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The Future Burden of CHD and Diabetes in Scotland: The Value of Health Care Innovation

A Final Report for ABPI Scotland

NERA

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The Value of Health Care Innovation

“In spite of recent progress, Coronary Heart Disease remains one of the major causes of morbidity and mortality in Scotland. We still suffer higher levels of premature death, chronic illness and reduced quality of life than comparable societies elsewhere.

This report is an important contribution to our understanding of the scale of the problem we face and, of even greater importance, the steps we can take to help reduce it. It provides valuable insights into the impact of recent innovations in pharmaceutical and other therapies, of organisational changes within the NHS, and of the vital lifestyle improvements which can all contribute to reduce the burden of CHD, for both individuals and society.”

David H. Clark

Chief Executive
Chest, Heart and Stroke Scotland

“This report is a very welcome summary of the challenge of diabetes for us all in Scotland. It highlights that both Type 1 and Type 2 diabetes are growing dramatically and the impact of living with diabetes has potentially devastating consequences for individuals, the NHS in Scotland and our society as a whole.

Our membership survey in 2004, “To make myself understood”, highlighted that people with diabetes do want to know about new treatments and technology. Most importantly it also reminds us that tight control, as recommended in this report, will only be achieved through education, information and support for all living with diabetes.”

Audrey Birt

National Director Scotland
Diabetes UK

Report Foreword

As you read this report, one of the most striking messages will be that many Scots today owe their health, if not their lives, to medicines. The best that the pharmaceutical industry produces is very good indeed and I am delighted to write a foreword to this summary of the evidence that showcases these very positive aspects. I found this a very clearly presented and thought-provoking read. Of course, the researcher in me still probes away at the numbers – do I really accept those projections? Does that piece of evidence really generalise to Scotland? But the health policy analyst in me wonders whether these medicines, that have proven their effectiveness and cost-effectiveness for these indications, are getting to everybody who could benefit from them. The evidence we have says that there is still a very patchy picture across Scotland and this simply cannot be allowed to continue.

The key to implementation could lie in the empowerment of managed clinical networks for chronic diseases, with the renewed emphasis given to this sector by the Kerr Report, “Building a Health Service Fit for the Future” in May 2005. But this is a reminder that medicines are one part of a team approach to the problem. We also need primary care staff, diagnostic facilities and access to specialists ... and there is this quite important individual called The Patient, who has a non-negligible role to play as well! Each one of these component parts of the care package can make a case for additional spending to allow them to expand and, despite NHS spending being at record levels, resources will continue to be stretched. When we decide to spend more money on one thing, such as a new medicine, that means there is less to spend on other things, like community-based specialists or local diagnostic services. This means we need to look at each new (and existing) medicine on its own merits – they can do good (in terms of helping people to live longer lives, with less symptoms), sometimes they can do harm (through side-effects) and they cost money that cannot now be spent on other health services. The same benefit-harm-cost analysis applies to additional members, new ways of working, diagnostic equipment and so on. The trick is to identify the mix of services (including medicines) that deliver as much health benefit as possible to the population of Scotland.

Groups such as the Scottish Medicines Consortium have a key role to play by independently evaluating the case made for each new medicine as it becomes available and issuing guidance to the NHS in Scotland on its use. The SMC is now internationally recognised as being one of the world leaders in this type of work, and that is thanks to the strong and enduring partnership that has been established between this consortium of NHS boards and the pharmaceutical industry. NHS Scotland needs to identify and build on these positive examples of partnership working that lead to benefits for everybody both at a national level and locally.

I compliment all of those involved in the production of this report and commend it to the NHS, to health policy decision-makers and the Scottish public as a demonstration of what can be achieved and, frankly, a very good read.

Dr Andrew Walker

Health Economist, Robertson Centre for Biostatistics, University of Glasgow

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Executive Summary

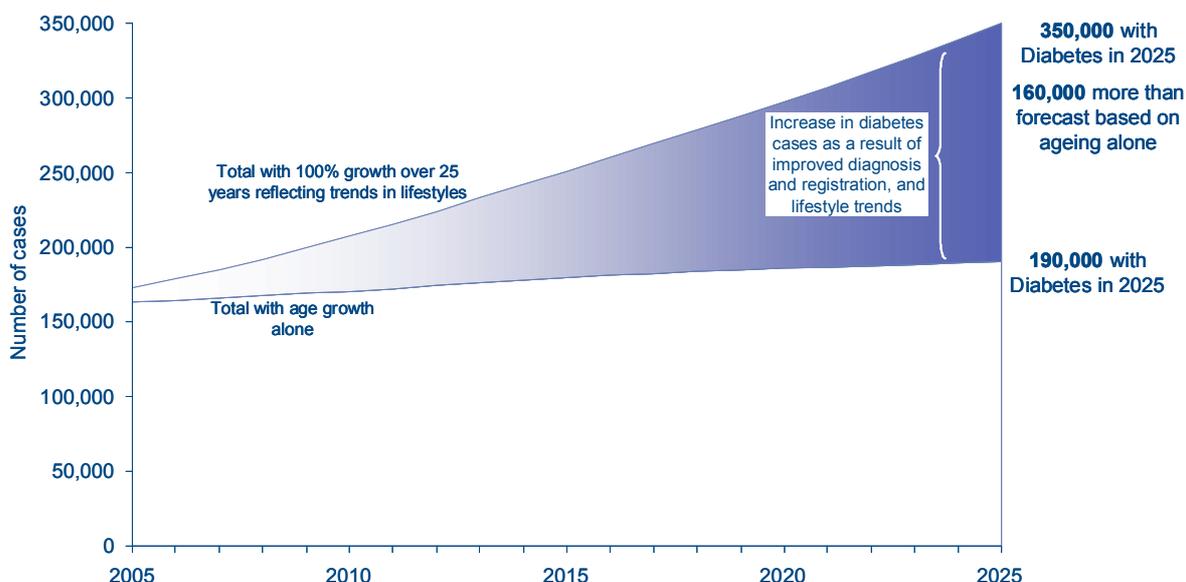
According to a report in 2001 by the Public Health Institute of Scotland “Scotland has the worst health in the United Kingdom”. Many factors contribute to this, including levels of deprivation and related lifestyle and socioeconomic influences, and perhaps a tendency for health systems to focus on treating rather than preventing illness. Much can also be done to address this position and a coordinated approach is called for by the Scottish Executive. The aim of this report is to assess how innovation in health care interventions can help to tackle some of the disease trends that will place increasing pressure on Scotland’s health service in the future.

We use case studies of Type 2 diabetes and coronary heart disease (CHD). For both diseases, we examine the factors that can contribute to the development of disease, such as diet and levels of physical activity, and present data on variations across Health Boards. We also look at the burden of these diseases on patients, the health system and the economy, and then assess the implications of growing pressures in the future. We discuss how innovations in treatment, coupled with other health and non-health interventions, can help to manage this disease burden. We focus primarily on pharmaceutical innovations, but many other innovations, such as in medical devices, and even innovation in how health systems operate (such as better administrative co-ordination and joint working), all play an important part.

A Growing Disease Burden

The overall implications of the analysis are clear. Both diseases impose a significant burden on Scotland’s health system. Research suggests that the annual health care costs of a patient with Type 2 diabetes are over 6 times higher than the costs of a person without diabetes. A portion of these costs are incurred in primary care, but the majority of costs arise either from complications, because the condition is poorly managed, or through other diseases associated with diabetes. Evidence suggests that the burden of diabetes will grow. At the moment, there are over 162,000 people diagnosed with diabetes in Scotland—a prevalence of 3.2 per cent of the population, which is higher than the UK average of 2.3 per cent. An ageing population will contribute to growth in the number of cases, but poorer diets, obesity and lack of physical exercise have the potential to greatly increase this burden. Over the next 20 years, the number of people with diabetes could double (figure 1). The pattern of growth will vary across Health Boards, reflecting their different demographic and socioeconomic profiles.

Figure 1
Scenario Around Future Prevalence of Diabetes, 2005-2025, Scotland



Source: NERA calculation using General Register Office for Scotland and Scottish Diabetes Survey (2004 and 2003) data

A similar story holds true for CHD. The morbidity and mortality impacts of CHD are significant, and again patterns vary across Health Boards. Whilst mortality from CHD has fallen consistently over the last 50 years, the UK has generally performed badly compared to other European countries. Within the UK, Scotland has the highest CHD mortality rates. Current estimates suggest that around half a million people have CHD in Scotland, with 180,000 requiring treatment for symptomatic disease. This is high compared to the rest of the UK and represents a significant cost to patients and the health system, and the burden is set to grow. The National Audit Office, for example, suggest that by 2010 over a quarter of all adults will be obese (obesity increases the relative risk of angina (a symptom of CHD) by around 2 per cent). We estimate that the total economic cost of CHD in Scotland in 2005 is around £1.8bn (1999 prices).

Managing Disease

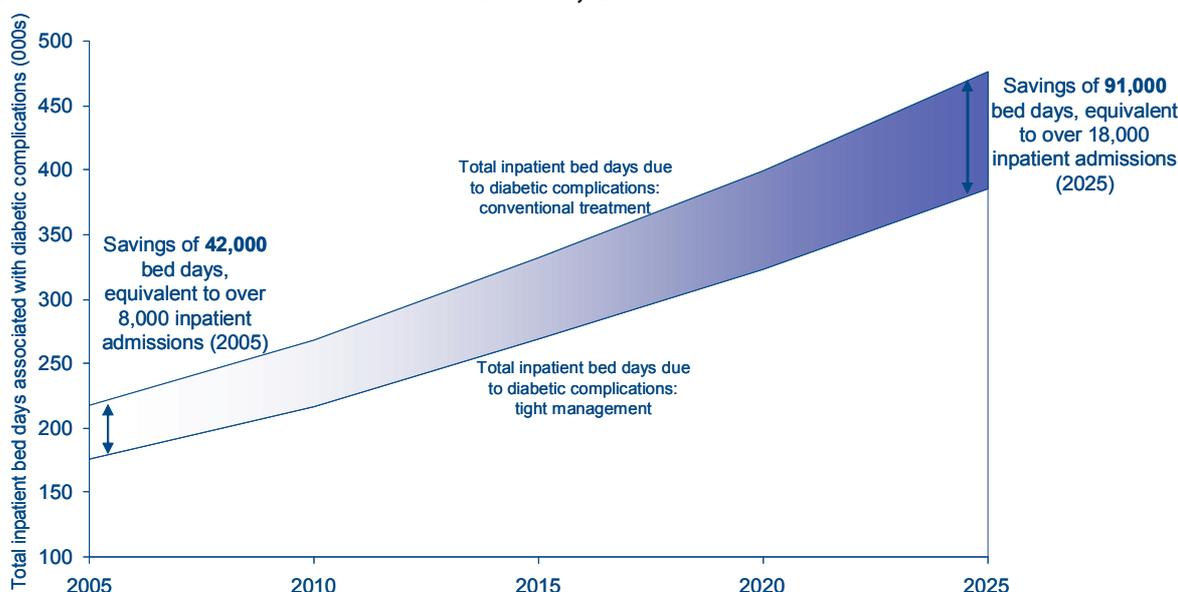
Scotland is taking a collaborative and multi-disciplinary approach to tackling these disease trends. Guidelines and strategies for managing diabetes have been set out, including treatment guidance and the formation of cross-disciplinary clinical networks, and Health Boards have been assessed against standards set by the Clinical Standards Board for Scotland, now part of NHS Quality Improvement Scotland (NHS QiS). Similarly for CHD, the Scottish Executive set out its strategy for tackling CHD and Stroke in 2002, and significant additional funding has been put into funding strategies that aim to reduce the incidence of CHD and provide better and earlier treatment.

The Importance of Innovation

Pharmaceuticals and medical devices have an important role to play in managing the burden of diabetes and CHD. Evidence suggests that early intervention and good management of disease lead to better outcomes and are cost effective approaches. Over the last 30 years,

innovation has improved the diagnosis of disease, markedly increased opportunities for treatment, and has changed the way illness is managed. In the case of diabetes, for example, there is strong evidence to suggest that tight management of blood glucose levels reduces the complications associated with the disease, such as kidney disease and eye disease. New innovations make tight management much easier and an increasingly common treatment approach. There are more pharmaceutical therapeutic options for managing diabetes, new delivery approaches (no longer relying on injection), and medical device innovation has improved testing for diabetes, monitoring of blood glucose levels (including minimally invasive devices that constantly monitor levels). These innovations, as well as improving quality of life for patients, can generate savings elsewhere. We estimate, for example, that tight management of Type 2 diabetes could currently save around 42,000 hospital bed days in Scotland, and the additional cost of tightly managing patients would be largely offset by savings elsewhere (figure 2). In addition, there are potential benefits to the economy through reductions in employee sickness absence. We estimate this benefit in 2005 could be around £44m (2004 values). Benefits to carers of people with diabetes increase the scope for savings.

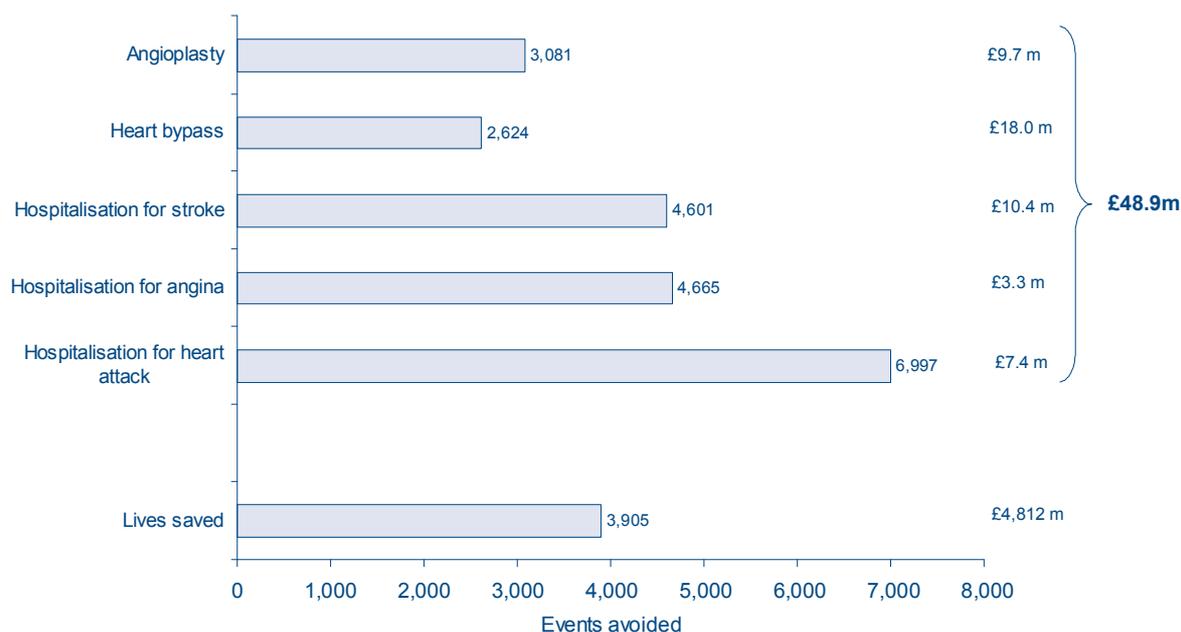
Figure 2
Estimated Inpatient Days Saved from Tight Management of Type 2 Diabetes, 2005-2025, Scotland



Source: NERA calculation using Gray, A., Raikou, M., McGuire, A. et al (2000) Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41), British Medical Journal, Vol 320 pp1373-78; Scottish Diabetes Survey 2004; and General Register Office for Scotland data

The message is similar for CHD. Lipid lowering drugs (statins) offer significant benefits to patients and the health sector by reducing the consequences of CHD, such as angioplasty, hospitalisation for stroke and heart bypass operations. Figure 3 below illustrates the scale of these benefits for Scotland over a 5 year period. By far the biggest benefit of statins is the lives they can save—in Scotland this is estimated to be almost 4,000 lives saved over 5 years. Yet there is significant variation across Health Boards in the prescribing of statins.

Figure 3
Events Avoided Through Treatment with Statins, Scotland Over 5 Years



Source: NERA calculations using HPSCG (2002) data and NHS Reference Costs (2003)

Similarly, the development of thrombolytic medicines has significantly improved survival following a heart attack. Thrombolytics break down blood clots to restore blood flow to the heart following a heart attack. Older thrombolytics, whilst highly effective, could only be administered once. Newer thrombolytics benefit patients who have repeat heart attacks. Thrombolytics are a good example to illustrate how innovation needs to work in partnership with other parts of the health system. They are most effective when delivered within 60 minutes of heart attack, which can be a challenge particularly in rural areas. Some Health Boards have experimented with community-based approaches to help meet these response times.

Future Challenges

The burden of CHD and Type 2 diabetes is widely predicted to grow in the future. An ageing population will contribute to this, but the real risk is that future growth will increasingly be driven by other factors, such as lifestyle and diet. These public health influences are hard to change, and policymakers have recognised the challenge they present and the need to act. The emphasis is very much on reducing incidence, improving diagnosis and intervening early. Such an approach cuts across health interventions, and innovation in medicines and medical devices are already supporting this through better diagnosis, new treatment options and easier management of disease. Variations across Health Boards indicate that challenges still remain, but the scale of costs and consequences of diabetes and CHD outlined in this report emphasise the importance of maintaining and building on the existing positive policy emphasis.

1. Introduction

Innovation is vital to tackling ill health in the modern era. Innovations have made substantial improvements to ill health, ranging from new methods for surgery (for example coronary artery bypass grafts which help to fix blockages in the vessels around the heart), changes in the way care is delivered (for example pre-hospital thrombolytics which help to prevent blood clots which can permanently damage the heart after a heart attack) and new medicines (for example statins which we discuss later in this report) have brought substantial benefits. These benefits include saving and improving the quality of life of patients as well as carers, avoiding hospitalisations and the wider benefits to the economy through fewer sickness absence days, and more efficient use of health and social service resources.

A full review of the way in which innovations in medicines have benefited Scotland is beyond the scope of this report. The aim of this report is to focus on two disease areas of key significance in Scotland and focus innovation in the treatment of coronary heart disease (CHD) and Type 2 diabetes. Despite improvements in CHD mortality the trend in Scotland remains above the rest of the UK, suggesting that more needs to be done to tackle this problem. Similarly for diabetes trends in lifestyle suggest that Scotland may have more of a problem in the future than it's UK counterparts.

The report first considers the factors which affect health in Scotland. This covers both lifestyle factors relevant to the prevalence and incidence (how many people currently have and are getting) of CHD and diabetes and the wider determinants of health. In Section 3 we consider the likely impact of these trends on both CHD and diabetes. We also consider the current costs associated with both diseases in Scotland. Sections 3.3 and 4.3 go on to look at the role of medicines in the treatment of CHD and diabetes in Scotland and the policies and strategies in place in Scotland to tackle these diseases. We have drawn out the benefits from selected types of medicines to Scotland, focusing upon tight management of Type 2 diabetes (using medicines to keep HbA1c levels – the level of glucose in the blood – below 7%) and statins and thrombolytics for CHD. These medicines improve quality of life for patients and their carers and, in some cases, lead to more effective use of health care resources.

2. Determinants of Health in Scotland

In this chapter we review some of the key health determinants in Scotland. We have focused on lifestyle trends such as diet, exercise, smoking, and obesity, and have also acknowledged the wider determinants of health, for example unemployment and income (proxied by car ownership). These determinants have a major impact on both CHD and diabetes.¹

Throughout this chapter we consider the relative position of Scotland compared to other parts of the UK and, where data is available, the relative position of different parts of Scotland.

2.1. Lifestyle Factors

There are a host of factors that are directly related to the way in which we choose to live that impact on our health. These are interrelated with the wider determinants of health (for example those on higher incomes can choose to buy more expensive types of food etc.) but can all be modified by our own behaviour.

2.1.1. Smoking

Smoking is recognised as a major factor in causing CHD. Around 1.2 million people smoke in Scotland, with 33 per cent of men and 29 per cent of women smoking cigarettes. This compares poorly with the average rate across the UK of 26 per cent.² Smoking rates have been consistently higher in Scotland over the last 25 years than in England, Wales and Northern Ireland.³ Figure 2.1 illustrates the percentage of men who smoke across the UK and within Scotland. Within Scotland almost all Health Boards have relatively high levels of smoking (28.5% and above). Only the Highlands and Islands and the Borders have smoking levels at lower rates.

Smoking prevalence is also greater in unskilled and manual social groups compared to those in professional groups. Passive smoking has also been shown to be an important contributor to CHD in adult non-smokers.⁴

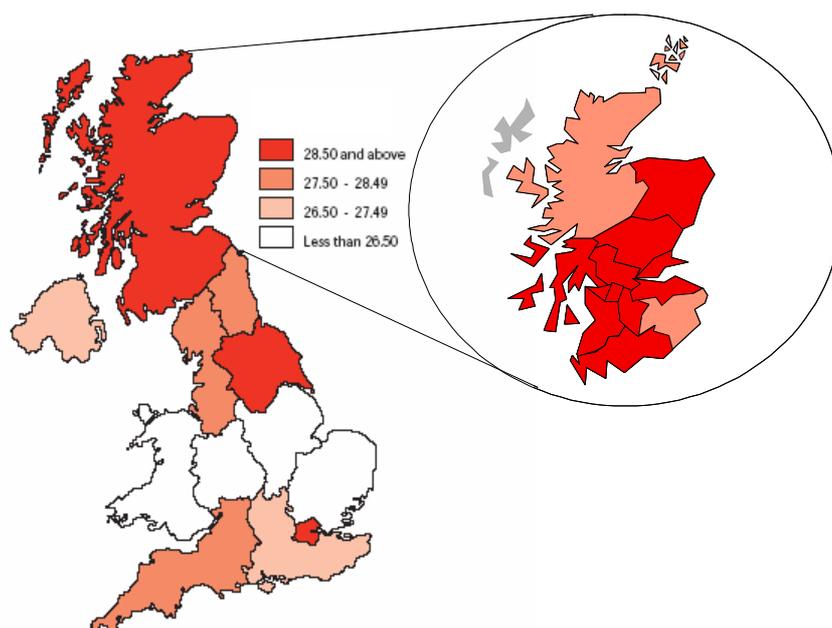
¹ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

² Scottish Executive (2003) *Health in Scotland 2003*

³ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

⁴ Scottish Executive (2003) *Health in Scotland 2003*

Figure 2.1
Percentage of Men Smoking by Region, UK and Health Boards



Source: BHF Coronary Heart Disease Statistics at www.heartstats.org and The Scottish Health Survey (1998)

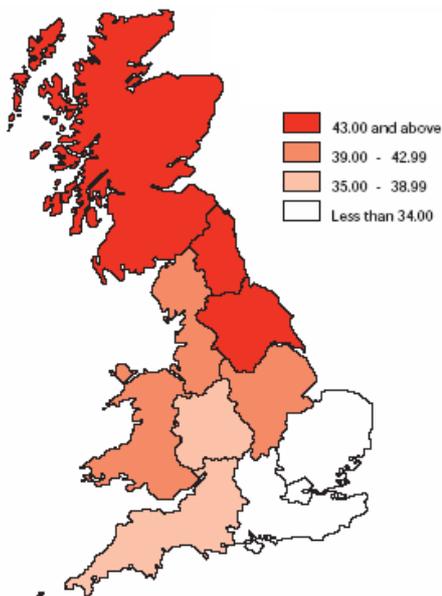
Note: Great Britain 2000/02 data, Local Health Boards 2002 data

2.1.2. Alcohol

Alcohol consumption is a cause for concern not only in relation to CHD and diabetes but also more widely for the short and long term health and social impacts of high levels of consumption. Unhealthy patterns of drinking by adolescents may lead to an increased level of addiction and dependence on alcohol in adulthood. Regular heavy alcohol consumption and binge drinking are associated with physical problems, antisocial behaviour, violence, accidents, suicide, injuries and road traffic accidents.⁵ Rates of alcohol consumption above the recommended 21 units and 14 units a week for men and women respectively are higher in Scotland, than elsewhere in the UK (Figure 2.2). As with smoking there are differences within Scotland, with much higher proportions of men drinking more than the recommended daily maximum in the Argyle and Clyde region (Figure 2.3). It is relevant to note that since 1998, the whole of Scotland is classified as 43 per cent and above of men drinking more than the maximum daily recommended allowance. This suggests that levels of drinking across Scotland have risen in recent years.

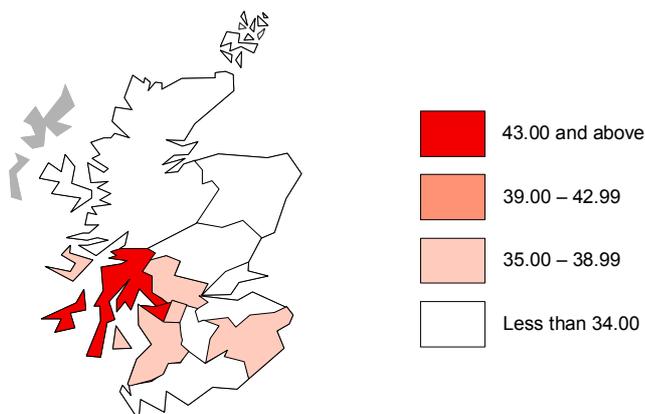
⁵ <http://www.bma.org.uk/ap.nsf/Content/Alcoholyoungpeople>

Figure 2.2
Percentage of Men Consuming More Alcohol than the Recommended Daily Maximum, 2002, Great Britain



Source: BHF Coronary Heart Disease Statistics at www.heartstats.org

Figure 2.3
Percentage of Men Consuming More Alcohol than the Recommended Daily Maximum, 1998, Health Boards



Source: The Scottish Health Survey (1998)

For children’s experience of drinking Scotland fares better than England, with only 8 per cent of boys and girls (aged below 16) drinking once a month or more, compared to 15 and 13 per cent in England.⁶

⁶ The Scottish Health Survey (1998)

2.1.3. Blood pressure

Data shows that for adults aged 40-69 an increase of 20mmHg increase in usual systolic blood pressure, or 10 mmHg increase in usual diastolic blood pressure doubles the risk of death from CHD.⁷ Current guidelines suggest that optimal blood pressure targets are a systolic blood pressure of less than 140mmHg and a diastolic blood pressure of less than 85 mmHg. For those with diabetes it is 130/85mmHg.⁸ In addition to these guidelines the new General Medical Services (GMS) contract includes its own targets for blood pressure to manage hypertension⁹;

- For non-complicated hypertension, hypertension with CHD and for hypertension with stroke $\leq 150/90$ mmHg
- For hypertension with diabetes $\leq 145/85$ mmHg

Scotland fares better than its UK counterparts with fewer men aged 16-74 (33%) having raised blood pressure in Scotland than England (40%) in 1998.¹⁰

2.1.4. Diet

Diet has been recognised as a major factor in the level of CHD, with around 30 per cent of deaths from CHD due to unhealthy diets.¹¹ According to the Scottish Executive, the Scottish diet includes too much fat, salt, sugar, and too little fruit and vegetables.¹² Current guidelines suggest that 5 portions of fruit and vegetables should be eaten a day.¹³ Figure 2.4 illustrates the percentage of male adults and children who are eating the minimum of one portion of fresh fruit per day. Lanarkshire, Ayrshire & Arran and the Forth Valley, Argyle & Clyde both have lower proportions than the Scotland average for men and boys eating a minimum of one portion of fresh fruit per day.

⁷ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

⁸ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

⁹ Clinical Governance Support Team of the NHS - Modernisation Agency
http://www.cgsupport.nhs.uk/downloads/GMS_Resource_Box/07_IndexCards_Hyper.pdf

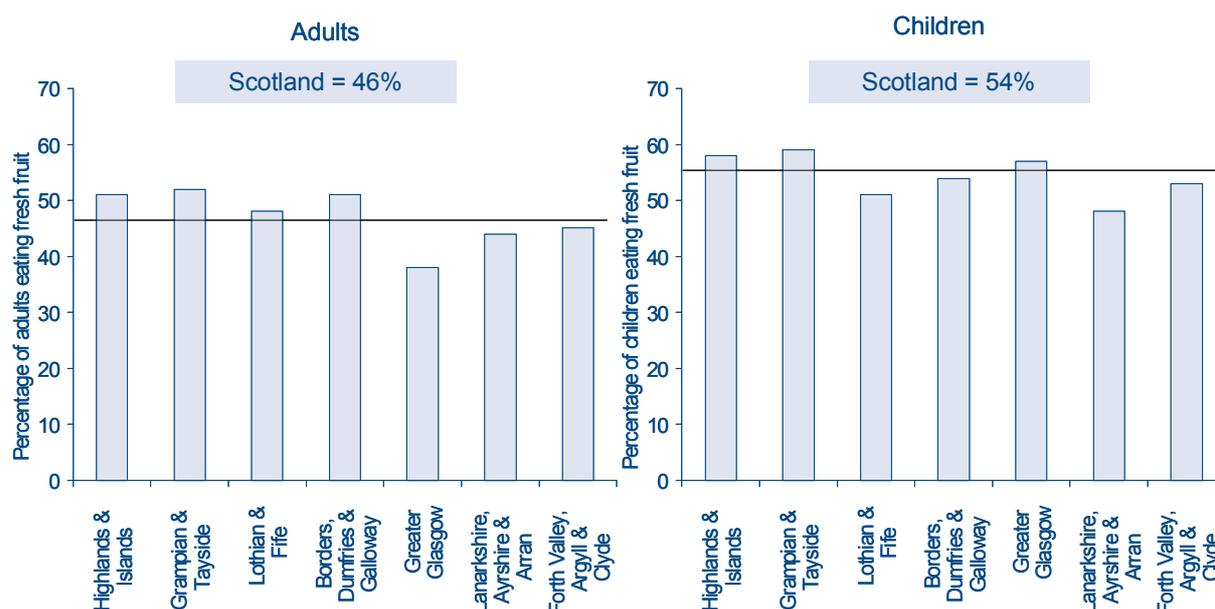
¹⁰ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

¹¹ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

¹² Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*

¹³ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

Figure 2.4
Percentage of Male Adults and Children Eating Minimum of One Portion of Fresh Fruit a Day, 1998, Health Boards



Source: The Scottish Health Survey (1998)

2.1.5. Obesity

Weight and obesity are key factors that affect the prevalence and incidence of CHD and Type 2 diabetes. An increase in Type 2 diabetes has been attributed to increasing levels of obesity amongst children and young people.^{14, 15} Excess weight around the abdomen increases the risk of ill health (known as central obesity). The prevalence of obesity – defined as a Body Mass Index (BMI) of thirty or higher – in Scotland is around 21 per cent of the adult population (around 850,000 adults) and it is higher in Scotland than in England.¹⁶ Estimates suggest that there are around 110,000 people who have had a heart attack in Scotland and 188,000 people suffering from angina as a result of obesity.¹⁷ There is a particular problem in the young in Scotland with 1 in 3 12 year olds overweight, 1 in 10 severely obese and 1 in 5 toddlers overweight before their fourth birthday.¹⁸ It has also been shown that children

¹⁴ House of Commons Health Committee (2004) *Obesity. Third report of session 2003-04*, London: The Stationery Office Ltd.

¹⁵ Scottish Intercollegiate Guidelines Network (1996) *Obesity in Scotland: Integrating Prevention with Weight Management: A National Clinical Guideline Recommended for use in Scotland* by SIGN

¹⁶ Walker, A (2003) *The Cost of Doing Nothing – The Economics of Obesity in Scotland*

¹⁷ Walker, A (2003) *The Cost of Doing Nothing – The Economics of Obesity in Scotland*

¹⁸ Scottish Executive (2003) *Health in Scotland 2003*

from lower socio-economic groups are more likely to be overweight than children from higher socio-economic groups¹⁹.

2.1.6. Cholesterol

It is estimated that over 50 per cent of CHD in developed countries is due to blood cholesterol levels in excess of the theoretical minimum of 3.8 mmol/l. The mean level of total cholesterol is similar in Scotland and England but more people have higher cholesterol in the 35 -54 age group in Scotland than in England (21.9 % above 6.5mmol/l in Scotland compared to 16.9% in England).²⁰ This suggests that there is greater scope to lower cholesterol in this age group in Scotland.

2.1.7. Physical activity

Physical activity is recognised as both an independent risk factor for CHD and also has an impact on the majority of other risk factors for CHD. A reduction in exercise is an accepted factor in the increasing prevalence of type 2 diabetes.⁵⁰ Those who are relatively inactive have almost twice the risk of CHD than those who are active.²¹ In Scotland physical activity is a cause for concern. Six out of 10 men and 7 out of 10 women take less than the minimum recommended amounts of activity in Scotland.^{22 23} Whilst those in the age ranges 16-54 take similar levels of exercise in England and Scotland, those aged 55-74 in Scotland take less than their English counterparts.²⁴

¹⁹ Jebb SA, Rennie KL, Cole TJ (2003) Prevalence of overweight and obesity among young people in Great Britain. *Pub Health Nutr*, 7, 461-65

²⁰ The Scottish Health Survey (1998)

²¹ Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*

²² Scottish Executive (2003) *Health in Scotland 2003*

²³ The current recommendation for physical activity is that adults should participate in a minimum of 30 minutes of at least moderate intensity activity (such as brisk walking, cycling or climbing the stairs) on five or more days a week. Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

²⁴ Petersen, S, Peto, V and Rayner, M (2004) *Coronary Heart Disease Statistics: 2004 Edition*, British Heart Foundation Health Promotion Research Group, Department of Public Health, University of Oxford

2.2. Responding to Lifestyle Factors

The Scottish Executive Health Department has recognised the risk of many of these lifestyle factors and Scotland's position relative to other parts of the UK. It has a number of strategies, which include targets for achievement of improvements in lifestyle factors. Box 1 illustrates some of these targets.

Box 1: Strategies and Targets for Improving Lifestyles in Scotland

DIET	Strategy	Hungry for Success (2002) set out a range of guidelines for healthy eating in schools and recommended that vending machines include healthier options like fruit juice and water. The programme also includes free fruit for children in primary 1 and 2.
	Targets	<p>Fat - To reduce the average percentage of food energy from total fat to no more than 35% by the year 2005.</p> <p>Saturated fat - To reduce the average percentage of food energy from saturated fatty acids to no more than 11% by the year 2005.</p> <p>Fruit and vegetables - To double the average intake of fruit and vegetables to more than 400g per day by the year 2005.</p> <p>Salt - To reduce the average intake of salt from 9.6g to 6g per day by the year 2005.</p>
SMOKING	Strategy	The White Paper <i>Smoking Kills</i> in 1998 highlighted some of the major impacts of smoking across the whole of the UK. This has resulted in the increase in smoking cessation services across Scotland. These services include nicotine replacement therapy and bupropion on prescription. This is supported in Scotland through the Partnership on Tobacco and Health (PATH) programme, launched in 2002, which gathers and disseminates research on best practice on smoking cessation. In addition the Smoking, Health and Social Care (Scotland) Bill introduced by the Scottish Parliament recognises the need to tackle smoking in Scotland and includes the provision of pharmaceutical care services (including medicines to help people to quit smoking).
	Target	Reduction in adult smoking from an average of 35% to 33% between 1995 – 2005 and to an average of 31% by 2010.
PHYSICAL ACTIVITY	Strategy	The National Physical Activity Strategy was published in 2003. This strategy focuses on increasing activity across four settings; Active Schools, Active Communities, Active Workplaces and Active Homes. Specific projects include exercise referral schemes which refers those with sedentary lifestyles to physical activity counsellors including those who have had a heart attack and need to increase exercise as part of their rehabilitation.
	Targets	<p>Men - To increase the proportion of men aged 16 – 64 taking 30 minutes of moderate activity on 5 or more occasions each week, from 32% in 1995 to 50% by 2005 and 60% by 2010.</p> <p>Women – To increase the proportion of women aged 16 – 64 taking 30 minutes of moderate activity on 5 or more occasions each week, from 22% in 1996 to 40% by 2005 and 50% by 2010.</p> <p>Young People – To increase the proportion of 11 – 15 year olds taking vigorous exercise 4 times or more weekly, from 32% in 1994 to 40% in 2005 and 50% in 2010.</p>
ALCOHOL	Strategy	The Plan for Action on alcohol problems focuses upon binge and harmful drinking and is encouraging more moderate drinking patterns. The plan includes education and communication strategies to increase awareness of the problems of irresponsible drinking.
	Targets	<p>Men – To reduce the proportion of men aged 16 – 64 exceeding the weekly limit of 21 units of alcohol from 33% to 31% between 1995 and 2005 and to 29% by 2010.</p> <p>Women – To reduce the proportion of women aged 16 – 64 exceeding the weekly limit of 14 units of alcohol from 13% to 12% between 1995 and 2005 and to 11% by 2010.</p> <p>Young people –To reduce the frequency and level of drinking from 20% of 12-15 year olds to 18% between 1995 and 2005 and to 16% by 2010.</p>

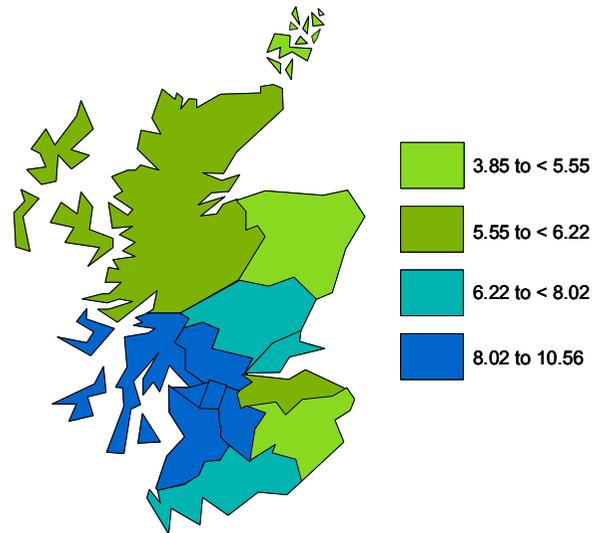
Source: Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*, BHF (2004) *CHD Statistics 2004*, Scottish Executive (2003) *Health in Scotland 2003* and *Smoking, Health and Social Care (Scotland) Bill (As Introduced) SP Bill 33 Session 2 (2004)*

2.3. Wider Determinants of Health

The causes of ill health are varied and complex and go further than the lifestyle factors that we have already considered. Socio-economic factors as well as genes, sex, ageing, the environment and access to all types of services affect the level of ill health. Many of these factors are also inter-related. Figure 2.5 to Figure 2.7 highlight differences across Scotland on some key socio-economic factors including economic inactivity (unemployment) due to ill health and for other reasons and car ownership (as a proxy for income).²⁵

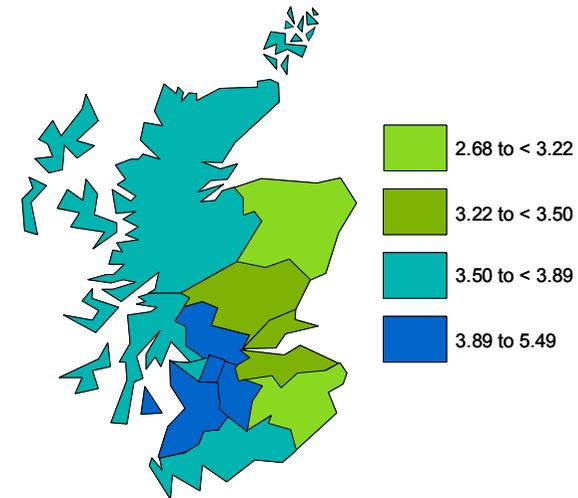
²⁵ It is recognised that car ownership may not be the most appropriate indicator of wealth in rural areas. Institute of Rural Health and General Practitioners Committee of the British Medical Association (2001) The Nature of Rural General Practice in the UK: Preliminary Research

Figure 2.5
Percentage of People (Aged 16-74) Economically Inactive –
Permanently Sick/Disabled, 2001, Health Boards



Source: SCROL

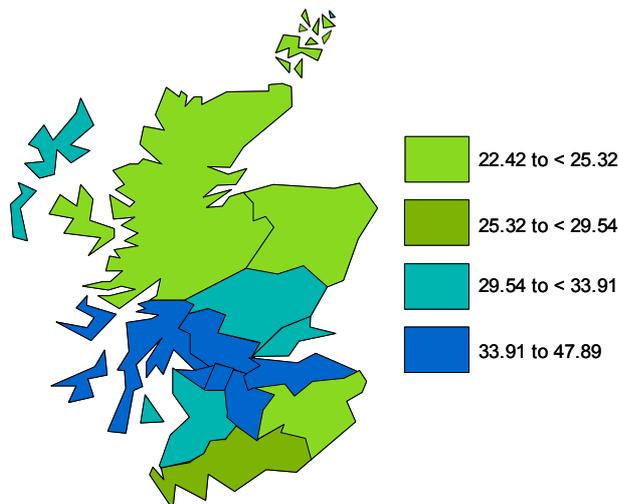
Figure 2.6
Percentage of People (Aged 16-74) Economically Inactive –
Other, 2001, Health Boards



Source: SCROL

Note: Other category covers all those who are not included in the following groups: those economically inactive because of retirement, studying, looking after the family home and permanently sick/disabled

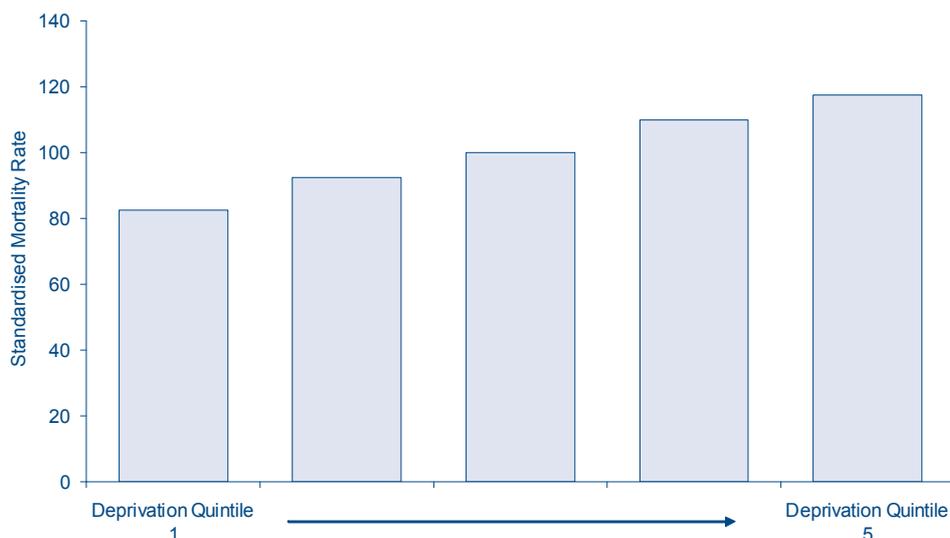
Figure 2.7
Percentage of Households with No Car/Van Ownership, 2001, Health Boards



Source: SCROL

These figures highlight some major differences across Scotland. For example Ayrshire and Arran, Lanarkshire and Greater Glasgow all have relatively low levels of car ownership (as a proxy for income), and relatively higher levels of economic inactivity for both permanently sick/disabled or other reasons. These differences will inevitably feed through into differences in health. For example Figure 2.8 illustrates how the prevalence of CHD varies across deprivation quintiles. The highest standardised mortality rate from CHD is seen in the most deprived quintile.

Figure 2.8
Standardised Mortality Rates from CHD by Deprivation Quintile



Source: Health Education Board for Scotland – statistics database at www.hebs.com

2.4. Concluding Comments

When reviewing mortality rates Scotland compares poorly with countries across Europe. This is partly attributable to Scotland's relative levels of deprivation. Analysis of census and mortality data has shown that deprivation accounts for only around 40 per cent of the excess deaths in Scotland. The excess deaths not accounted for by relative deprivation have been referred to as the 'Scottish Effect'. The overall finding of work to understand the causes for higher mortality in Scotland has led to the need to get Scotland to 'catch-up' compared to other European countries.²⁶ This is despite recent reports that Scotland spends more money per person on the NHS than in the rest of the UK and that annual expenditure has grown substantially in recent years. This relatively poor record of health in Scotland is therefore one of the most important challenges for the Scottish Executive²⁷.

This 'catching up' applies to both CHD and diabetes. In the following sections we illustrate the scale of the problem and then go on to highlight the role of medicines and other innovations in tackling CHD and diabetes in Scotland.

²⁶ Public Health Institute of Scotland (2001) *Chasing the Scottish Effect, Why Scotland needs a step -change in health if it is to catch up with the rest of Europe*.

²⁷ Bolger, A (18 January 2005) "Scotland fights back against poor health amid escalating NHS costs", Financial Times

3. Diabetes in Scotland

3.1. What is Diabetes?

Diabetes mellitus is a chronic condition characterised by high levels of glucose (sugar) in the blood. Diabetes occurs when the body is not able to produce enough insulin to process glucose properly. Type 1 diabetes develops if the body is unable to produce insulin, and usually appears before the age of 40.²⁸ This type of diabetes is treated by insulin injections in conjunction with a healthy lifestyle and a balanced diet. Type 2 diabetes develops later in life and occurs when the body isn't able to make enough insulin or becomes resistant to insulin (and can not use the insulin produced properly). Type 2 diabetes is treated with medicines in conjunction with a healthy lifestyle and a balanced diet.²⁹

People with diabetes face a risk of developing a number of complications (from a build up of glucose) and are at greater risk of other forms of ill health. These include:

- **Coronary heart disease and stroke:** People with diabetes have a four times greater risk of developing CHD than those without diabetes (this reflects in part many similar risk factors including obesity and lack of exercise).³⁰ CHD accounts for 80 per cent of mortality of people with diabetes.^{31,32,33,34} The risk of a transient ischaemic attack (precursor to a stroke) and stroke is also increased for people with diabetes;³⁵
- **Kidney disease:** This can lead to kidney failure and death,^{36,37,38}
- **Eye disease:** Diabetic-related eye disease is the leading cause of blindness in the working age population in the UK;

²⁸ Diabetes UK, <http://www.diabetes.org.uk/diabetes/under.htm>

²⁹ Diabetes UK, www.diabetes.org.uk, What is Diabetes?

³⁰ Diabetes UK (2002) *Consultation Response: NICE Health Technology Appraisal: Patient Education Models for Diabetes*, <http://www.diabetes.org.uk/infocentre/submission/patiented.doc>

³¹ Laing, S.P. et al. (1999) "The British Diabetic Association Cohort Study, I: all cause mortality in patients with insulin-treated diabetes mellitus", *Diabetic Medicine*, 16: 459-466

³² Laing, S.P. et al. (1999) "The British Diabetic Association Cohort Study, I: all cause mortality in patients with insulin-treated diabetes mellitus", *Diabetic Medicine*, 16: 466-471

³³ Currie, C.J., Morgan, C.L.L., Gill, L., Peters, R.J., (1997) "Patterns and costs of hospital care for coronary heart disease related and not related to diabetes", *Heart*, 78: 544-550

³⁴ Currie, C.J., Morgan, C.L.L., Gill, L., Stott, N.C.H., Peters, R.J. (1997) "The epidemiology and costs of acute hospital care for cerebrovascular disease in the diabetic and non diabetic populations", *Stroke*, 28: 1142-1146

³⁵ Kuusisto, J. et al. (1994) "Non-insulin-dependent diabetes and its metabolic control are important predictors of stroke in elderly subjects", *Stroke*, Vol. 25, No. 6, pp.1157-64

³⁶ Cameron, J.S. and Challah, S. (1986) "Treatment of end-stage renal failure due to diabetes in the United Kingdom, 1975-84", *Lancet*, 2: 962-966

³⁷ Brancati, F.L., et al. (1997) "Risk of end-stage renal disease in diabetes mellitus. A prospective cohort study of men screened for MRFIT", *Journal of the American Medical Association*, 278 (23): 2069-2074

³⁸ Wang, S.L., et al. (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 (4): 305-312

- **Foot ulcers:** Diabetic foot ulceration can lead to amputation and is the main cause of hospitalisation of people with diabetes;
- **Peripheral diabetic neuropathy:** This damages nerve fibres and can result in numbness, tingling, and pain of the extremities;
- **Peripheral vascular disease:** People with diabetes have four times the risk of peripheral vascular disease – whereby arteries in the legs narrow causing sub-optimal wound-healing and lower-extremity ulceration.³⁹
- **Urinary Tract Infection;**⁴⁰
- **Erectile dysfunction;**
- **Fatigue;** and
- **Higher infection rates.**

Around 162,000 people are currently diagnosed with diabetes in Scotland, equivalent to 3.2 per cent of the population.⁴¹ This is high compared to the rest of the UK, where there is an overall prevalence rate of 2.3 per cent. The number of people with diabetes in Scotland is rising with an increase of over 55,000 diagnosed cases in 2004 compared to 2001. This reflects improvements in diagnosis and registration of those with diabetes, although some gaps still exist in some Health Boards, which suggests that a further increase in diagnosed sufferers can be expected in the future. The number of diabetes cases will increase in the future due to demographic change and lifestyle changes. Indeed there are an increasing number of children with diabetes. Twenty five children in every 100,000 in Scotland have diabetes, compared to 17 in England and Wales.⁴² Diabetes UK in Scotland suggests that this rate is growing by around 2 per cent every year,⁴³ and there has been a near tripling of new cases in the last 30 years.⁴⁴ Diabetes amongst children is primarily Type 1 diabetes, but Type 2 diabetes is increasingly being diagnosed in Europe. This is likely to be linked to growing obesity in children, which is of particular concern for Scotland where the childhood obesity rate is amongst the highest in the world.⁴⁵

There are significant differences in the prevalence of diabetes by Health Board in Scotland (Figure 3.1).⁴⁶

³⁹ Gibbons, G.W. (1998). *Peripheral vascular disease*. In H.E. Lebovitz (Ed.), *Therapy for diabetes mellitus* (3rd ed., pp. 290-302). Alexandria, VA: American Diabetes Association.

⁴⁰ Geerlings, S.E. et al. (2000) *Risk factors for symptomatic urinary tract infection in women with diabetes*, *Diabetes Care*, Vol. 23, No. 12, pp. 1737-41

⁴¹ Scottish Diabetes Survey Monitoring Group data from the Scottish Diabetes Survey (2004), supplied by ABPI Scotland (11th April 2004)

⁴² <http://www.netdoctor.co.uk/diseases/facts/diabeteschildren.htm>

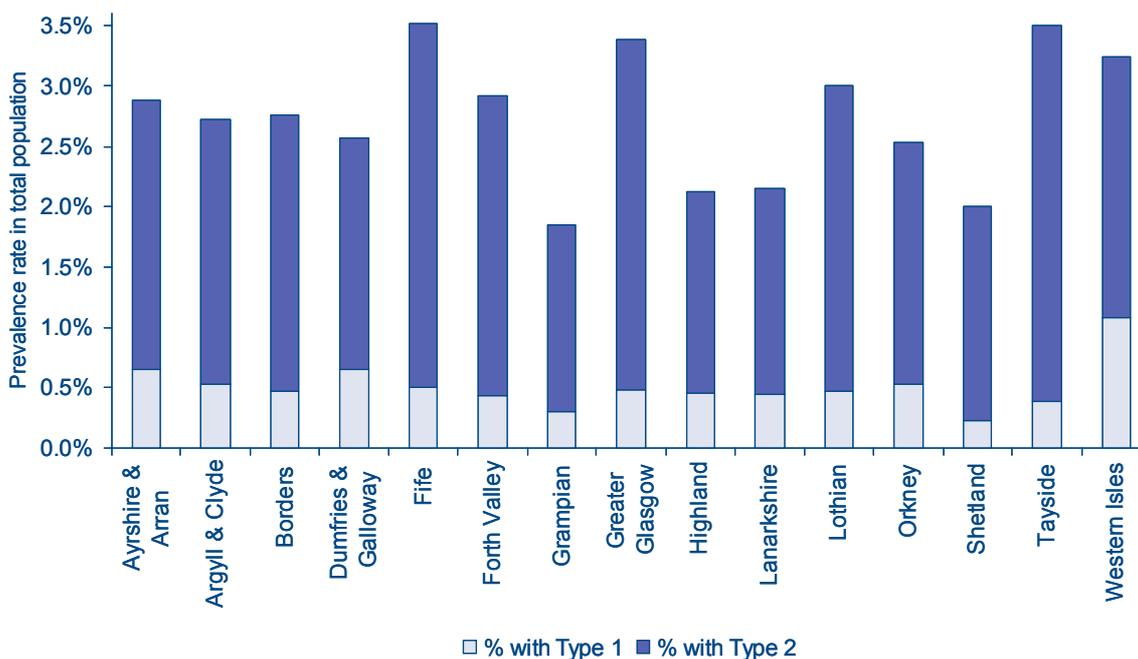
⁴³ <http://www.diabetes-scotland.org/>

⁴⁴ Scottish Intercollegiate Guidelines Network (2001) *Guideline 55: Management of Diabetes*

⁴⁵ NHS Quality Improvement Scotland (2003) *Clinical Outcomes Indicators*, Clinical Outcomes Group – November 2003

⁴⁶ 2004 prevalence data for Local Health Boards is not currently available (April 2005) and so we have used 2003 data.

Figure 3.1
Prevalence of Diabetes, 2004, Health Boards⁴⁷



Source: Scottish Diabetes Survey (2004), using a 2002-based projected population by the General Register Office for Scotland.

There is concern that a large number of people with Type 2 diabetes go undiagnosed in Scotland. The total population with any type of diabetes, including estimates of the undiagnosed population, could be as much as 4 per cent of the population (204,000 people), illustrating that the undiagnosed population is thought to be around 20 per cent of the currently diagnosed population.⁴¹ Survey data states that in 2005 15.6 per cent of diabetes patients in Scotland suffered from Type 1 diabetes, and 79.6 per cent had Type 2 diabetes (the remainder have either unknown or other types of diabetes including gestational diabetes). However estimates suggest that people with Type 2 are likely to be under-represented in the survey, and in fact it is most likely that around 14 per cent of diagnosed cases of diabetes in Scotland have Type 1 diabetes, and 80 to 90 per cent have Type 2 diabetes.^{48,49}

There are a range of risk factors for diabetes. Many include the lifestyle factors which we highlighted in Section 2. Increasing levels of obesity and a relative lack of exercise is considered a major contributory factor in the recent and dramatic increase in the incidence of

⁴⁷ Note: Data for Borders is from the 2003 Scottish Diabetes Survey, and data for the Western Isles is from the 2002 survey. The accuracy of the prevalence figures for Grampian and Lanarkshire is compromised as process data (and so diabetes type data) is only available for 10,356 of the 16,855 sufferers in Grampian and 13,210 of 18,252 in Lanarkshire.

⁴⁸ Scottish Diabetes Survey Monitoring Group (2005) *Scottish Diabetes Survey 2004*

⁴⁹ Scottish Diabetes Survey Monitoring Group (2004) *Scottish Diabetes Survey 2003*

Type 2 diabetes. Obese women are at least 27 times more likely to get Type 2 diabetes than women of a healthy weight, and obese men are at least 7 times more likely.⁵⁰

Overall, the people with the following factors are more likely to develop Type 2 diabetes:²⁹

- People with poor diet, and who are overweight/obese;
- People with low levels of exercise;
- People aged between 40 and 75;
- People of Asian or African-Caribbean origin;
- People with a family history of diabetes;
- People with circulation problems or high blood pressure;
- Women who suffer from diabetes during pregnancy (gestational diabetes);
- Women who suffer from polycystic ovary syndrome and are obese;
- Women who have given birth to a large baby; and
- Those known to have impaired glucose tolerance or impaired fasting glycaemia.

Statistics on some of the risk factors for diabetes show that Scotland has a bigger problem than elsewhere in the UK. For example, although the average body mass index is similar in Scotland and England, Scottish men have a significantly greater average waist-to-hip ratio than English men (carrying extra weight around the middle is of greater concern than body mass index alone), and this increases the risk of both CHD and Type 2 diabetes.⁵¹

Prevalence of Type 2 diabetes also differs by deprivation, with evidence suggesting that socio-economic deprivation in Scotland is associated with an increased prevalence of Type 2 diabetes.⁵²

⁵⁰ Scottish Executive (2002) *Scottish Diabetes Framework*

⁵¹ <http://www.show.scot.nhs.uk/thpc/PDFs/2004%20-%20Tayside%20obesity%20strategy.pdf>

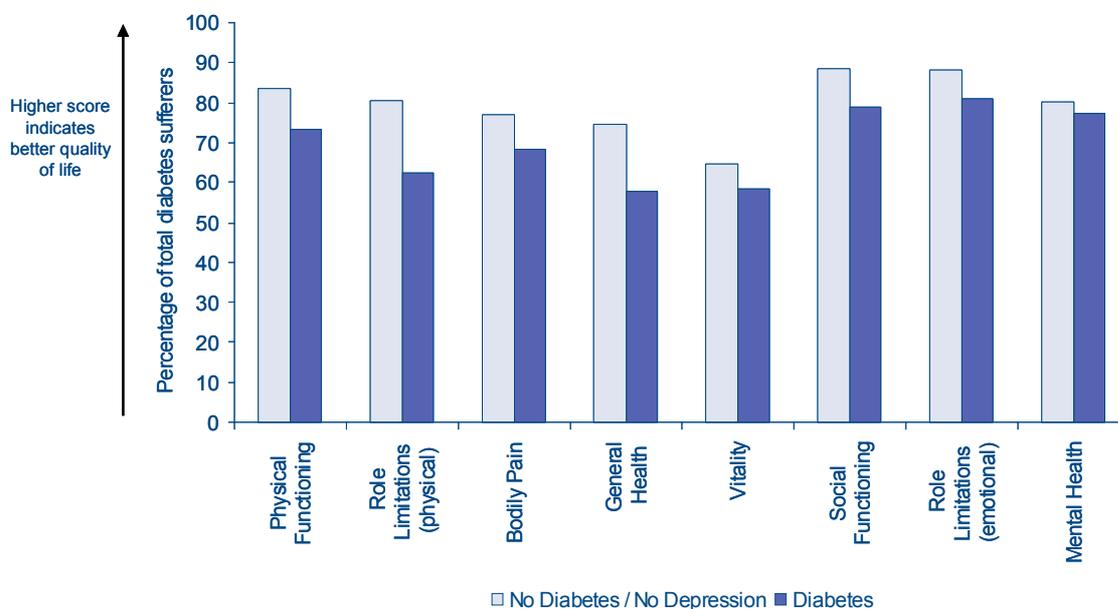
⁵² Scottish Diabetes Survey Monitoring Group (2004) *Scottish Diabetes Survey 2003*

3.2. The Burden of Diabetes in Scotland

3.2.1. Patients

Diabetes has a significant impact on patients. It reduces both quality and length of life, largely due to complications that can arise such as CHD, stroke, foot problems, eye disease and kidney disease. Figure 3.2 compares the quality of life of patients with diabetes compared to those without using the Short Form 36 survey measure of quality of life. Evidence suggests that quality of life is lower and falls further as complications increase.^{53,54} In addition to the impact on sufferers there is also a knock-on impact on carers, the cost of which is discussed in more detail later in this report.

Figure 3.2
Comparison of SF-36 Quality of Life Scores



Source: Goldney, R.D., Phillips, P.J., Fisher, L.J., and Wilson, D.H. (2004) "Diabetes, Depression, and Quality of Life", *Diabetes Care*, Vol 27 pp1066-1070

⁵³ Goldney, R.D., Phillips, P.J., Fisher, L.J., and Wilson, D.H. (2004) "Diabetes, Depression, and Quality of Life", *Diabetes Care*, Vol 27 pp1066-1070

⁵⁴ Jacobson, A.M., and De Groot, D.Q. (1994) "The Evaluation of two Measures of Quality of Life in Patients with Type 1 and Type 2 Diabetes", *Diabetes Care*, Vol 17 pp267-274

3.2.2. Health Care System

The cost of diabetes to the health system is significant. The direct costs of managing Type 2 diabetes (including both primary and secondary care) in Scotland has been estimated at around £60 million (2002 prices), given a prevalence of 2.4 per cent of the population.¹⁶ Overall, including both direct and indirect costs (those from complications and diseases attributable to diabetes), diabetes is estimated to account for about 5 per cent of NHS expenditure in Scotland in 2002/3 (approximately £320 million).⁵⁰ Hospital costs dominate the total costs reflecting the complications of diabetes and the higher incidence of other types of ill health (including CHD). Estimates vary but suggest that the total cost to the health system per person per year with Type 2 diabetes across the UK is £2,201 compared to around £308 for those without diabetes.⁵⁵

3.2.3. Economy

In addition to the costs to the patient, their carers and the health system there are broader costs including the costs to the economy (through higher sickness absence). Estimates for the UK suggest that patients with diabetes who develop complications and lose earnings are likely to lose £14,000 per year through an inability to work.⁵⁶

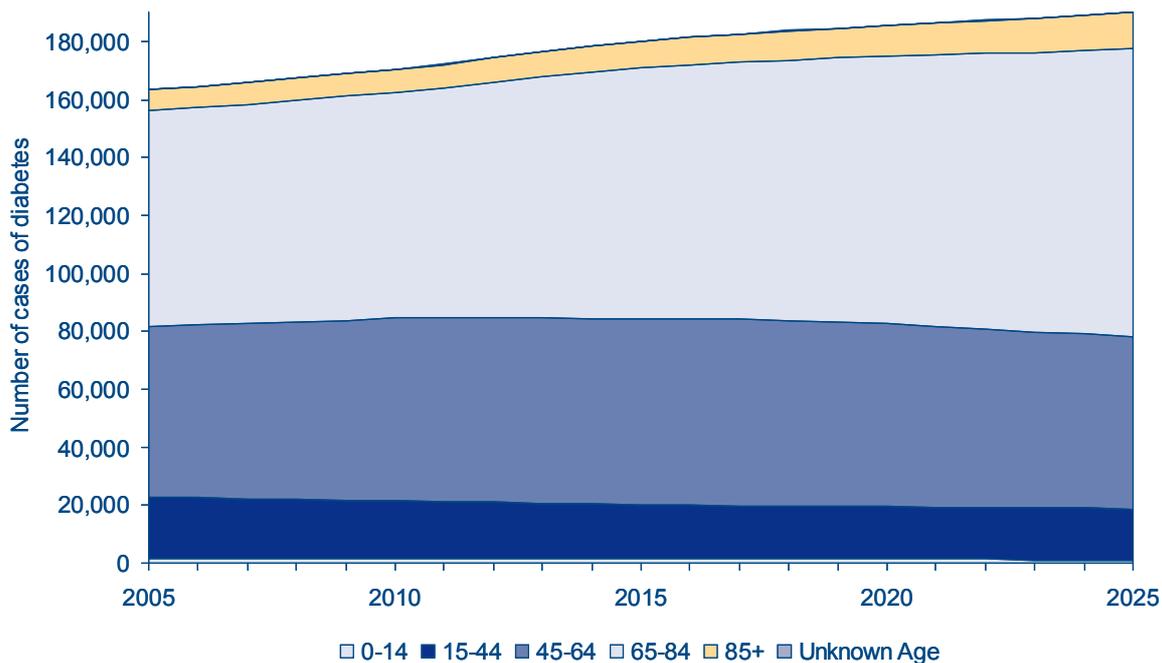
3.2.4. Future Trends in Diabetes in Scotland

We illustrate the likely increase in all patients with diabetes in Scotland in Figure 3.3 . This is a simple application of age-specific prevalence rates to projections of the population in Scotland but provides an indicative estimate of the likely scale of the problem. On this basis Scotland could have around 190,000 cases of diabetes in 2025 compared to 163,000 in 2005. This increase is likely to be a significant underestimate of what will actually occur because lifestyle trends and improved diagnosis are not considered.

⁵⁵ Currie, C.J., Kraus, D., Morgan, C.L., Gill, L., Stott, N.C., Peters, J.R. (1997) NHS acute sector expenditure for diabetes: the present, future, and excess in-patient cost of care, *Diabet. Med.*, Vol 14 Issue 8 pp686-92

⁵⁶ Greenhalgh, J., Georgiou, A., Long, A., Williams, R., and Dyas, J (2002) *Measuring the health outcome of Diabetes care*, The Nuffield Institute for Health

Figure 3.3
Projected No. of People with Diabetes, 2005-2025, Scotland⁵⁷



Source: NERA calculation using General Register Office for Scotland and Scottish Diabetes Survey (2004) data.

We have also estimated the likely scale of diabetes for each Health Board by applying age based prevalence rates (Table 3.1). Every Health Board can expect the number of diabetes patients to grow in the next fifteen years by a rate of between 0.4 per cent per year to 1.5 per cent per year, based on demographic change alone.⁵⁸ This expected growth does not take into account the increase expected because of unhealthy lifestyles, or due to an increase in the number of diagnosed cases. The true numbers are therefore likely to be much greater.

⁵⁷ Note: Data for some Health Boards was incomplete in 2004. For these Health Boards some figures from earlier surveys were used to inform the projection.

⁵⁸ Note that the data for Borders, Grampian and Lanarkshire is inaccurate due to a high number of diabetes cases being of unknown age. Also data for the Western Isles is calculated from 2002 figures as more recent data is not available.

Table 3.1
Projected Diabetes Cases, 2004 – 2018, Health Boards⁵⁹

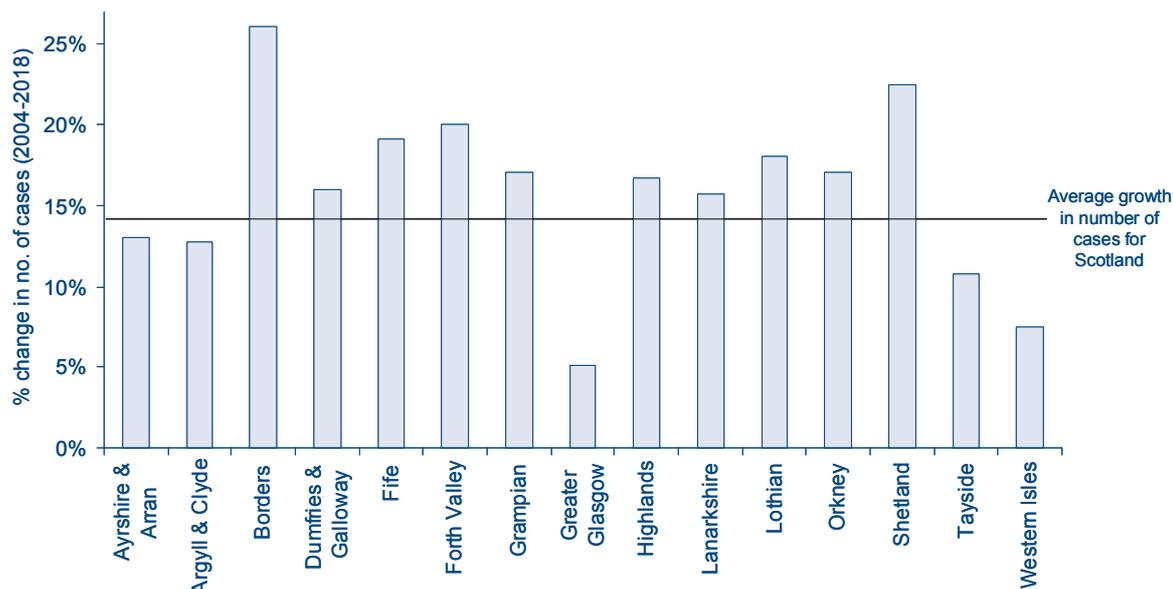
Health Board	2004	2008	2013	2018	Av. growth (% per yr)	% change in no. of cases (2004-2018)
Ayrshire & Arran	10,641	11,064	11,648	12,028	0.8%	13.0%
Argyll & Clyde	11,293	11,735	12,344	12,742	0.9%	12.8%
Borders	2,662	2,818	3,098	3,356	1.7%	26.1%
Dumfries & Galloway	5,662	5,970	6,330	6,568	1.1%	16.0%
Fife	12,681	13,338	14,339	15,107	1.3%	19.1%
Forth Valley	8,230	8,666	9,330	9,873	1.3%	20.0%
Grampian	16,853	17,647	18,772	19,717	1.1%	17.0%
Greater Glasgow	29,537	29,949	30,615	31,035	0.4%	5.1%
Highland	5,141	5,389	5,732	6,000	1.1%	16.7%
Lanarkshire	18,252	19,132	20,260	21,112	1.0%	15.7%
Lothian	24,213	25,288	27,004	28,563	1.2%	18.0%
Orkney	677	714	759	792	1.1%	17.0%
Shetland	443	471	509	543	1.5%	22.5%
Tayside	13,784	14,224	14,850	15,267	0.7%	10.8%
Western Isles	735	751	772	790	0.9%	7.5%
Scotland	160,804	167,156	176,363	183,493	0.9%	14.1%

Source: NERA calculation using the Scottish Diabetes Survey (2004) and General Register Office for Scotland (GROS) data.

Figure 3.4 illustrates the Health Boards that are likely to face the biggest increase in cases of diabetes. Borders, Dumfries and Galloway, Fife, Forth Valley, Grampian, Highland, Lanarkshire, Lothian, Orkney and Shetland are all expected to experience an average annual proportional increase in the number of diabetes cases that is higher than the average yearly growth rate for Scotland as a whole, because of the ageing of their populations.

⁵⁹ Note: Scotland totals are underestimates as the Scottish Diabetes Survey (2004) has a number of diabetes patients of unknown age. Where age data was not available for 2004 (Borders, Western Isles), and where process data was not available for substantial amounts of patients (Grampian, Lanarkshire), alternative techniques were used to include all patients in these areas in order to allow the most accurate projections possible.⁵⁷ Projections are limited to 2018 as GROS data extends only to this year.

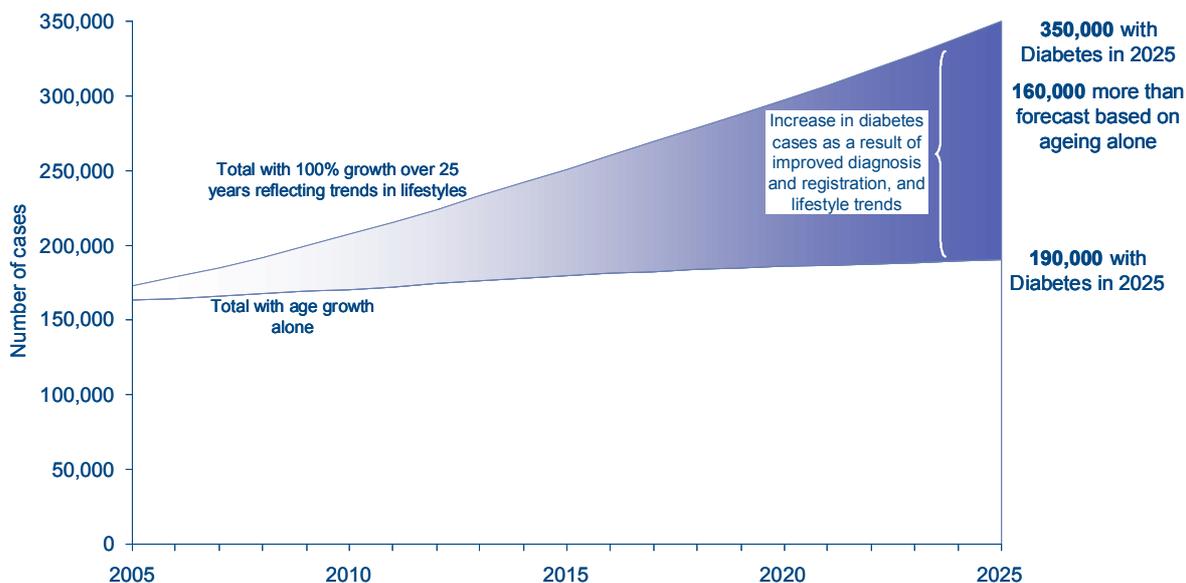
Figure 3.4
Percentage Change in Diabetes Cases, 2004-2018, Health Boards



Source: NERA calculation using the Scottish Diabetes Survey (2004) and General Register Office for Scotland data

The above projections only reflect the changing demographics of the population. Given lifestyle trends, especially increasing levels of obesity, the true number with diabetes is likely to be even greater. The World Health Organisation (WHO) suggests that the total number of people with diabetes will double over the next 10-15 years and the Scottish Diabetes Framework suggests that by 2010, 4 per cent of the Scottish population could suffer from diabetes.⁵⁰ Both of these estimates also include the impact of changing lifestyles. We have made some assumptions to illustrate the likely impact of these trends. In Figure 3.5 we have assumed that the number of people with diabetes will increase by 100 per cent between 2004 and 2025, resulting in 350,000 cases in 2025. This is a conservative projection compared to the WHO estimate (effectively a 100 % increase over the next 10-15 years), and is consistent with a prediction that 4.1 per cent of the Scottish population will be diagnosed with diabetes by 2010, which is very similar to the projection made by the Scottish Diabetes Framework.

Figure 3.5
Scenario Around Future Prevalence of Diabetes, 2005-2025, Scotland⁵⁷



Source: NERA calculation using General Register Office for Scotland and Scottish Diabetes Survey (2004 and 2003) data

This projection, which is likely to be a far more realistic estimate than our earlier estimate based on demographic change alone, illustrates the magnitude of the diabetes problem in Scotland. Such a projection implies that diabetes must be managed very carefully if the disease is to be controlled.

3.3. Managing Diabetes – The Role of Medicines

3.3.1. Managing Diabetes in Scotland

Scotland has developed guidance on the treatment and management of diabetes in Scotland. Box 2 illustrates the key points from guidelines and the strategy for diabetes care in Scotland. Most guidance is based around improved management of the disease. This is in line with the recommendations of the English National Service Framework (NSF), which emphasises management and self management of diabetes, as well as meticulous blood glucose control.^{60,61}

⁶⁰ <http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Diabetes/fs/en>

⁶¹ Department of Health (2001) *National Service Framework for Diabetes: Standard*, December 2001

**Box 2:
Strategies for Improving Diabetes Care**

Treatment Guidelines	<p>The Scottish Intercollegiate Guidelines Network (SIGN) set out guidelines for the treatment of patients with diabetes (Guidance Number 55: Management of Diabetes (2001)). The guideline contains many recommendations for treatment practice for all types of people with diabetes, including guidance for treatments given diabetic complications. The emphasis is on:</p> <ul style="list-style-type: none"> -Tight management of glycaemic (blood sugar) and blood pressure levels, through education, self-monitoring and the use of glucose lowering drugs (e.g. Metformin), blood pressure lowering drugs (e.g. Thiazides, β-blockers, ACE inhibitors and calcium channel blockers) and cholesterol lowering medicines (e.g. statins); -Lifestyle change to reduce risk factors; -Increased screening for kidney disease; -Screening for eye disease; and -Screening for foot disease and structured diabetic foot care. <p>The National Institute for Clinical Excellence (NICE) has issued guidance for a number of diabetes drugs and treatment plans.</p> <ul style="list-style-type: none"> - 'Step-up' treatment is recommended for people with Type 2 diabetes. This begins with advice on diet and physical exercise, followed by treatment with oral glucose lowering drugs as monotherapy, followed by combination therapy, and finally the use of insulin if glucose targets are not achieved. -Structured patient education using specialist nurses and dieticians is also recommended. -Guidance advocates the use of Glitazones, but only if a patient cannot take metformin and a sulphonylurea in combination due to an intolerance or contraindication. <p>NHS Quality Improvement Scotland endorses each of these guidelines. The Scottish Medicines Consortium (SMC) recommend that metformin prolonged release tablets are not used instead of standard metformin.⁶²</p>
Clinical Management	<p>The Clinical Standards Board for Scotland (CSBS) introduced standards for community and hospital care of diabetes in Scotland (Clinical Standards: Diabetes, Second Edition (2002)).⁶³ The standards include:</p> <ul style="list-style-type: none"> -Clinical management systems to co-ordinate information on care -Clinical pathways including annual or more frequent examinations, measurement of glycaemic levels -Education and information for patients -Referrals to specialists for eye disease, foot problems and kidney disease -Rapid care for emergency cases <p>The range of specific standards set out by CSBS are considered in more detail in Box 3</p>
Management Frameworks	<p>The Scottish Executive (2002) produced the Scottish Diabetes Framework, and outlined the creation of Managed Clinical Networks to address the following priorities:</p> <ul style="list-style-type: none"> -Patient Information, Education and Empowerment -Coronary Heart Disease -Eye Care -Strategy, Leadership and Teamworking -Education and Training for Professionals -Diabetes Registers -Implementation and Monitoring

Sources: Scottish Intercollegiate Guidelines Network (2001), Guideline 55: Management of Diabetes; Clinical Standards Board for Scotland (2002) Clinical Standards: Diabetes, Second Edition; Scottish Executive (2002) Scottish Diabetes Framework

⁶² Scottish Medicines Consortium (SMC) (2004) *Metformin prolonged release tablets (Glucophage SR®) No. (148/04)*, NHS Scotland

⁶³ Clinical Standards Board for Scotland (2001) *Clinical Standards: Diabetes*

Throughout 2003 NHS Quality Improvement Scotland (NHS QIS) carried out a review performance of Health Boards in achieving the standards set out by CSBS (as outlined in Box 3).⁶⁴ Their review found substantial variation in care across Health Boards (Table 3.2).

Box 3:

Clinical Standards Board for Scotland (CSBS) standards for Diabetes Care

- 1. Organisation: IM&T, Clinical Management Systems, Audit and Monitoring.** All people with diabetes, with appropriate consent, are placed on a clinical management system which contains core information about their care and allows ongoing useful clinical information to be recorded for use in direct patient care and service audit.
- 2. Organisation: Pathway of Care, Teamworking and Integration of Services.** There is an agreed area-wide structured programme of care which clearly defines: reporting arrangements and accountability; the care that people with diabetes should expect to receive; the processes of care that will be followed after diagnosis (including pre- and perioperative management); the protocols and guidelines that determine which clinician is responsible for the delivery of specific aspects of care; criteria for referral.
- 3. Patient Focus:** All people with diabetes have equitable access to information and multidisciplinary programmes of education, which are tailored to individual needs and specific client groups.
- 4. Clinical Review:** All people with diabetes are offered annual or more frequent examination, where clinically indicated, to monitor the management and progression of their condition. There is intervention as required, and support for the modification of lifestyle risk factors.
- 5. Clinical Management: Eyes.** All people with diabetes who have identified signs of developing diabetes-related, sight threatening retinopathy, according to Health Technology Board for Scotland (HTBS) grading recommendations are referred to an ophthalmologist for assessment, and, if necessary, treatment.
- 6. Clinical Management: Cardiovascular Status.** All people with diabetes who have identified associated cardiovascular problems are managed according to locally agreed protocols and are considered for referral and additional treatment as clinically indicated.
- 7. Clinical Management: Feet.** All people with diabetes who have identified associated foot problems are referred for specialist assessment and, if necessary, treatment.
- 8. Clinical Management: Glycaemia.** All people with diabetes have HbA1c measured and recorded as clinically indicated.
- 9. Clinical Management: Renal.** All people with diabetes and identified associated kidney problems are referred for specialist assessment and, if necessary, treatment.
- 10. Clinical Management: Acute Management.** All people with diabetes who experience an acute diabetic emergency including hypoglycaemia, diabetic ketoacidosis (DKA) or hyperosmolar non-ketotic state are rapidly assessed and managed according to local protocols.

Source: NHS Quality Improvement Scotland (2004) National Overview: Diabetes

⁶⁴ NHS Quality Improvement Scotland (2004) National Overview: Diabetes

Table 3.2 NHS QIS Review of Health Boards' Diabetes Care Standards

Standard	Argyll & Clyde	Ayrshire & Arran	Borders	Dumfries & Galloway	Fife	Forth Valley	Grampian	Greater Glasgow	Highland	Lanarkshire	Lothian	Orkney	Shetland	Tayside	Western Isles
Organisation: IM&T, Clinical Management Systems, Audit and Monitoring (out of 5)															
	1	1	1	1	1	1	1	1	1	1	1	0	1	3	1
Organisation: Pathway of Care, Teamworking and Integration of Services(out of 6)															
	3	4	4	2	5	2	5	3	1	2	4	3	6	6	4
Patient Focus (out of 6)															
	4	4	2	2	4	2	5	3	3	5	4	5	3	4	4
Clinical Review (out of 6)															
	1	2	2	1	2	1	2	2	1	1	1	2	0	1	2
Clinical Management: Eyes (out of 3)															
	1	2	1	1	2	2	3	2	2	2	2	2	1	3	3
Clinical Management: Cardiovascular Status (out of 5)															
	4	5	3	2	5	5	5	5	2	1	4	1	5	5	5
Clinical Management: Feet (out of 4)															
	1	3	3	2	4	3	1	3	1	4	2	2	2	3	2
Clinical Management: Glycaemia (out of 5)															
	5	4	5	2	5	4	4	4	2	4	4	5	3	4	5
Clinical Management: Renal (out of 4)															
	1	3	4	1	2	2	3	2	1	2	2	2	2	4	2
Clinical Management: Acute Management (out of 4)															
	2	3	4	1	3	1	3	3	1	2	3	1	3	4	4

Sources: NHS Quality Improvement Scotland (2004) Local Reports for each Scottish Health Board: Diabetes Note: For each standard, a score is given for each sub-category achieved. The higher the score the better the care.

The General Medical Services (GMS) contract also sets out targets for diabetes management and treatment.⁶⁵ These are largely in line with the guidelines already specified, and draw on SIGN, NICE, and NSF recommendations. GMS indicators are shown in Box 4

**Box 4:
Diabetes Indicators in GMS Contract**

Management and Records

- Register of all patients with diabetes mellitus.
- Records of health status and interventions including BMI, smoking status, offer of smoking cessation where appropriate, HbA1c or equivalent recorded, retinal screening, neuropathy, blood pressure, microalbuminuria (a type of protein) testing where appropriate, serum creatinine (a protein that provides energy for muscle contraction produced by the kidneys) testing, cholesterol level and influenza immunisation.

Disease Targets

- The percentage of patients with diabetes in whom the last HbA1C is 7.4 or less and 10 or less (or equivalent test/reference range depending on local laboratory) in last 15 months.
- The percentage of patients with diabetes in whom the last blood pressure is 145/85 or less.

Treatment Indicators

- The percentage of patients with diabetes with proteinuria or micro-albuminuria who are treated with ACE inhibitors (or A2 antagonists).

Source: Department of Health (2003) Delivering investment in general practice: implementing the new GMS contract

The Quality and Outcomes Framework (QOF) is a fundamental (though voluntary) component of the GMS contract. It is designed to remunerate general practices for providing good quality care to their patients, and is another indicator of variations in quality of care across Health Boards in Scotland. The recently published QOF scores for 2004-2005 (shown below in Table 3.3) show a high level of achievement with respect to the clinical indicators laid out by the GMS contract with regards to diabetes management and treatment. Some variation between Health Boards is evident, particularly in areas where practices have not explicitly agreed to implement the QOF.⁶⁶

⁶⁵ Department of Health (2003) *Delivering investment in general practice: implementing the new GMS contract*

⁶⁶ The QOF is part of the new GMS contract, but may be used in part, entirely, or not at all by practices with section 17c and 2c agreements as part of the Primary Medical Services (Scotland) Act 2004. These agreements may also include arrangements to provide and monitor high quality care via a mechanism other than the QOF.

Table 3.3
Quality and Outcomes Framework Achievement Points: Diabetes

Health Board	Number of practices with QOF as a specific part of their contract	% of achieved	Points	Number of practices without QOF as a specific part of their contract	% of achieved	Points
Argyll & Clyde	90	94.1		5	97.8	
Ayrshire & Arran	52	96.5		9	97.3	
Borders	23	98.0		1	96.1	
Dumfries & Galloway	34	97.8		1	94.2	
Fife	53	95.1		4	95.8	
Forth Valley	50	96.2		7	92.5	
Grampian	67	94.9		17	85.2	
Greater Glasgow	208	98.2		2	98.6	
Highland	61	92.3		9	82.9	
Lanarkshire	94	93.6		6	92.8	
Lothian	99	97.2		27	95.8	
Orkney	5	93.4		8	69.3	
Shetland	1	98.7		9	94.4	
Tayside	70	97.3		1	99.0	
Western Isles	6	92.9		6	93.6	
Scotland	913	96.0		112	90.9	

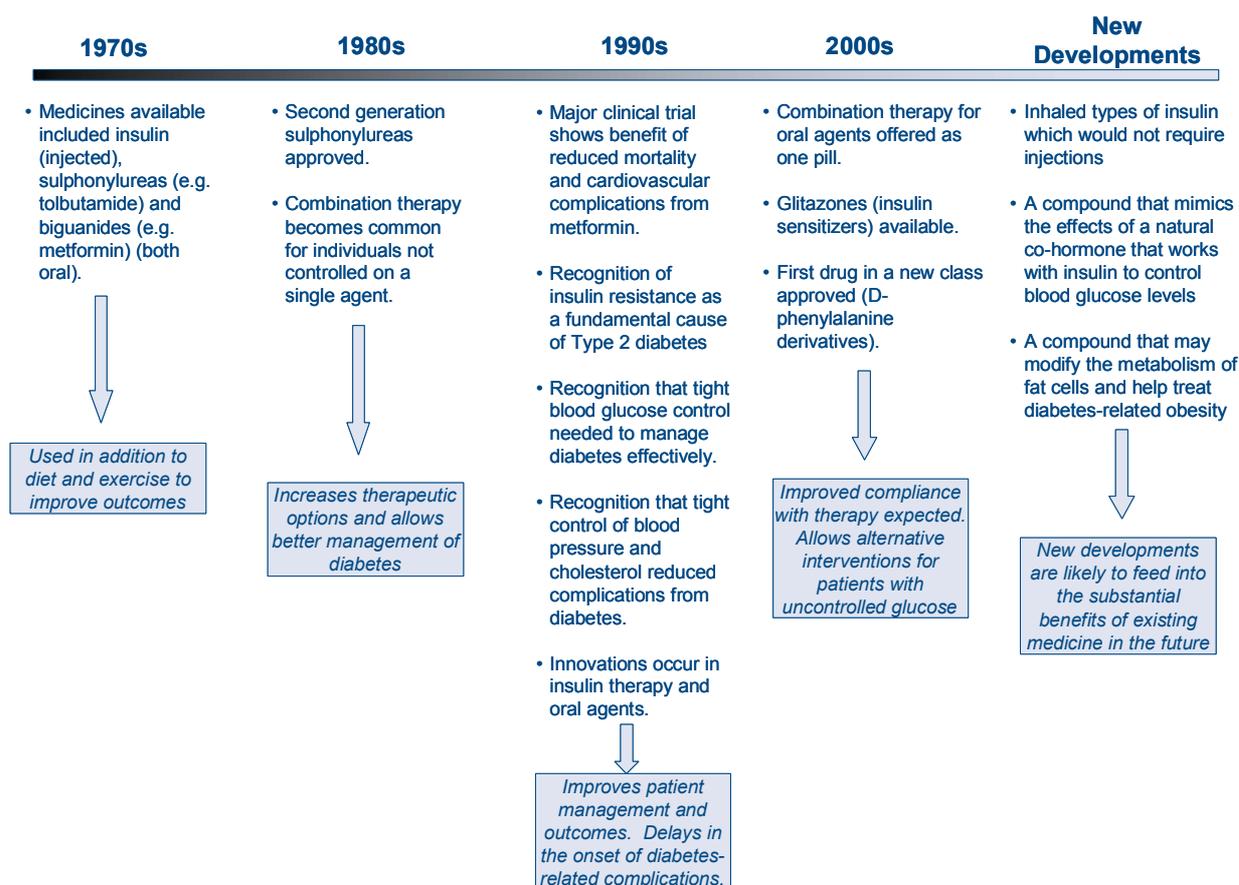
Source: ISD Scotland National Statistics, Quality Management and Analysis Computer System (QMAS) database as at 4th May 2005

As high-lighted in Box 2 management of diabetes covers a range of interventions. Figure 3.6 illustrates the development of medicines to treat Type 2 diabetes and Figure 3.8 illustrates developments in medical devices. In addition to these interventions, surgery can be of use in the treatment of diabetes. Evidence suggests patients with diabetes may benefit from gastric bypass surgery even if they are not obese,⁶⁷ while kidney transplants and heart surgery is used for those who have suffered kidney and heart complications. There is also promising results from transplants of insulin producing islet cells from the pancreas of a healthy donor to a patient with diabetes, although this is at early stages of testing. This type of transplant has

⁶⁷ Sugarman, H.J. et al. (2003) Diabetes and Hypertension in Severe Obesity and Effects of Gastric Bypass-Induced Weight Loss, *Annals of Surgery*, Vol. 237, No. 6, pp. 751-758

been shown to be able to make diabetes sufferers insulin independent.⁶⁸ If this technique is proven to be successful, a future challenge will be to provide a sufficient amount of islet cells to treat the number of people with diabetes.⁶⁹

Figure 3.6
Development in Medicines to Treat Type 2 Diabetes, 1970s – 2000s

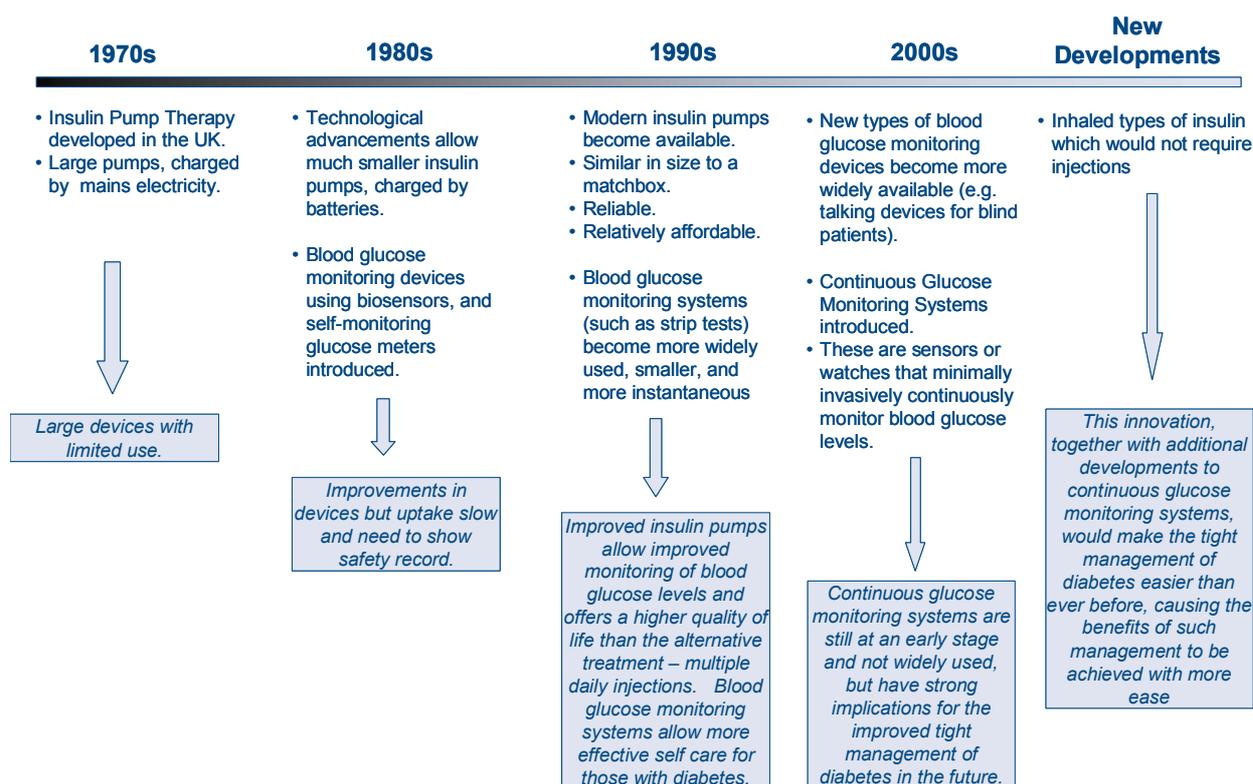


Source: *The Value of Investment in Health Care: Better Care, Better Lives*, MEDTAP International (2004) UKPDS 34 and ABPI; *PhRMA (2003) Diabetes and Pharmaceutical Spending: New Treatments, New Solutions*
 Reproduced from NERA (2004) *The Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS*

⁶⁸ Markmann, J. et al. (2003) Insulin Independence Following Isolated Islet Transplantation and Single Islet Infusions, *Annals of Surgery*, Vol. 237, No. 6, pp. 741-750

⁶⁹ Diabetes UK, Information Centre, Islet Cell Transplantation, <http://www.diabetes.org.uk/infocentre/inform/islet.htm>, accessed on 14/04/2005

Figure 3.7
Development in Devices to Treat Diabetes, 1970s – 2000s



Source: Torrance, T, Franklin, V, and Greene, S, (2003) *Insulin Pumps*, Archives of Disease in Childhood, Vol. 88: 949-953; Diabetes UK (2004) <http://www.diabetes.org.uk/infocentre/inform/altsiteimeter.htm>; Diabetes UK (2004). <http://www.diabetes.org.uk/infocentre/inform/gluow.htm>; Raskin, P et al (2003) *Continuous Subcutaneous Insulin Infusion and Multiple Daily Injection Therapy Are Equally Effective in Type 2 Diabetes*, Diabetes Care, Vol 26 pp 2598-2603; PhRMA (2003) *Diabetes and Pharmaceutical Spending: New Treatments, New Solutions*

There is strong evidence of the benefits of using insulin pumps. Bode and Steed (1994) found that the use of continuous subcutaneous insulin infusion (CSII) rather than multiple daily injections (MDA) is associated with a significant reduction in high and low blood sugar attacks,⁷⁰ improved glucose control,⁷¹ and improved nocturnal control of these attacks compared to MDA.⁷² Boland (1998, 1999) also found that pumps offer a better control of diabetes and that adolescents in particular can benefit from a pump.^{73, 74}

⁷⁰ Bode, B.W., and Steed, R.D. (1996) Reduction in Severe Hypoglycaemia with Long-term CSII in Type 1 Diabetes, *Diabetes Care*, vol. 19: 324-327

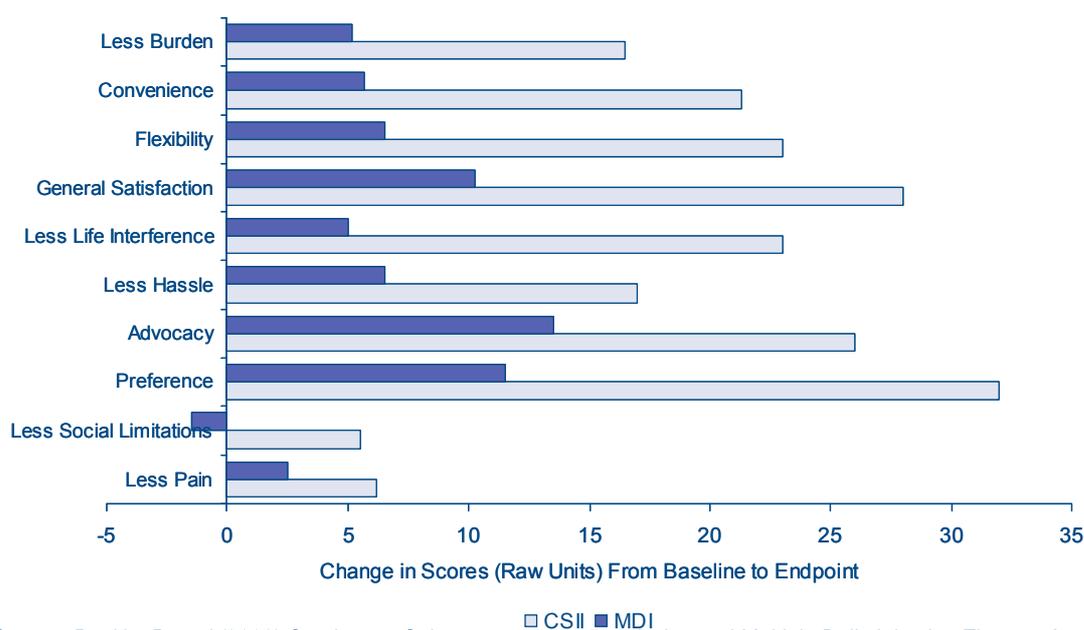
⁷¹ Bode, B.W., Steed, R.D., and Davidson, P. (1994) Long-term Pump Use and SMBG in 205 Patients, *Diabetes*, Vol 43: Suppl. 1, p 691

⁷² Kanc, K., Keulen, E, Jacobs, M.A.J.M., Popp-Snijders, C, Nasser, K, and Heine, R.J. (1995) The influence of night-time continuous subcutaneous insulin infusion (CSII) therapy on counterregulatory hormonal responses and warning symptoms of hypoglycaemia in IDDM patients during clamping., *The Netherlands Journal of Medicine* 47(6) (1995) pp. A60-A61

⁷³ Boland, E.A., Ahern, J., and Grey, M. (1998) A primer in the Use of Insulin Pumps in Adolescents, *the Diabetes Educator*, Vol 24 pp 78-87

Evidence also suggests that pump therapy increases patient satisfaction compared to MDI. Raskin et al (2003) studied 132 Type 2 diabetes patients who had switched to either MDI or CSII therapy from non-intensive treatment. Both groups reduced their blood sugar levels by similar amounts, however patient surveys found CSII patients were more satisfied with their treatment than MDI patients.⁷⁵ Figure 3.8 illustrates the change from baseline improvements in patient satisfaction subscores at the end of the study.⁷⁵

Figure 3.8
Change-From-Baseline Improvements in Patient Satisfaction



Source: Raskin, P et al (2003) Continuous Subcutaneous Insulin Infusion and Multiple Daily Injection Therapy Are Equally Effective in Type 2 Diabetes, *Diabetes Care*, Vol 26 pp 2598-2603

The 2004 review of the Scottish Diabetes Framework recommended that more needs to be known about the benefits of insulin pumps and their use in Scotland. No figures are available on the number of pumps used in Scotland but Diabetes UK estimates that 0.19 per cent (approximately 650 patients) of Type 1 diabetes sufferers in the UK use pumps. This compares poorly with international comparators, such as 8 per cent use in the US, 10 per cent in Germany and 12 per cent in Sweden.

NICE guidance recommends the use of insulin pumps for patients with Type 1 diabetes who fail to maintain satisfactory blood glucose levels using multiple daily injections.⁷⁶ NHS Quality Improvement for Scotland has endorsed these recommendations.⁷⁷

⁷⁴ Boland, E.A. (1999) Continuous Subcutaneous Insulin Infusion: A New Way to Lower Risk of Severe Hypoglycaemia and Improve Metabolic Control and Enhance Coping in Adolescents with Type 1 Diabetes, *Diabetes Care* Vol 22 pp1779-1784

⁷⁵ Raskin, P et al (2003) Continuous Subcutaneous Insulin Infusion and Multiple Daily Injection Therapy Are Equally Effective in Type 2 Diabetes, *Diabetes Care*, Vol 26 pp 2598-2603

⁷⁶ National Institute for Clinical Excellence (NICE) (September 2002) Clinical Guideline for the Management of Type 2 Diabetes – Management of Blood Glucose

Evidence illustrates the benefits of glucose monitoring. In some trials, self monitoring has been shown to improve blood glucose levels and can therefore help to avoid high or low blood sugar attacks.^{78,79} Self monitoring allows patients to identify when they are feeling unwell because of their blood glucose level and gives confidence over blood glucose levels at critical times (such as when driving or at work). This could combine to improve people's attitudes to self management.⁸⁰ The long-term effects of glucose monitoring systems are anticipated to be fewer diabetic complications reflecting improved glycaemic control.

In addition to medicines highlighted in Figure 3.6 other medicines offer significant benefits to people with diabetes (Box 5).

⁷⁷ NHS Quality Improvement Scotland, 2005, Evidence Note 8

⁷⁸ Evans JMM, Newton RW, Ruta DA, MacDonald TM, Stevenson RJ, Morris AD (1999) Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. *British Medical Journal* Vol 319 pp 83-86 have shown this for Type 1 patients in Scotland

⁷⁹ Franciosi M, Pellegrini F, De Bernardis G, Belfiglio M, Nicolucci A (2001) The impact of blood glucose self-monitoring on metabolic control and quality of life in Type 2 diabetic patients. *Diabetes Care* Vol 24pp 1870-1877, have shown this for Type 2 patients able to alter their regimen

⁸⁰ Diabetes UK, <http://www.diabetes.org.uk/infocentre/external/ndst1.pdf>

**Box 5:
Benefits of Medicines to Treat Type 2 Diabetes**

Tight control of blood pressure leads to:

- 24% decline in diabetes related outcomes
- 32% reduction in mortality risk from diseases increased by diabetes
- 37% reduction in combined occurrence of eye disease (diabetic retinopathy, neuropathy and nephropathy)
- 37% reduction in the occurrence of any diabetes related complication
- 44% reduction in strokes
- 56% reduction in heart failure
- 6 patients need to be treated over 10 years to avoid developing any complication

Cholesterol lowering with statins leads to:

- 37% reduction in major cardiovascular disease events
- 48% reduction in strokes
- 27% reduction in all cause mortality
- 25% reduction in the risk of coronary events (including heart attacks)
- 23% reduction in the risk of bypass operation

Sources: Testa MA & Simonson DC (1998) Health economic benefits and quality of life during improved glycaemic control in patients with Type 2 diabetes mellitus: A randomised controlled, double blind trial, JAMA; 280 (17): 1490-1496; UKPDS (1998a) Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38, British Medical Journal; 317: 703-713; UKPDS (1998b) 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 (9131): 837-853; Collaborative Atorvastatin Diabetes Study Investigators (2004) Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial, The Lancet, Vol. 364, Issue 9435, pg. 685

3.3.2. Tight management of Type 2 Diabetes

A number of studies have shown that tight management of blood glucose levels can help reduce the impact, or delay the occurrence of, diabetic complications. Tight control of blood glucose is aimed at keeping HbA1c levels below 7 per cent, and can be achieved through the use of insulin or insulin stimulating medicines. Box 6 below sets out the benefits of tight management of Type 2 diabetes.

Box 6: The Benefits of Tight Management of Type 2 Diabetes

Tight control of blood glucose levels leads to:

- 12% reduction in the risk of any diabetes-related outcomes (e.g. heart attack, heart failure, stroke, amputation, death)
- Much of this is due to a 25% reduction in microvascular outcomes
- Reduction in time to first adverse event (mean gain of 1.14 years)
- Reduction in costs associated with complications

Tight management of diabetes leads to:

- Improvements in quality of life
- Positive impact on employment, absenteeism, productivity, bed days and days of restricted activity. For example, 97% of patients receiving medicines were employed compared to 85% in the group not receiving medicines

Sources: Testa MA & Simonson DC (1998) Health economic benefits and quality of life during improved glycaemic control in patients with Type 2 diabetes mellitus: A randomised controlled, double blind trial, JAMA; 280 (17): 1490-1496; UKPDS (1998a) Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38, British Medical Journal; 317: 703-713; UKPDS (1998b) 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 (9131): 837-853

Tight management of Type 2 diabetes brings benefits for patients and also for the health system reflecting lower levels of complications. The UK Prospective Diabetes Study has shown that tight management of blood glucose, using insulin, sulphonylureas or metformin, can help to reduce/delay the onset of diabetic complications.^{81, 82, 83} This has two consequences: it can increase the up-front costs of managing diabetes in a primary care setting, because of greater use of medicines; and it can reduce longer-term costs of treating diabetic complications (which often involves costly inpatient care). Evidence suggests that increased primary care costs (including more expenditure on medicines) from tight management are largely cancelled out by lower inpatient care costs from fewer diabetic complications.⁸⁴

⁸¹ UKPDS, (1998) Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38, *British Medical Journal*; Vol 317 pp 703-713

⁸² UKPDS (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 (9131): 837-853

⁸³ UKPDS (1998) Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34), *The Lancet*, 1998; 352: 854-865

⁸⁴ Gray, A., Raikou, M., McGuire, A. et al (2000) Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41), *British Medical Journal*, Vol 320 pp1373-78

We can compare the overall costs of intensive blood glucose level management (using a sulphonylurea or insulin) to the costs associated with conventional (primarily diet) glucose control by combining cost data with our predictions of the number of people with diabetes in Scotland.⁸⁵ As no data is currently collected about the numbers of people with diabetes who tightly manage their Type 2 diabetes in Scotland we simply show the costs if all patients are tightly managed compared to the costs if patients receive only conventional treatment. Only 73.6 per cent of patients had a HbA1cs (blood glucose) test in the 15 months prior to the 2004 Scottish Diabetes Survey, which sets an upper bound on the proportion who could be receiving tight management of their disease, as such measurement would be necessary under a tight management treatment regime. It is estimated that the number of patients currently receiving tight management of blood glucose levels in the UK is very small, at between 100,000 and 150,000 people compared to the 1.4 million across the UK who are diagnosed with diabetes.⁸⁶ This number suggests there is significant scope to increase the number of patients who have their diabetes tightly managed in the UK as a whole.

Table 3.4 illustrates our projected total costs using either conventional or intensive treatment strategies for people with Type 2 diabetes. We estimated the number of Type 2 diabetes patients by estimating that the number of Type 1 patients remains constant over time, accounting for 14 per cent of the population with diabetes.⁸⁷ The costs of intensive medicine treatment and the costs of conventional treatment are taken from Gray et al (2000) and uprated to 2001/2 prices. Overall, intensive medicine treatment is more expensive, costing an expected £8.1 million extra in 2004, which represents just 0.12% of overall health expenditure in 2004. This rises to £20.6 million in 2028.

⁸⁵ Cost data used here is taken from Gray, A., Raikou, M., McGuire, A. et al (2000) Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41), *British Medical Journal*, Vol 320 pp1373-78, and are not Scotland specific

⁸⁶ Diabetes UK (April 2004) personal communication to NERA

⁸⁷ In line with previous NERA publication, based on Amos et al (1997)

Table 3.4
Estimated Costs of Managing the Population with Type 2 Diabetes with Conventional or Intensive Medicine Treatment in Scotland (2001/2 Prices)

	2004	2008	2013	2018	2023	2028
Projected no. of Type 2 diabetes patients (000s)	144	170	210	256	305	364
Total primary care costs:						
Intensive medicine treatment (£m)	52.9	62.4	77.4	94.1	112.2	134.0
Conventional treatment (£m)	28.4	33.5	41.5	50.5	60.2	71.9
Change in expenditure (£m)	24.5	28.9	35.9	43.6	52.0	62.1
Total hospital costs (incl. complications):						
Intensive medicine treatment (£m)	90.0	106.1	131.7	160.1	190.8	227.9
Conventional treatment (£m)	106.4	125.4	155.6	189.2	225.5	269.4
Change in expenditure (£m)	-16.4	-19.3	-24.0	-29.1	-34.7	-41.5
Change in expenditure (£m)	8.1	9.6	11.9	14.5	17.3	20.6

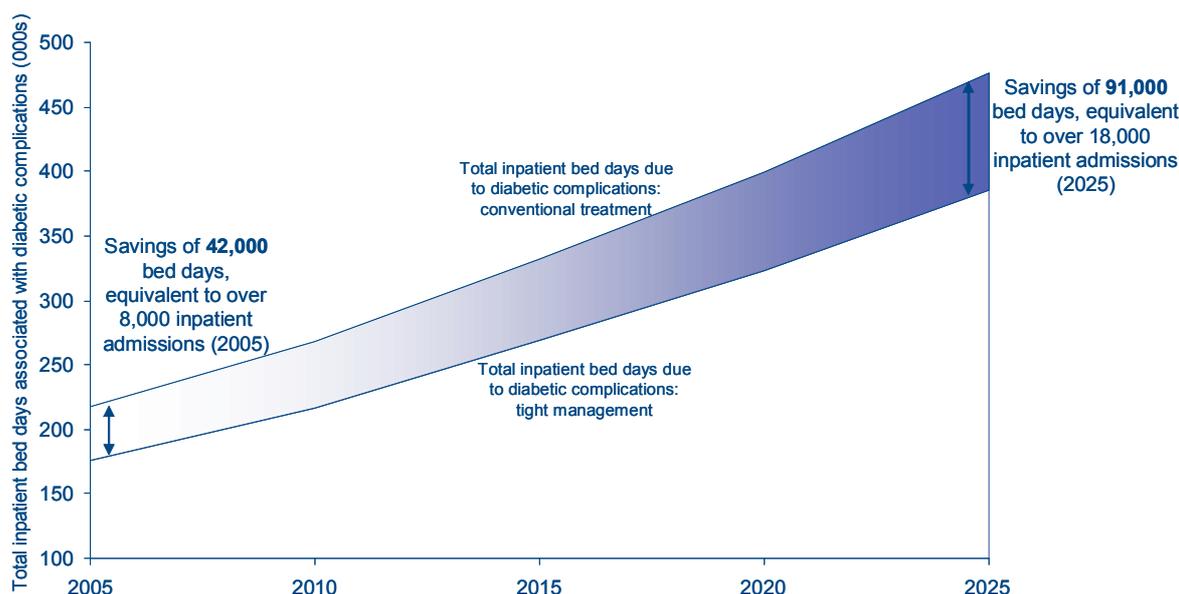
Source: NERA calculations combining cost data from Gray A, Raikou M McGuire A et al (2000) Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41), British Medical Journal, 2000Vol 320 pp 1373-78 with NERA projections for numbers of diabetes sufferers in the future, derived from the Scottish Diabetes Survey (2004), and General Register Office for Scotland population projections

Gray et al (2000) estimate that the cost of an event free year of intensive blood glucose control treatment is £1,166 (1997 prices), and that there is an 80 per cent probability that this cost will be under £2,500. They suggest that tight management is therefore a cost effective treatment of Type 2 diabetes compared to conventional treatment, considering recognised cost effectiveness thresholds.

Table 3.4 suggests that tight management of Type 2 diabetes will save resources in the secondary sector. A reduction in complications would also reduce hospital bed days and correspondingly free-up resources. If all patients were treated with intensive pharmaceutical treatment rather than conventional treatment, in 2005 a maximum of around 42,000 bed days could be saved (Figure 3.9). This could rise to 91,000 by 2025. This equates to around 8,000 hospital admissions in 2005 and over 18,000 in 2025, assuming an average length of stay of

just under 5 days.⁸⁸ This makes up a substantial proportion of the 112,010 people on inpatient and day case waiting lists in Scotland in March 2005.⁸⁹

Figure 3.9
Estimated Inpatient Days Saved from Tight Management of Type 2 Diabetes, 2005-2025, Scotland



Source: NERA calculation using Gray, A., Raikou, M., McGuire, A. et al (2000) Cost effectiveness of an intensive blood glucose control policy in patients with type 2 diabetes: economic analysis alongside randomised controlled trial (UKPDS 41), British Medical Journal, Vol 320 pp1373-78; Scottish Diabetes Survey 2004; and General Register Office for Scotland data

Personal and employment costs are also important when considering the future costs of diabetes. Diabetes results in lost earnings for people with the condition and their carers. UK studies have shown that 6 per cent of people with diabetes of working age are unable to work because of their condition. Those who lose earnings lose, on average, £14,000 per year, while their carers lose £11,000 per year.⁹³ 70 per cent of these individuals receive state benefits.⁹³ People with diabetes also lose, on average, £230 per annum in personal costs (which include over-the-counter medicines, residential care/nursing costs, and transport) while their carers lose £160 per annum.⁹³ Diabetic complications increase personal costs by a factor of three, and also double the likelihood of needing a carer.⁹³ A treatment strategy that reduced diabetic complications would result in substantial money savings to those with diabetes and their carers.

Costs that result from diabetes will also be incurred by employers in Scotland. Latest figures suggest that the average Scottish worker lost 8.9 days to sickness in 2004.⁹⁰ Studies have shown that people with diabetes lose twice as many days of work as people without the

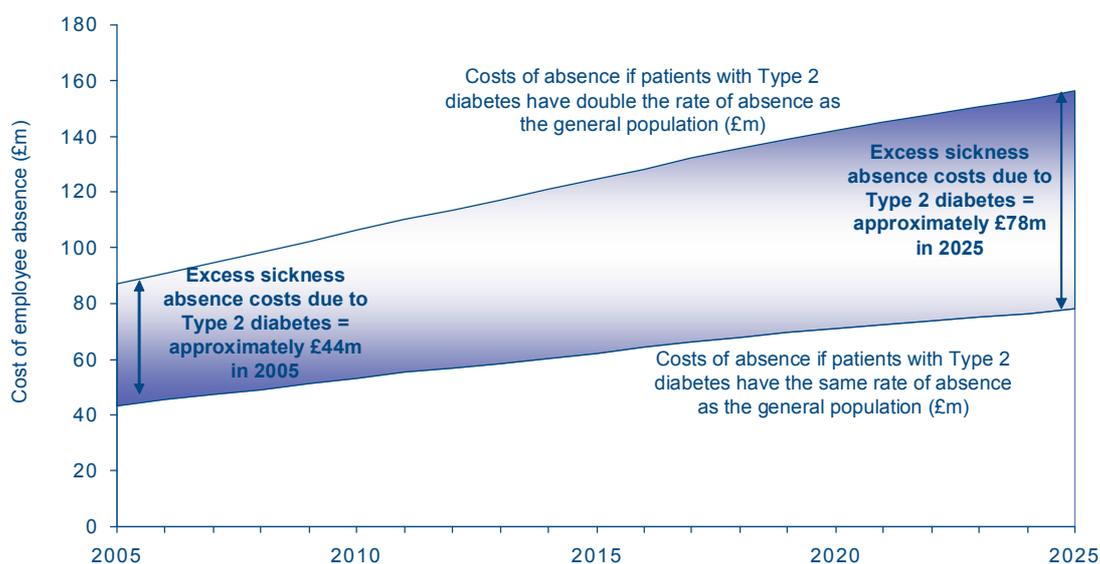
⁸⁸ Department of Health HES Statistics (2001-2)

⁸⁹ Scottish Health Statistics (2005) http://www2.isdscotland.org/acute_activity/quarterly.asp

⁹⁰ Chartered Institute of Personnel and Development (2004) *Employee absence 2004: A survey of management policy and practice*

condition.^{91, 92} We have estimated the likely cost of diabetes-related absenteeism in Scotland by using this ratio combined with an estimated daily cost of absenteeism. Figure 3.10 illustrates our estimates and projections for the future. We estimate that the sickness absence cost of Type 2 diabetes to employers in Scotland is approximately £44 million in 2005. This is projected to grow to around £78 million by 2025. Studies showed that the majority of those people not working as a result of their diabetes had microvascular or macrovascular complications, or both.⁹³ This suggests that tight management of Type 2 diabetes, which reduces these complications, could cut absence costs incurred by employers in Scotland.

Figure 3.10
Estimated Costs of Working Days Lost Due to Type 2 Diabetes, 2005-2025, Scotland



Source: NERA calculation using General Register Office for Scotland data, Chartered Institute of Personnel and Development (2004) Employee absence 2004: A survey of management policy and practice, Scottish Diabetes Survey (2004)

⁹¹ Skerjanc, A (2001) Sickness absence in diabetic employees, *Occup Environ Med*; Vol 58 pp 432-436

⁹² Songer, T.J. (1995) Disability in diabetes <http://diabetes.niddk.nih.gov/dm/pubs/america/pdf/chapter12.pdf>

⁹³ GlaxoSmithKline in collaboration with Diabetes UK, The King’s Fund, The Nuffield Institute and Beaufort International (2002) *The True Costs of Type 2 Diabetes in the UK: Findings from T²ARDIS and CODE-2 UK*

4. CHD in Scotland

4.1. What is CHD?

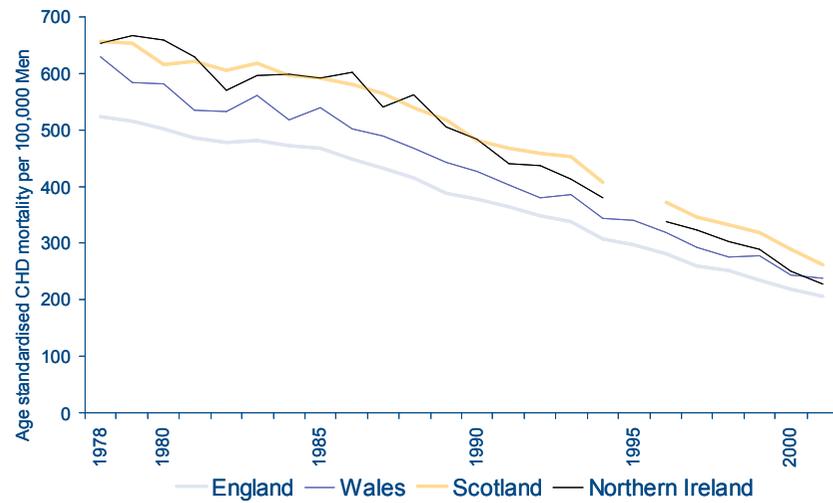
CHD is a chronic disease of the heart that occurs when the walls of the coronary arteries (vessels which supply oxygen-rich blood to the heart) become narrowed by a gradual build up of fatty material (atheroma).⁹⁴ The heart needs a constant supply of oxygenated blood in order to work well. This fatty material reduces the amount of oxygen rich blood reaching the heart, reducing its ability to work efficiently.

In Scotland, an estimated half a million people have CHD, of whom 180,000 require treatment for symptomatic disease.⁹⁵ Prevalence of CHD in Scotland is higher than elsewhere in the UK, which feeds through into mortality trends. Figure 4.1 illustrates the relative CHD mortality trends for the devolved regions and Figure 4.2 for selected European countries. Whilst all countries have a relative decline in the mortality rate, Scotland fares less well in absolute terms compared both to the devolved regions and other European countries. Taken together, this suggests that Scotland could do better.

⁹⁴ Wanless, D (2003) *Securing Good Health for the Whole Population, Population Health Trends*.

⁹⁵ Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*.

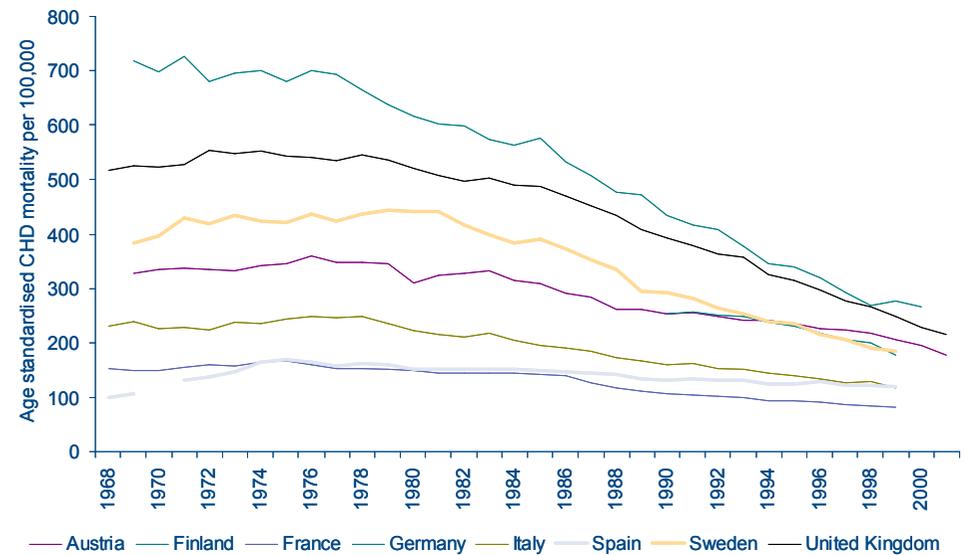
Figure 4.1
Age Standardised CHD Mortality Men Aged 34-75, 1978-2001, UK Regions



Source: BHF Coronary heart disease statistics at www.heartstats.org and Wanless (2003) *Securing Good Health for the Whole Population, Population Health Trends*

Reproduced from NERA (2004) *The Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS*

Figure 4.2
Age Standardised CHD Mortality, 1968-2001, Selected European Countries

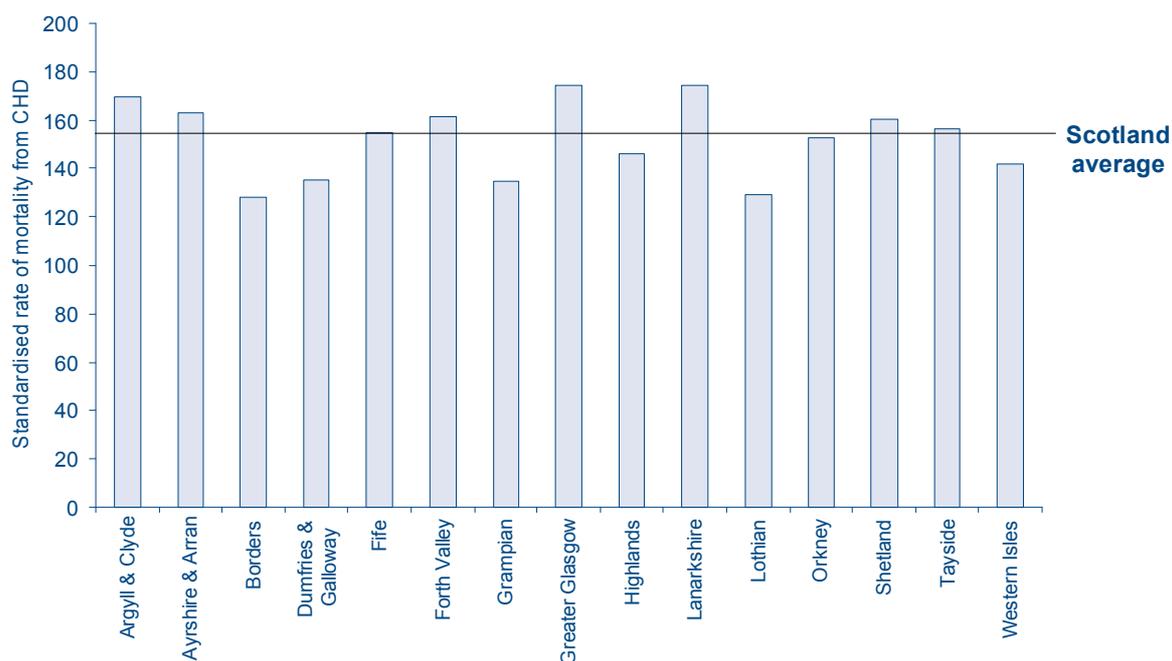


Source: BHF Coronary heart disease statistics at www.heartstats.org

Reproduced from NERA (2004) *The Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS*

There are also marked differences within Scotland. Figure 4.3 illustrates the standardised mortality rate across Health Boards. Greater Glasgow has the highest rate of 174.6 compared to the Scottish average rate of 154.8 per 100,000 population.

Figure 4.3
Standardised Mortality from CHD, 2002, Health Boards



Source: Health In Scotland (2003)

4.2. The Consequences of CHD to Scotland

4.2.1. Patients

In 2003, over 14,000 people died from CHD in Scotland.⁹⁶ In addition to mortality there are a number of other costs for patients and their carers.⁹⁷ These include the morbidity from suffering from CHD, the main symptoms of which are outlined in Box 7.

⁹⁶ ISD Scotland

⁹⁷ We are not aware of studies quantifying these costs in Scotland.

Box 7 Symptoms of CHD

Angina – Angina is an uncomfortable feeling in the chest. It can feel like a heaviness or tightness in the centre of the chest, which starts behind the sternum (breast bone) and can spread to the arms, neck, jaw, back or stomach.

Heart Attack – The pain from a heart attack is more severe than that associated with angina. Symptoms of a heart attack in addition to pain can include sweating (diaphoresis), nausea, light headedness, shortness of breath (dyspnea), anxiousness and sleep disturbance. In clinical terms the sudden occlusion (blockage) of a coronary artery leads to myocardial cell death (death of cells in the heart).

Source: British Heart Foundation, Clinical Evidence Concise, Issue 10, December 2003, McSwenney, J C et al (2003) Women's Early Warning Symptoms of Acute Myocardial Infarction, Circulation, Vol 108, pp 2619, Bajzer, C T (2002) Acute Myocardial Infarction and www.heartinfo.org

These symptoms will necessarily have an impact on the quality of life for patients. CHD will also have knock on consequences for the carers of sufferers, such as reducing the hours worked or giving up work altogether.

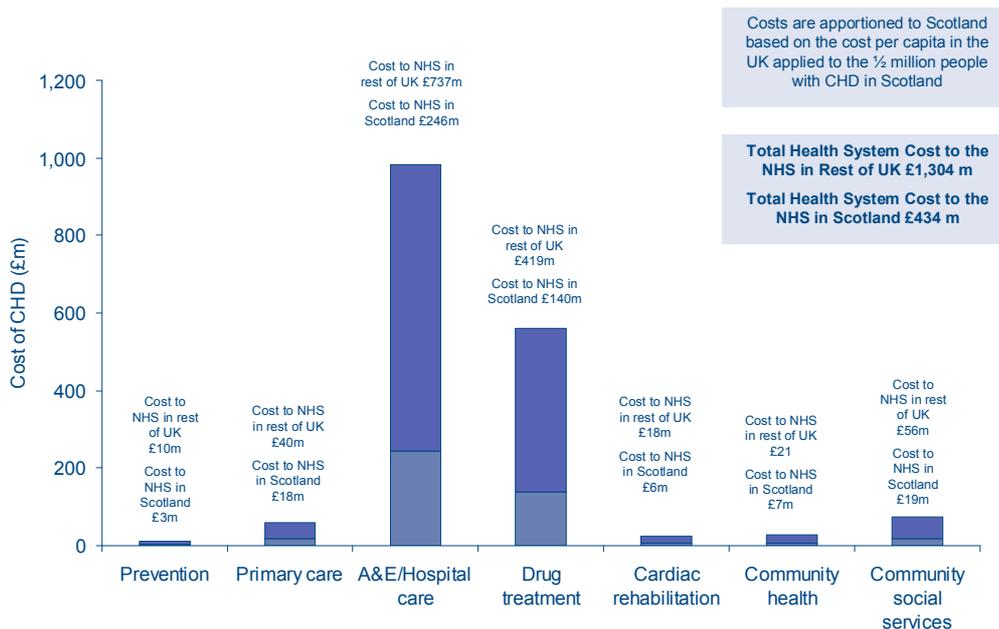
4.2.2. Health Care System

CHD represents a significant cost to the health system in Scotland. The total cost of CHD for the NHS in the UK has been estimated as £1,738 million a year (1999 value).⁹⁸ Comparable work has not been undertaken in Scotland. However we can apply the per capita cost of CHD to the number of people with CHD in Scotland (Figure 4.4). This provides an indicative estimate of the likely scale of the cost in Scotland and this cost is likely to increase over time (we return to the likely increase in costs later on in this report). This is likely to underestimate the true cost because the Scottish population uses the health care system more intensively. For example people in Scotland see their GP on average 4.1 times per year for hypertension compared to just 2.5 times per year for England.⁹⁹

⁹⁸ J L Y Liu, N Maniadakis, A Gray, M Rayner (2002) The economic burden of coronary heart disease in the UK, *Heart* 88: 597-603 and data correction from Gray, A (15.3.04) personal communication to NERA.

⁹⁹ Walker, A (2003) *The Cost of Doing Nothing – The Economics of Obesity in Scotland*

Figure 4.4
Estimated Cost of CHD to the NHS in Scotland and the Rest of UK (1999 Values)



Source: NERA calculations using Liu et al (2002) "The Economic Burden of Coronary Heart Disease in the UK" Heart Vol 88, pp 597-603 and corrected data personal communication to NERA (15.3.04)

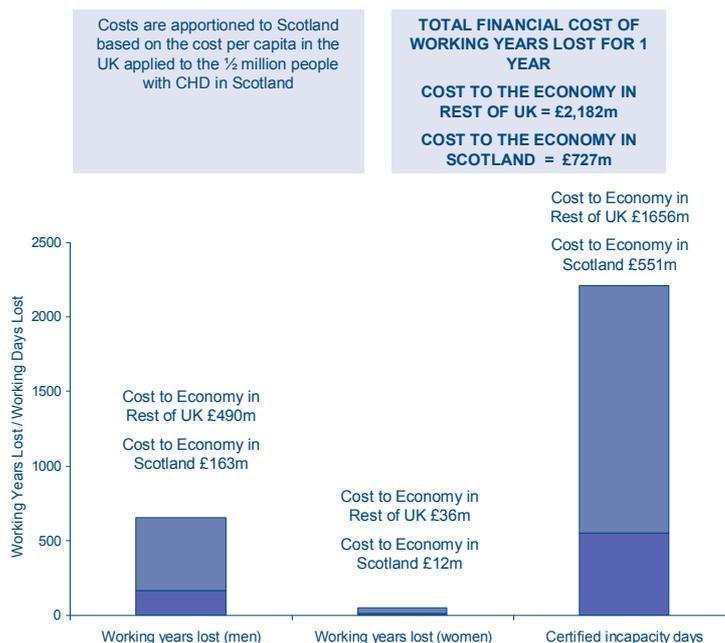
The cost of CHD to the health system is particularly felt in the acute sector. In 2003/4 there were some 40,000 CHD-related discharges in the whole of Scotland and over 13,000 CHD-related procedures carried out.¹⁰⁰

4.2.3. Economy

We have not identified any work that estimates the cost to the Scottish economy from CHD. As an indication, we have applied a UK estimate of costs per person with CHD to the number of people with CHD in Scotland. As before there has been no Scottish specific work which has estimated the total cost to the economy from CHD. We have used the same approach of applying the productivity cost per person with CHD to the estimated 500,000 with CHD in Scotland to provide an estimate of the likely scale of the cost to the Scottish economy. This approach suggests that the cost is in the region of £727m in Scotland.

¹⁰⁰ ISD Scotland

Figure 4.5
Estimated Cost of CHD to the Economy in Scotland and the Rest of UK (1999 Values)



Source: NERA calculations using Liu et al (2002) "The Economic Burden of Coronary Heart Disease in the UK" Heart Vol 88, pp 597-603

4.2.4. Future Trends in CHD in Scotland

It has been widely recognised that the prevalence of CHD will rise over time in Scotland.¹⁰¹ This reflects an ageing population and concerns about lifestyle trends and the higher levels of deprivation in Scotland than elsewhere in the UK. Current prevalence estimates drawn from a survey of GP practices suggests around 192,000 patients are being treated for CHD by GPs in Scotland.¹⁰² This is a large underestimate compared with the total number of people thought to have CHD in Scotland (around 1/2 million).¹⁰³ However this gap may close over time as GPs bring in CHD registers as part of the GMS contract. We have taken this difference into account when predicting the likely scale of CHD for Scotland in the future, as illustrated in Figure 4.6. Due to ageing alone 620,000 people could have CHD in Scotland by 2025.

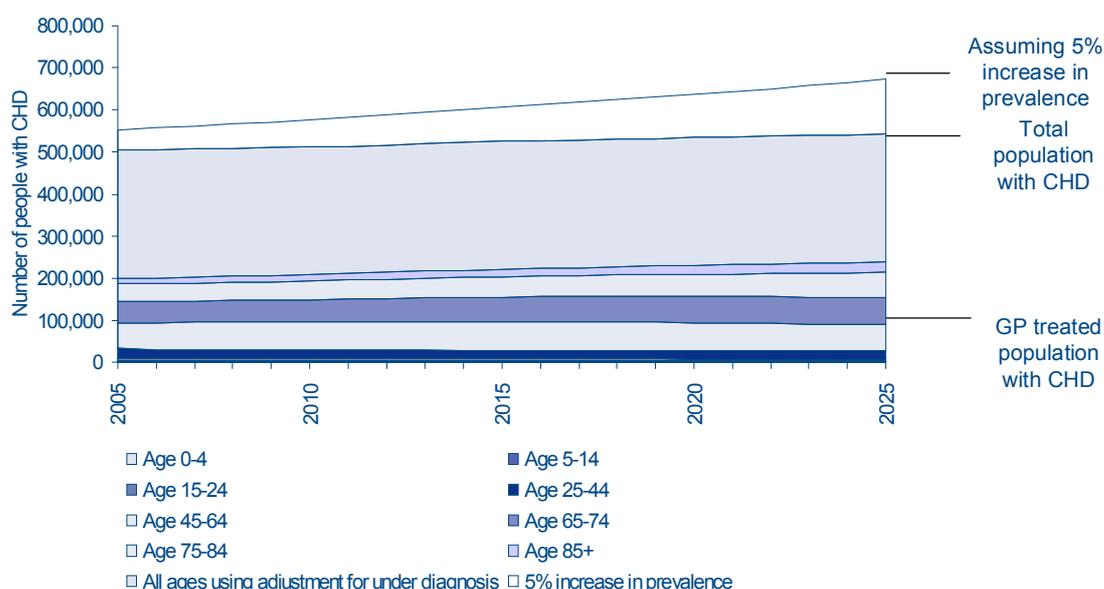
The number of people with CHD is also likely to rise from trends in lifestyle. For example, the National Audit Office (NAO) suggests that by 2010 over a quarter of all adults are going to be obese. The NAO also suggest that being obese increases the relative risk for heart attacks by 3.2 per cent and 1.5 per cent for women and men respectively. Obesity increases the relative risk of angina by 1.8 per cent for both women and men. As an illustration, in Figure 4.6, we show the impact of a 5 per cent increase in prevalence over a 20 year period.

¹⁰¹ <http://www.show.scot.nhs.uk/sehd/publications/cdtf/cdtf-04.htm>

¹⁰² ISD Scotland

¹⁰³ Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*

Figure 4.6
Forecasted Population with CHD, 2005-2025, Scotland



Source: NERA calculations using CMR data and GAD population projections.

If we translate the cost per person with CHD that we applied earlier we can illustrate the likely scale of the cost to Scotland in the future. Table 4.1 illustrates the costs in the health system and costs to the economy based on ageing alone. These are likely to be a substantial underestimate if the scenario in Figure 4.6 is realistic.

Table 4.1
Projected Cost of CHD in Scotland, £m (1999 Values)

	1999	2005	2010	2015	2020	2025
Direct health care cost	434	451	471	499	520	539
Productivity loss:						
- Sickness absence	175	182	190	201	210	217
- Early death	551	572	598	634	660	684
Informal care cost	604	626	655	694	722	749
Total economic cost	1,766	1,831	1,915	2,029	2,111	2,190

Source: NERA calculations based on J L Y Liu, N Maniadakis, A Gray, M Rayner (2002) *The economic burden of coronary heart disease in the UK, Heart 88: 597-603* and data correction from Gray, A (15.3.04) personal communication to NERA.

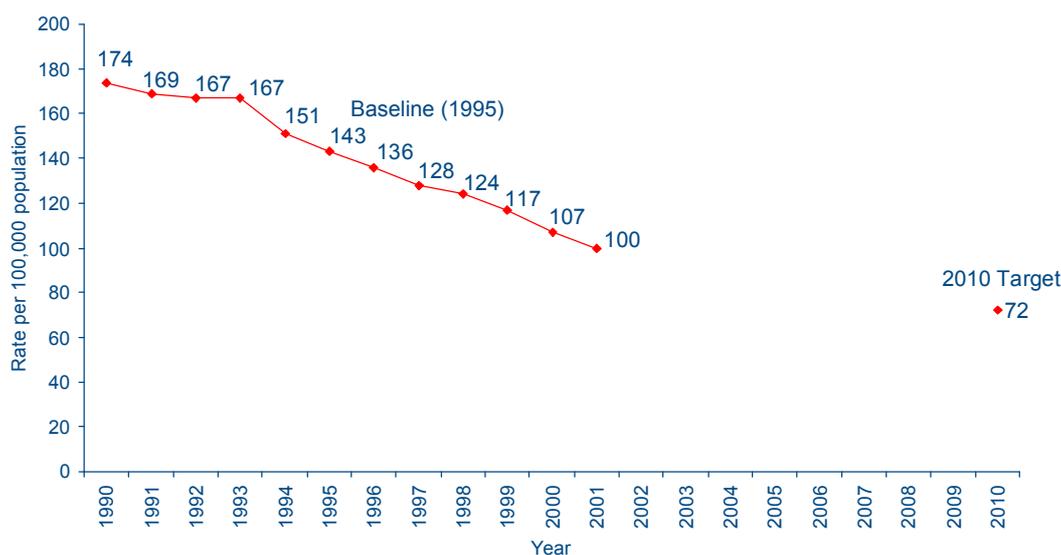
4.3. Medicines and Managing CHD

4.3.1. Managing CHD in Scotland – CHD and Stroke Strategy for Scotland

The Scottish Executive Health Department has set out a strategy to tackle both CHD and Stroke in Scotland (the *Coronary Heart Disease and Stroke Strategy for Scotland*) which was launched in 2002. This strategy includes an additional £10 million in funding in 2003/4 and a further £30 million in the future to tackle CHD and Stroke. The strategy includes a challenging target to reduce the mortality rate from CHD in people under 75 years by 50 per cent between 1995 and 2010.¹⁰⁴ Figure 4.7 illustrates the recent trend in CHD mortality and sets out the target of 72 deaths per 100,000 population by 2010. The strategy is intended to result in a number of major benefits including:

- Fewer people developing the disease;
- Earlier treatment, and therefore better outcomes, for those who do develop it;
- A continuation of the reduction of premature deaths; and
- A voice for patients and clinicians in the planning and development of services.

Figure 4.7
CHD Mortality and Target for Reduction in CHD Mortality, 1990 – 2010, Scotland



Source: Health Education Board for Scotland – statistics database at www.hebs.com

The strategy focuses upon managed clinical networks (MCNs) across Scotland which play an active role in both primary and secondary prevention of CHD and Stroke. MCNs are a

¹⁰⁴ <http://www.hebs.com/topics/statschart.cfm?topic=heart&serialno=222>

virtual organisation of health care professionals from across primary and secondary care and across locations working with patients. Local MCNs in Health Boards are involved in a range of activities to tackle CHD, including developing rapid access chest pain clinics, setting targets for the secondary prevention of CHD (including treatment with medicines such as statins to lower cholesterol) and monitoring progress against targets, and developing and implementing primary care standards for care for those with CHD in the community. The strategy is explicit about the role of medicines, and in particular the value of statins, saying that

“research upholds the value of appropriately targeted preventative measures such as the prescription of statins to a wider group of at-risk people than was previously recognised”¹⁰⁵

Also, the Quality and Outcomes Framework (QOF) – part of the GMS contract – set indicators so that the standards of secondary prevention of CHD could be assessed in different practices within Health Boards. QOF scores for 2004-2005 (shown below in Table 4.2) indicate that in general secondary prevention of CHD is being managed impressively, though some variation between Health Boards and practices is evident, especially in those practices that are not bound to implement the QOF.⁶⁶

¹⁰⁵ Scottish Executive (2002) *Coronary Heart Disease and Stroke: Strategy for Scotland*

Table 4.2
Quality and Outcomes Framework Achievement Points: CHD

Health Board	Number of practices with QOF as a specific part of their contract	% achieved	Points	Number of practices without QOF as a specific part of their contract	% achieved	Points
Argyll & Clyde	90	91.5		5	84.1	
Ayrshire & Arran	52	96.7		9	93.1	
Borders	23	96.5		1	100.0	
Dumfries & Galloway	34	96.8		1	93.6	
Fife	53	96.1		4	97.8	
Forth Valley	50	95.8		7	78.9	
Grampian	67	95.8		17	90.7	
Greater Glasgow	208	96.4		2	97.4	
Highland	61	90.1		9	76.7	
Lanarkshire	94	92.9		6	82.3	
Lothian	99	96.2		27	96.7	
Orkney	5	81.9		8	51.1	
Shetland	1	99.1		9	84.7	
Tayside	70	97.5		1	97.8	
Western Isles	6	89.0		6	93.6	
Scotland	913	95.0		112	87.1	

Source: ISD Scotland National Statistics, Quality Management and Analysis Computer System (QMAS) database as at 4th May 2005

4.3.2. The Role of Medicines in Managing CHD

There is a range of medicines available to manage CHD, set out in Box 8.

Box 8: Medicines and their benefits for CHD

- **Aspirin** – this helps to thin the blood and reduce subsequent heart attacks and/or strokes. Taking aspirin is estimated to lead to around 10 fewer deaths or recurrent strokes in the first 4 weeks following a stroke for each 1,000 patients treated. Clopidogrel can be given as a substitute
- **Nitrates** – these medicines expand the arteries allowing more blood through. Fast acting sprays are often used for angina. Long acting versions are also available, which help to prevent angina attacks and help to shorten the duration of attacks.
- **Beta blockers** - These medicines slow down the heart rate. Clinical trials have shown that beta blockers can reduce the long-term risk of death from a heart attack by 23 per cent.
- **Calcium channel blockers** – These reduce muscle tension in the arteries and so expand the arteries.
- **Potassium channel activators** – These work in a similar way to calcium channel blockers and reduce the tension in the arteries.
- **ACE inhibitors** - These medicines lower blood pressure and improve the output of heart. Clinical trials have shown that they reduce the risk of fatal heart attacks by 22 per cent, the risk of a any type of stroke by 32 per cent and the risk of both heart attack and stroke by 22 per cent.
- **Angiotensin 2 antagonists (AT2 antagonists)** – These medicines also lower blood pressure but in a slightly different way to ACE inhibitors, by blocking the restriction of arteries.
- **Diuretics** – These help the body to deal with extra fluids and salt in the body and thereby lower blood pressure.
- **Cholesterol lowering medicines (statins)** – These help to lower the level of cholesterol in the blood. Clinical trials have shown that statins reduce the risk of death from 10 to 30 per cent, the risk of heart attack by 60 per cent, the risk of strokes by between 15 and 30 per cent and reduce hospitalisation. Intensive statin therapy (reducing cholesterol levels to even lower levels) with calcium channel blockers helps patients reach cholesterol and blood pressure targets to prevent cardiovascular disease in high-risk patients.
- **Combination therapy.** Taking a combination of medicines to lower blood pressure and lower cholesterol has the potential to reduce the risk of death by between 72 to 87 per cent.

Sources: Law, MR et al (2003) Quantifying effect of statins on low density lipoprotein cholesterol, ischaemic heart disease, and stroke: systematic review and meta-analysis, British Medical Journal Vol 326 pp1423:1427, Heart Protection Study Collaborative Group (2002) MRC/BHF Heart Protection Study of Cholesterol Lowering with Simvastatin in 20,536 High-Risk Individuals: A Randomised Placebo Controlled Trial, The Lancet Vol 360p7-22, Freemantle, N et al (1999) Beta Blockade after Myocardial Infarction: Systematic Review and Meta Regression Analysis, British Medical Journal 318 pp 1730 – 1737, Mayor, S (1999) ACE inhibitor reduces cardiovascular events by 22%, British Medical Journal 319 p661, Mukherjee, D, Fang, J, Chetcuti, S, Moscucci, M, Kline-Rogers, E and Eagle, K A, (2004) Impact of Combination Evidence-Based Medicla Therapy on Mortality in Patients With Acute Coronary Syndromes, Circulation Vol 109, Part 6, pp 745-74, Bocsh, J et al (2002) Use of ramipril in preventing stroke: double blind randomised trial, British Medical Journal, Vol 324, p 1-5. , Larner, A J and Farmer, S F (1999) Recent Advances Neurology, British Medical Journal, Vol 319, pp 362-366. Bandolier Statin Effectiveness: ASCOT update, Sever, P et al (2005) ASCOT A Randomised Controlled Trial of the Prevention of CHD and other vascular events by BP and cholesterol lowering in a factorial study design” Presentation at the American College of Cardiology 8th March 2005, Koren, M J and Hunninghake, D B (2004) Clinical Outcomes in Managed-Care Patients With Coronary Heart Disease Treated Aggressively in Lipid-Lowering Disease Management Clinics, Journal of the American College of Cardiology, Vol 44, No 9, 1772-1779 and Dorval, JF et al (2005) Reaching Recommended Lipid and Blood Pressure Targets With Amlodipine/Atorvastatin Combination in Patients With Coronary Heart Disease

The role of medicines in managing CHD is clearly acknowledged in Scotland, with some 40 per cent of the reduction in mortality from 1975 to 1999 (around 7,000 fewer deaths from CHD) attributed to improved treatment including resuscitation, thrombolysis, coronary care, and secondary prevention including medicines. The remaining reduction is attributed to lifestyle changes such as reduced smoking, control of blood pressure and lowering of raised cholesterol levels.¹⁰⁶ Specific Scottish guidance on the use of medicines is highlighted in Box 9.

Box 9

SIGN Guidelines for Using Medicines in Scotland for CHD

The Scottish Intercollegiate Guidelines Network produces guidelines for the treatment of diseases in Scotland. These guidelines cover a variety of treatments (including lifestyle modification, appropriate monitoring etc.) but also cover the use of medicines in Scotland. Specific guidelines covering the treatment of CHD include:

Guideline 40: Lipids and the Primary Prevention of Coronary Heart Disease. This recommends the use of statins to tackle lipids (cholesterol in the blood).

Guideline 41: Secondary Prevention of Coronary Heart Disease following Myocardial Infarction (heart attack). This guideline recommends the use of aspirin (or an alternative if aspirin is not well tolerated or contra-indicated), beta blockers, ACE inhibitors, nitrates (relax the heart muscles), and calcium channel blockers (which widen veins and arteries).

Guideline 48: Hypertension in Older People. This recommends the use of thiazide diuretics (to lower blood pressure), beta-blockers, calcium channel antagonists (which widen veins and arteries), and ACE inhibitors with the choice of treatment dependent upon the individual patient (for example some medicines are less well tolerated in those with diabetes etc.). The guideline notes that achieving reductions in blood pressure may need a combination of these types of medicines in older patients.

Guideline 51: Management of Stable Angina. This recommends the use of aspirin (or an alternative if aspirin is not well tolerated or contra-indicated), sublingual glyceryl trinitrate (GTN) (to make veins and arteries dilate), beta-blockers, calcium channel blocker and nitrates. As before choice of treatment is dependent upon the individual patient.

Source: SIGN. Selected SIGN guidelines for CHD are under currently under review.

With the recent publication of trial results (in March 2005) from the TNT (Treating to New Targets) clinical trial could lead to a change in guidelines.¹⁰⁷ TNT found that, in a population of patients with CHD, aggressive lipid-lowering treatment with high-dose

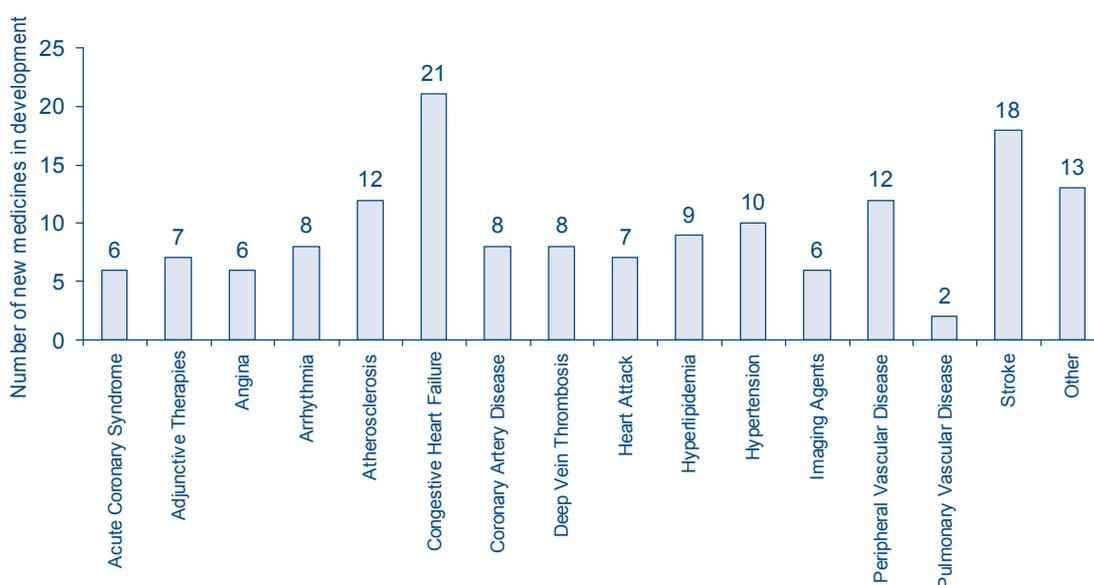
¹⁰⁶ <http://www.show.scot.nhs.uk/sehd/publications/cdtf/cdtf-04.htm>

¹⁰⁷ AMNews (4th April 2005) High-dose statins reduce cardiac risk, study says.

atorvastatin (80mg) to mean cholesterol levels of 77 mg/dL was associated with a 22 per cent reduction in the risk of major cardiovascular events (such as heart attack) compared with patients treated with 10 mg atorvastatin to cholesterol goals of 100 mg/dL.¹⁰⁸ Guidelines may now include lower cholesterol level target and statins could be an important way to meet it.

New medicines for CHD are under development. The PhRMA 2003 survey of new medicines in development highlights 123 medicines in the pipeline to tackle heart disease and stroke, as illustrated in Figure 4.8. This includes 7 for heart attack, 6 for angina and 10 for hypertension.

Figure 4.8
New Medicines in Development for CHD and Stroke, 2003



Source: PhRMA (2003)

Note: Some medicines appear in more than one category

We present two case studies to illustrate the benefits of innovative medicines in tackling CHD, statins and thrombolytics.

4.3.3. A case study of statins in Scotland

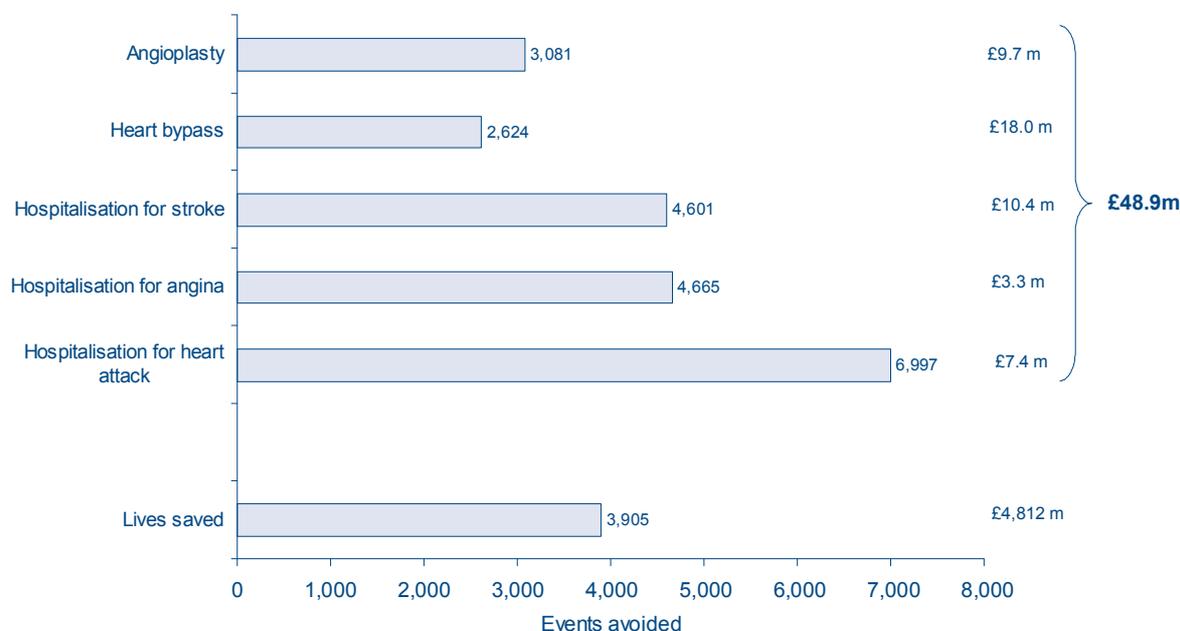
High cholesterol has been recognised as a major factor in the risk of CHD. Statins, which reduce cholesterol in the blood, are a major breakthrough for tackling CHD. Statins were first licensed in the UK in 1989 and their use has been increasing over time. A number of statins have been recommended for use in Scotland by the Scottish Medicines Consortium (an agency that advises the Scottish NHS about the use of new medicines). In Scotland the

¹⁰⁸ LaRosa, J C et al (2005) Intensive Lipid Lowering with Atorvastatin in Patients with Stable Coronary Disease, *The New England Journal of Medicine*, Vol 352.

number of prescriptions for statins has risen from 1.3 million in 2001 to over 2.4 million in 2004.¹⁰⁹

Statins are particularly important because of the range of benefits they generate to both patients and the health system. There are no estimates of the number of people receiving statins in Scotland. Data from ISD Scotland suggest that 123 million defined daily doses were dispensed in Scotland in 2002/3.¹¹⁰ This suggests that 330,000 people take statins in a year. This may overestimate the true number because of differences in prescribing patterns between doctors compared to the daily dose assumed by the World Health Organisation. However, it provides an estimate we can use to extrapolate results from a major clinical trial (the UK based Heart Protection Study) to estimate the benefits of statins over a 5 year period in Scotland (Figure 4.9).

Figure 4.9
Events Avoided Through Treatment with Statins, Scotland Over 5 Years



Source: NERA calculations using HPSCG (2002) data and NHS Reference Costs (2003)

The likely scale of benefits is large with around 4,000 lives saved over 5 years. Other benefits include the reduction in surgery (and associated hospital days saved etc.) and hospitalisations for stroke, heart attack and angina. Taken together and applying the average length of stay for cardiology in Scotland in 2004 (4.5 days) this suggests that around 197,000 bed days can be saved, an average of just under 40,000 a year. We have also applied estimated costs for hospitalisations to illustrate the scale of the financial expenditure avoided. Scotland does not currently collate information on the cost of individual procedures related to

¹⁰⁹ ISD Scotland

¹¹⁰ Defined daily doses is the total number of doses at the suggested level by the World Health Organisation. Actual prescribing practice may differ.

CHD so we have used English costs as a proxy.¹¹¹ This suggests that almost £50 million over 5 years could be saved by statins, equivalent to almost £10 million a year. With current spending at around £85 million per year on statins these savings do not cover the direct cost of statins but the benefits of 4,000 lives saved over 5 years are clear. We have used the estimated value of life saved from road traffic accidents to provide an indication of the value of lives saved (Figure 4.9).

We can also estimate the number of events avoided across Health Boards using daily defined doses for each Health Board (Table 4.3).

Table 4.3
Events Avoided by Statins Over 5 Years, Health Boards

	Estimated no. taking Statins	Lives saved	Non-fatal heart attack	Unstable or worsening angina	Events Avoided Stroke	CABG	Angioplasty
Argyll & Clyde	29,934	348	624	416	410	234	275
Ayrshire & Arran	25,116	292	523	349	344	196	230
Borders	5,212	61	109	72	71	41	48
Dumfries & Galloway	10,031	117	209	139	137	78	92
Fife	22,344	260	465	310	306	175	205
Forth Valley	21,639	252	451	301	296	169	199
Grampian	30,350	353	632	422	416	237	278
Greater Glasgow	64,845	754	1,351	901	888	507	595
Highland	10,782	125	225	150	148	84	99
Lanarkshire	44,750	520	932	622	613	350	411
Lothian	42,351	492	882	588	580	331	389
Tayside	24,280	282	506	337	333	190	223
Orkney	922	11	19	13	13	7	8
Shetland	1,032	12	22	14	14	8	9
Western Isles	2,258	26	47	31	31	18	21
Scotland	335,845	3,905	6,997	4,665	4,601	2,624	3,081

Source: NERA calculations using ISD Scotland data and Heart Protection Study Collaborative Group (2002) MRC/BHF Heart Protection Study of Cholesterol Lowering with Simvastatin in 20,536 High-Risk Individuals: A Randomised Placebo Controlled Trial, The Lancet Vol 360p7-22.

As before we can apply costs to provide an indication of the likely scale of financial benefits to Health Boards. Table 4.4 illustrates the cost savings by Health Board.

¹¹¹ We used the same costs as in our earlier report, The Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS (May 2004) to allow comparison between the UK and Scotland.

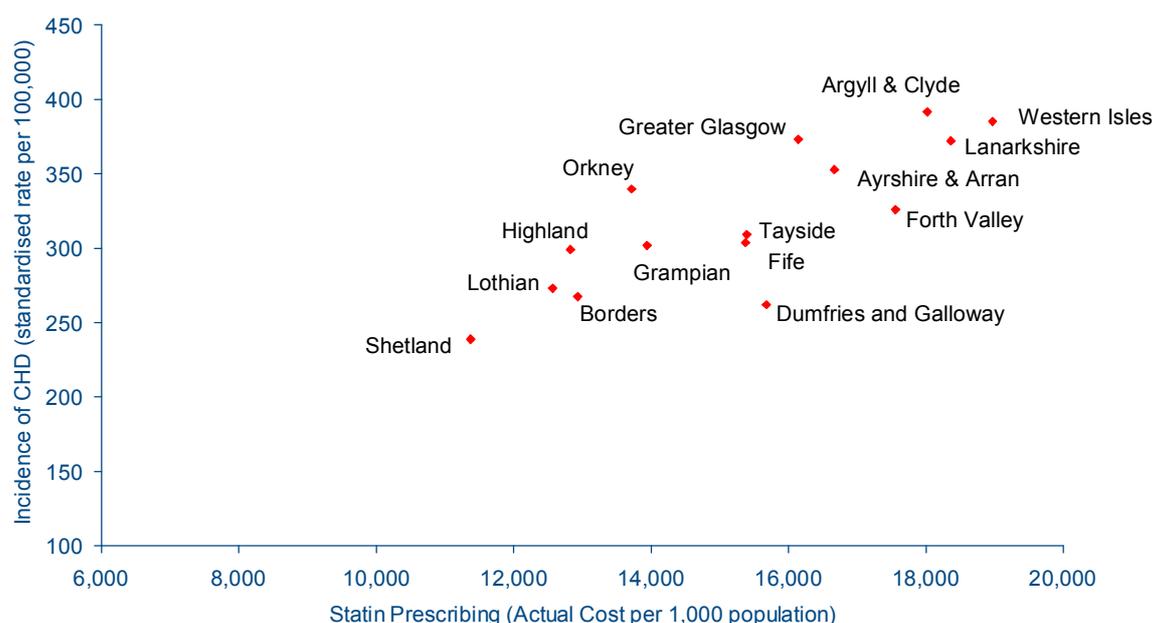
Table 4.4
Value of Events Avoided by Statins Over 5 Years, Health Boards (£000s)

	Estimated no. taking Statins	Lives saved	Non- fatal heart attack	Unstable or worsening angina	Stroke	CABG	Angioplasty
Argyll & Clyde	29,934	428,896	659	296	931	1,606	863
Ayrshire & Arran	25,116	359,856	553	248	781	1,347	724
Borders	5,212	74,674	115	51	162	280	150
Dumfries & Galloway	10,031	143,717	221	99	312	538	289
Fife	22,344	320,137	492	221	695	1,199	644
Forth Valley	21,639	310,042	477	214	673	1,161	624
Grampian	30,350	434,849	669	300	944	1,628	875
Greater Glasgow	64,845	929,092	1,428	641	2,016	3,479	1,869
Highland	10,782	154,485	238	107	335	578	311
Lanarkshire	44,750	641,172	986	442	1,392	2,401	1,290
Lothian	42,351	606,797	933	418	1,317	2,272	1,220
Tayside	24,280	347,876	535	240	755	1,303	700
Orkney	922	13,213	20	9	29	49	27
Shetland	1,032	14,793	23	10	32	55	30
Western Isles	2,258	32,354	50	22	70	121	65
Scotland	335,845	4,811,953	7,398	3,318	10,443	18,018	9,678

Source: NERA calculations using ISD Scotland data, Heart Protection Study Collaborative Group (2002) MRC/BHF Heart Protection Study of Cholesterol Lowering with Simvastatin in 20,536 High-Risk Individuals: A Randomised Placebo Controlled Trial, The Lancet Vol 360p7-22 data and NHS Reference Costs (2003)

Prescribing of statins differs across Health Boards in Scotland. A simple cross tabulation of statin prescribing and incidence (new cases) of CHD illustrates that on the whole all Health Boards are prescribing in relation to the need for statins although some appear to have higher prescribing rates than others (Figure 4.10). For example Ayrshire and Arran are prescribing more statins but with a comparable incidence of CHD compared to Orkney.

Figure 4.10
Statin Prescribing and CHD Incidence, 2002/3, Health Boards



Source: ISD Scotland

The next step in the innovation of statins was to combine the statin with other medicines in one single tablet. The combined tablet includes both a calcium channel blocker and a statin and was introduced in the UK in 2004. The expected benefit of this is to maximise compliance with treatment to ensure that patients will get the full benefits of the medicines.

4.3.4. A case study of thrombolysis

Thrombolytics are used following a heart attack to break down blood clots that cause a heart attack and restore blood flow to the heart.¹¹² Thrombolytics are vital to improve the change of survival following a heart attack. Evidence suggests that the faster that thrombolytics can be given to patients, the greater the chance of survival. In the first three hours after a heart attack, every minute of delay in giving a thrombolytic leads to a loss on average of 11 days of life.¹¹³ It is generally recommended that thrombolytics are given within 60 minutes of a heart attack (often called the ‘call to needle’ time).

Major innovations have occurred in thrombolytics. The relatively older thrombolytic, *Streptokinase*, has been available since before the 1970s, but newer alternatives are now available and offer substantial benefits for patients. The newer *Atlepaste* can be used more than once whereas *Streptokinase* can only be given once because it leads to the development of antibodies that render it inactive if given again. This means that patients who have previously had a heart attack and have been treated with thrombolytics can be treated again –

¹¹² NICE (2002) *Guidance on the use of drugs for early thrombolysis in the treatment of acute myocardial infarction*, Technology Appraisal Guidance No. 52

¹¹³ National Assembly for Wales (2001) *Tackling CHD in Wales: Implementing Through Evidence*.

this increases survival rates. Figure 4.11 charts the progression of pharmaceutical innovation in thrombolytics since the 1970s. In addition to new medicines, the method of delivery of some of these thrombolytics is changing over time. *Retoprase*, for example, is no longer given through a drip.¹¹⁴

Figure 4.11
Thrombolytic Innovations, 1970s – 2000s

	1970s	1980s	Late 1980s	Late 1990s	Early 2000s
Treatment	<ul style="list-style-type: none"> •Treatment focus on life threatening arrhythmias (irregular heart beat) •Specialist coronary care units in hospitals 	<ul style="list-style-type: none"> •Large clinical trials of Streptokinase •Meta-analysis (summary analysis of all clinical trials) showed 22% risk reduction of death 	<ul style="list-style-type: none"> •Thrombolytic therapy is standard care for heart attacks 		<ul style="list-style-type: none"> •NSF target for fast access to thrombolytics
Medicines	<p>Streptokinase</p> <ul style="list-style-type: none"> •Intravenous infusion (through a drip) •Can only be used once 		<p>Alteplase</p> <ul style="list-style-type: none"> •Intravenous infusion (through a drip) •Given with another medicine (heparin) •Can be used more than once •Less likely to lead to side effects 	<p>Retepase</p> <ul style="list-style-type: none"> •Rapid intravenous infusion (through a drip) •Given with another medicine (heparin) •Can be used more than once 	<p>Tenectapase</p> <ul style="list-style-type: none"> •Rapid intravenous infusion (through a drip) •Given with another medicines (heparin) •Can be used more than once

Source:NERA based on NICE (2002) and Liverpool Reviews and Implementation Group (2002)

Reproduced from NERA (2004) *The Human and Economic Value of Pharmaceutical Innovation and Opportunities for the NHS*

Scotland faces particular difficulties in ensuring that the ‘call to needle’ time is within the preferred 60 minute window reflecting its rural and remote communities. Research in Scotland has found that pre-hospital thrombolysis (where thrombolytics are given to the patient before they reach the hospital) adds to life expectancy compared to hospital thrombolysis. Table 4.5 compares life expectancy with community and hospital thrombolysis drawing on the Grampian Region Early Anistreplase Trial (GREAT).

Table 4.5
Average Life Expectancy at 5 Years

	Life Expectancy
Community thrombolysis	4.15
Hospital thrombolysis	3.58
Gain (years)	0.570

Source: Health Economics Research Unit, Briefing Paper for the NHS in Scotland No. 9

¹¹⁴ ABPI Scotland (5th April 2005) Personal communication to NERA.

“Call to needle” time has been improved in pilots of the ‘dual response’ approach in Scotland. Under dual response a rural GP and paramedic attend at the same time and the paramedic provides the thrombolytic and 12 lead ECG (to monitor the heart). The proportion of patients receiving pre-hospital thrombolytics has increased from 34 to 45 per cent and the median call to “needle time” has fallen from 115 to 90 minutes.¹¹⁵

In a comparison of “call to needle” time between urban areas and rural areas with and without pre-hospital thrombolysis available (delivered by the paramedic), pre-hospital thrombolytics were delivered in 52 minutes on average. This compares to 125 minutes for hospital delivered thrombolytic in patients from rural areas and 80 minutes for patients from urban areas. The authors suggest that much faster delivery of thrombolytics, particularly within the 60 minute window following a heart attack, is likely to lead to around 2 lives saved for every 100 patients treated.¹¹⁶

Another approach is to use a telemedicine link between doctors at A&E departments and General Practitioners (GPs) to offer thrombolytics remotely. In the Scottish scheme GPs in remote rural areas can be linked up by video conference to emergency doctors who can diagnose a heart attack from ECG readings. The success of pilot sites has led to plans to install the necessary equipment in every ambulance in Scotland so that paramedics can deliver a thrombolytic before the patient reaches hospital. It is hoped that the scheme will continue to provide early access to thrombolytics and therefore save more lives.¹¹⁷

¹¹⁵ Health in Scotland (2003)

¹¹⁶ Pedley, D K et al (2003) Prospective Observational Cohort Study of Time Saved by Pre-Hospital Thrombolysis for ST Elevation Myocardial Infarction Delivered by Paramedics, *British Medical Journal*, Vol 327, pp 22-6.

¹¹⁷ T is for Telemedicine. <http://www.bma.org.uk/ap.nsf/Content/AtoZofDocs~AtZofDocsST>

5. Facing the Challenges in the Future

The significance of the challenge that diabetes and CHD present to Scotland are clear. Commentators agree that the burden of diabetes is set to rise significantly. The World Health Organisation estimates that the number of people with diabetes is set to double over the next 10 to 15 years, and the Scottish Diabetes Survey suggests that prevalence rates will rise from 3 to 4 per cent of Scotland's population having diabetes by 2010. This report has illustrated the consequences of this for patients, in terms of their quality of life and the complications to their health. Such a rise would also bring significant financial costs to individuals, the health system and the economy.

The challenge this brings to Scotland is twofold. The issue for policymakers is how to work across health care boundaries and engage individuals, public health, the health service and social care in managing the risk factors that drive growth in diabetes. Diet and lifestyle are important. The issue for the health service is how to manage patients once diabetes has been diagnosed. This matters, because it links to the consequences for patients and the costs to the health service. From the statistics outlined in this report, diagnosis and care of those with diabetes varies by Health Board. Tight management of Type 2 diabetes can deliver quality of life improvements for patients at only modest cost to the health service. Diabetic complications are less severe as a result. Whilst evidence is limited, Diabetes UK suggest that the patients tightly managing their diabetes are a minority of those who could benefit. Yet health care innovation has made tight management of diabetes a more straightforward treatment option than has historically been the case. Improvements in medicine, blood testing and drug delivery mechanisms all support better treatment of diabetes. Innovation is a dynamic process and future innovations, such as inhaled insulin, should help to improve compliance with treatment regimes in the future.

A similar message applies to CHD. Lifestyle and diet are important risk factors for CHD (as is diabetes), and a challenge for public health is again how to engage with individuals and address these risk factors. They are important in their own right, but the relative levels of deprivation in Scotland make this more pressing and, most likely, more difficult. The health service is engaged in the challenge. Mortality rates from CHD in Scotland are falling, although they are lagging behind other parts of the UK and many parts of Europe. The use of statins to help reduce cholesterol levels has also grown in Scotland, and is predicted to deliver significant benefits to the Scottish health economy. We estimate that over a five year period, 3,905 lives will be saved, and around £50m of hospital interventions will be avoided. But again, variations across Health Boards imply that more could be done. Statin use is relatively low in the UK by European standards and variations within Scotland suggest that some patients who could benefit from treatment are not yet accessing medicines. As with diabetes, health care innovation has contributed to the treatment of CHD and significant new innovations, both to improve compliance with treatment and to expand treatment options, are being developed. The Scottish Medicines Consortium (SMC) and others involved in developing guidance and protocols that will help to ensure these innovations are used appropriately.

Experience with thrombolytic medicines illustrates the need to work across health borders and co-ordinate interventions. Efforts to improve "call to needle" time, by co-ordinating input from different health care professionals, have improved access to these medicines,

ensuring that patients can benefit more fully from the benefits of new innovations. Similar cross-working has much to offer in the broader treatment of CHD and diabetes. Disease management approaches, for instance, rely on effective working across health and social care boundaries, to support active engagement with individuals to take responsibility for their health needs. Scotland has made good progress in supporting these ideas and many elements of the process are in place to support good identification and management of disease. NHS Health Scotland is working to support public engagement, the SMC is providing advice on the use of new medicines in Scotland, and SIGN guidelines help support the management and treatment of disease. The trends outlined in this report emphasise the need to gain momentum and ensure proper engagement by all stakeholders, including patients, for the benefits of all preventive and treatment approaches to be delivered.

ABPI Scottish Diabetes Industry Group

Aims:

To work with all relevant agencies to help implement the Scottish Diabetes Framework. This will be achieved through:

- Raising standards of evidence based patient care;
- Improving outcomes for people with diabetes;
- Ensuring people with diabetes have equitable access to the best available medicines and services;
- Highlighting opportunities for aligning plans and policies across national groups and related disease areas at both strategic and tactical levels.

Membership:

Merck Sharpe and Dohme Limited
Roche Products Ltd
Pfizer Limited
Boehringer-Ingelheim Limited
GlaxoSmithKline
Bristol Myers Squibb
Lilly UK
Roche Diagnostics
Abbott Laboratories Ltd
Servier
Sanofi-Aventis
NovoNordisk
AstraZeneca
Takeda

ABPI Scottish CHD and Stroke Industry Group

Aims:

To work with all the relevant organisations to help implement the Scottish Executive CHD and Stroke Strategy and to improve patient care and health outcomes for people with or at risk from CHD, Stroke and peripheral vascular disease. This will be achieved through:

- Raising standards of evidence based patient care by working in partnership with the Scottish Collegiate Guidelines Network (SIGN), NHS Quality Improvement Scotland (NHSQiS) and by supporting the role-out of Managed Clinical Networks (MCNs) across Scotland;
- Ensuring people with CHD and Stroke have equitable access to the best available medicines and services;

- Highlighting opportunities to work in partnership with the Scottish Executive National Advisory Group for Stroke and other strategic bodies which are able to align plans and policies across national groups and related disease areas;
- Working in partnership with other organisations such as NHS Health Scotland to support disease awareness and good quality, non-promotional health education;
- Promoting patient and public involvement by supporting patient advocacy groups such as Chest, Heart and Stroke Scotland and the British Heart Foundation (Scotland).

Membership:

Merck Sharpe and Dohme Ltd

Pfizer Ltd

Novartis

Boehringer-Ingelheim

Servier

Takeda

Astra Zeneca

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Roche Diagnostics

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