and review in DAC. Start with Ramipril 2.5mg, titrate to 10mg if necessary then add Bendrofluamethiazide 2.5mg, if BP still >130/80 add further antihypertensives.

Note: BHS BP target in non-problematic diabetics of <130/80. There is Grade 1 (SIGN) evidence for ACE-inhibition in a variety of situations (eg. post-MI) in hypertension in diabetes so we have chosen to recommend it as default 1st line agent. Diabetes NSF recommends 1st line use of ACE-inhibitors for all people with diabetes & raised BP.

Note: International guidelines differ in their recommendation targets for BP in microalbuminuria & nephropathy. Existing (level 1-2) evidence suggests SBP target in the range 122-140 & DBP in the range 75-85. We have adopted 125/75 on this basis.

STATIN, FIBRATE, ACE-INHIBITOR & ASPIRIN INITIATION

	Simvastatin 40 mg * if TC >6 or LDL > 3 initiate Atorvastatin 40mg	HDL <1.0 or Trigs. >2.0 or both	Ramipril 10mg	Aspirin 75mg
Type 2 diabetes (non-proteinuria)	Yes	Fenofibrate** 267mg	Yes	Yes (if SBP <145)
Any Vascular Disease / secondary Risk (T1)	Yes	Fenofibrate 267mg	Yes	Yes
Nephropathy / Microalbuminuria T1 & T2	Yes	Fenofibrate 267mg	Yes (T2 use Irbesartan)	Yes (if SBP <145)
Type1 diabetes >50yrs	Yes	Fenofibrate 267mg	Yes	Yes (if SBP <145)
Type 1 diabetes No proteinuria / vascular disease	Use Judgement based on risk (not necessarily using risk table)			

****Try Fenofibrtae for 3 months, if no change or HDL has fallen, stop Fenofibrate & switch to NIASPAN, titrated (using pack) to max. dose taken at night with Aspirin.**

Review lipid results (or ask GP to) following treatment.

If LDL >2.0mM with Simvastatin 40mg try Atorvastatin 80 mg. If LDL remains >2.0mM add Ezetimibe 10mgs od.

If patient taking a fibrate and a statin explain to patient not to take them at the same time – to take statin at night and Fenofibrate in the morning. Consider using Niaspan in renal impairment.

Do not use Statin + Fibrate + Ezetimibe

Note: target lipids: total cholesterol ≤4; HDL-C ≥1.0; & trigs. ≤2.0 are NSF recommendations, based on level 2 evidence. LDL target ≤2.o is a BHS recommendation. Aim for LDL <1.6 in high risk patients.

Standard 22

Review ACR result if > target repeat.

Two raised ACRs are needed to diagnose microalbuminuria / nephropathy. **Diagnosis:**
Microalbuminuria: albumin:creatinine ratio ≥ 2.5mg/mmol (men) or 3.5mg/mmol (women), or albumin concentration ≥ 20mg/l.
Nephropathy: albumin:creatinine ratio ≥ 30mg/mmol or albumin concentration ≥ 200mg/l.

Note: Grade C recommendation, NICE 2002.

Standard 23

Review BMI. If BMI ≥ 28 write to GP and recommend they consider a weight reducing drug (Orlistat) as per BNF and NICE.

Standard 24

If new drugs have been started give patient drug information sheets.

Standard 25

It is vital that patients understand the importance of attending education clinics (EC) - this must be emphasised. Including the fact that if they DNA 1 clinic their programme will be terminated and their GP informed. If education or insulin clinic is not appropriate then organise an alternative appointment for the patient (DAC, CPC, FC, CSC, JANC, ICE) or if appropriate discharge them from the clinic.

There is level 1 evidence for education to improve knowledge, blood glucose control, weight, dietary management, physical activity & psychological well being (NSF, 2002).

Standard 26

If the patient is for Insulin / tablet combination therapy or a change of insulin, organise: CC (combo clinic) for type 2 requiring combination therapy or Insulin Clinic for type 2 or type 1 requiring other insulin changes.

Standard 27	**Sort date for next appointment and give them a copy of clinic sheet & explain a copy of letter will be posted to them.**

Diabetes New Patient Clinic Pathway & Standards

Issue Date: June 2005

Version: 16

Review Date: May 2006

Responsibility for pathway / review: Mrs S O'Brien, Dr K Hardy

Developed by: Mrs S O'Brien, Dr K hardy

References / Guidelines:

- American Diabetes Association. Clinical Practice Recommendations 2004/5. **Diabetes Care** 2002; 25 (Suppl 1) S21 – S147.
- Department of Health. Diabetes National Service Framework for Diabetes. www.doh.gov.uk/nsf/diabetes.htm
- Scottish Intercollegiate Guidelines Network. Management of Diabetes. A national clinical guideline. **SIGN** 2001.

LEVELS OF EVIDENCE:

SIGN:

Level	Evidence
1^{++}	High quality meta-analysis, systematic reviews of RCTs, or RCTs with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1^{-}	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2^{++}	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias & a high probability that the relationship is causal
2^{+}	Well-conducted case control or cohort studies with a low risk of confounding or bias & moderate probability that the relationship is causal
2^{-}	Case control or cohort studies with a high risk of confounding or bias & a significant risk that the relationship is not causal
3	Non-analytical studies, e.g. case reports, case series
4	Expert opinion

DIABETES NSF:

Level	Evidence
1	Meta-analyses, systematic reviews of randomised controlled trials, or

	randomised controlled trials
2	Systematic reviews of case control or cohort studies, or case control or cohort studies
3	Non-analytic studies, eg case reports, case series
4	Expert opinion (in absence of any of the above)

ADA:

Level	Evidence
A	Clear / supportive evidence from well-conducted, generalizable, randomised controlled trials that are adequately powered
B	Supportive evidence from well-conducted cohort studies
C	Supportive evidence from poorly controlled or uncontrolled studies
E	Expert consensus or clinical experience

Location: Standards are located in diabetes centre (PDU resource room), pathways used at each visit are located in patients notes. Clinic sheets & letters from each visit are located in patients notes.

Pages: Standards 9 pages, pathway for each visit 1 page.

DIABETES PATHWAYS

Hospital Outpatients:
New Patient Clinic
Education Clinic
Insulin Clinic
Discharge Assessment Clinic
Community Support Clinic
Young Adults Clinic
Joint Ante-natal Clinic
Complex Patient Clinic
Foot Clinic

Hospital In-patients:
Blood Glucose Monitoring
Investigations

Diabetes New Patient Clinic Care pathway

Patient details

Date: _____

Time Seen by Specialist: _____

Consultant	**Y**	**N**		**Variance** (cont. over page if needed)
Explain clinic / visit	☐	☐		_____
Explain all medications	☐	☐		_____
HbA1c < target?	☐	☐	If no, adjust DM management	_____
Creatinine <120 μM?	☐	☐	If no, stop Metf./fibrate, do FBC/Ferritin	_____
Creatinine <120 μM?	☐	☐	If no, do Ca^{2+}, PO_4^{3-}, HCO^{3-}, & PTH	_____
BP < target?	☐	☐	If no, ask GP to adjust meds.	_____
Right statin or not indicated?	☐	☐	If no, ask GP to start / ↑ statin	_____
On fibrate or not indicated?	☐	☐	If no, ask GP start Fenofibrate 267mg	_____
Aspirin or not indicated?	☐	☐	If no, ask GP to start 75mg od	_____
Ramipril or not indicated?	☐	☐	If no, ask GP to start & titrate 10mg od	_____
Urine clear of blood/nitrite?	☐	☐	If no, do MSSU	_____
Is ACR < target?	☐	☐	If no, repeat ACR	_____
Is BMI ≤ 28?	☐	☐	If no, advise GP to consider Orlistat	_____
Has Pt got drug info sheets?	☐	☐	If no, give drug info. sheets	_____
Discuss EC / IC / FU	☐	☐		_____
Sort appts/paperwork & advise to see GP in 10 days	☐	☐		_____

Signature _____

Record Time finish _____

DIABETES NURSE 4 WEEK EDUCATION CLINIC

The education programme is an integral part of the hospital diabetes service. New referrals seen in NPC will be offered an appointment for education clinic. Patients will attend weekly for three consecutive weeks and will receive an individual appointment with a dietitian. Patients will always be given the opportunity to ask questions and when necessary will be seen individually by a diabetes nurse specialist. The sessions will be interactive, patients will be encouraged to participate as much as possible.

Note: There is level 1 evidence for education to improve knowledge, blood glucose control, weight, dietary management, physical activity & psychological well being (NSF, 2002).

The education programme has been associated with an improvement in HbA1c, knowledge and well being *(O'Brien SV & Hardy KJ. Impact of a care-pathway-driven diabetes education programme. **The Journal of Diabetes Nursing** 2000;4:147-49).*

GUIDELINES / STANDARDS FOR VISIT 1

1. Patients will be seen individually by a dietitian.

STANDARD 1 **Patients will spend 30mins with a dietitian.**

STANDARD 2 **Patients will be seen at the correct appointment time.**

2. The diabetes education pack will be used for all teaching sessions.

STANDARD 3 **A dietary history will be taken and patients will receive individual advice from the dietitian regarding any changes they need to make.**

GUIDELINES / STANDARDS FOR VISIT 2

1. Patients will be seen for group education.

STANDARD 1 **Patients will spend 1hr with a diabetes nurse.**

STANDARD 2 **Patients will be seen at the correct appointment time.**

2. The diabetes education pack will be used for all teaching sessions.

STANDARD 3 **Patients will be educated on the following:**

- **Definition of diabetes.**
- **Controlling diabetes. What we mean by 'good control', HbA1c explained, strategies to achieve control discussed. The impact on blood glucose of exercise, alcohol and food.**
- **Complications (definition, prevention, screening)**
    - **Retinopathy**
    - **Nephropathy**
    - **Neuropathy**
    - **Cardiovascular disease (inc. risk reduction – exercise, diet, smoking advice, BP & lipid control)**
- **Driving (inc. to monitor before driving).**
- **Diabetes UK**

STANDARD 4 **LIFESTYLE CHANGES - patients will have the opportunity to discuss changes (& potential difficulties associated with these changes) they may need to make to successfully manage their diabetes. This may include exercise programmes, dietary changes, new medication.**

STANDARD 5 **All patients will have the necessary information to make an informed decision regarding BG monitoring. If they are already testing and do not feel a need for further education they will not need to attend visit 2 but will be made an appointment for visit 3.**

STANDARD 6 **Patients will be presented with a case study concerning type of diabetes, target for HbA1c, BP and cholesterol. The case study will facilitate a discussion on these issues and the nurse will use it to go over issues covered in the session.**

3. Patients will have the opportunity to ask questions and discuss issues of importance to them.

4. Patients will receive a further appointment for the following week.

GUIDELINE / STANDARDS FOR VISIT 3

1. Patients will be seen for group education.

STANDARD 1 **Patients will spend 1hr with a diabetes nurse.**

STANDARD 2 **Patients will be seen at the correct appointment time.**

2. The diabetes education pack will be used for all teaching sessions.

STANDARD 3 **Patients will be trained how to use a Blood Glucose Meter and a meter will be supplied. The reasons for testing will be discussed (monitor BG levels, understand diabetes and impact of lifestyle better, can be guided by readings during acute problems such as illness). They will be taught:**

- How to use meter
- Technique for gaining a sample of blood
- Where to test
- When to test
- How to record results
- What levels to aim for
- How to interpret levels
- High & low levels and appropriate action
- How to clean the meter
- Quality control

Note: there is no evidence that blood glucose monitoring per se improves outcomes, but both the ADA guidelines (2002) and the NSF (2002) acknowledge the usefulness of HBGM for patients treated with insulin. As part of a package of care it is widely considered to be useful, we offer HBGM to <u>all</u> patients with diabetes and facilitate them in learning the skill and interpreting & acting on the results.

STANDARD 4 **Individual questions will be answered. An appointment for visit 4 will be made.**

GUIDELINE / STANDARDS FOR VISIT 4

1. Patients will be seen for group education.

STANDARD 1 **Patients will spend 1hr with a diabetes nurse.**

STANDARD 2 **Patients will be seen at the correct appointment time.**

2. The diabetes education pack will be used for all teaching sessions.

STANDARD 3 **Patients will be educated on the following:**

- **Hypoglycaemia**
- **Hyperglycaemia**
- **Illness (inc. DKA / HHS)**
- **Foot care**
- **Annual Review**

HYPOGLYCAEMIA:

i. Patients on insulin or a sulphonylurea should have Hypostop. If the patient has no Hypostop and is currently experiencing hypos supply them with some. If they are not experiencing hypos give them a prescription letter for the GP to prescribe it.

ii. Patients on insulin therapy should know about Glucagon and if appropriate (someone would be able to administer it when necessary) should have Glucagon at home. New Type 1 patients, pregnant patients and those experiencing problems with hypo should be supplied Glucagon, other patients should be given a prescription letter.

DKA / HHS

All patients (Type 1 & Type 2) with diabetes should have Ketone testing sticks at home, know how to use them and understand when they expire. Explain to patient that expiry depends on type of stick prescribed, some expire within 6 months of opening the pack others i.e. Ketur – Test sticks expire as per expiry date if kept airtight. Advise patient to read leaflet and ask prescribing clinician to clarify expiry date for them. Sick day rules will be explained during this session. If they haven't got any Ketone sticks give them a prescription letter for the GP. If you think they are at high risk of DKA supply them.

Note: type 2 diabetes is increasingly presenting in younger individuals and distinction from slow-onset type 1 diabetes is becoming more difficult. There have been a number of high profile cases of DKA in type 2 diabetes & we recommend ketone testing for all patients with diabetes.

STANDARD 4 **Patients will be presented with two case studies concerning sick day rules and hypoglycaemia.**

The case studies will facilitate a discussion on these issues and the nurse will use it to go over issues covered in the session.

STANDARD 5 **Individual questions will be answered.**

STANDARD 6 **Explain what to expect at DAC (if patient has an appointment). If any patients require further blood or urine tests before DAC, organise. Ensure they know how to contact diabetes nurses.**

STANDARD 7 **A letter will be sent to the GP (& a copy to the patient) summarising education programme.**

Diabetes Nurse 4 Week Education Clinic Pathway & Standards

Issue Date:	August 2005
Version:	3
Review Date:	July 2006
Responsibility for pathway / review:	Mrs S O'Brien, Dr K Hardy
Developed by:	Mrs S O'Brien, Dr K Hardy in consultation with diabetes team.

References / Guidelines:

- American Diabetes Association. Clinical Practice Recommendations 2002. **Diabetes Care** 2002; 25 (Suppl 1) S21 – S147.
- Department of Health. Diabetes National Service Framework for Diabetes. www.doh.gov.uk/nsf/diabetes.htm
- Scottish Intercollegiate Guidelines Network. Management of Diabetes. A national clinical guideline. **SIGN** 2001.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Renal disease – prevention and early management. **NICE** 2002; 1-16.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Retinopathy – screening and early management. **NICE** 2002; 1-15.

LEVELS OF EVIDENCE:

NICE:

Level	Type of Evidence
Ia	Evidence from meta-analysis of randomised controlled trials
IIa	Evidence from at least one randomised controlled trial
IIa	Evidence from at least one controlled study without randomisation
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies & case control studies
IV	Evidence from expert committee reports or opinions &/or clinical experience of respected authorities

Grading of clinical recommendations

Grade	Evidence (see table above)
A	Directly based on category I evidence
B	Directly based on category II evidence, or extrapolated recommendation from category I evidence
C	Directly based on category III evidence, or extrapolated recommendation from category I or II evidence

D	Directly based on category 1V evidence, or extrapolated recommendation from category1, 11 or 111 evidence

Eccles M et a. (1998) North of England Based Guidelines Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *BMJ* 316:1369.

SIGN:

Level	Evidence
1^{++}	High quality meta-analysis, systematic reviews of RCTs, or RCTs with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1^{-}	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2^{++}	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias & a high probability that the relationship is causal
2^{+}	Well-conducted case control or cohort studies with a low risk of confounding or bias & moderate probability that the relationship is causal
2^{-}	Case control or cohort studies with a high risk of confounding or bias & a significant risk that the relationship is not causal
3	Non-analytical studies, e.g. case reports, case series
4	Expert opinion

DIABETES NSF:

Level	Evidence
1	Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials
2	Systematic reviews of case control or cohort studies, or case control or cohort studies
3	Non-analytic studies, eg case reports, case series
4	Expert opinion (in absence of any of the above)

ADA:

Level	Evidence
A	Clear / supportive evidence from well-conducted, generalizable, randomised controlled trials that are adequately powered
B	Supportive evidence from well-conducted cohort studies
C	Supportive evidence from poorly controlled or uncontrolled studies
E	Expert consensus or clinical experience

Location: Standards are located in diabetes centre (Clerical Processing Room), pathways used at each visit are located in patient diabetes file.

Pages: Standards 7 pages, pathway 1 page.

DIABETES PATHWAYS
Hospital Outpatients:
New Patient Clinic
Education Clinic
Insulin Clinic
Discharge Clinic
Community Support Clinic
Young Adults Clinic
Joint Ante-natal Clinic
Complex Patient Clinic
Foot Clinic
Hospital In-patients:
Blood Glucose Monitoring
Investigations

Education Clinic Care pathway

Patient details

Visit 1 **Date:** _____ **Sign:** _____

	Y	N	Variance(Cont. over page if needed)
Individual review with dietitian	☐	☐	_____

Visit 2 **Date:** _____ **Sign:** _____

Definition of Diabetes	☐	☐	_____
Lifestyle (exercise, alcohol, food)	☐	☐	_____
Control & Complications:	☐	☐	_____
• Retinopathy	☐	☐	_____
• Nephropathy	☐	☐	_____
• Neuropathy	☐	☐	_____
• Cardiovasc. Disease (↓ risk)	☐	☐	_____
Driving	☐	☐	_____
Diabetes UK	☐	☐	_____
Discuss BGM	☐	☐	_____
Visit 2 case study	☐	☐	_____
Sort appt (V3 if BGM or V4)	☐	☐	_____

Visit 3 **Date:** _____ **Sign:** _____

Why test blood glucose	☐	☐	_____
How to use meter	☐	☐	_____
Interpreting high & low readings	☐	☐	_____
Make V4 appt.	☐	☐	_____

Visit 4 **Date:** _____ **Sign:** _____

Hypoglycaemia (tablets/insulin):	☐	☐	_____
• Supply / Rx Hypostop	☐	☐	_____
• Supply / Rx Glucagon	☐	☐	_____
Hyperglycaemia	☐	☐	_____
Illness (DKA / HONK):	☐	☐	_____
• Supply / Rx Ketone sticks	☐	☐	_____
Foot care	☐	☐	_____
Annual Review	☐	☐	_____
Visit 4 case studies	☐	☐	_____
Check DAC appt	☐	☐	_____

Diabetes Discharge Assessment Clinic (DAC)

Overall Guideline and Standards

1. Discharge Assessment Clinic (DAC) will form part of the Hospital Diabetes Service and many patients passing through NPC and Education Clinic (EC) / Insulin Clinic (IC) will pass through this clinic. DAC patients will typically be seen 12 wk after they are seen in NPC.

Standard 1	**If patient fails to attend (DNA) they will be sent a DNA letter and a copy sent to their GP, this will be recorded clearly in case notes.**
Standard 2	**Patient to be greeted within 5 min of being seated and clinic nurse to explain to carer that they can go with Pt if Pt is happy with this.**
Standard 3	**All patients to have height recorded on clinic sheet in metres. Use value recorded on last clinic sheet.**
Standard 4	**All patients to have weight measured without shoes and coat and recorded on clinic sheet in kilograms. This includes patients in wheelchairs unless they are completely unable to stand even with support. Patients must place their feet on the bar when being weighed.**
Standard 5	**Body mass index (BMI) to be calculated using electronic scales and recorded on clinic sheet.**
Standard 6	**Urine to be tested either visually with strip or by machine for glucose, ketones, protein, nitrite and blood in all patients and recorded on sheet. Negative results to be recorded as 'Neg'. If no specimen provided then this to be recorded on sheet as 'No specimen'.**
Standard 7	**Check Pt had eyes screened by accredited optometrist and feet by podiatrist. If still not screened, then clinic nurse to advise Pt to get done ASAP & why.**
Standard 8	**Blood pressure to be recorded in all patients after they have been seated quietly for 5 min., by method described in British Hypertension Society Guidelines. BP to be repeated after a further 5 min**

	in all patients in whom first reading was > 130/80. If three readings made record all on clinic sheet.
Standard 9	**HbA1c to be measured and recorded on sheet and in HbA1c book. Record date of test, Pt details, expiry date and Lot number for HbA1c cartridge. Any machine errors to be recorded with code book.**
Standard 10	**All patients to receive introduction & explanation of visit from doctor / consultant nurse.**
Standard 11	**Review notes, targets, medications and results to ensure that all relevant issues have been dealt with. Organise repeat tests as needed. The usual target HbA1c should be less than < 7.0% as this is proven to reduce risk of complications developing or progressing. However, >6.2% is still above normal range and the lower the HbA1c the better, patients with Type 2 diabetes, BMI>22, HbA1c<7% ≥6.2% and treated by diet alone should be offered Metformin 500mgs tds (providing they can tolerate it and Creatinine is ok). You may need to negotiate a higher target in those at risk from hypoglycaemia and in other individual circumstances. The target for creatinine is <120 μM, stop metformin or a Fibrate when creatinine is above this. Obviously, when creatinine is raised it is rarely possible to lower it again. Target microalbumin:creatinine ratio is < 2.5 for men & < 3.5 for women. Target BP is <130/80 unless they have Nephropathy or Microalbuminuria when it is < 125/75. SEE HOSPITAL GUIDE FOR DETAILED DISCUSSION.** ***Note: Level 1 evidence for tight blood glucose control in type1 & type 2 diabetes, NSF 2002.*** ***Note: target lipids: total cholesterol <4; HDL-C ≥ 1.0; & trigs. ≤2.0 are NSF recommendations, based on level 2 evidence. LDL target ≤2.0 is a BHS recommendation. Aim for LDL<1.6 in high risk patients.***
Standard 12	**Review HbA1c result, if above target ask GP to prescribe more / new tablets for Type 2 patients (Metformin or Gliclazide) or adjust insulin for Type**

1 and insulin treated Type 2 patients. If control very poor and Pt willing to try and change consider CSC appointment. If patient requires Combination Therapy / change insulin regimen refer into CC / IC respectively. Patients will be offered Glitazone according to district policy.

Standard 13

Review BP result, if above target arrange GP to monitor or start BP treatment. Start with Ramipril 2.5mg, titrate to 10mg if necessary then add Bendroflumethiazide 2.5mg, if BP still >130/80 add further antihypertensives. If this is first time BP has been raised consider arranging further monitoring first.

Note: BHS BP target in non-problematic diabetics of <130/80. There is Grade 1 (SIGN) evidence for ACE-inhibition in a variety of situations (eg. post-MI) in hypertension in diabetes so we have chosen to recommend it as default 1st line agent. Diabetes NSF recommends 1st line use of ACE-inhibitors for all people with diabetes & raised BP.

Note: International guidelines differ in their recommendation targets for BP in microalbuminuria & nephropathy. Existing (level 1-2) evidence suggests SBP target in the range 122-140 & DBP in the range 75-85. We have adopted 125/75 on this basis.

Standard 14

STATIN, FIBRATE, ACE-INHIBITOR & ASPIRIN INITIATION

	Simvastatin 40 mg	HDL <1.0 or	Ramipril	Aspirin 75mg

	* if TC >6 or LDL > 3 initiate Atorvastatin 40mg	Trigs. >2.0 or both	10mg	
Type 2 diabetes (non-proteinuria)	Yes	Fenofibrate** 267mg	Yes	Yes (if SBP <145)
Any Vascular Disease / secondary Risk (T1)	Yes	Fenofibrate 267mg	Yes	Yes
Nephropathy / Microalbuminuria T1 & T2	Yes	Fenofibrate 267mg	Yes (T2 use Irbesartan)	Yes (if SBP <145)
Type1 diabetes >50yrs	Yes	Fenofibrate 267mg	Yes	Yes (if SBP <145)
Type 1 diabetes No proteinuria / vascular disease	Use Judgement based on risk (not necessarily using risk table)			

**Try Fenofibrtae for 3 months, if no change or HDL has fallen, stop Fenofibrate & switch to NIASPAN, titrated (using pack) to max. dose taken at night with Aspirin.

Review lipid results (or ask GP to) following treatment.

If LDL >2.0mM with Simvastatin 40mg try Atorvastatin 80 mg. If LDL remains >2.0mM add Ezetimibe 10mgs od.

If patient taking a fibrate and a statin explain to patient not to take them at the same time – to take statin at night and Fenofibrate in the morning. Consider using Niaspan in renal impairment.

Do not use Statin + Fibrate + Ezetimibe

Note: target lipids: total cholesterol ≤4; HDL-C ≥1.0; & trigs. ≤2.0 are NSF recommendations, based on level 2 evidence. LDL target ≤2.o is a BHS recommendation. Aim for LDL <1.6 in high risk patients.

Standard 15

Review urinalysis & ACR results:

Two raised ACRs are needed to diagnose microalbuminuria / nephropathy.
Diagnosis:

MICROALBUMINURIA: albumin:creatinine ratio ≥ 2.5mg/mmol (men) or 3.5mg/mmol (women), or albumin concentration ≥ 20mg/l.

NEPHROPATHY: albumin:creatinine ratio ≥ 30mg/mmol or albumin concentration ≥ 200mg/l.

High risk Nephropathy should be referred to Nephropathy Clinic.

Note: Grade C recommendation, NICE 2002.

Standard 16 — **Sheet for GP should be completed. Comments for GP, such as recommendations for treatment changes, must be printed clearly.**

Standard 17 — **Explain all results and investigations to Pt and record on their information sheet.**

Standard 18 — **Organise follow up. Discharge to GP is default option. Most patients will be discharged. Only retain patients who fulfil criteria set out on DAC pathway.**

Standard 19 — **Community Support Clinic (CSC) is nurse run. It is for fine-tuning of control and patients with Hypo Unawareness. Patients should only in exceptional circumstances be followed here for > 1 yr (they must be discussed with Dr Hardy).**

Standard 20 — **Insulin Clinic (IC) is primarily for patients on insulin who require a change of insulin regimen. Combo Clinic (CC) is for patients on maximum oral treatment with sub-optimal control who require a tablet -insulin combination.**

Standard 21 — **Nephropathy Clinic is for those with confirmed Nephropathy. Neuropathy Clinic is for those with problematic Autonomic or Painful Neuropathy.**

Standard 22 — **Foot clinic is for those with active ulceration below the malleclus. Predominantly ischaemic problems should be referred to Vascular Surgeon.**

Standard 23 — **Young Adults Clinic is for those under 26 years of age.**

Standard 24	**Joint Ante-natal Clinic for those who are pregnant / planning pregnancy (Pre-concetion).**
Standard 25	**If patient requires follow up explain clinic, make appointment & give them appointment card and record the time they leave department.**

Diabetes Discharge Assessment Clinic Pathway & Standards

Issue Date: August 2005

Version: 14

Review Date: July 2006

Responsibility for pathway / review: Mrs S O'Brien, Dr K Hardy

Developed by: Mrs S O'Brien, Dr K Hardy.

References / Guidelines:

- American Diabetes Association. Clinical Practice Recommendations 2004/5. **Diabetes Care**
- Department of Health. Diabetes National Service Framework for Diabetes. www.doh.gov.uk/nsf/diabetes.htm
- Scottish Intercollegiate Guidelines Network. Management of Diabetes. A national clinical guideline. **SIGN** 2001.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Renal disease – prevention and early management. **NICE** 2002; 1-16.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Retinopathy – screening and early management. **NICE** 2002; 1-15.

LEVELS OF EVIDENCE:

NICE:

Level	Type of Evidence
1a	Evidence from meta-analysis of randomised controlled trials
11a	Evidence from at least one randomised controlled trial
11a	Evidence from at least one controlled study without randomisation
11b	Evidence from at least one other type of quasi-experimental study
111	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies & case control studies
1V	Evidence from expert committee reports or opinions &/or clinical experience of respected authorities

Grading of clinical recommendations

Grade	Evidence (see table above)
A	Directly based on category 1 evidence
B	Directly based on category 11 evidence, or extrapolated recommendation from category 1 evidence
C	Directly based on category 111 evidence, or extrapolated recommendation from category 1 or 11 evidence
D	Directly based on category 1V evidence, or extrapolated recommendation

	from category I, II or III evidence

Eccles M et a (1998) North of England Based Guidelines Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *BMJ* 316:1369.

SIGN:

Level	Evidence
1^{++}	High quality meta-analysis, systematic reviews of RCTs, or RCTs with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1^{-}	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2^{++}	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias & a high probability that the relationship is causal
2^{+}	Well-conducted case control or cohort studies with a low risk of confounding or bias & moderate probability that the relationship is causal
2^{-}	Case control or cohort studies with a high risk of confounding or bias & a significant risk that the relationship is not causal
3	Non-analytical studies, e.g. case reports, case series
4	Expert opinion

DIABETES NSF:

Level	Evidence
1	Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials
2	Systematic reviews of case control or cohort studies, or case control or cohort studies
3	Non-analytic studies, eg case reports, case series
4	Expert opinion (in absence of any of the above)

ADA:

Level	Evidence
A	Clear / supportive evidence from well-conducted, generalizable, randomised controlled trials that are adequately powered
B	Supportive evidence from well-conducted cohort studies
C	Supportive evidence from poorly controlled or uncontrolled studies
E	Expert consensus or clinical experience

Location: Standards are located in diabetes centre (Clerical Processing Room), pathways used at visit are located in patient notes. Clinic sheets & letters from visit are located in patients notes.

Pages: Standards 7 pages, pathway for each visit 1 pages.

DIABETES PATHWAYS

Hospital Outpatients:
New Patient Clinic
Education Clinic
Insulin Clinic
Discharge Clinic
Community Support Clinic
Young Adults Clinic
Joint Ante-natal Clinic
Complex Patient Clinic
Foot Clinic

Hospital In-patients:
Blood Glucose Monitoring
Investigations

Diabetes Discharge Clinic Care Pathway

Patient details

Date: _____
Time Seen by Specialist: _____

Cons/SPR/Nurse Cons (delete as app.)

	Y	N		**Variance** (cont. over page if needed)
Explain clinic	☐	☐		
Review meds./targets	☐	☐	Repeat tests as nec.	
Is HbA1c < target?	☐	☐	If no, adjust DM management	
Is BP < target?	☐	☐	If no, ask GP to adjust meds.	
Right statin or not indicated?	☐	☐	If no, ask GP to start / ↑ statin	
On fibrate or not indicated?	☐	☐	If no, ask GP to start Fenofibrate 267 mg	
Urine clear of blood/nitrite?	☐	☐	If no, do MSSU	
Is ACR < target?	☐	☐	If no, & no Neph. repeat ACR	
Aspirin or not indicated?	☐	☐	If no, ask GP to start 75mg od	
Ramipril or not indicated?	☐	☐	If no, ask GP to start & titrate 10mg od	
Have drug info sheets?	☐	☐	If no, give drug info. sheets	
Organise Follow Up Appointment				
All parameters in target	☐	☐	Discharge to GP	
Expected to hit targets	☐	☐	Discharge to GP	
Informed choice not to act	☐	☐	Discharge to GP	
Microalb., & on treatment	☐	☐	Discharge to GP	
Need input to improve BG	☐	☐	CSC /YAC	
Need insulin / a change	☐	☐	IC / CC	
Problematic Neuropathy	☐	☐	Neuropathy Clinic	
Problematic hypo unawareness	☐	☐	CSC	
Nephropathy	☐	☐	Nephropathy Clinic	
Sort FU & paperwork	☐	☐		
& to see GP in 10 days				

Signature _____
Record Time finish _____

APPENDIX 3

SEMI-STRUCTURED INTERVIEW OF PROFESSIONALS FOR KNOWLEDGE QUESTIONNAIRE DEVELOPMENT

EXPLAIN PURPOSE OF INTERVIEW

I am designing a questionnaire to examine nurses knowledge and management of hospital in-patients with diabetes. The purpose of this interview is to find out what you think.

EXPLAIN STRUCTURE OF INTERVIEW

The interview will be taped, however your answers will be confidential. The interview should take no longer than 1 hour to complete.

- nurses = ward based staff nurses
- management of hospital in-patients

QUESTIONS

DEFINITIONS OF DIABETES

Q1. What would you expect nurses to know about the physiology of diabetes?

Q2. Discuss what nurses should know about Type 1 diabetes?

Q3. Discuss what nurses should know about Type 2 diabetes?

If the response is short, pick up on key words they mention, ie. Pancreas, insulin, glucose, liver, glucogenesis etc. try and gain a lot of detail on what they should know.

BLOOD GLUCOSE MONITORING

Q1. In your opinion, is this aspect of diabetes well managed in hospitals?

Q2. Do you think nurses understand the importance of BGM?

Q3. What are the main issues around BGM by staff nurses?

Q4. Would you expect nurses to understand about different levels of blood glucose, if yes, what would you expect them to know.

Q5. How can we tackle the problems associated with BG monitoring in hospital?

Q6. In your opinion, is it appropriate for unqualified members of staff to perform BG monitoring?

MEDICATIONS

Q1. What would you expect nurses to know about oral diabetic medications?

Q2. What would you expect nurses to know about the different types of insulin?

Follow this with: Is this important?

Q3. In your experience, is the administration of diabetic medications and insulin well managed in hospital?

If No, how do you think we can improve the administration of diabetes medications?

HYPOGLYCAEMIA

Q1. What would you expect nurses to know about hypoglycaemia and it's treatment?

Q2. If a patient with type 1 diabetes had symptoms of hypoglycaemia pre lunch, and their insulin was due, what actions would you expect the nurse to take?

HYPERGLYCAEMIA

Q1. What would you expect nurses to know about hyperglycaemia?

Q2. At what level of BG would you expect nurses to be concerned about hyperglycaemia, and what action would you expect them to take?

COMPLICATIONS

Q1. What would you expect nurses to know about the complications associated with diabetes?

EYES

Q2. What do you think nurses should know about diabetes and eye disease?

Follow with a why is this important?

FEET

Q1. What would you expect nurses to know about diabetic foot complications?

Q2. What advice would you expect a nurse to give a patient with diabetes on caring for their feet?

NEPHROPATHY

Q1. Would you expect nurses to know about diabetic nephropathy? If yes, what should they know?

NEUROPATHY

Q1. Should nurses know about neuropathy? If yes, what would you expect them to know?

HEART DISEASE

Q1. What would you expect nurses to know about IHD and diabetes?

Why is it important that nurses understand about the complications associated with diabetes?
How would you expect them to use this knowledge when caring for patients on the ward?
Are there any particular complications of diabetes where you feel knowledge is poor?

DIET

Q1. What should nurses know about the dietary recommendations for people with diabetes, how would you expect them to use this knowledge?

FASTING/SURGERY

Q1. What should nurses know about how to manage patients with diabetes who are not eating?

Q2. How would you expect them to care for patients who are not eating?

EDUCATION/DISCHARGE

Q1. Should general nurses be educating patients with diabetes?

Follow yes or no answer with a Why question if not explained.

Q2. Which areas if any, do you think nurses should be educating patients on?

Q3. What advice would you expect nurses to give patients/families on discharge?

Q4. Do you think the pre-registration training provides nurses with adequate knowledge of diabetes?

If no, what other forms of education regarding diabetes, are available to nurses?

GENERAL

Q1. Overall, in your experience do you think nurses have an adequate understanding of how to manage in-patients with diabetes?

Q2. In your opinion, what is the best way to ensure ward nurses have adequate knowledge to management diabetes appropriately?

Q3. What concerns you the most about nurses management of in-patients with diabetes?

Q4. What is the worst incident you have experienced relating to the management of an in-patient with diabetes?

Q5. Are there any other issues related to nurses knowledge of diabetes, which you wish to discuss?

Please complete the following questionnaire by circling Yes, No or Don't Know for each answer.

PHYSIOLOGY

Q1	Type 1 diabetes is caused by an absolute lack of insulin production.	**Y**	**DK**	**N**
Q2	Type 2 diabetes is usually associated with insulin resistance.	**Y**	**DK**	**N**
Q3	Insulin increases blood glucose.	**Y**	**DK**	**N**
Q4	Type 1 diabetes is more serious than Type 2 diabetes.	**Y**	**DK**	**N**
Q5	All patients treated with insulin have Type 1 diabetes.	**Y**	**DK**	**N**
Q6	Obesity is a risk factor for Type 2 diabetes.	**Y**	**DK**	**N**

BG MONITORING

Q7	When the BG meter on the ward is in use Quality Assurance checks should be carried out once a day.	**Y**	**DK**	**N**
Q8	Whilst in hospital patients with Type 1 diabetes always need 4 tests a day, pre-meal & pre-bed.	**Y**	**DK**	**N**
Q9	When in hospital patients with Type 2 Diabetes always need to do one BM per Day.	**Y**	**DK**	**N**

Q10	A BM greater than 12mM should always be reviewed by a doctor.	Y	DK	N
Q11	It is important to have a pattern of BMs over a few days before changing treatment.	Y	DK	N
Q12	BMs in hospital may differ from those recorded by the patient at home.	Y	DK	N

MEDICATIONS

Q13	Metformin typically causes hypoglycaemia.	Y	DK	N
Q14	Glibenclamide is the drug of choice in Type 2 diabetes.	Y	DK	N
Q15	Metformin is the drug of choice in patients with Type 2 diabetes who are overweight.	Y	DK	N
Q16	Gliclazide should be taken after meals.	Y	DK	N
Q17	Patients should not take their tablets if they are unable to eat their food.	Y	DK	N
Q18	Metformin is safe in kidney impairment.	Y	DK	N

INSULIN

Q19	Human Mixtard 30 contains 70% cloudy insulin & 30% soluble.	Y	DK	N

Q20	If you had to mix Actrapid with Insulatard the best technique is to draw up the Insulatard first.	Y	DK	N
Q21	Pre-mixed insulins are typically taken twice a day.	Y	DK	N
Q22	Soluble insulin can be given IV.	Y	DK	N
Q23	Actrapid should be given 5min before food.	Y	DK	N
Q24	Insulin pen devices must be stored in a fridge.	Y	DK	N

HYPOGLYCAEMIA

Q25	Aggression is a symptom of hypoglycaemia.	Y	DK	N
Q26	Shaking is a symptom of hypoglycaemia.	Y	DK	N
Q27	Diabetics may go hypo many hours after exercise.	Y	DK	N
Q28	Poor intake of carbohydrate is a cause of hypoglycaemia in patients on insulin.	Y	DK	N
Q29	A cheese sandwich is an appropriate initial treatment for hypoglycaemia.	Y	DK	N
Q30	When a BM is less than 4mM you should omit insulin.	Y	DK	N

HYPERGLYCAEMIA

Q31	Hyperglycaemia is high blood sugars.	**Y**	**DK**	**N**
Q32	Lethargy is a symptom of hyperglycaemia.	**Y**	**DK**	**N**
Q33	Impotence can be caused by longstanding hyperglycaemia.	**Y**	**DK**	**N**
Q34	Acute illness is a typical cause of hyperglycaemia.	**Y**	**DK**	**N**
Q35	Thirst is a symptom of hyperglycaemia.	**Y**	**DK**	**N**
Q36	If a patient with Type 1 diabetes is ill and has hyperglycaemia, you should check for ketones.	**Y**	**DK**	**N**

COMPLICATIONS

Q37	Retinopathy is the leading cause of blindness in young adults in developed countries.	**Y**	**DK**	**N**
Q38	Most Type 2 patients with Nephropathy are dead within 5 years of diagnosis.	**Y**	**DK**	**N**
Q39	Loss of sensation is an indication that the patient is at risk of diabetic foot disease.	**Y**	**DK**	**N**
Q40	Tight BP control is important			

	in patients with Nephropathy.	**Y**	**DK**	**N**
Q41	Good glycaemic control can prevent complications of diabetes.	**Y**	**DK**	**N**
Q42	Patients with diabetes are more at risk of coronary heart disease than patients without diabetes.	**Y**	**DK**	**N**

SCREENING / PREVENTION

Q43	Patients with diabetes should have their eyes checked only if they have problems.	**Y**	**DK**	**N**
Q44	Patients with diabetes should have their feet checked by a chiropodist or doctor at least every 5 years	**Y**	**DK**	**N**
Q45	Proteinuria can signify diabetic kidney disease.	**Y**	**DK**	**N**
Q46	Patients with diabetes should never cut their own toe nails.	**Y**	**DK**	**N**
Q47	Patients should only have their eyes checked in the hospital diabetes clinic.	**Y**	**DK**	**N**
Q48	The Annual Review is a yearly Check of eyes, feet, kidneys, cholesterol and BG control.	**Y**	**DK**	**N**

DIET

Q49	Patients with diabetes should have a diet with no sugar, restricted protein, low fat, restricted carbohydrates.	**Y**	**DK**	**N**

Q50	Patients with diabetes must never eat cakes or sweets.	**Y**	**DK**	**N**
Q51	Special Diabetic Foods are a good choice for patients with diabetes.	**Y**	**DK**	**N**
Q52	Peas, beans & lentils can help control BG levels.	**Y**	**DK**	**N**
Q53	Patients with type 1 diabetes need a late night snack.	**Y**	**DK**	**N**
Q54	Patients with diabetes must not drink alcohol	**Y**	**DK**	**N**

SURGERY/FASTING

Q55	The most appropriate way to manage a patient on insulin going to theatre is to use an insulin pump & sliding scale.	**Y**	**DK**	**N**
Q56	When changing from a GKI regimen back to the patients normal insulin you *should stop* the GKI the night before you start the normal insulin.	**Y**	**DK**	**N**
Q57	Patients with diabetes often need to stay in hospital longer after surgery than patients without diabetes.	**Y**	**DK**	**N**
Q58	Patients with diabetes must never be fasted for a hospital procedure.	**Y**	**DK**	**N**
Q59	When possible patients with diabetes should be on the morning list for surgery.	**Y**	**DK**	**N**

Q60	Patients with Type 1 diabetes who are unable to eat should be on a GKI regimen.	**Y**	**DK**	**N**

GENERAL

Q61	HbA1c is a test to measure average BG over 6-12 weeks.	**Y**	**DK**	**N**
Q62	Patients treated with tablets or insulin for their diabetes must inform the DVLA.	**Y**	**DK**	**N**
Q63	Patients on insulin cannot drive public service vehicles.	**Y**	**DK**	**N**
Q64	Patients with diabetes are not excluded from any forms of employment.	**Y**	**DK**	**N**
Q65	All patients with diabetes have to pay for their prescriptions.	**Y**	**DK**	**N**
Q66	There are national guidelines for the management of diabetes.	**Y**	**DK**	**N**

IN-PATIENT MANAGEMENT OF DIABETES –AUDIT

Pt. NAME: _____

HOSP. NO: _____

Date Admitted: _____

Date Discharged: _____

Ward: _____

Reason for Admission: _____

Record frequency of BG monitoring & timing:

_____

_____

_____

_____

_____

	Y	N	NA
Was Pt on a GKI?	☐	☐	☐
If yes, were bloods done as per guidelines?	☐	☐	☐
Was HbA1c checked?	☐	☐	☐
Was HbA1c above target?	☐	☐	☐
If yes was it acted on?	☐	☐	☐
HbA1c checked at 3 months?	☐	☐	☐
Urinalysis for protein?	☐	☐	☐
Was it positive ?	☐	☐	☐
If positive was it acted on?	☐	☐	☐
Creatinine checked?	☐	☐	☐
Was it abnormal?	☐	☐	☐

If yes was it acted on?	☐	☐	☐
Cholesterol checked?	☐	☐	☐
Cholesterol above target?	☐	☐	☐
If yes was it acted on?	☐	☐	☐
Any record of foot exam?	☐	☐	☐
Referral to DLN?	☐	☐	☐
If yes, seen by DLN?	☐	☐	☐
Has pt been readmitted since this episode?	☐	☐	☐

If yes, record when:

_____

_____

NOTES:

_____

_____

_____

_____

_____

_____

_____

_____

BARTHEL INDEX

Bowels
0 = Incontinent
1 = Occasional accident
2 = Continent

Bladder
0 = Incontinent or catheterised & unable to manage
1 = Occasional accident (max 1x24hours)
2 = Continent

Grooming
0 = Needs help
1 = Independent. face / hair, teeth / shaving

Toilet Use
0 = Dependent
1 = Needs some help but can do something
2 = Independent (on & off, dressing, wiping)

Feeding
0 = Unable
1 = Needs help cutting, spreading butter etc.
2 = Independent

Transfer
0 = Unable
1 = Major help (1-2 people, physical)
2 = Minor help (verbal or physical)
3 = Independent

Mobility
0 = Immobile
1 = Wheelchair independent including corners
2 = Walks with help of 1 person (verbal or physical)
3 = Independent

Dressing
0 = Dependent
1 = Needs help, but can do half unaided
2 = Independent

Stairs
0 = Unable
1 = needs help (verbal, physical, carrying aid)
2 = Independent

Bathing
0 = Dependent
1 = Independent

TOTAL:

APPENDIX 4

PATIENT INFORMATION SHEET

IMPACT OF INTEGRATED CARE PATHWAY ON MANAGEMENT OF HOSPITAL IN-PATIENTS WITH DIABETES

Dear Sir/Madam

This leaflet explains the project in which you have been asked to participate. Please read it carefully. If there is anything you do not understand, please ask the project leader (Sarah O'Brien).

WHAT IS THE STUDY ABOUT

The overall aim of this study is to develop a care pathway to assist in the management of in-patients with diabetes. A care pathway is a set of guidelines for nursing and medical staff explaining the care that should be given to patients. Care pathways for diabetes are being tested on the medical wards at Whiston Hospital. Patients with diabetes will be randomised to either a care pathway or a usual nursing care plan for diabetes. In order to assess the impact of the pathway on the management of diabetes, staff will be interviewed, case notes will be reviewed and patients will be asked to complete a questionnaire about their satisfaction with the treatment they received. The management of patients on pathways will be compared to patients not on pathways.

WHAT DO I HAVE TO DO

You have been asked to give your consent to the study. This means you agree to being randomised to either a care pathway or a normal care plan for diabetes. If you agree to take part you will be asked to complete a questionnaire (Diabetes Treatment Satisfaction Questionnaire) at the start and end of your stay in hospital. The purpose of the questionnaire is to assess how satisfied you are with the treatment you receive for your diabetes. It should take no more than 10 minutes to complete.

You will be invited to attend the Diabetes Centre approximately 3 months after your stay in hospital. The purpose of this visit will be to assess your diabetes control and find out what you thought of your management during your stay in hospital.

RISKS/BENEFITS

There are no risks involved in terms of your personal safety.

The potential benefits of participating are that you will be helping in the development of a tool which may help staff to deliver a higher quality of care to patients with diabetes.

CONFIDENTIALITY

You may be assured that the study documents are confidential and your identity will not be disclosed. For the purposes of the study, you will have an Identification number, a record sheet of all identification numbers and the subjects names will be kept and it will be securely locked away. You will not be identified in any publications arising from this study, and your replies will not be disclosed to anyone.

YOUR VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary and you are free to withdraw at any time.

If you refuse to take part this will not affect the care you receive within the hospital.

FURTHER INFORMATION

If you have any questions or require further information, please contact Sarah O'Brien 0151 426 1600 bleep 1480 or Susan Michaels 0151 426 1600 bleep 1344.

Thank you for taking the time to read this information leaflet. If you wish to take part, please read and sign the consent form.

You should keep a copy of this information for future reference.

PATIENT CONSENT FORM

DIABETES CARE PATHWAYS

The patient should complete the whole of this sheet him / herself.

TITLE OF PROJECT : Impact of care pathway on management of hospital in-patients with diabetes.

	Please delete as appropriate
Have you read and understood the patient information sheet?	**Yes/No**
Have you had an opportunity to ask questions about the study?	**Yes/No**
Have you received satisfactory answers to all your questions?	**Yes/No**
Have you received enough information about the study?	**Yes/No**

Do you understand that you are free to withdraw from the study:

- at any time
- without having to give a reason
- without affecting your care **Yes/No**

Patient's signature: _____ Date: _____

Print Name: _____

I confirm that I have explained details of this study to the above named person and I am satisfied that he/she has given informed consent.

Investigator's signature: _____ Date: _____

Print Name: _____

APPENDIX 5

NEPHROPATHY CARE PATHWAYS

DIABETES NEPHROPATHY SERVICE CLINIC STANDARDS

1. Patients referred with Nephropathy (Neph) and Microalbuminuria (MA) will be assessed. Those at greatest risk will be followed up, others will be discharged with a management plan.

   - Only patients with confirmed Neph or MA will be seen in this clinic. Two raised ACRs are needed to confirm MA / Neph. **Diagnosis:**

   MA: albumin:creatinine ratio ≥ 2.5mg/mmol (men) or 3.5mg/mmol (women), or albumin concentration ≥ 20mg/l.

   Neph: albumin:creatinine ratio ≥ 30mg/mmol or albumin concentration ≥ 200mg/l.

   Note: Grade C recommendation, NICE 2002.

2. Patients with Microalbuminuria will generally be discharged with management plan.

3. At the first appointment an appropriately full evaluation will be carried out and this will be repeated approximately annually thereafter. At any subsequent appointments progress will be monitored and adjustments made to help patients to meet their targets.

4. The Nephropathy Clinic form will be used for all appointments and sent to the GP (after each appointment) with a typed letter. For patients under a nephrologist a copy will be sent to the nephrologist. Patients will be sent a copy of the clinic form and GP letter.

5. If a patient does not attend for their appointment (DNA) they will be sent a DNA letter (with a copy to their GP) and discharged from the clinic. If the patient subsequently phones and asks for another appointment (they genuinely forgot the first one) they will be sent another appointment, otherwise they must be re-referred by their GP.

DIABETES NEPHROPATHY CLINIC

STANDARDS FOR EACH VISIT

STANDARD 1 **Patients will be seen at the correct appointment time.**

STANDARD 2 **Patients will spend up to 25mins with a Consultant Nurse / Doctor.**

STANDARD 3 **NEW PATIENTS:**

Explain diagnosis and give information sheet.

ALL PATIENTS:

STANDARD 4 **Patients will have all their medications explained to them.**

STANDARD 5 **Patients will have HbA1c checked.**

- **If above target adjust diabetes treatment. If patient requires insulin change – refer to *Insulin Clinic***
- **Discuss diet and exercise when necessary**

STANDARD 6 **Patients with type 2 diabetes should be on Irbesartan 300mgod and patients with type 1 diabetes should be on Ramipril 10mgod for renoprotection (patients already on maximum dose of a different ACE-inhibitor or Angiotensin-II receptor antagonist may not be switched to Irbesartan / Ramipril). Initiate and titrate as outlined below:**

- **IRBESARTAN typically start 150mgod and ask GP to increase to 300mgod after one week.**
- **RAMIPRIL start 2.5mgod and ask GP to titrate over 2-4 weeks to 10mgod.**
- **U&Es must be checked before initiation and approximately 1 week after they are on maximum dose (ask GP). Large rises in creatinine should be discussed**

with Dr Hardy and advise GP to contact clinic if creatinine rises significantly (≥ 40μM or >20%). If potassium rises above 5.5 stop Irbesartan / Ramipril, monitor and also check bicarb levels. If patient hasn't already seen dietitian for low potassium diet, refer. Consider re-introduction if potassium corrects, especially in patients with a low bicarb who are commenced on Sodium Bicarb treatment (Type IV Renal Tubular Acidosis).

- **If Angiotensin-II receptor antagonist / Ace-Inhibitor are contraindicated concentrate on achieving BP target.**

Note: Level 1 evidence for use of ACE-inhibitor in type 1 diabetes & use of A11RA in type 2 diabetes with nephropathy.

Note: Creatinine typically rises after initiation of ACE-inhibitor or A11RA but a large progressive rise may signal acute renal failure secondary to renovascular compromise. Evidence from recent large A11RA nephropathy trials suggests a better outcome for those who remain where possible on RAAS blockade despite a creatinine rise.

STANDARD 7 **Patients will have BP checked. If not ≤ 125 / 75 adjust treatment as per protocol summarised below:**

- **If not already on Irbesartan / Ramipril initiate as outlined in standard 6.**
- **If BP still >125 / 75, start Bendroflumethiazide 2.5mg od (if creatinine normal) or Furosemide 20mg od (if creatinine abnormal).**
- **If BP still above target, add Amlodipine 5mg od, increased to 10mg od.**
- **If BP still above target, then in the absence of contraindications add Atenolol 50mg od, titrated up or down as necessary to maintain heart rate at approximately 60bpm.**
- **If after this, still >125 / 75, add Doxazosin (plain) 4mgod, increase to 8mgod. If still above target increase**

Doxazosin in 4mg increments until on max dose of 16mg od.

- **If still above target, use Moxonidine 200mcgod, increase to 200mcg bd if necessary and 300mcg bd (max. dose).**
- **If still above target after all these options, DISCUSS WITH Dr HARDY and an individual management plan will be agreed. Some patients may be commenced on a combination of Irbesartan and an Ace-Inhibitor.**
- **Where possible encourage patients to do home BP monitoring and review these results. Patients with persistently high BP will be loaned a home BP machine by the clinic if possible.**

Note: International guidelines differ in their recommendation targets for BP in microalbuminuria & nephropathy. Existing (level 1-2) evidence suggests SBP target in the range 122-140 & DBP in the range 75-85. We have adopted 125/75 on this basis.

STANDARD 8 **Patients will typically be referred to a dietitian at their first visit for low potassium, low phosphate and protein restriction (0.8-1g/kg) dietary advice. At subsequent visits patients will typically be referred to a dietitian (Nicola) as outlined below:**

- **Creatinine > 150μM**
- **Potassium >5.2**
- **Raised Phosphate**
- **Weight reducing advice (if none previously)**
- **Poor glycaemic control where dietary intake judged to be a key factor**
- **Nicola will repeat blood tests as needed to monitor impact of dietary intervention (U&Es, biacarb, phosphate, calcium).**

Note: There is level 1 evidence (SIGN, 2002) for protein restriction in type 1 diabetes & most authorities recommend it (ADA, 2002).

STANDARD 9 **Patients will be weighed, and BMI recorded.**

- **If overweight / gained weight discuss options for losing weight & refer to dietitian (Nicola) as necessary.**

STANDARD 10 **Typically patients should be on a statin. Patients not on statin treatment will be started on Simvastatin 40mgod. Patients already on statin treatment will have dose optimised (aim is to have all patients on either Simvastatin 40mgod or Atorvastatin 40mgod). Lipids will be checked at annual review or if lipid treatment was adjusted last visit, therapy will be adjusted as outlined below:**

- **Target LDL ≤ 2.0mmol/L, if above target increase statin. If already on Simvastatin at dose <40mgod increase it to 40mgod. If on Atorvastatin <40mgod increase it to 40mgod. If LDL still >2.0 on Simvastatin or Atorvastatin 40mgod change patient to Atorvastatin 80mgod. If LDL remains >2.0mmol/L add Ezetimibe.**
- **Target HDL ≥1.0mM (Ideal). Use Fenofibrate micro 267mg od. If HDL doesn't respond consider Niaspan instead of fibrate. Consider Niaspan if renal impairment.**
- **Target Triglycerides ≤2.0mM (Ideal), use Fenofibrate 267 mg od.**
- **If a patient requires both a statin and a fibrate advise them to take fibrate in the morning and the statin at night (pre-bed).**

Note: target lipids: total cholesterol <4; HDL-C ≥1.0; & trigs. ≤2.0 are NSF recommendations, based on level 2 evidence. LDL target is BHS guidance 2004.

Note: the European Task Force for CHD is of the view that beneficial effects of statins are a class effect &

Atorvastatin, which has a good safety record, is the current most cost-effective statin.

STANDARD 11 **All patients should be on Aspirin 75mgod (if no contraindications) once BP controlled (systolic <145). If patient allergic to Aspirin use Clopidogrel 75mgod. If dyspepsia use Aspirin 75mg od and Lansoprazole 15mg od.**

Note: There is level 1 evidence (HOT Study) for primary prevention of CHD in high risk diabetic patients (SIGN, 2002) but this must be balanced against a risk of bleeding.

STANDARD 12 **Patients will have urinalysis. If nitrite or haematuria an MSSU will be sent. Urinary tract infections (UTI) will be treated with appropriate antibiotics. Persistent haematuria (≥ 2 occasions) patients will be referred to One Stop Haematuria Clinic (Mr Gana). If patient has pyuria sample will be repeated. If have pyuria on 3 occasions arrange 3 early morning samples to test for TB & refer to Mr Gana (he will organise IVU).**

STANDARD 13 **U&Es will be checked & results discussed with Dr Hardy as necessary. Patients known to have a creatinine >120μM will have FBC & Ferritin checked. Patients known to have creatinine > 150μM will also have calcium, phosphate, bicarb, & PTH checked.**

Note: Level IV evidence – Renal Association recommendations, 2002.

STANDARD 14 **ANAEMIA:**

- **If Haemoglobin <11.5 g/dl (female), <13 g/dl (male) & MCV ≤76 fl do GI Investigations.**
- **GI Investigations:**
  - **Barium enema**

- Sigmoidoscopy
- OGD
- Antigliadin antibodies (Type 1 only)

- If Haemoglobin <11.5 g/dl (female), <13 g/dl (male) & MCV 77-96 fl send patient standard anaemia letter (patient will decide whether to have GI investigations).
- If Haemoglobin <11.5 g/dl (female), <13 g/dl (male) & MCV >96 fl do B12 & folate. If B12 & or folate abnormal treat. If B12 & folate normal do GI investigations as letter.

- Once investigations completed (or patient chosen not to have them) treat anaemia:
- Ferrous sulphate 200mg b.d., monitor Hb & Ferritin every 3 months, target Ferritin >150μg / l.
- If Ferritin <100μg/l in 3 months, refer to RLUBH as they may require IV Iron.

STANDARD 15 CALCIUM, PHOSPHATE, BICARB, PTH:

- If Calcium low start Alfacalcidol 0.25mcg od. Write to patient & explain starting drug & send them a blood form to have calcium levels checked two weeks after start Alfacalcidol. If result is low or normal leave & re-check at next visit, if calcium high stop Alfacalcidol. Increase dose at each visit according to serum calcium levels, always checking 2 weeks after increased dose & acting as outlined above.

- If Phosphate raised, use Phosphate binder. Start Calcium Carbonate 420mg tds & refer to dietitian for low phosphate diet. Repeat Phosphate in one month (send form to patient) if still raised refer to nephrologist.

- If Bicarb low, start Sodium Bicarb 600mg tds, increase dose according to bicarb levels (max. 4.2g per day).

- If PTH > 2x upper limit of normal start Alfacalcidol 0.25mcg od. If not <2x upper limit of normal when re-checked refer to nephrologist.

Note: Level IV evidence – Renal Association recommendations, 2002.

STANDARD 16 **ACR will be checked at each visit. Creatinine clearance will be calculated if and when needed (MDRD Formula).**

STANDARD 17 **An appropriate medical history will be recorded on clinic form and list of complications updated on diabetes folder. Patients will be reminded to have their eyes & feet screened in the community programmes & if necessary given a list of accredited optometrists / podiatrists if they are not already in the programme. Patients will be asked if they have a copy of the diabetes education book & whether they have read & understood it. They will be advised to re-read the sections on Hypo, Driving & Sick Day Rules. If they do not know about these sections they will be educated as per staff education pack.**

Patients will be asked if they wish to receive structured education for an update and if they do they will be referred to education clinic.

STANDARD 18 **Discuss CVS risk factors with patient, if they smoke strongly advise against it and advise re: community cessation programmes. Encourage patients to exercise regularly and eat a healthy diet.**

Note: There is level 1 evidence (SIGN, 2002) for a small but significant benefit from advice ± smoking cessation programmes ± pharmacological intervention in smoking cessation. Bupropiocin appears to be the most effective agent.

STANDARD 19 **Patients will be given a Diabetes Education Book if they haven't already got one and advised to read it & ask about any sections they don't understand at their next visit or to contact Sarah.**

STANDARD 20 **If any new drugs are started patients will be given appropriate Drug Information Sheets.**

STANDARD 21 **Patients will be given a further appointment before they leave and a copy of the clinic sheet. They will be sent a copy of the GP letter once it is typed.**

STANDARD 22 **The GP will be sent a copy of the clinic sheet & a letter typically within 48 hours of the clinic (unless secretary away), once the results of any tests come back they will be recorded on the clinic sheet & this copy also sent to the GP.**

Diabetes Complex Patient Clinic -Nephropathy Pathway & Standards

Issue Date: January 2005

Version: 17

Review Date: January 2006

Responsibility for pathway / review: Mrs S O'Brien, Dr K Hardy, Dr S Hulme

Developed by: Mrs S O'Brien, Dr K Hardy, Dr S Hulme (Dr Harper – nephrologist consulted)

References / Guidelines:

- American Diabetes Association. Clinical Practice Recommendations 2002. **Diabetes Care** 2002; 25 (Suppl 1) S21 – S147.
- Department of Health. Diabetes National Service Framework for Diabetes. www.doh.gov.uk nsf diabetes.htm
- Scottish Intercollegiate Guidelines Network. Management of Diabetes. A national clinical guideline. **SIGN** 2001.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Renal disease – prevention and early management. **NICE** 2002; 1-16.
- National Institute for Clinical Excellence. Management of type 2 diabetes. Retinopathy – screening and early management. **NICE** 2002; 1-15.

LEVELS OF EVIDENCE:

NICE:

Level	Type of Evidence
Ia	Evidence from meta-analysis of randomised controlled trials
IIa	Evidence from at least one randomised controlled trial
IIa	Evidence from at least one controlled study without randomisation
IIb	Evidence from at least one other type of quasi-experimental study
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies & case control studies
IV	Evidence from expert committee reports or opinions &/or clinical experience of respected authorities

Grading of clinical recommendations

Grade	Evidence (see table above)
A	Directly based on category 1 evidence

B	Directly based on category 11 evidence, or extrapolated recommendation from category 1 evidence
C	Directly based on category 111 evidence, or extrapolated recommendation from category 1 or 11 evidence
D	Directly based on category 1V evidence, or extrapolated recommendation from category1, 11 or 111 evidence

Eccles M et a (1998) North of England Based Guidelines Development Project: guideline for angiotensin converting enzyme inhibitors in primary care management of adults with symptomatic heart failure. *BMJ* 316:1369.

SIGN:

Level	Evidence
1^{++}	High quality meta-analysis, systematic reviews of RCTs, or RCTs with a very low risk of bias
1^{+}	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1^{-}	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2^{++}	High quality systematic reviews of case control or cohort studies. High quality case control or cohort studies with a very low risk of confounding or bias & a high probability that the relationship is causal
2^{+}	Well-conducted case control or cohort studies with a low risk of confounding or bias & moderate probability that the relationship is causal
2^{-}	Case control or cohort studies with a high risk of confounding or bias & a significant risk that the relationship is not causal
3	Non-analytical studies, e.g. case reports, case series
4	Expert opinion

DIABETES NSF:

Level	Evidence
1	Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials
2	Systematic reviews of case control or cohort studies, or case control or cohort studies
3	Non-analytic studies, eg case reports, case series
4	Expert opinion (in absence of any of the above)

ADA:

Level	Evidence
A	Clear / supportive evidence from well-conducted, generalizable, randomised controlled trials that are adequately powered
B	Supportive evidence from well-conducted cohort studies
C	Supportive evidence from poorly controlled or uncontrolled studies
E	Expert consensus or clinical experience

Location: Standards are located in diabetes centre, pathways, clinic sheets and letters for each visit are located in patients notes.

Pages: Standards 10 pages, pathway for each visit 1 page.

DIABETES PATHWAYS
Hospital Outpatients:
New Patient Clinic
Education Clinic
Insulin Clinic
Discharge Clinic
Community Support Clinic
Young Adults Clinic
Joint Ante-natal Clinic
Complex Patient Clinic
Foot Clinic
Hospital In-patients:
Blood Glucose Monitoring
Investigations

Diabetes Complex Patient Clinic
Nephropathy Care pathway

Patient details

Date: _____

Time Seen by Specialist : _____

Cons/ Nurse Cons. (delete as approp.)

	Y	N		Variance (cont. over page if needed)
Explain clinic	☐	☐		
Pt been before?	☐	☐	If no, give Neph. Sheet	
Explain meds.	☐	☐		
HbA1c < target?	☐	☐	If no, adjust DM management	
Pt on max. AIIRA / ACE- ?	☐	☐	If no, ask GP to start/titrate to max.	
BP < target?	☐	☐	If no, ask GP to adjust meds.	
Right statin or not indicated?	☐	☐	If no, ask GP to start / ↑ statin	
On fibrate or not indicated?	☐	☐	If no, ask GP to start Fenofibrate 267 mg	
Under nephrologist/ not nec.?	☐	☐	If no, then refer	
Aspirin or not indicated?	☐	☐	If no, ask GP to start 75mg od	
Urine clear of blood/nitrite?	☐	☐	If no, do MSSU	
Last creatinine <120 μM?	☐	☐	If no, do FBC & Ferritin	
Last creatinine <150 μM?	☐	☐	If no, do Ca^{2+}, PO_4^{3-}, HCO^{3-}, & PTH	
Have drug info sheets?	☐	☐	If no, give drug info. sheets	
Sort appts & paperwork & to see GP in 10 days	☐	☐		

Signature _____

Record time finish _____

Diabetes Nephropathy Clinic

NAME: NO. Attach sticky label	Urinanalysis G K P B N	Date	Appointments
	Wt (kg) / Ht (m) / B.M.I.	B.P.(1) / B.P.(2)	

KNOWN COMPLICATIONS

MICROVASCULAR	MACROVASCULAR
1.	1.
2.	2.
3.	3.
4.	4.
5.	5.

PATIENT Age ____ Diabetes Duration ____

MEDICATIONS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

DIABETES Type Type 1 ☐ Type 2 ☐ Other _____ ☐
DIABETES Rx Diet only ☐ OHA ☐ Insulin +OHA ☐ Insulin ☐

	Y	N	
Weight loss	☐	☐	_____
Hypoglycaemia	☐	☐	_____
Major (in last yr)	☐	☐	_____
Unawareness?	☐	☐	_____
Nocturnal?	☐	☐	_____
BG↑ Emerg in last yr	☐	☐	_____
Childbearing Age?	☐	☐	_____

Rapid Communication (letter to follow)

HISTORY

	Y	N
MI / Angina / Re-vasc	☐	☐
Stroke / TIA	☐	☐
Claudication / Re-vasc.	☐	☐
BP↑ on Treatment	☐	☐
Painful Neuropathy	☐	☐
Attends Nephrologist	☐	☐
Dialysis/Transplant	☐	☐
Registered Blind / Pt sighted	☐	☐
Erectile dysfunction	☐	☐
Metformin Intolerance	☐	☐

KJH:Nephform605
June 2005; Review June 2007

FOOT SCREENING	Y	N
In Community Foot Programme	☐	☐
Advised - join CFP within 4 wk	☐	

EYE SCREENING		
In Eye Programme / Eye Clinic	☐	☐
Advised - join CEP within 4 wk	☐	

SMOKING		
Current Smoker	☐	☐
Advised see GP re Cessn. Prog.	☐	

ALCOHOL		
Alcohol (U/wk _____)	☐	☐
Moderation Advice	☐	

INVESTIGATIONS		RESULTS	TARGETS
HbA1c	☐	____	Target Hba1c _____ %
Creatinine	☐	____	Normal Creatinine < 120 μM
Total cholesterol	☐	____	Target total cholesterol. ≤4.0 mM
Fasting Trigs.	☐	____	Ideal ≤2.0; Pancreatitis risk >10 mM
HDL-cholesterol	☐	____	Target HDL ≥1.0 mM
LDL-cholesterol	☐	____	Target LDL-cholesterol. ≤2.0 mM
Urine ACR	☐	____	Normal ACR M< 2.5 F< 3.5 mg/mM
MSSU	☐	____	Normal
Ca^{2+}	☐	____	Normal 2.20-2.63 mM.
PO_4^{3-}	☐	____	Normal 0.8 - 1.4 mM.
PTH	☐	____	Target ≤2xULN (13.8 pM)
HCO_3^-	☐	____	Normal 22 - 30 mM.
Hb	☐	____	Normal M13.0-17.5, F11.5 –16.5 g/dl
Ferritin	☐	____	Target > 150 ng/ml in CKD
Transferrin Sat^n	☐	____	Target > TSAT 20%
24-hr U Protein	☐	____	Target – "stabilisation" & < 1g/24 hr.
eGFR (MDRD)	☐	____	CKD < 60; severe < 30; ESRD <15

Mx discussed and agreed with Pt, including being given written/verbal information on:

Nephropathy / Microalb.	☐	Clopidogrel	☐	Morphine	☐
Discharge Sheet	☐	Doxazosin	☐	Moxonidine	☐
Dual blockade	☐	Duloxetene	☐	Niaspan	☐
Alfacalcidol	☐	Erythropoietin	☐	Orlistat	☐
Amitriptyline/Imipramine	☐	Ezetimibe	☐	Pregabalin	☐
Amlodipine	☐	Fenofibrate	☐	Ramipril	☐
Aspirin	☐	Ferrous Sulph.	☐	Rosiglitazone	☐
Atorvastatin	☐	Frusemide	☐	Sibutramine	☐
Bendroflumethiazide	☐	Gabapentin	☐	Sildenafil	☐
Bumetanide	☐	Gliclazide	☐	Simvastatin	☐
Calcichew	☐	Irbesartan	☐	Sodium Bicarb.	☐
Carvedilol	☐	Metformin	☐	Tramadol	☐

What Happens Next?

The clinic is run by Sarah O'Brien (Nurse Consultant), Dr Hardy (Consultant), and Dr Hulme (Locum Consultant). You will usually be seen by Sarah O'Brien. If you have any problems in between visits contact Sarah on the number below.

CONTACT NUMBERS

Sarah Obrien 0151 430 1480
(Nurse Consultant)

Produced By Nephropathy Team, Department of Diabetes

Creation date – November 2001
Latest review – September 2005
Review date – August 2007

St Helens and Knowsley Hospitals NHS
NHS Trust

Nephropathy Clinic

NEPHROPATHY PATIENT INFORMATION LEAFLET

Department of Diabetes

Whiston Hospital
Warrington Road
Prescot L35 5DR

What is Nephropathy?

Diabetes can cause kidney damage. This is typically associated with protein leak into the urine. At first only small amounts of protein leak into the urine – MICROALBUMINURIA. Later, larger amounts of protein may leak into the urine – NEPHROPATHY. Left untreated, Nephropathy may progress to kidney failure, heart attack and stroke.

How can I Protect my Kidneys?

You have Diabetic Nephropathy. The aim is to prevent you developing kidney failure, heart attack or stroke.

There are 6 important things we must try to do and these are listed opposite.

1. We must lower your blood pressure, typically to less than 125 / 75. You may need 3 or more tablets to achieve this blood pressure.

2. We must try to use the highest dose you can take of a Kidney-Protecting tablet (Irbesartan or Ramipril).

3. We must start you on a 'Statin' tablet (Simvastatin or Atorvastatin) and maintain your blood lipid levels as follows:
   - LDL <2.0mM (bad fats)
   - Trigs.<2.0mM (bad fats)
   - HDL ≥1.0mM (good fats)

4. We must help you to stop smoking.

5. We must start you on Aspirin 75mg daily.

6. We must try to maintain good blood sugar control.

APPENDIX 6

PUBLICATIONS

O'Brien, S.V., Michaels, S.B., Marsh, J., Hardy, K.J. (2004) The impact of an inpatient diabetes care pathway. *Journal of Diabetes Nursing*, **8**, 253-256.

O'Brien, S.V., Hardy, K.J. (2003) Developing and implementing diabetes care pathways. *Journal of Diabetes Nursing*, **7**, 2, 53-56.

O'Brien, S.V., Michaels, S.B., Hardy, K.J. (2003) A comparison of general nurses' and junior doctors' diabetes knowledge. *Professional Nurse*, **18**,5,257-260.

O'Brien, S.V., Michaels, S.B., Furlong, N.J., Hardy, K.J. (2001) Guidelines make nurses feel better but do they improve care? *The Journal of Diabetes Nursing*, **5**,3,72-74.

O'Brien, S.V., Hardy, K.J. (2000) Impact of a care-pathway-driven diabetes education programme. *The Journal of Diabetes Nursing*, **4**,147-49.

ABSTRACTS AND PRESENTATIONS TO LEARNED SOCIETIES

Hulme, S.A., O'Brien, S.V., Marsh, J., Hardy, K.J. (2005) Aggressive multiple risk factor intervention in Type 2 diabetic nephropathy associated with very low incidence of death, dialysis, doubling serum creatinine and incidence of new cardiovascular disease after 26 months of follow-up. *Diabetes*, **54** (suppl. 1), A55.

Hulme, S.A., O'Brien, S.V., Marsh, J., Hardy, K.J. (2005) Aggressive multiple risk factor intervention in Type 2 diabetic microalbuminuria associated with very low incidence of death, dialysis, doubling serum creatinine and incidence of new cardiovascular disease after 26 months of follow-up. *Diabetes,* **54**(suppl. 1), A196.

O'Brien, S.V., Marsh, J., Michaels, S., McNulty, S.J., Hardy, K.J. (2004) Improved diabetes care and reduced emergency readmissions with inpatient diabetes care pathway – results of a 1-year randomised controlled trial (RCT). *Diabetic Medicine*, **21** (suppl 2),P182.

O'Brien, S.V., Hulme, S.A., Furlong, N.J., Hardy, K.J. (2002) Effects on Death, Dialysis & Doubling of Serum Creatinine of Renin-Angiotensin-Aldosterone-System Blockade and Blood Pressure Control in Diabetic Nephropathy Achievable in Routine Clinical Care. *Diabetes*, **51** (suppl.2), A188.

O'Brien, S.V., Hulme, S.A., Furlong, N.J., Hardy, K.J. *(2002) Comparison* of recent diabetes nephropathy trials with routine care in UK. *Diabetic Medicine,* **19** (Suppl 2), P283.

O'Brien, S.V., Hardy, K.J. (2001) Nurse-led Nephropathy Clinic associated with improved management. *Diabetic Med*, **18** Suppl 2, A94.

Michaels, S.M., O'Brien ,S.V., Furlong, N.J., Hardy, K.J. (2001) Guidelines make nurses feel better but do they improve care. *Diabetic Medicine,* **18** (Suppl 2), A92.

O'Brien, S.V., Hardy, K.J. (2000) Integrated care pathway-driven diabetes education associated with highly significant improvement in diabetes knowledge, diabetes wellbeing and HbA1c. *Diabetologia,* **43** (Suppl 1), A222.

O'Brien, S.V., Hardy, K.J. (1999) Integrated Care Pathway driven diabetes education associated with highly significant improvement in diabetes knowledge, dioabetes wellbeing and HbA1c. *Diabetic Medicine,* **17**, A59.

Hardy, K.J., O'Brien, S.V. (1999) Integrated Care Pathway associated with reduction in diabetes non-attenders from 19% to 1%. *Diabetic Medicine,* **17**, P38.

O'Brien, S.V., Nicholson, J., Hardy, K.J. (1999) Undiagnosed diabetic nephropathy in a UK health district. *Diabetes Update.*

O'Brien, S.V., Nicholson, J., Hardy, K.J. (1999) Improved diagnosis and management of diabetic nephropathy in primary care. *Diabetes Update.*

O'Brien, S.V., Kinloch, T., Hardy, K.J. (1999) Prevalence of Nephropathy in 25 GP Practices (population 135,538 patients) in a UK Health District. *Diabetic Medicine,* **16**, P102.

COPIES PUBLISHED PAPERS

Impact of a care pathway-driven diabetes education programme

Sarah V O'Brien, Kevin J Hardy

Introduction

It is often difficult to incorporate effective programmes of patient education into routine clinical care. This article describes a local initiative in which a care pathway-driven patient education programme was established for people with diabetes. The impact of this programme was evaluated. Results showed that the programme was successful and associated with significant improvements in patient knowledge, wellbeing and glycaemic control. *The article is based on the authors' winning entry to the annual RCN Forum/Novo Nordisk Award for Innovation in Diabetes Nursing (see page 145).*

Education is the cornerstone of diabetes self-management and an essential component of modern diabetes care (BDA, 1987; Dunn, 1990; Fain et al, 1999).

Effective education improves self-management skills and increases patient satisfaction (Brown, 1988; Mensing et al, 2000). However, it is not always a priority for hard-pressed clinicians (Bradshaw et al, 1999). Often, it is delivered in an ad hoc fashion in busy outpatient clinics or as one-off large group sessions with little scope for evaluation or patient feedback.

The Audit Commission (2000) found that the quality of diabetes education in the UK is highly variable. It recommended that structured programmes of patient education should be established as a priority. A major challenge for providers of diabetes care is therefore how to deliver effective education to the very large numbers of people who need it.

Care pathways

Care pathways map a route of care for patients with a given condition in a given setting (Kitchiner et al, 1996; Johnson, 1997; Campbell et al, 1998). Pathways originated from case management and their goal was to establish co-ordinated evidence-based care, maximising use of scarce resources (Currie and Harvey, 1997). The greatest strength of pathways is that the inherent ongoing evaluation of the care process (variance analysis) drives continuous quality improvement.

Local initiative

In March 1999, the diabetes multidisciplinary team at Whiston Hospital implemented a care pathway-driven patient education programme for all patients referred to the clinic. The pathway mapped patient care from GP referral; the new patient clinic (NPC); a week later; to the newly established five-week education programme; right through to the discharge assessment clinic (12 weeks after NPC).

The education programme

All referrals to the NPC are put onto the programme. This consists of five consecutive weekly sessions. Each involves individual and small group work (2–4 people); is highly structured; and has predefined content. Clinicians are encouraged, however, to be flexible and to accommodate patients' needs. Patients could also repeat sessions if need be.

A comprehensive staff education pack, developed by the team, ensures standardisation of advice given. Each step of the programme is underpinned by clearly defined standards. A variance is recorded for any standard not met, allowing for continuous improvement.

Our aim

Our aim was to examine the impact of the care pathway-driven patient education programme on blood glucose control, knowledge and wellbeing in people with diabetes.

Evaluating the programme

Patient knowledge and wellbeing were

ARTICLE POINTS

1 Patient education is the cornerstone of modern diabetes management.

2 Care pathways may facilitate structured evidence-based care.

3 A care pathway-driven education programme was developed to improve patient education.

4 A prospective study was conducted to assess the impact of the education programme.

5 Patient knowledge, wellbeing and HbA_{1c} improved significantly following the education programme.

KEY WORDS

- **Care pathway**
- **Education programme**
- **Quality of life**
- **Blood glucose**
- **Patient knowledge**

Sarah V O'Brien is Diabetes Nurse Specialist and Kevin J Hardy is Consultant Physician and Endocrinologist, at the Diabetes Centre, Whiston Hospital, Prescot.

PAGE POINTS

1 Knowledge and wellbeing were measured at week 0 and week 6.

2 HbA_{1c} was measured at week 0 and week 12.

3 After the programme, there were significant improvements in knowledge, wellbeing and HbA_{1c}.

4 The programme has been incorporated into routine clinical care.

measured at baseline and at six weeks. The general wellbeing score of the wellbeing questionnaire was used (Bradley, 1996). This questionnaire is diabetes specific and has been validated. The range is 0–66, with higher scores representing improved wellbeing. The locally developed knowledge questionnaire had a possible score of 0–30, with higher values representing improved knowledge.

Glycated haemoglobin (HbA_{1c}) was measured at baseline, six and twelve weeks using a DCCT-aligned assay (reference range 4.6—6.2%). Qualitative assessment of patients' application of knowledge was tested at their last appointment by problem-based, diabetes-specific clinical scenarios.

Statistics

Two-tailed paired *t*-tests were used for comparisons before and after intervention. We also assessed the impact of the programme on the proportion of patients with different levels of glucose control by proportions analysis, using the following categories:

- Good glucose control (HbA_{1c} < 7.0%)
- Poor glucose control (HbA_{1c} 7.0–8.0%)
- Very poor glucose control (HbA_{1c} > 8.0%)

Results

The first 301 patients to complete the 12-week pathway were analysed. Patient characteristics are shown in *Table 1*.

Table 1. Patient characeristics at baseline

Mean age	59±13 years
Known diabetes duration	6.7±8 years
Type 1/Type 2 diabetes	36 (15%)/265 (85%)
Good blood glucose control (HbA_{1c} of <7.0%)	19%

Table 2. Comparison of blood glucose control (HbA_{1c}), knowledge and wellbeing in 301 patients with diabetes before and after a care pathway-driven education programme (mean±standard devia-

	Week 0	Week 6	Week 12	*P* value
HbA_{1c}	8.45±1.74	7.91±1.49	7.49±1.38	< 0.0001*
Knowledge	20.5±6.3	25.6±4.7	Not tested	< 0.0001
Wellbeing	47.5±11.9	49.7±11.9	Not tested	< 0.0001

* = Week 0 versus week 12

The education pathway was associated with highly significant improvements in blood glucose control, knowledge and wellbeing (*Table 2*). Overall, there was a highly significant increase in the proportion of patients with good control and a commensurate highly significant fall in the proportion with very poor control (*Table 3*).

Discussion

The aim of our study was to examine the impact of care pathway-driven diabetes education on patient knowledge, wellbeing and blood glucose control, but also to examine the suitability of a care pathway-driven education programme for delivery of diabetes education in a busy clinical unit. On both counts, the care pathway has proved to be a resounding success: our patients achieved highly statistically significant improvements in knowledge, well-being and HbA_{1c}. We have also found a practical tool to deliver consistent, effective patient education with limited resources.

Routine clinical care has improved

Many authors have shown the benefits of patient education on outcomes, but much of this work was based in the USA or described small projects isolated from clinical practice (Mazzuca et al, 1986; Rubin et al, 1989; Barth et al, 1992; meta-analysis by Padgett et al, 1988). Our results describe outcomes from an initiative that has been incorporated into routine clinical care.

Better outcome

Improved patient knowledge, demonstrated by questionnaire scores, does not necessarily correlate with a change in behaviour or glycaemic control. Our patients gained knowledge, were happier and had better blood glucose control and it is particularly encouraging that qualitative assessment using real-life scenarios suggested that improvements in knowledge were associated with enhanced self-management skills.

Improved control

The Diabetes Control and Complications Trial (1993) and UK Prospective Diabetes Study (1998) have provided robust evidence that for every percentage fall in HbA_{1c} there is a significant (approximately 20%)

fall in potential complications. Patients in this study achieved a mean fall in HbA_{1c} of 1% and encouragingly the proportion with very poor control fell significantly.

What our study cannot address is the relative contribution of knowledge and other simultaneous interventions, such as changes in diet and medication, on this fall in HbA_{1c}; this will require a further prospective study.

Quality of life

Quality of life and patients' psychological wellbeing are important outcome measures in diabetes. The scale used in this study to measure general wellbeing was specifically designed for patients with diabetes, has been well validated and measures both negative and positive changes in mood.

Previous studies have presented mixed results in terms of changes in wellbeing following education. The actual change in general wellbeing in this study appears small but the important factor is that it was in a positive direction, and that wellbeing, knowledge and HbA_{1c} all improved following the education programme.

Conclusions

This study differed significantly from previous work in that a care pathway was used to develop, drive and implement the education programme. Use of care pathways in diabetes is limited and there have been no previous studies examining the use of a pathway-driven diabetes education programme. Before developing the pathway, we had no structured education programme and like many centres, finding time to offer effective education to patients within busy outpatients clinics was a problem. Development of the pathway has prompted us to examine critically our service and we now use care pathways extensively and have found that they have greatly enhanced multidisciplinary team working and patient care.

Future work in this area should include longer-term studies examining hard clinical endpoints and might examine in greater detail behavioural consequences of better diabetes education. ■

Table 3. Proportion of 301 patients with diabetes with good, poor and very poor blood glucose control before and after care pathway-driven education programme

	Number (%) patients with specified HbA_{1c}		
	Good	Poor	Very poor
	HbA_{1c} <7.0%	HbA_{1c} 7.0–8.0%	HbA_{1c} >8.0%
Week 0	58 (19%)	77 (26%)	166 (55%)
Week 12	117 (39%)	81 (27%)	103 (34%)
	P<0.0008	non-significant	P<0.001

Audit Commission (2000) *Testing Times: A Review of Diabetes Services in England and Wales*. Belmont Press, Northampton

Barth R, Campbell LV, Allen S et al (1992) Intensive education improves knowledge, compliance and foot problems in type 2 diabetics. *Diabetic Medicine* **8**: 111–17

Bradley C (1996) *Handbook of Psychology and Diabetes*. Harwood Academic Publishers, Amsterdam.

Bradshaw C, McColl E, Eccles M et al (1999) Can we improve the education for type 2 diabetes patients in general practice? *Practical Diabetes International* **16**(8): 241–5

BDA (1987) *Minimum Educational Requirements for the Care of Diabetes in the UK*. BDA, London.

Brown SA (1988) Effects of educational interventions in diabetes care: a meta-analysis of findings. *Nursing Research* **37**(4): 223–30

Campbell H, Hotchkiss R, Bradshaw N et al (1998) Integrated care pathways. *British Medical Journal* **316**: 133–7

Currie L, Harvey G (1997) *The Origins and Use of Care Pathways in The USA, Australia and The United Kingdom*. RCN Institute, Oxford.

Control and Complications Trial (DCCT) Research Group (1993) The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* **329**: 977–86

Dunn SM (1990) Rethinking the models and modes of diabetes education. *Patient Education and Counselling* **16**: 281–6

Fain JA, Nettles A, Furnell M et al (1999) Diabetes patient education research: an integrative literature review. *The Diabetes Educator* **25**(6): 7–11

Johnson S (1997) *Pathways of Care*. Blackwell Science, Oxford

Kitchiner D, Davidson C, Bundred P (1996) Integrated care pathways: tools for continuous evaluation of clinical practice. *Journal of Evaluation in Clinical Practice* **2**(1): 65–9

Mazzuca SA, Moorman NH, Wheeler ML (1986) The diabetes education study: a controlled trial of the effects of diabetes patient education. *Diabetes Care* **9**: 1–10

Mensing C, Boucher J, Cypress M et al (2000) National standards for diabetes self-management education. *Diabetes Care* **23**(5): 682–9

Padgett D, Mumford E, Carter R et al (1988) Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *Journal of Clinical Epidemiology* **41**: 1007–30

Rubin RR, Peyrot M, Saudek C (1989) Effect of diabetes education on self-care, metabolic control and emotional well-being. *Diabetes Care* **12**: 673–9

UK Prospective Diabetes Study Group (1998) Intensive blood glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The Lancet* **352**: 837–53

Developing and implementing diabetes care pathways

Sarah V O'Brien, Kevin J Hardy

Introduction

Implementation of the National Service Framework for Diabetes will pose a significant challenge to professionals in both primary and secondary care. We report our experience of developing and implementing a whole-system, pathway of care driven approach to diabetes management across a health community over the past 4 years. Our aim is to share our experiences in pathway development and provide clinicians with templates that they can adapt to their own clinical environment to facilitate implementation of the diabetes NSF.

People with diabetes rightly expect care that is timely, accessible and of uniformly high quality. But diabetes care is complex, multifaceted and delivered in a wide range of clinical settings by healthcare professionals from diverse backgrounds and with diverse skills.

Care pathways improve the delivery of effective care, facilitate critical evaluation of that care and strengthen multidisciplinary communication (Kitchiner et al, 1996; Schaldach, 1997; Chang et al, 1999). They promote a uniform standard of care delivery in a wide variety of clinical settings.

The Welsh National Assembly (1999), *The NHS Plan* (Secretary of State for Health, 2000), the Commission for Health Improvement, the National Institute for Clinical Excellence and recent National Service Frameworks (including the diabetes NSF) all emphasise the importance of care pathways in realising national goals for better health care.

What are care pathways?

There are many definitions of care pathways and no nationally agreed format, but certain key features separate care pathways from clinical guidelines. A pathway maps the expected route of care for a patient within a specified setting. Timeframes are often explicit, with interventions specified in chronological order, and pathways are typically multidisciplinary.

A core feature of pathways is variance analysis (Gottlieb et al, 1996; Kitchiner et al, 1996; Campbell et al, 1998). Variance analysis is a record of deviations from the care pathway, with an explanation of the deviation. Analysis of these variances is undertaken to inform (and improve) care. Variances from a pathway may be coded in a variety of ways to facilitate analysis. Variance from a pathway should not be viewed as a failure, as it allows clinicians to individualise care, to record shortfalls in the system that are preventing optimum care, and to record situations where the clinician's experience and clinical judgment dictate a different pattern of care from the norm. Variance analysis permits continuous audit and quality improvement.

The first pathways to be developed and used in health care were largely for surgical procedures, such as cataract extraction, and much of the literature on care pathways relates to surgical conditions and interventions. Complex medical problems, such as diabetes, are more difficult to map, and pathway development in medicine is less developed as a result. Our experience, however, suggests that care pathways are also useful for such conditions.

Development of the care pathways

In 1997, we invited a Regional Accreditation Visit of District Diabetes Services, which included a survey of patients' views. We were able to identify several areas of concern:

ARTICLE POINTS

1 Care pathways are widely regarded as an important tool for delivering the NSF for Diabetes.

2 Care pathways improve care and strengthen multidisciplinary communication.

3 Care pathways were developed for diabetes management across the whole health community.

4 The care pathways described here were tested and have significantly transformed local diabetes services.

5 The successful development of care pathways requires a strong team leader and dedicated time.

6 Our pathways could be used and adapted to fit other diabetes services.

KEY WORDS

- **Care pathways**
- **Variance analysis**
- **Diabetes management**

Sarah V O'Brien is Consultant Nurse and Kevin J Hardy is Consultant Physician and Endocrinologist, Diabetes Centre, Whiston Hospital, Prescot, Merseyside.

PAGE POINTS

1 Changes were needed to improve consistency of patient care.

2 The care pathway was a chronological summary of each intervention experienced by the patient during a clinical episode and formed part of the patient record.

3 A key factor in the success of the pathways was that they were developed in stages.

4 Patient feedback after implementation of the pathways was very positive.

- There was no system in place to ensure that patients received consistent medical management and advice (patients who responded to surveys highlighted inconsistent advice as a particular source of frustration).
- There was no formal programme of patient education, and education was delivered in busy clinics with constant interruptions, or as one-off sessions to unacceptably large groups.
- There were few means of measuring the effectiveness of education and other interventions.
- No measures of patient satisfaction were being undertaken.
- Documentation was ad hoc, incomplete and non-centralised. Nurse specialists often recorded interventions separately from doctors, dietitians and podiatrists, and advice given to patients was not clearly documented.

It was evident that changes were needed to improve consistency of patient care, to standardise and improve documentation of patient education, to promote more efficient use of resources, to develop and improve tools for measuring effectiveness of clinical care and patient satisfaction, and to facilitate better audit and evaluation. A review of the literature failed to reveal an appropriate pathway so we devised our own.

All the pathways we have developed comprise two key elements: a set of evidence-based standards underpinning the pathway, and the pathway itself. The standards did not form part of the patient record but were kept in clinical areas for reference. They were also available for audit or external review to explain the patient care process fully. The pathway was a chronological summary of each intervention experienced by the patient during a clinical episode, and formed part of the patient record.

What worked for us

Our pathways mapped screening and diagnosis, initial management in primary care, referral to secondary care, all care in hospital specialist clinics, inpatient care and ongoing management in primary care.

A key factor in the success of the pathways was that they were developed in stages. We started with hospital outpatient clinics, and only moved on to inpatient pathways and the current pilot studies of pathways in primary care once these had been refined and accepted.

We incorporated tools and initiatives into the pathways to address previous shortfalls in our service, such as: a reminder phone call and pack sent to patients before the first appointment to reduce non-attendance; knowledge, wellbeing and patient satisfaction questionnaires to measure the impact of our education programmes; a staff education pack to ensure consistency of information and advice; and a patient information book to ensure consistency of written information throughout the health community.

The outpatient pathways were first implemented in March 1999; initially we did not measure variance analysis, in order to allow clinicians time to adjust to the new system and paperwork. Subsequently, variance analysis proved to be an invaluable tool for identifying and subsequently addressing weaknesses in the pathway format and the clinical process. The pathways transformed our care programme into a highly structured, evidence-based, patient-centred service.

As reported elsewhere (Hardy et al, 2001), formal evaluation of the new patient clinic pathway demonstrated a highly significant reduction in non-attendance, improvements in patient knowledge and wellbeing and better HbA_{1c} results (O'Brien and Hardy, 2000). Introduction of care pathways was also associated with a change in culture within our unit. The service was no longer didactic and systems-oriented, but more flexible and responsive to patients' views. Every patient was given a 'feedback form' and encouraged to record their views (good or bad) on the service. Feedback has been extremely positive.

Following the success of the initial pathways, we developed pathways for all our outpatient clinics, including those for: nephropathy; combination therapy (for patients starting insulin and tablets); insulin (for patients starting insulin monotherapy); community support (nurse-led clinics); foot ulcer; and joint antenatal and young persons. Improvements in the nephropathy clinic

since the introduction of the pathway have included lower mean blood pressure, more patients on angiotensin-converting enzyme inhibitors, improvements in mean HbA_{1c}, and very favourable rates of death, dialysis and doubling of serum creatinine (O'Brien and Hardy, 2001; O'Brien et al, 2002).

Following the success of our outpatient pathways, we developed inpatient care pathways in consultation with ward staff. These care pathways include blood glucose monitoring, management of glucose potassium insulin (GKI) infusion regimens, investigations to be ordered for inpatients with diabetes, and interpretation and action on diabetes-related inpatient investigations. We have recently completed a randomised controlled trial of these pathways in the medical wards of our district general hospital.

The final stage was to develop care pathways for primary care. After 2 years of use and refinement of the outpatient pathways, the format was working successfully and was accepted by representatives from primary care as a template for care pathways. A pathway subgroup of the local Diabetes Health Improvement Programme group was established and pathways were developed for screening, diagnosis, initial management, ongoing management, education and referral to secondary care. These primary care pathways are currently being piloted.

Every effort has been made to make our pathways clear, simple to use, not excessively time-consuming and a comprehensive record of each interaction between the patient and multidisciplinary team member. Our outpatient pathways have been well tested and their success proven. However, success of the inpatient pathways and primary care pathways has not yet been demonstrated, but experience suggests that they too will enhance the care we deliver to our patients with diabetes.

Where we struggled

Development of the pathways was time consuming. Regular multidisciplinary team meetings were essential to gain acceptance by members of the diabetes team. Critical evaluation of current practice and identification of key areas for change were crucial to the development and implementation of the pathways. This process was sometimes a difficult and potentially threatening experience.

The inpatient and primary care pathways presented other difficulties. It was essential to involve key stakeholders, and the largest hurdle was convincing a wide range of professionals to change the way they approached diabetes care. Regular meetings and dedicated time to develop the pathways were crucial.

Ongoing, regular analysis of variances from pathways is an essential component of services driven by care pathways, but is time consuming. We overcame this problem to some extent by reviewing pathway variances from a selection of clinics on a monthly basis and giving feedback on the results at our weekly team meetings. Our experience suggests that we will only be able to fully evaluate variances from the care pathways when we have an electronic patient information system.

Lessons learned

A strong team leader and dedicated time are the key to successful development and implementation of care pathways.

It is essential that care pathways are simple to use and that other paperwork is kept to a minimum. We have constantly evaluated the format of our care pathways and they have evolved from masses of paperwork into increasingly concise documents. We ensured that detailed standards underpinned the pathways, but kept these separate from the paperwork to enable us to specify the pathways of care in great detail while keeping paperwork to a minimum. Pathways provide a robust method for defending potential complaints.

Conclusions

Care pathways are widely believed to be an important tool for ensuring the delivery of high quality, evidence-based care and are a key feature of the diabetes NSF. We have developed, implemented and evaluated diabetes care pathways extensively over the last 4 years and strongly advocate their use as a tool to improve the quality of diabetes services. The pathways presented in this paper could be used and adapted to fit

PAGE POINTS

1 Every effort was made to make the pathways a comprehensive record of each interaction between the patient and multidisciplinary team member.

2 It is essential that care pathways are simple to use and that paperwork is kept to a minimum.

3 Care pathways are widely believed to be an important tool for ensuring the delivery of high quality, evidence-based care, and are a key feature of the diabetes NSF.

Date:		**Diabetes Care Pathways**	
Time arrived:		**Hospital outpatients:** Clinics: New patient; Education; Insulin; Discharge assessment; Community support; Joint antenatal and young persons; Nephropathy; Foot ulcer	
Clinic nurse notes to Dr:		**Hospital inpatients:** Blood glucose monitoring, investigations, GKI	
Appt. time:		**Primary care:** Screening & diagnosis, initial management, ongoing management, education, referrals	
Clinic nurse:			
Time seen:			
New Patients Only	**Y**	**N**	
Is diagnosis confirmed?	__	__	If yes, give info. sheet __ If no, explain possibility __
Has Pt completed Educ. Clinic	__	__	If no, arrange Friday am clinic __
Get KQ & WBQ & record score	__	__	
All Patients			
Pt satisfaction questionnaire	__	__	
Urinalysis	__	__	If nitrite or blood, do MSSU __
Explain medications	__	__	
Is HbA_{1c} < target?	__	__	If no, adjust meds / review exercise & diet __
Is Pt on max. irbesartan / ramipril?	__	__	If no, start & ask GP to titrate __
Is BP < target?	__	__	If no, adjust prescription as protocol __
Does Pt need dietitian?	__	__	1st visit __ , Creat.>150 __ , K^+>5.2 __ ,↑ Phos. __ , gly __
Has Pt gained weight?	__	__	If yes, discuss __ or refer dietitian __
Does Pt need fasting lipids?	__	__	Annual check or if Rx changed last visit
Does statin need starting or ↑?	__	__	If yes, ask GP to start / ↑ atorvastatin or simvastatin __
Does fibrate need starting?	__	__	If yes, ask GP to start gemfibrozil __
Arrange ACR	__	__	
Arrange U&Es	__	__	
Was last creatinine >120 µmol/litre?	__	__	If yes, do FBC, ferritin (see standard 13 for Mx) __
Was last creatinine >150 µmol/litre?	__	__	If yes, do Ca^{2+}, PO_4^{3-}, HCO_3-, PTH (see standard 14) __
Does Pt need referral to nephrologist?	__	__	EPO __ ,↑PO_4^{3-} __ general deterioration __
Is Pt on aspirin?	__	__	If no & no contraindications, start 75mg od __
Is annual check due?	__	__	If yes, medical history, remind eyes & feet & to re-read education book __
Discuss CVS risk reduction	__	__	
Does Pt have education book?	__	__	If yes, check read & understood it __ if no, give one __
Have new drugs been started?	__	__	If yes, give drug information sheet __
Arrange appointments	__	__	
Give Pt copy sheet	__	__	Ask Pt if want copy GP letter (to be posted) __
Send GP sheet & letter	__	__	
Record time finish			Doctor/DSN:

Figure 1. Diabetes nephropathy clinic care pathway (adapted from the original) ACR = albumin:creatinine ratio; BP = blood pressure; CVS = cardiovascular system; EPO = erythropoietin injections; FBC = full blood count; GKI = glucose potassium insulin; Gly = glycaemia; KQ = knowledge questionnaire; MSSU = midstream specimen of urine; Mx = management; PTH = parathyroid hormone; U&Es = urea and electrolytes; WBQ = wellbeing questionnaire.

other diabetes services. If there is commitment and sufficient support within the healthcare team, care pathways can be a tool for achieving effective, evidence-based diabetes care. ■

Figure 1 shows a sample pathway. Copies of the actual pathway can be obtained by emailing the author at: sarahobuk@yahoo.co.uk

Campbell H, Hotchkiss R, Bradshaw N et al (1998) Integrated care pathways. *British Medical Journal* **316**: 133–7

Chang PL, Wang TM, Huang ST et al (1999) Effects of implementation of 18 clinical pathways on costs and quality of care among patients undergoing urological surgery. *The Journal of Urology* **161**: 1858–62

Department of Health (2003) *National Service Framework for Diabetes*. DoH, London

Gottlieb LD, Roer D, Jega K et al (1996) Clinical pathway for pneumonia: development, implementation, and initial experience. Best Practice and Benchmarking in Healthcare **1**: 262–5

Hardy KJ, O'Brien SV, Furlong NJ (2001) Information given to patients before appointments and its effect on non-attendance rate. *British Medical Journal* **323**: 1298–300

Kitchiner D, Davidson C, Bundred P (1996) Integrated care pathways: effective tools for continuous evaluation of clinical practice. *Journal of Evaluation in Clinical Practice* **2**: 65–9

National Assembly for Wales (1999) *An Introduction to Clinical Pathways*. National Assembly for Wales, Cardiff

O'Brien SV, Hardy KJ (2000) Impact of a care pathway-driven diabetes education programme. *Journal of Diabetes Nursing* **4**: 147–9

O'Brien SV, Hardy KJ (2001) Nurse-led nephropathy clinic associated with improved management. *Diabetic Medicine* (Suppl 2): A94

O'Brien SV, Hulme SA, Furlong NJ, Hardy KJ (2002) Effects on death, dialysis and doubling of serum creatinine of renin-angiotensin-aldosterone-system blockade and blood pressure control in diabetic nephropathy achievable in routine clinical care. *Diabetes* **51**(Suppl 2): A188

Schaldach DE (1997) Measuring quality and cost of care: evaluation of an amputation clinical pathway. *Journal of Vascular Nursing* **15**(1): 13–20

Secretary of State for Health (2000) *The NHS Plan: A Plan for Investment, A Plan for Reform*. Stationery Office, London

Guidelines make nurses feel better but do they improve care?

Sarah V O'Brien, Susan B Michaels, Niall J Furlong, Kevin J Hardy

ARTICLE POINTS

1 Inpatients with diabetes are often managed inappropriately.

2 Hospital guidelines were developed to improve the management of inpatients with diabetes.

3 A retrospective study examined the impact of the guidelines on management and nurses' confidence.

4 Nurses were more confident at managing diabetes after introduction of the guidelines.

5 The guidelines did not improve the management of inpatients with diabetes.

6 Guidelines are useful but used in isolation they may not improve care.

KEY WORDS

- **Evidence-based guidelines**
- **Inpatients with diabetes**
- **Nurse confidence**
- **Inappropriate management**

Sarah O'Brien is DSN, Susan Michaels is DSN, Niall Furlong is Research Fellow and Kevin Hardy is Consultant Physician & Endocrinologist at Diabetes Centre, Whiston Hospital, Prescot.

Introduction

Evidence-based guidelines are regarded by many as an important tool for facilitating optimal management of patients with diabetes. This article describes the development of hospital guidelines for with diabetes and reports on a retrospective study evaluating the impact of the guidelines. Introduction of the guidelines improved nurses' confidence but failed to improve the management of inpatients with diabetes. Implementation strategies and and specialist team support may be essential.

Patients with diabetes stay in hospital longer and use more services than those without diabetes (Koproski et al, 1997; Kennedy et al, 1999); accounting for 8% of inpatient beds and 9% of hospital costs (Audit Commission, 2000). This extra inpatient activity and its associated costs may be a consequence of diabetes itself but there is evidence that sub-optimal inpatient management may be a contributory factor (Driskill, 1996; Hamilton et al, 2000).

Guidelines

Guidelines might improve these management deficiencies, but the recent *Testing Times report* (Audit Commission, 2000) into diabetes highlighted a general lack of inpatient diabetes guidelines. Diabetes UK recommends that inpatients have access to the diabetes team, but large numbers of inpatients with diabetes, burgeoning outpatient activity and the predicted doubling in numbers of patients with diabetes over the next ten years (Audit Commission, 2000), may make this increasingly difficult. Development of guidelines for managing inpatients with diabetes may facilitate appropriate management by non-specialist health professionals.

Development of our guidelines

Comprehensive hospital guidelines for the management of people with diabetes were developed. Our guidelines were underpinned by evidence wherever it was available and consistent with international and national guidelines, e.g. European IDDM Policy Group (1993); Alberti et al (1994); European Diabetes Policy Group (1999). A wide range of inpatient management issues from acute problems such as diabetic ketoacidosis, hypoglycaemia and hyperosmolar non-ketotic coma to the non-acute, such as blood glucose monitoring and hypertension, were covered. The guidelines were split into two sections, the first providing brief summaries, intended for quick reference and easy use, and the second providing more detail and explanation of recommended management strategies and the underlying evidence base.

A meeting attended by consultants, junior doctors and a nurse from each ward was held to launch the guidelines. Every ward and ward doctor was provided with a copy and staff were encouraged by the diabetes team to use the guidelines when managing patients with diabetes.

Study aim and methods

One year after introduction of the guidelines, a study was carried out to determine their impact on:

- Inpatient diabetes management
- Nurses' confidence in dealing with patients with diabetes.

Case notes were examined for 157 patients with diabetes admitted to the medical unit over a 10-month period (August 1999 to May 2000). An anonymised nurse survey was mailed to 143 staff nurses working on the medical unit (*Figure 1*).

Endpoints of the study were:

- Nurse care planning (was it appropriate, based on the guidelines and adhered to?)

- Blood glucose monitoring (was it appropriate and based on the guidelines?)
- Measurement of HbA_{1c} and action taken
- Measurement of cholesterol and action taken
- Screening for diabetic nephropathy (urinalysis for protein).

Results

Only 23 (15%) patients were admitted as a result of their diabetes and mean length of stay was 7.6±8.8 days (mean±SD).

Retrospective study

Eighty-six of the 157 patients (55%) had a care plan for diabetes, and in only 40% of these (35/86) was it concordant with our guidelines. In only 16% (14/86) of those with a care plan was it followed.

Common errors included:

- Mislabelling patients as type 1 when they were type 2.
- Requesting inappropriate blood glucose or urine monitoring.

Blood glucose monitoring was appropriate (as defined by our hospital guidelines) in only 12% (19/157) of patients, typically being measured either too often or too infrequently. For example, acutely ill, unstable patients might have had one random blood glucose test a day while stable patients with no evidence of high blood sugars were being tested every 2 to 4 hours.

The guidelines encouraged HbA_{1c} testing of all patients with diabetes on admission, but this occurred in only 64 (41%) of the 157 patients studied. In those 64 patients it was above target in 44 (69%) but treatment was only adjusted in 27 patients (61%), so 17 patients were found to have sub-optimal diabetes control but nothing was done to redress it.

Cholesterol was checked in 48% (75/157) of patients: 29 of these patients had a raised cholesterol but only 9 received intervention. Only 40 (25%) of the 157 patients had urinalysis for protein on the ward: half (20/40) were found to have proteinuria, which can signify diabetic nephropathy. Investigation was undertaken in only 15.

Survey

Only 45% (64/143) of the nurses returned the survey. Anonymity meant that we were unable to identify non-responders and improve the return rate.

Half of the respondents (32/64) were happy with their knowledge of diabetes, 70% (45/64) said they felt confident when managing patients with diabetes and nearly all of them (92%; 59/64) felt that the guidelines had helped them in their management. Seventy two per cent (46/64) felt they received enough support from the diabetes team and the majority (92%; 59/64) said they would like to have a care pathway to assist in their management of inpatients with diabetes.

Twenty-four nurses provided further comment. Of these, 14 identified a lack of support at night and the need for better links between night staff and the diabetes team.

Discussion

Only 15% of the patients studied had been admitted directly as a consequence of diabetes, but all should have had a care plan for the management of diabetes.

Acute illness can adversely affect diabetes and be complicated by the disease, yet 45% of the patients in this study had no nursing care plan relating to diabetes. The UKCC Standards for Records and Record Keeping (1993) state clearly that nursing records should 'provide evidence of care required, intervention by professional practitioners and also support standard setting, quality assessment and audit.'

The care plans reviewed in this study were of a poor standard, they did not identify appropriate care for individual patients and most were not based on the standards set out in the inpatient guidelines.

Of greater concern, where a care plan was appropriate and based on the guidelines, there was no evidence in the documentation that the care had been given. For example, one care plan appropriately stated that the patient would have blood glucose testing pre-meal and pre-bed but on the blood glucose monitoring chart the patient had had blood glucose testing only three times in 7 days!

Blood glucose monitoring

In common with other studies (Rodgers and Wood, 2001), our results show that blood glucose monitoring was either too intensive or too infrequent and often

Please answer yes or no to the following questions:

Are you satisfied with your knowledge of diabetes?
Y/N

Do you feel confident when managing in-patients with diabetes in the wards?
Y/N

Do you think you get enough support from the hospital diabetes team?
Y/N

Have the hospital guidelines for diabetes helped in your management of patients with diabetes?
Y/N

Would you like more specific guidelines on managing diabetes, ie. a care pathway?
Y/N

Figure 1. Questionnaire sent to staff nurses on the medical unit.

unrelated to a patient's condition. Our guidelines encouraged nurses to test pre-meal and pre-bed daily in patients who were acutely ill or who had unstable blood glucose monitoring (BGM) results, but only two days a week in those whose diabetes was stable. It was evident from the study that this guideline had not been followed and that blood glucose testing remained inappropriate and often did not contribute to a patient's management because results were not acted upon.

Most inpatient referrals to the diabetes team relate to high BGM results. Often the referral is inappropriate and could be managed by the ward doctor. The guidelines explained how to titrate diabetes medication and suggested measuring HbA_{1c} for patients with apparent poor blood glucose control. It was evident from the study that patients were not routinely having an HbA_{1c} test, and in 39%, when it was measured and showed sub-optimal control, no action was taken.

Diabetic nephropathy

Diabetic nephropathy is the leading cause of end-stage renal failure worldwide, and these patients are at high risk of premature death from cardiovascular disease. Screening for nephropathy is simple (dip-stick urine for protein) and cheap and there is robust evidence for effective intervention (angiotensin-converting enzyme inhibitors and tight blood pressure control). It is essential therefore that this group of patients are identified early. Patients admitted to hospital in this study did not routinely have ward urinalysis for protein and those found to have proteinuria were not consistently investigated for nephropathy.

Introduction vs implementation

The findings suggest that shortfalls in inpatient diabetes management were not redressed by the development and implementation of detailed guidelines. The Audit Commission (2000) suggests that the problems we identified are not unique to our hospital but endemic in the NHS. The report suggests a need for guidelines to improve management, but our study has demonstrated that guidelines may not improve care and that effective implementation of diabetes guidelines poses a significant challenge.

Rutter et al (2001) found poor uptake of guidelines for managing hyperglycaemia post-myocardial infarction and used intensive education sessions to improve compliance. Employment of diabetes nurses dedicated solely to reviewing ward patients may help (Cavan et al, 2001) but burgeoning numbers of people with diabetes means many patients will inevitably have to be cared for primarily by generalists — perhaps the diabetes liaison nurse's role should be primarily to educate and re-enforce guidelines.

Feel-good factor

The response rate to our nurse survey was disappointing, but it is noteworthy that respondents viewed the guidelines as useful and felt more confident managing patients with diabetes as a result. It is cause for concern that this guideline-associated confidence was sometimes misplaced. Future initiatives, either research or clinical practice, must be sure to assess both confidence and competence.

The night staff responding to our survey felt under-supported. The need for specialist teams to link adequately with people working nights must be addressed and appropriate education and support be provided.

Conclusion

Our study suggests that work is needed to improve inpatient diabetes management. Guidelines are useful and make nurses feel more confident, but effective (ongoing) implementation strategies and specialist team support may be essential to fully effect improvements in patient care.

Care pathways are regarded by many as a key to guideline implementation, but so far supporting evidence is anecdotal and more research into this area is needed.

As a result of this study, we are conducting a large randomised controlled trial of the effectiveness of inpatient care pathways in diabetes. ■

Alberti KGMM, Gries FA, Jervell J et al (for the European NIDDM Policy Group) A desktop guide for the management of non-insulin dependent diabetes mellitus (NIDDM): an update. *Diabetic Medicine* **11**: 899–909

Audit Commission (2000) *Testing Times A review of Diabetes Services in England and Wales*. Belmont Press, Northampton.

Cavan D, Hamilton P, Everett J et al (2001) Reducing hospital inpatient length of stay for patients with diabetes. *Diabetic Medicine* **18**: 162–4

Driskill W (1996) What every LPN should know. *The Journal of Practical Nursing* **14**: 14–18.

European IDDM Policy Group (1993) Consensus guidelines for the management of insulin-dependent diabetes. *Diabetic Medicine* **10**: 990–1005

European Diabetes Policy Group (1999) A desktop guide to type 2 diabetes mellitus. *Diabetic Medicine* **16**: 716–30

Hamilton P, Everett J, Kerr D et al (2000) A ward-based clinical nurse advisor: effect on length of stay for patients with diabetes. *Diabetic Medicine* **17** (Supplement 1): 1

Kennedy R, Pachipala K, Abd Rabou A et al (1999) Emergency Medical Admissions in Patients with Diabetes: Increased Rate of Admission and Length of Stay. *Diabetic Medicine* **16** (Supplement 1): 50

Koproski J, Pretto Z, Poretsky L (1997) Effects of an Intervention by a Diabetes Team in Hospitalized Patients With Diabetes. *Diabetes Care* **20**(10): 1553–5

Rodgers J, Wood J (2001) Standards for professional monitoring of capillary blood glucose. *Practical Diabetes International* **18**(3): 79–82

Rutter M, Wilcox E, Easton J et al (2001) Improving the early management of blood glucose in emergency admission with chest pain. *Practical Diabetes International* **18**(3): 75–8

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1993) *Standards for Records and Record Keeping*. UKCC, London

A comparison of general nurses' and junior doctors' diabetes knowledge

People with diabetes may be hospitalised for the condition or another reason. Either way, they need special care to avoid diabetes-related complications. General ward nurses and trainee doctors were tested on their knowledge of diabetes, with poor results in some areas. The questionnaire used could prove a useful tool for identifying and addressing these problems

Sarah V. O'Brien, BA, RN, Consultant Nurse — Diabetes; Susan E. Michaels, RN, Diabetes Nurse Specialist; Kevin J. Hardy, FRCP, Consultant Physician and Endocrinologist, Diabetes Centre, Whiston Hospital, Prescot, Merseyside

DIABETES, INPATIENTS, KNOWLEDGE, QUESTIONNAIRE

Patients with diabetes account for 9% of total hospital costs and 8% of inpatient beds. They have poorer outcomes than other patients, as well as spending longer in hospital (Audit Commission, 2000; Donnan et al, 2000; Koproski et al, 1997; Davies et al, 1999).

These differences may be inherent to diabetes, but sub-optimal management in general wards may also contribute (Driskill, 1996; Hamilton et al, 2000). Patients lack confidence in general nurses' and doctors' ability to manage their diabetes (Callaghan and Williams, 1994), and nurses' knowledge of diabetes is often inadequate (Leggett-Frazier and Vincent, 1994; Drass et al, 1989; Scheiderich et al, 1983).

Not least because of a predicted doubling in numbers of people with diabetes over the next 10 years (Audit Commission, 2000), these shortfalls in knowledge and management of diabetes by non-specialists need addressing. One standard in the diabetes National Service Framework (NSF) is to improve the management of inpatients with diabetes (DoH, 2001). If specialist diabetes teams are to provide ongoing education and support to health professionals, we need to be able to measure basic knowledge to evaluate interventions to improve it.

This paper reports on a questionnaire developed to test general nurses' and trainee doctors' knowledge of how to manage patients with diabetes in their wards, whatever their reason for admission.

Background to the study

A literature search of the Medline, Cinahl and Psyclit databases revealed few diabetes-specific knowledge questionnaires, and none from the UK. Some tools are in use but they are unpublished or have not been robustly validated.

Drass et al developed the most widely used diabetes knowledge questionnaire in the USA (1989), which is a modification of an earlier tool (Scheiderich et al, 1983).

All existing tools reviewed had been developed specifically for use with nurses (Baxley et al, 1997; Gossain et al, 1993; Jayne and Rankin, 1993; Leggett-Frazier and Vincent, 1994; Moriarty and Stephens, 1989). They had not been tested on doctors and did not meet our study's requirements. Many tools had methodological weaknesses.

In particular, no study examined test re-test reliability of the questionnaires used. This is a measure of whether the questionnaire will produce similar results when administered at different time points to the same people. This is essential if the tool is going to be used before and after an intervention designed to improve knowledge. With no measure of test re-test reliability, results showing improved knowledge after a teaching programme would be unreliable.

We developed this new tool to measure nurses' and doctors' knowledge of how to manage diabetes because of the lack of UK-specific questionnaires, methodological problems with the existing tools and the lack of research undertaken among trainee doctors.

Research design and methods

Seven professionals from three hospitals in the north west of England were interviewed to determine what they expected ward based-nurses and trainee doctors to know about diabetes. They comprised five diabetes specialist nurses and two diabetologists.

The researchers developed the questionnaire on the basis of these interviews, a review of the literature on diabetes management, the US questionnaires and clinical experience.

The questionnaire contained 11 sections, each comprising six items. The sections were: physiology, blood glucose monitoring, medications, ▷

For copies of the questionnaire used in this study, write to:
Sarah O'Brien, Diabetes Centre, Whiston Hospital, Prescot, Merseyside L35 5DR.
Email:
sarahobuk@yahoo.co.uk

References

Audit Commission. (2000) *Testing Times: A review of diabetes services in England and Wales*. London: Audit Commission.

Baxley, S.G., Brown, S.T., Pokorny, M.E., Swanson, M.S. (1997) Perceived competence and actual level of knowledge of diabetes mellitus among nurses. *Journal of Nursing Staff Development* 13: 2, 93-99.

Callaghan, D., Williams, A. (1994) Living with diabetes: issues for nursing practice. *Journal of Advanced Nursing* 20: 132-138.

Davies, M., Currie, C., Dixon, S. et al. (1999) Evaluation of hospital diabetes specialist nursing (DSN): a prospective randomised controlled trial (abstract). *Diabetic Medicine* 16: A29.

Department of Health. (2001) *National Service Framework for Diabetes: Standards*. London: Department of Health.

Donnan, P.T., Leese, G.P., Morris, A.D. (2000) Hospitalizations for people with Type 1 and Type 2 diabetes compared with the nondiabetic population of Tayside, Scotland. *Diabetes Care* 23: 1774-1779.

Drass, J.A., Muir-Nash, J., Boykin, P.C. et al. (1989) Perceived and actual level of knowledge of diabetes mellitus among nurses. *Diabetes Care* 12: 351-356.

Driskill, W. (1996) Diabetes education: what every LPN should know. *Journal of Practical Nursing* 46: 1, 14-18.

Gossain, V.V., Bowman, K.A., Rovner, D.R. (1993) The actual and self-perceived knowledge of diabetes among staff nurses. *Diabetes Educator* 19: 215-219.

Hamilton, P., Everett, J., Kerr, D., Cavan, D.A. (2000) A ward-based clinical nurse advisor: effect on length of stay for patients with diabetes (abstract). *Diabetic Medicine* 17: (supp 1), A3.

(Continued on page 260)

Table 1. Some of the topics used and questions asked in the diabetes knowledge questionnair

Please complete the following questionnaire by circling Yes, No or Don't know for each answer (Correct answers did not appear in original questionnaire)

Question	Yes	Don't know	No	(Co ans
Physiology Q1 Type 1 diabetes is caused by an absolute lack of insulin production	Y	DK	N	
Blood glucose monitoring Q10 A BM (random blood glucose finger test) greater than12mmol/l should always be reviewed by a doctor	Y	DK	N	
Medications Q15 Metformin is the drug of choice in patients with Type 2 diabetes who are overweight	Y	DK	N	
Insulin Q20 If you had to mix Actrapid with Insulatard the best technique is to draw up the Insulatard first	Y	DK	N	
Hypoglycaemia Q30 When a BM is less than 4mmol/l you should omit insulin	Y	DK	N	
Hyperglycaemia Q34 Acute illness is a typical cause of hyperglycaemia	Y	DK	N	
Complications Q37 Retinopathy is the leading cause of blindness in young adults in developed countries	Y	DK	N	
Screening/prevention Q43 Patients with diabetes should have their eyes checked only if they have problems	Y	DK	N	
Diet Q51 Special diabetic foods are a good choice for patients with diabetes	Y	DK	N	
Surgery/fasting Q56 When changing from a GKI (a glucose potassium insulin infusion) regimen back to the patient's normal insulin you should stop the GKI the night before you start the normal insulin	Y	DK	N	
General Q61 HbA1c is a test to manage average blood glucose over 6–12 weeks	Y	DK	N	

hypoglycaemia, insulin, hyperglycaemia, complications, diet, screening/prevention, surgery, and a general section. The questionnaire is not exhaustive, but covers the areas identified in the literature and interviews as most problematic in relation to the management of inpatients with diabetes. Respondents were asked to reply 'Yes', 'No', or 'Don't know' to each question (Table 1).

Effort was made to ensure items were not ambiguous. The reading level was pitched at no higher than 12 years — generally accepted as good practice in questionnaire design (Steiner and Norman, 1995; Oppenheim, 1966).

Validity and reliability

Face and content validity establish whe tool is appropriate for its intended use and Norman, 1995). Face validity refers to a tool appears to measure what it should b uring and content validity refers to whe questionnaire has covered all relevant to establish validity, a first draft of the quest was sent out to four specialists — two d ogists and two nurse specialists — a general nurses from three hospitals, t its clarity, content and readability. necessary, some items were then reworded

Table 2. Examples of where doctors scored better than nurses and *vice versa* in the diabetes knowledge questionnaire

Question	Junior doctors who scored correctly (per cent/number: n=27)	General nurses who scored correctly (per cent/number: n=105)	Correct answer (Yes or no)
Where doctors scored better			
Q2 Type 2 diabetes is usually associated with insulin resistance	96% (26)	58% (12)	Yes
Q38 Most Type 2 patients with nephropathy are dead within five years of diagnosis	62% (17)	11% (12)	Yes
Q45 Proteinuria can signify diabetic kidney disease	100% (27)	76% (80)	Yes
Where nurses scored better			
Q7 When the blood glucose meter in the ward is in use quality assurance checks should be carried out once a day	63% (17)	98% (103)	Yes
Q13 Metformin typically causes hypoglycaemia	48% (13)	70% (73)	No
Q19 Human Mixtard 30 contains 70% cloudy insulin and 30% soluble	37% (27)	82% (86)	Yes

Reliability refers to how reproducible a test is (Oppenheim, 1966) — measurement at different times or by different people or with similar tests should produce the same results (Steiner and Norman, 1995).

For this study we measured internal reliability in nurses and trainee doctors using Cronbach's alpha, and test re-test reliability, in nurses only, using Kappa statistic. The SPSS statistical package was used.

The higher the Cronbach's alpha score (usually a range of 0 to 1), the greater the internal reliability of the tool. Cronbach's alpha for the nurses was 0.81 and for the doctors 0.72, demonstrating acceptable internal reliability for both groups. Kappa statistic was also used, with a range from -1 to +1 and results about +0.60 are defined as indicative of good reliability. The Kappa coefficient was 0.689, indicating that the questionnaire has good stability over time. If scores were to increase following intervention, this should indicate a real improvement in knowledge (Litwin, 1995; Steiner and Norman, 1995).

Subjects

The staff nurses in this study were of varying grades, from newly qualified to ward managers qualified for more than 10 years. All worked in general medical wards. Most nurses receive basic training in diabetes in their pre-registration courses and some may go on to do post-registration courses. None of the nurses in this study had done diabetes-specific training at a higher level.

The doctors were in their pre-registration year after completing their medical degree. Both groups managed patients with acute medical problems. Some of those with diabetes would have been admitted because of it; others might have had co-existing medical problems that complicated their diabetes during their hospital stay.

The questionnaire was sent to all 143 staff nurses in the medical unit in one general hospital and a convenience sample of 27 pre-registration house officers. (A convenience sample is a group that is easily accessible but may not be representative of the population as a whole.) The response rate was better for the doctors (100%) than the nurses (73%). The nurses were mailed their questionnaire because there were so many; the doctors filled in theirs in the presence of the investigator.

The number of nurses tested was much larger because within the hospital only a few trainee doctors are in post at any one time.

The junior doctors frequently rotate shifts and location, making it difficult to post questionnaires. Researchers asked them to fill in the questionnaire during a compulsory teaching session at which all the hospital's trainee doctors should have been present.

Results

Nurses and doctors' responses were compared. Total scores from both groups were similar: doctors got an average 48 answers right out of 66 questions, and the nurses an average of 51 out of 66.

However, there were differences between the ▷

References (continued)
Jayne, R.L., Rankin, S.H. (1993) Revisiting nurse knowledge about diabetes: an update and implications for practice. *Diabetes Educator* **19**: 497-502.
Koproski, J., Pretto, Z., Poretsky, L. (1997) Effects of an intervention by a diabetes team in hospitalised patients with diabetes. *Diabetes Care* **20**: 1553-1555.
Leggett-Frazier, N., Vincent, P.A. (1994) Measuring the diabetes knowledge of nurses in long-term care facilities. *Diabetes Educator* **20**: 307-310.
Litwin, M.S. (1995) *How To Measure Survey Reliability and Validity*. London: Sage Publications.
Moriarty, D.R., Stephens, L.C. (1989) Factors that influence diabetic patient teaching performed by hospital staff nurses. *Diabetes Educator* **16**: 31-35.
Oppenheim, A.N. (1966) *Questionnaire Design and Attitude Measurement*. London: Heinemann.
Scheiderich, S.D., Freibaum, C.N., Peterson, L.M. (1983) Registered nurses' knowledge about diabetes mellitus. *Diabetes Care* **6**: 57-61.
Steiner, D.L., Norman, G.R. (1995) *Health Measurement Scales*. Oxford: Oxford University Press.

two professions in what they knew about some aspects of diabetes management. The questions relating to physiology and complications of diabetes were scored better by the doctors, whereas the nurses scored better on the questions relating to practical management of diabetes (Table 2). Both groups scored poorly on the questions relating to the timing of administration of insulin and whether to omit insulin when the patient's blood glucose is low.

Both scored well on the sections relating to physiology of hypoglycaemia and hyperglycaemia. Both scored poorly on the questions relating to care of feet, management of insulin regimens during surgery, and driving and employment.

Discussion

General nurses and trainee doctors have an important role to play in managing patients with diabetes. With the expected rise in the number of patients, and the long-term complications associated with it, all professionals involved in its management need an adequate knowledge base. A single tool to test diabetes knowledge accurately among nurses and doctors may be useful for future research examining diabetes management and strategies to improve it.

This study showed that knowledge of this field among general nurses and doctors is sub-optimal. Admission to hospital often signifies a period of instability for patients with diabetes. Regular screening for long-term complications and self-care skills are essential.

A hospital stay presents a chance to identify undiagnosed complications such as proteinuria and to reinforce patient education. But this cannot happen if, as these results suggest, ward staff lack the necessary knowledge.

This questionnaire took nurses and doctors only about 15–20 minutes to fill in, and could be used as an integral part of education programmes to improve their knowledge.

Following this study, we have developed an integrated care pathway at one hospital for the management of inpatients with diabetes. A randomised controlled trial to test the pathway has recently being completed. Patients admitted to the medical unit were randomised to either a care pathway for diabetes or to usual care. Results are being analysed.

A key endpoint of the randomised controlled trial will be the assessment of diabetes knowledge. The nurses tested for this study will be re-tested with the questionnaire to examine whether the pathway has improved knowledge. We intend to use this tool before and after diabetes education programmes to evaluate any change in professionals' knowledge.

Currently, nurses and doctors are educated separately about diabetes management. The differences in knowledge among them suggest their combined knowledge would be complementary. A multidisciplinary programme of education and knowledge-sharing may be more effective than separate education programmes.

This study focused on hospital staff in general medical wards, where the nurses and trainee doctors had received no additional training to their pre-registration course. But it would be reasonable for the tool to be used with staff working in other areas, such as surgery. It would also be useful to test staff working in primary care and the community.

The NSF will encourage more diabetes care in these settings, and staff will need the necessary skills. Altering some of the questions for use with community-based nurses would not be difficult. This study's response rates were good, indicating that people were willing to be tested. Many were keen to know how they had scored.

One limitation was the possibility of bias caused by the small number of trainee doctors. Another was the failure to examine test re-test reliability on these doctors. This will be necessary if we want to test the reliability of any interventions to improve doctors' knowledge of diabetes. Although it would be difficult to track this particular group of doctors, internal reliability in junior doctors could be established by planning test and re-test dates to fit in with their rotation in the hospital.

Knowledge is only one factor influencing management of patients with diabetes. Future studies need to also consider causes of sub-optimal care in general wards.

Conclusion

Previous studies found knowledge of diabetes among general nurses was inadequate and this was confirmed by our questionnaire, which also identified a problem with trainee doctors.

This key area needs addressing to meet the standards of the diabetes framework. The fact that the combined knowledge of junior doctors and general nurses complements each other indicates that a joint approach to education might be beneficial. This questionnaire could become a useful tool for assessing the effectiveness of education programmes in the future. □

The impact of an inpatient diabetes care pathway

Sarah O'Brien, Susan Michaels, Janet Marsh and Kevin Hardy

Introduction

This article reports the development and subsequent testing of a care pathway for inpatient diabetes management. We examined the impact of care pathway-driven diabetes inpatient management on quality of care, length of stay (LoS), re-admissions within one year, nurse knowledge (using a validated questionnaire) and HbA_{1c} three months post discharge. The inpatient pathway was associated with improvements in all the parameters measured.

Ten per cent of hospital inpatients have diabetes, but most are not admitted as a result of their diabetes and will not be cared for by clinicians with specialist diabetes expertise. Standard 8 of the Diabetes National Service Framework (Department of Health, 2001) aims to improve the care of hospital inpatients with diabetes, and many contemporary recommendations, e.g. NSF and National Institute for Clinical Excellence guidance, advocate the use of care pathways to improve care.

Diabetes is a common chronic disorder affecting approximately 3% of the UK population and associated with 9% of hospital costs (Audit Commission, 2001). It is well documented that hospital admission rates and length of hospital stay are substantially greater for people with diabetes (Pickup and Williams, 1991). This may partly explain excessive expenditure on this group of patients; even when the admission diagnosis is similar, people with diabetes stay in hospital up to twice as long as their non-diabetic counterparts (MacKinnon, 1993). The reason for this costly difference in length of hospital stay may, in part, be inherent to the condition itself – people with diabetes have more extensive myocardial damage following myocardial infarction, for example, with more complications (Abbot, 1988). However, it is widely believed that suboptimal management of diabetes on general wards may also be a contributing factor (Driskill, 1996; McDermott, 1995; Callaghan and Williams, 1994).

We were aware of no randomised controlled trials (RCTs) of care pathway-driven inpatient diabetes care. The aim of this study was to design and test the impact of a care pathway (CP) for inpatients with diabetes. CP impact was assessed through measurement of length of stay (LoS), HbA_{1c} management, if there were any re-admissions within one year, nurse knowledge and the quality of diabetes inpatient care.

Development of the care pathway

The pathway was developed in consultation with ward staff. It consisted of two key elements: a set of evidence-based standards underpinning the pathway, and the pathway itself. The standards do not form part of the patient record but are kept in clinical areas for reference. The pathway includes direction for general staff on blood glucose monitoring (see *Figure 1* for an example of a pathway record sheet for blood glucose monitoring on the wards) and investigations to be ordered for inpatients with diabetes. It also includes information for interpretation and action on the results, management of glucose potassium insulin (GKI) infusion regimens, and a patient-held pathway. The pathway was piloted and refined on one ward before being used in the study.

Research design and methods

The study was a single-centre, open-label, RCT conducted at Whiston Hospital in Prescot, Merseyside. Suitable people were recruited from the medical admissions unit between December 2000 and November 2001. All gave written informed consent prior to participation in the study.

ARTICLE POINTS

1 A care pathway for the management of inpatients with diabetes was developed and tested.

2 We measured the impact of the pathway on length of stay, quality of care, nurse knowledge, HbA1c and re-admissions within one year.

3 Non-specialist staff may require ongoing support in the use of a care pathway.

4 The inpatient care pathway was associated with improved nurse knowledge, fewer re-admissions, improved diabetes care and shorter length of stay.

KEY WORDS

- **Inpatient**
- **Care pathway**
- **Support**
- **Audit**
- **Re-admission**

Sarah O'Brien, is Nurse Consultant in Diabetes, Susan Michaels is a DSN, Janet Marsh is a DSN and Kevin Hardy is a Consultant Physician and Endocrinologist at the Diabetes Centre at Whiston Hospital in Merseyside

PAGE POINTS

1 The care pathway (CP) was designed for use by both medical and nursing staff.

2 Whether staff required constant support and education to use the CP was examined.

3 Staff knowledge was measured before and after the trial using a questionnaire.

Patients

Male and female patients over 18 years of age with either type 1 or type 2 diabetes admitted to the medical admissions unit with either a diabetes-related problem or another medical complaint were invited to participate in the study. People in this group were excluded if they were unable to give informed consent or if they had already been on the admissions ward for more than 24 hours.

General ward staff

The CP was designed for use by both medical and nursing staff. It was, however, intended to be kept with other nursing charts at the end of the patient's bed and it was anticipated that nursing staff would drive its use.

A secondary objective of the study was to examine whether staff required constant support and education to use the CP accurately or whether the pathway's use required little external support following implementation. To assess this, the medical wards were divided into two groups. Wards in group one received ongoing support in the use of the pathway. They were visited regularly by the investigator and reminded how to use it. Wards in group two received no ongoing support in the pathway's use. Staff nurses' knowledge of diabetes was measured prior to the start of the RCT using a validated knowledge questionnaire (O'Brien et al, 2003). Nurses were re-tested at the end of the study to assess the impact of the pathway on staff knowledge.

Baseline

Having secured informed consent, the following information was recorded:

- type and duration of diabetes
- current diabetes therapy and other medications
- reason for admission, number of hospital admissions in last 12 months
- body habitus (slim, normal, large, obese)
- diabetes complications
- Barthel score (a measure of dependency determining that the patients in the two groups were similarly independent)
- HbA_{1c} (Diabetes Control and Complications Trial-aligned assay, normal range 4.6–6.2%) (DCCT, 1993).

If HbA_{1c} had not been measured in the preceding four weeks, a test was arranged.

Figure 1. A pathway record sheet relating to blood glucose monitoring on the wards.

ST HELENS & KNOWSLEY HOSPITALS
BLOOD GLUCOSE MONITORING CHART
(SVO:Ver 3:7/99)

Pt name & address or sticky label.

Please answer questions below on admission to pathway.				Day 1		Day 2		Day 3		Day 4		Day 5	
				Date: Time: Do 6 hourly BMs		Date: Time: Do ——— tests		Date: Time: Do ——— tests		Date: Time: Do ——— tests		Date: Time: Do ——— tests	
		Initials		*VALUE*	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*	*VALUE*	*Initials*
Does Pt self BG monitor at home?	Y N		Pre-breakfast										
			Pre-lunch										
Does Pt use BG meter at home?	Y N		Pre-Tea										
			Pre-bed										
Does Pt wish to see DLN to get meter	Y N		Ketones if required										
Important note			1.BG profile/Pt status reviewed?	Y N		Y N		Y N		Y N		Y N	
If the answer to any of the shaded questions to the right is 'no', then you must immediately complete a variance (colour) sheet.			2.Does Rx need changing?	Y N		Y N		Y N		Y N		Y N	
			3.If 2=yes then, was Rx changed?	Y N		Y N		Y N		Y N		Y N	
			4.No.of tests for next day specified.	Y N		Y N		Y N		Y N		Y N	

For when to check ketones – see **Monitoring Pathway**; for Rx. changes – see **Treatment Pathway**; if in doubt, then contact **Diabetes Liaison Nurse** on 1348

People participating were randomised to either a CP or usual care (non-pathway, NP) using computer-generated numbers in sealed, sequenced envelopes that were concealed from the investigators until assignment to a participating person.

Intervention period

Following randomisation patients were not seen again by the investigator and the intervention period lasted for as long as their length of stay (LoS). People randomised to a CP were expected to stay on the pathway until discharged, with their diabetes being managed according to the pathway. Patients randomised to NP had their diabetes managed in the usual way. The investigator continued to support those wards in group one, reminding them how to use the care pathway.

Follow-up

Following discharge, the patients' case notes were audited to assess the quality of diabetes care received and compliance with the pathway. To measure the quality of diabetes care we took four parameters – HbA_{1c}, urinalysis for protein, cholesterol levels and appropriate referral to the diabetes team. We calculated the average number of patients that received the parameter tests and compared CP to NP using the Yates-corrected chi-squared test.

We also looked at management of GKI regimen, standard of documentation, and HbA_{1c} three months post discharge. If an HbA_{1c} test had not been organised by the patient's GP, they were invited to attend the diabetes centre where it was done using a DCA 2000 Analyser (DCCT-aligned). Re-admission data were collected using the hospital electronic patient information system.

Once the trial had finished, the nurses who had completed the knowledge questionnaire before the RCT were invited to complete a second one. Comparisons were made between their first and second answers and between staff located on wards in group one (support in use of pathway) versus those on wards in group two (no ongoing support).

Results

Ninety-three patients were recruited to the study: 38 to CP and 57 to NP. Eighty-one were included in the final analyses of which 33 were randomised to CP, and 48 to NP. The reasons for exclusion from the analyses were either missing three-month HbA_{1c} data (10 patients) because patients failed to attend for a repeat HbA_{1c}, or missing hospital case notes (two patients), therefore diabetes management could not be evaluated. The two groups were matched at baseline for age, diabetes duration, sex, percentage with type 2 diabetes and baseline HbA_{1c} (*Table 1*).

Table 1. Baseline demographics for people in group one (care pathway with ongoing support) and group two (CP without support)

Demographic	Group 1	Group 2
Age	66 ± 13 years	65 ± 13 years
Diabetes duration	10 ± 11 years	10 ± 9 years
Sex	Male: 16 (48%)	Male: 33 (69%)
	Female: 17 (52%)	Female: 15 (31%)
Type 2 diabetes	28 (85%)	42 (88%)
HbA_{1c}	7.8 ± 1.8	8.0 ± 1.8

The frequency of blood glucose monitoring was more appropriate with the CP group. Twenty-three out of 33 people in the CP group (70%) compared to eight out of 48 people (17%) of the NP group had an appropriate number of tests recorded.

Almost all of the patients (33 CP and 45 NP) had their blood pressure and creatinine done, as these are measured routinely on admission.

The CP was associated with a significantly better quality of diabetes care (management of HbA_{1c}, cholesterol, urinalysis, and referrals to team), CP 26/33 people versus NP 24/48 people ($p=0.02$).

The GKI section was not completed on any of the pathways, although patients were on a GKI regimen. Similarly, the patient-held part of the pathway was filed in many of the notes, indicating that this had not been completed and given to patients. The standard of documentation in both the CP and NP groups was sub-optimal. Many sections of the CP were not completed, in particular the doctors' sections were often blank.

The CP was associated with a significant improvement in staff knowledge, fewer re-admissions and non-significant shorter LoS (*Table 2*). HbA_{1c} fell in both groups by 0.6%.

PAGE POINTS

1. Patients were randomised to either normal care or a CP.
2. Following discharge patients' notes were audited to assess quality of care received.
3. Frequency of blood glucose monitoring was more appropriate in the CP group.
4. The CP was associated with a significantly better quality of care.
5. Standard of documentation was sub-optimal in both the CP and non-pathway groups. Many sections of the CP were not completed.

PAGE POINTS

1 Length of hospital stay and HbA_{1c} control were improved, but not significantly.

2 On wards using a CP, those with ongoing support had a greater increase in knowledge than those without.

3 Overall, CPs were associated with significant improvement in staff knowledge, fewer re-admissions, and a reduction in length of stay in hospital.

4 Quality of diabetes care was significantly better when CPs were used.

Discussion

The CP was associated with a significant improvement in the quality of inpatient diabetes care. More of the patients on the pathway had tests for HbA_{1c}, cholesterol, proteinuria and blood glucose monitoring. Referrals to the diabetes team were more appropriate than in patients not on a pathway. In addition, staff were more likely to act on abnormal results for patients on a pathway.

We have recently re-written each of our many outpatient care pathways to fit one page, which has made them much more user-friendly and has increased their effectiveness and improved use to almost 100%. We are in the process of doing the same for these inpatient pathways with the intention of having a single side for this CP for all wards.

In both groups the documentation of care given was sub-optimal and staff did not consistently complete all sections of the pathway. The GKI chart and patient-held pathway were not completed and, prior to further implementation of the pathway, these sections and others may need revising to improve compliance.

Staff on wards in group one (which had ongoing support in the use of the pathway) had a greater increase in knowledge than those in group two. The results indicate that successful implementation of a pathway for diabetes management amongst non-specialist staff requires continuous support in its use. This support is sustainable with larger numbers of patients because it is more efficient and practicable than specialists seeing all of the patients.

A limitation of the study was the small number of patients recruited into the subgroups. Larger subgroups may have revealed more significant differences between wards in group one and group two.

The study did not demonstrate statistically significant differences in LoS or HbA_{1c} but both parameters improved in those on the CP.

Re-admissions at one year were fewer with the patients in the CP group. It is beyond the scope of our study to determine why patients whose treatment was guided by a CP had a lower re-admission. However, this is an interesting topic for further research.

We conclude that inpatient CPs are associated with a significantly better quality of diabetes care, improved nurse knowledge, significantly fewer re-admissions after one year, shorter LoS, and better diabetes control. CPs may be a useful tool to facilitate inpatient diabetes management by non-specialists. ■

Abbott RD, Donahue RP, Kannel WB, Wilson PW (1988) The impact of diabetes on survival following myocardial infarction in men vs women. The Framingham Study. *Journal of the American Medical Association* **260**: 3456–60

Audit Commission (2001) *Testing times: a review of diabetes services in England and Wales*. Belmont Press: Northampton.

Callaghan D, Williams A (1994) Living with diabetes: issues for nursing practice. *Journal of Advanced Nursing* **20**: 132–39

Department of Health (2001) *National Service Framework for Diabetes: Standards*. DoH: London.

The Diabetes Control and Complications Trial Research Group (1993) The effect of intentensive treatment of diabetes complications on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* **329**: 977–86

Driskill W (1996) Diabetes education: what every LPN should know. *The Journal of Practical Nursing* 14–18

MacKinnon M (1993) *Providing Diabetes Care in General Practice*. Class Publishing: London.

McDermott J. (1995) Communication and education: Developing the role of the diabetes specialist nurse. *Professional Nurse* 290–92

O'Brien SV, Michaels SE, Hardy KJ (2003) A Comparison of general nurses' and junior doctors' diabetes knowledge. *Professional Nurse* **18**: 257–60

Pickup J and Williams G, eds (1991) *Textbook of Diabetes*. Blackwell Scientific Publications : London.

Table 2. Differences in outcomes with (Group 1) and without (Group 2) assistance in the use of a care pathway

	Group 1 (N=33)	Group 2 (N=48)	P value
Staff knowledge (increase in total scores)	57	82	0.04
Number of patients readmitted	12	33	0.008
Length of stay (days)	8 ± 7	9.2 ± 10	0.5