

1 Diabetes Mellitus

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1 Summary

This chapter provides:

- information to assess the need for services for people with diabetes and its complications
- criteria to assess the success of programmes for the care and early detection of this group of disorders.

The chapter does not aim to provide a systematic review of the literature on diabetes epidemiology and health care. There are a number of systematic reviews available in the Cochrane Library and other sources. Instead, the chapter highlights the most recent important studies in these areas and suggests issues, particularly in the domain of health services research, where more information is needed. Considerable documentation and a large measure of agreement exist on the aims of diabetes care and how these might be achieved. The most important consensus documents on the subject are listed in Appendix II and some feature as specific references in the text. (Further explanation and relevant references for the statements made below are included in subsequent sections.)

Statement of the problem/introduction

Definition and diagnostic criteria

Diabetes mellitus is a group of disorders with common features, of which a raised blood glucose is the most evident. It is a chronic disease which can cause substantial premature morbidity and mortality.

The diagnosis of diabetes is based on clinical symptoms and/or measurements of plasma glucose. Existing World Health Organisation (WHO) diagnostic criteria for diabetes are being revised following recommendations by a WHO Consultation Group. The American Diabetes Association (ADA) has also suggested a revision. Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) are indicators of increased risk of diabetes. The definition of gestational diabetes mellitus (GDM) is controversial although guidelines for its detection and diagnosis are available for the UK.

The problem

- Diabetes mellitus and its complications can cause severe problems for affected individuals and their families. They impose a heavy burden on health services.
- The primary prevention of some cases of type 2 diabetes is potentially feasible, but has yet to be implemented as a public health measure.
- The organisation of services for the care of people with diabetes is complex, involving hospital-based diabetes teams, community services, those working in primary care, patients and their families.

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The solution

- There is now proof that, both in type 1 and type 2 diabetes (*see* below for explanation), effective control of hyperglycaemia prevents the development and progression of the microvascular complications of diabetes (retinopathy, neuropathy and nephropathy). Attainment of near-normal glycaemic control, while minimising the risk of hypoglycaemia, is a priority.
- The impact of diabetes and its complications can be reduced by providing well-organised, integrated care including, in particular, the education and empowerment of patients and their families and the early identification of complications.
- Health authorities (HAs) and primary care groups (PCGs), and their equivalents elsewhere in the UK, together with providers of hospital-based diabetes services and community services, must work together, with the patient and the family at the centre of the process.

The challenges

- Some of the greatest current challenges to those involved in planning and delivering diabetes services are: (i) the involvement of all people with diabetes in a continuing, planned programme of care; (ii) resolving local issues of where and by whom that care should be given; and (iii) ensuring that, wherever that care is provided, its quality is set and maintained at the highest possible level.
- Assessing the impact of diabetes services also presents considerable challenges. However, the relevant process and outcome measures necessary for this are largely agreed and, with some exceptions, are measurable with the careful use and interpretation of routine sources of information and *ad hoc* studies.
- Keeping pace with new developments in diabetes care will also be a challenge. Some of the main areas relevant to future prevention and care are summarised below.

Sub-categories of diabetes

There are four sub-categories of diabetes:

- 1 type 1
- 2 type 2
- 3 other specific types, e.g. drug induced
- 4 gestational.

It has been suggested that the terms 'insulin-dependent diabetes mellitus' (IDDM) and 'noninsulin-dependent diabetes mellitus' (NIDDM) be replaced by the aetiologically based categories type 1 and type 2 diabetes. Any form of diabetes may require insulin therapy. In type 1 diabetes this therapy is essential to maintain life. In type 2 diabetes it is a treatment option used to improve control of blood glucose.

Complications of diabetes may be classified into macrovascular (coronary heart disease, cerebrovascular disease and peripheral vascular disease) and microvascular (retinopathy, nephropathy and neuropathy).

Prevalence and incidence

The prevalence of type 2 diabetes is increasing because of the ageing population and an increase in the prevalence of risk factors (e.g. obesity). An increasing incidence of childhood diabetes is also contributing to this.

There are many published studies on the incidence and prevalence of diabetes in various parts of the UK. Most studies involve Caucasian populations and the results are not applicable to non-Caucasian populations. It is known that the prevalence of diabetes is higher in people of South Asian and Afro-Caribbean origin. When estimating local incidence or prevalence it is preferable, rather than extrapolating findings from elsewhere, to use data from local studies if these are available. The incidence of type 2 diabetes in adults is difficult to determine given the latency of the condition. The incidence in children is easier to estimate, and has been shown to be around 14 per 100,000 children aged 14 and under per year. The overall prevalence of clinically diagnosed diabetes in people of all ages in the UK is between 2 and 3%. The prevalence of diabetes in children and young people (aged under 20) is around 0.14%. The prevalence of self-reported diabetes in adults is around 3%.

Macrovascular and microvascular complications contribute to premature mortality and morbidity. For example, mortality due to coronary heart disease is 2–3 times higher in people with diabetes than in those without. Also, the complications of diabetes have been shown to be more prevalent in areas of socio-economic deprivation, with increased mortality rates.

Services available

People with diabetes are cared for by a wide range of health care staff in primary and secondary care. Staffing levels and facilities vary between localities. People with diabetes have been shown to utilise health services in general more than people without. It is also likely that those who do not attend for regular review of their diabetes are likely to be the most frequent users of secondary care services for ensuing complications.

The direct health care costs of diabetes include those associated with prevention, diagnosis and treatment. It has been estimated that 8.7% of acute sector costs are spent on the care of people with diabetes. It has been predicted that the overall cost of hospital care for people with diabetes will increase by 15% by 2011.

Effectiveness and cost-effectiveness of services

Screening

Currently, population screening is an issue only in relation to type 2 diabetes. Screening for diabetes for all people aged 40 or over has been recommended by the ADA. In the UK the National Screening Committee (NSC) is reviewing the issues of both retinal screening in people with diabetes and screening for diabetes itself. Screening for retinopathy has been shown to be an effective and cost-effective intervention. Current recommendations are that eye examinations should be performed annually as part of regular surveillance. Further research is required to determine whether this is the optimum frequency for all people with diabetes.

As a method of screening for diabetes itself, urine testing is known to have a low specificity with between 140 and 170 people identified for each true positive detected. It is also uncertain whether early diagnosis affects outcome, although several studies have clearly shown that complications are present in many people at diagnosis. This is an important area for further research. Opportunistic screening (also known as case-finding) is recommended good practice when adults present in primary or secondary care for other reasons.

Optimal glycaemic control

Robust evidence has now shown that, in type 1 diabetes, intensive insulin therapy (IIT) delays the onset and slows the progression of retinopathy, nephropathy and neuropathy. Any improvement in glycaemic

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control in type 1 diabetes is likely to reduce the risk of these complications. However, IIT carries with it an increased risk of hypoglycaemia.

Similarly, robust evidence has also shown that intensive treatment with oral hypoglycaemics and/or insulin in type 2 diabetes reduces the risk of microvascular complications. Tight control of high blood pressure is also important for the reduction of diabetes microvascular complications. These measures may also be effective in preventing or delaying macrovascular complications.

Delivery of care

Patients with diabetes are cared for in primary care, secondary-based care or a combination of both. It is still unclear which is the most effective setting, although it is clear that primary care with a recall system ('prompted care') can be as effective as secondary care in terms of glycaemic control and adherence to follow-up. It is the quality of care, rather than its location, which is likely to be the main determinant of patient satisfaction and outcome.

Models of care

The appropriate model of care for a locality will depend on the current service arrangements and the enthusiasm and motivation of staff to make improvements in the quality of care. Planning these improvements should involve a multidisciplinary approach across primary and secondary care with representation of user and carer views. HAs and PCGs, and their equivalents elsewhere in the UK, should assess the health care need of the local population, and develop and monitor, in collaboration with their local diabetes services advisory groups (LDSAGs) or their equivalent, a local strategy for diabetes care.

There is a plethora of nationally and internationally agreed standards for care, protocols for treatment and measures for monitoring improvements. There are also several established and innovative planning tools: these include population databases (also known as 'registers'), case-mix systems [e.g. Health care Resource Groups (HRGs)] and commissioning matrices. A national service framework (NSF) for diabetes is currently being compiled and is planned for release in 2001. The further development and enhancement of local diabetes services should not, however, be placed 'on hold' until that time. There is already evidence that a considerable gap exists between the performance of services and currently available evidence or professional consensus on what is desirable practice.

Outcome measures

There are established process and outcome measures for diabetes services which are useful for clinical audit or for monitoring purposes. Process measures include clinic waiting times and quality of communication with health care workers, the proportion of people receiving planned care, in particular an annual review, and the frequency with which key examinations and investigations are carried out and recorded.

Outcomes of diabetes care depend on whose perspective is being considered (patient, clinician or commissioner of services). They include quality of life and well-being, the achievement of optimal blood glucose, blood lipid and blood pressure levels and reduced incidence of short- and long term complications.

Information and research requirements

The main requirements are:

- more evidence on the effectiveness and cost-effectiveness of population screening for diabetes
- more research into the primary prevention of diabetes

- further use and development of population databases to ensure that those with diagnosed diabetes are able to maintain contact with appropriate services.

2 Introduction

Diabetes: The problems and challenges

Diabetes mellitus and its complications can cause severe problems for affected individuals and their families. In turn, these impose a heavy burden on health services. There is no cure for diabetes, however, the primary prevention of some cases of type 2 diabetes is potentially feasible but has yet to be implemented as a public health measure. A further problem is the organisation of services for the care of people with diabetes. This is complex, involving hospital-based diabetes teams, community services, those working in primary care, patients and their families.

Some of the greatest current challenges to those involved in planning and delivering diabetes services are:

- the involvement of all people with diabetes in a continuing, planned programme of care
- resolving the local issues of where and by whom that care should be given
- ensuring that, wherever that care is provided, its quality is set and maintained at the highest possible level.

Assessing the impact of diabetes services also presents considerable challenges. However, the relevant process and outcome measures necessary for this are largely agreed and, with some exceptions, measurable with the careful use and interpretation of routine sources of information and *ad hoc* studies.

Definition and diagnostic criteria

Diabetes is a group of disorders with common features, of which a raised blood glucose is the most evident. Existing WHO diagnostic criteria for diabetes are being revised following recommendations by a WHO Consultation Group.¹ The ADA has also suggested a revision.² WHO recommendations will also include criteria for the definition of diabetes complications and for the clinical staging of these complications.

The ADA and WHO recommendations are similar (although not, unfortunately, identical) but both differ from the 1985 WHO recommendations which were the previous worldwide standard.³ The essential features of the ADA recommendations (for non-pregnant adults) are listed in Table 1 together with the main differences between these new provisional recommendations and the previous WHO recommendations.³

If the ADA or new WHO recommendations are adopted in the UK, there will be little impact on clinical management. The main consequences are likely to be:

- an *increase* in the estimated prevalence of diabetes as a result of the *lowering* of the minimum fasting plasma glucose (FPG) concentration necessary for diagnosis
- a reduced emphasis on the oral glucose tolerance test (OGTT) in the diagnosis of diabetes, although this is still likely to be regarded as the investigation of choice for epidemiological research.

The magnitude of the effect on prevalence is likely to differ between groups of different ethnic origin. For example Unwin *et al.*⁴ reported results from men and women aged 25–74 years living in Newcastle and participating in an epidemiological study of diabetes (i.e. including previously known and unknown cases). They calculated that the effect of changing from a definition of diabetes based on previous

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Table 1: Essential features of the American Diabetes Association (ADA) recommendations for diabetes (in non-pregnant adults)² and the main differences between these and the *previous* WHO recommendations.³

Provisional ADA recommendations	Previous WHO recommendations
General: Based on clinical <i>stages</i>	Based on clinical <i>states</i>
Diabetes: Symptoms of diabetes plus 'casual' PG ≥ 11.1 mmol/l <i>or</i> FPG ≥ 7.0 mmol/l <i>or</i> 2 h PG ≥ 11.1 mmol/l during an OGTT Any of the above need to be confirmed on a subsequent day for the diagnosis to be made.	Same FPG ≥ 7.8 mmol/l or 2 h PG ≥ 11.1 mmol/l during an OGTT
Impaired glucose tolerance (IGT): 2 h PG ≥ 7.8 mmol/l but < 11.1 mmol/l	Same
Impaired fasting glucose (IFG): FPG ≥ 6.1 mmol/l and < 7.0 mmol/l	Not previously recognised
Normal glucose tolerance: FPG < 6.1 mmol/l <i>or</i> 2 h PG < 7.8 mmol/l	Not specified

'Casual' is defined as any time of day without regard to time since last meal. FPG, fasting plasma glucose; PG, plasma glucose; OGTT, oral glucose tolerance test.

WHO criteria to the new ADA criteria was an increase in the prevalence of diabetes from 4.8 to 7.1% in Caucasians, from 4.7 to 6.2% in people of Chinese origin and from 20.1 to 21.4% in people of South Asian origin. Note that these findings differ from those already published for the US population aged 40–74 years in which the prevalence of diabetes was *reduced* (from 6.34 to 4.35%) by the use of the new criteria.²

Impaired glucose tolerance and impaired fasting glucose

The 1985 WHO recommendations introduced the term 'impaired glucose tolerance' (IGT) (*see* Table 1 for diagnostic criteria).³ IGT has long been recognised as a risk factor for ischaemic heart disease and, in some people, it is a precursor of type 2 diabetes.⁵ The recent ADA recommendations proposed the adoption of an additional category – impaired fasting glucose (IFG).² The diagnostic criteria for this are also included in Table 1.

IGT and IFG are not yet regarded as clinical entities in their own right, but as indicators of increased risk for the future development of diabetes and for cardiovascular disease. Abnormal glucose tolerance is a component of the 'insulin resistance syndrome' also known as 'Reaven–Modan syndrome' or 'syndrome X'. In addition, this syndrome has one or more of the following features: obesity, dyslipidaemia (usually high triglyceride and/or low HDL cholesterol) and hypertension.^{6,7}

Gestational diabetes

The ADA criteria summarised in Table 1 refer to non-pregnant adults. The definition of gestational diabetes mellitus (GDM), the magnitude of its effects on the outcome of pregnancy and the best method of

screening for this condition are controversial. Opinions and practices in the UK vary considerably from place to place and differ from those of the US.^{2,8} The most recent summary of UK practice is that published by the Pregnancy and Neonatal Care Group of the joint [British Diabetic Association (BDA) and Department of Health (DH)] Saint Vincent Task Force, which proposed that new diagnostic criteria for gestational diabetes should be formulated based on prospective studies of pregnant women.⁸ In the meantime, it recommended the screening procedures and definitions summarised in Box 1.

Box 1: Screening procedures and definition of gestational diabetes.⁸

Urine should be tested for glycosuria at every antenatal visit.

Timed random laboratory blood glucose measurements should be made:

- whenever glycosuria (1+ or more) is detected
- at the booking visit and at 28 weeks gestation

A 75 g OGTT with laboratory blood glucose measurements should be carried out if the timed random blood glucose concentrations are:

- > 6 mmol/l in the fasting state or 2 h after food
- > 7 mmol/l within 2 h of food.

The interpretation of the OGTT during pregnancy is as follows:

<i>Category</i>	<i>Plasma glucose Fasting</i>	<i>2 h after glucose load</i>
Diabetes	> 8 mmol/l	> 11 mmol/l
IGT	6–8 mmol/l	9–11 mmol/l
Normal	< 6 mmol/l	< 9 mmol/l

The management of established diabetes in women who become pregnant is a separate issue from GDM and gestational IGT. There is no controversy about the fact that stringent control of blood glucose during pregnancy is beneficial in terms of perinatal mortality and that the prevention of congenital malformation requires careful pre-pregnancy care.⁸

The diagnosis of type 1 diabetes, especially when it occurs in children, does not usually pose problems of definition because there are usually one or more of the classical symptoms of diabetes – thirst, polyuria, malaise and weight loss. The clinical picture, taken with the result of a urine glucose or ‘casual’ blood glucose estimation (Table 1) is usually sufficient to make the diagnosis. On the rare occasions that an OGTT is required in a child, the dose is calculated on a dose per body weight basis.

3 Sub-categories of diabetes

The ADA and WHO recommend that the subclassification of diabetes based on insulin dependency, IDDM and NIDDM, should now be abandoned in favour of the aetiologically based classification shown in Box 2. This is partly because patients with *any* form of diabetes may require insulin treatment at some stage of their disease. The most important sub-categories in public health terms are type 1 and type 2 diabetes. The most important long term vascular complications of diabetes are also outlined in Box 2. Diabetes may also predispose to non-vascular conditions, such as cataract. Table 2 lists the relevant categories in the International Classification of Diseases (ICD).

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Box 2: Aetiological classification of diabetes mellitus.²

Type 1 diabetes: β -cell destruction, usually leading to absolute insulin deficiency.

Type 2 diabetes: may range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance.

Other specific types:

- genetic defects of β -cell function, e.g. chromosome 7, glucokinase (formerly MODY2)
- genetic defects in insulin action, e.g. leprechaunism
- diseases of the exocrine pancreas, e.g. pancreatitis
- endocrinopathies, e.g. acromegaly
- drug- or chemical-induced diabetes, e.g. caused by thiazides
- infections, e.g. congenital rubella
- uncommon forms of immune-mediated diabetes, e.g. due to anti-insulin antibodies
- other genetic syndromes sometimes associated with diabetes, e.g. Down's syndrome.

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Long-term vascular complications of diabetes.

Macrovascular complications:

- coronary heart disease
- cerebrovascular disease
- peripheral vascular disease.

Microvascular complications:

- retinopathy
- nephropathy
- neuropathy.

Table 2: Diabetes categories in the International Classification of Diseases (ICD) – 10th revision.

Number	Title	Includes
E10	Insulin-dependent diabetes mellitus	diabetes (mellitus): <ul style="list-style-type: none"> ● brittle ● juvenile-onset ● ketosis-prone ● type I
E11	Non-insulin-dependent diabetes mellitus	diabetes (mellitus) (nonobese) (obese): <ul style="list-style-type: none"> ● adult-onset ● maturity-onset ● nonketotic ● stable ● type II
E12	Malnutrition-related diabetes mellitus	non-insulin-dependent diabetes of the young malnutrition-related diabetes mellitus: <ul style="list-style-type: none"> ● insulin-dependent ● non-insulin-dependent
E13	Other specified diabetes mellitus	
E14	Unspecified diabetes mellitus	diabetes NOS
E15	Nondiabetic hypoglycaemic coma	

4 Prevalence and incidence

The epidemiological information needed for health care needs assessments of diabetes

One of the first steps in assessing need in a locality involves assembling information on the frequency of occurrence of diabetes:

- the number of individuals with clinically diagnosed diabetes in a given population (prevalence)
- the number of new patients needing diagnosis, stabilisation and programmes of education and long term care (incidence)
- the number of individuals with, or likely to develop, specific complications.

There are a number of ways to estimate the above. In practice, a trade-off between precision and feasibility will need to be made. The following list is roughly in descending order of precision:

- examining a validated, up-to-date population database of those with diabetes living in the locality. (We prefer to use the term 'population database' rather than 'register', in keeping with advances in information technology. The term 'register' has, at least to us, the connotation of a list of affected people which is held at one location. The term 'population database' might also encompass systems in which data may be distributed over a number of different sites.)
- using a recently carried out epidemiological study of diabetes in the locality, or part of it calculating 'indicative prevalences' (and/or incidence and mortality rates) by extrapolation from data collected elsewhere⁹
- estimating the number of people with diabetes from prescribing data and knowledge of 'average daily dose'.

The text below gives brief descriptions of prevalence, incidence and mortality. Appendix III is intended to be used in the practical tasks of calculating local numbers of people affected by diabetes and its complications. A computer-based model using the data from Appendix III is now available to assist local planning of diabetes services (Appendix III gives details of how to obtain a copy of this model).

Published data on diabetes incidence and prevalence

Since 1980, diabetes incidence^{10–26} and prevalence^{27–46} estimates for the UK have been published from a number of local and national studies. Clearly, when estimating local incidence or prevalence it is preferable, rather than extrapolating findings from elsewhere, to use data from local studies if these are available. For that reason, the references to these published studies are given in full. Some of these are now quite dated and most, although not all, were of populations that were largely Caucasian in origin. For localities in which no suitable data are available, age- and sex-specific incidence and prevalence estimates, derived from published studies, are given in Appendix III to allow locally relevant calculations to be made.

Incidence is well documented in children because of the relatively clear-cut nature of the condition in this age group and the presence of well-validated population databases.^{11–25} A recent estimate, from one of these databases²⁴ gives an annual incidence, in children aged 0–14 years, of 13.91 per 100 000 (95% Confidence Interval: 13.51–14.66), when age- and sex-standardised to an external reference population.⁴⁷ The prevalence of diabetes in children and young people (aged under 20) is reported as 14.0 per 1000.⁴⁸

For diabetes in adults, 'incidence' is not a useful concept because the diagnosis of diabetes may be made a considerable time after the disease process has begun. Information on the frequency of diagnosis of new cases is sparse and some of this is now out-dated (e.g. Barker *et al.*¹⁰), although some more recently published data are available.²⁶

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The prevalence of diabetes in adults is well documented, for specific localities, by means of *ad hoc* epidemiological studies. Poole, in the south of England, estimated the crude prevalence of diabetes, in 1996, to be 2.13% in males, 1.60% in females and 1.86% overall.⁴⁶ The equivalent age-adjusted (to the 1991 UK Census population) prevalences were 1.74, 1.37 and 1.55%.

Routine data are available from general practice.⁴⁹ The General Practice Morbidity Survey provides data on prevalence, 'incidence' (more correctly, frequency of presentation of new cases) and consultation rates from a number of general practices with a total patient population base of around 2.5 million.⁴⁹ Cases are defined as those permanently registered with a general practitioner (GP) who have a clinical diagnosis of diabetes recorded at any time and/or treatment with diabetic drugs from defined sections of the British National Formulary. The overall prevalence of diabetes (all ages, types 1 and 2 combined) estimated from this source is 1.19% for males and 1.02% for females.

The National Health Survey for England⁴⁵ has also published prevalence data, in this case self-reported diabetes recorded by interview questionnaire in a sample of just under 12,000 adults. The survey has also estimated the prevalence of undiagnosed diabetes, as defined by a glycosylated haemoglobin concentration of 5.2% or more. In men, the prevalence of self-reported diabetes was 3%, whereas the corresponding figure in women was 1.8% (overall, men and women combined, 2.4%). The prevalence of previously undiagnosed diabetes was 1% in men and 1% in women. Thus, the prevalence of all diabetes, diagnosed and undiagnosed, estimated from this source, was 4% in men, 2.8% in women and 3.4% in all adults.

The main advantages of using data from *ad hoc* epidemiological studies are that diabetes is usually defined in a consistent manner (most commonly following the 1985 WHO definition³) and that information on IGT and the prevalence of previously undiagnosed diabetes has often been estimated by means of the OGTT. The main disadvantages of using national GP morbidity statistics are that no consistent definition of diabetes has been used and that the burden on local services may be underestimated due to the failure to ascertain some cases, particularly those treated by dietary therapy alone. The problem of definition also applies to self-reported diabetes, although this method is more likely to identify people treated with dietary therapy alone.

Some of the listed epidemiological studies make specific reference to populations of non-Caucasian origin.^{28,31,36,38,41} In general, the prevalence of diabetes in these groups is higher, sometimes much higher, than in Caucasian populations of the same age. For diabetes in children, there is little difference between incidence in the various ethnic groups.²⁰ However, for adults, diabetes (mainly type 2 diabetes) is 2–4 times as common (depending on gender and age) in people of South Asian origin as in those of Caucasian origin.^{36,48} People of South Asian origin are heterogeneous and prevalence may vary among them, although detailed analysis of prevalence in relation to area of origin and religion suggests that there is much less difference between South Asian groups than there is between them and their Caucasian neighbours.⁵⁰ In people of Afro-Caribbean origin, prevalence is also high and the majority of diabetes is, again, type 2.^{31,48}

Prevalence and incidence of diabetic complications

The most important consequence of diabetes is premature death from coronary heart disease (CHD). It has long been known and is still the case, that mortality rates from CHD are 2–3 times higher in people with diabetes than in their non-diabetic peers, and that the additional risk of CHD in people with diabetes cannot be explained in terms of the 'classic' risk factors for CHD, i.e. smoking, hypertension and serum lipid concentrations.^{51–53}

There are now a large number of studies of mortality rates in people with diabetes.^{54–66} Again, these are listed in full to enable specific local rates to be calculated if the relevant studies exist.

Other macrovascular complications of diabetes are cerebrovascular disease (CVD) and peripheral vascular disease (PVD). The consequences of these are premature mortality and morbidity as a result of

stroke or circulatory problems of the lower limb resulting in ischaemic pain, ulceration, gangrene and amputation.

The pathognomonic sequelae of diabetes are the microvascular complications, i.e. retinopathy, nephropathy and neuropathy. Alone or, more frequently in combination, these contribute greatly to morbidity from diabetes and, particularly in the case of nephropathy, to premature mortality from renal failure.

Diabetes and socio-economic deprivation

The complications of diabetes, e.g. retinopathy or cardiovascular disease, have been shown to be more prevalent in areas of high socio-economic deprivation.^{67,68} Also, the use of insulin in these areas has been shown to be less than elsewhere.^{67,69} Mortality due to diabetes is higher in people from lower socio-economic groups, the unemployed and in those with a 'low attained level of education'.^{65,70,71}

Future epidemiological trends

The prevalence of diabetes will increase in the next decade, if only because of the ageing of the population. In addition to this influence, however, a number of other temporal trends, particularly the increase in adult obesity will contribute to the increase in the number of people with type 2 diabetes in the population of the UK.⁷² The incidence of type 1 diabetes in children has also been found, in some population studies, to be increasing. The rate of this increase has been put as high as a doubling of incidence every 20–30 years.⁷³ A general increase in incidence in children has not been confirmed by all studies.⁷⁴ However, the best evidence for such an increase relates to the youngest age group (birth to 4 years), children who will have the longest time to develop complications.

Estimates of the future prevalence of diabetes have been made on a global basis and for the UK.^{75,76} The latter highlights the inadequacy of current data, particularly for mortality, for the prediction of future prevalence in the UK. Their 'best guess' is that the total prevalence of diabetes will increase by 25% for males and 14% for females from 1992 to 2010.

5 Services available

Structure and process

As with all chronic diseases, services for people with diabetes must be organised around the evolving, individual needs of the affected person. With this in mind, WHO and the International Diabetes Federation (IDF) have consistently stressed self-care and the role of patients and patients' organisations in determining how care should be provided. Thus the strategic recommendations of the Saint Vincent Declaration⁷⁷ (see Appendix IV) and the related Acropolis Affirmation⁷⁸ were formulated by joint discussion between professional carers, affected individuals and patients' organisations. Similarly, the best of national and local policies and protocols have been drawn up in consultation with patients and their relatives [e.g. a 'Patients' Charter'⁷⁹ (Appendix V)] often under the guidance of LDSAGs⁸⁰ or similar bodies.

The main components of diabetes services are the hospital-based diabetes team or teams (usually one or more consultant diabetologist, or paediatrician, other consultant staff, specialist nurse, dietician and podiatrist, with suitable junior medical, laboratory and administrative support), the primary care team

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(GP, practice nurse and administrative support) and other community support (podiatrist, dietician and community nurse). Seventy-five per cent of districts or their equivalent have a 'diabetes centre'.⁸¹ More detailed information on the facilities offered by diabetes centres is given in Appendix VI. The range of components is outlined in Table 3.

Table 3: Staff necessary for a comprehensive diabetes service.

Service	Staff	Service	Staff
Services provided in primary care	General practitioners Practice nurses Supported by: <ul style="list-style-type: none"> ● dieticians ● podiatrists ● optometrists ● district nurses ● laboratory services ● administrative staff and, in some localities <ul style="list-style-type: none"> ● diabetes facilitators ● and/or specialist nurses 	Services provided in hospitals, for children	Paediatrician with a special interest in diabetes** Specialist nurses/liason health visitors Supported by: <ul style="list-style-type: none"> ● dieticians ● podiatrists ● optometrists ● clinical psychologists ● laboratory services ● administrative support
Services provided in hospitals, for adults	Diabetologists* Specialist nurses Supported by: <ul style="list-style-type: none"> ● dieticians ● podiatrists ● optometrists ● clinical psychologists ● laboratory services ● administrative support 	Services provided in hospitals, for pregnant women with pre-existing diabetes and women who develop diabetes during pregnancy	As for adults with the addition of obstetricians and midwives
Services for the management of patients with complications	As for adults with the addition of ophthalmologists, vascular surgeons, cardiologists, renal physicians and psychosexual counsellors	Preventive and support services in the community	Health promotion staff Local authority staff Social services Residential/nursing home staff Voluntary services

* Older people may be cared for by a geriatrician with a particular interest in diabetes or in jointly run clinics.

** Increasingly, young people with diabetes are managed in clinics run jointly by paediatricians and diabetologists. Staffing levels and facilities vary from place to place. More detailed information staff and facilities have been collected by the BDA.^{31,32}

Service utilisation

The frequency of diabetes 'episodes' in general practice (i.e. 'an instance of diabetes-related sickness in which there was one or more general practitioner consultations') is 11.1 per 1000 persons at risk per year.⁴⁹ This is more than twice the rate of the general population. Age- and sex-standardised admission rates are available for use as primary care effectiveness indicators, a part of the National Framework for Assessing Performance.⁸³

A study in South Glamorgan has shown that patients with diabetes accounted for 5.5% of hospital admissions and 6.4% of outpatient attendances, and that patients with diabetes occupy 9.4% of acute sector bed days.⁸⁴ Inpatient and outpatient activity was studied for patients with and without diabetes for all diagnoses and procedures, even if not related to diabetes.⁸⁴ Some results are summarised in Table 4.

Table 4: Hospital utilisation by patients with and without diabetes.

Patients with diabetes	Patients without diabetes
Mean length of stay of 11.4 bed days	Mean length of stay of 7.1 bed days
Mean of 5 outpatient attendances per patient per year (for patients aged 25–34 years)	Mean of 0.5 outpatient attendances per patient per year (for patients aged 25–34 years)
Mean of 4 outpatient attendances per patient per year (for patients aged over 75 years)	Mean of 1.5 outpatient attendances per patient per year (for patients aged over 75 years)
Occupy 5–6 acute hospital bed days per person per year ^{85,86}	Occupy one acute hospital bed day per person per year

The use of hospital resources by people with diabetes is heavily influenced by the presence or absence of complications. The CODE-2 (Cost of Diabetes in Europe – Type 2, a registered trademark of SmithKline Beecham plc) study demonstrated that, compared with patients with no recorded complications, those with only microvascular complications use just over twice the amount of hospital resource.⁸⁷ For patients with macrovascular complications this figure is around three and those with both microvascular and macrovascular complications require around five and a half times the hospital resources of those without complications.

These crude estimates of service usage mask a substantial unmet need, the two most important aspects of which are:

- the numbers of individuals whose diabetes is currently undiagnosed
- the proportion of patients with clinically diagnosed diabetes who have no planned programme of care.

The proportion of patients with no established programme of care will vary from district to district. There are data on the proportion who have a programme of follow-up care at a hospital (estimates range from 29 to 46%), but these studies are now rather dated because they were carried out before the establishment of diabetes centres which are likely to have increased access to hospital-based care.^{81,88–90}

Although there is little published evidence on the subject, it is likely that patients not attending for regular clinical review (either in primary or secondary care) will be the most frequent users of hospital inpatient facilities, particularly for problems such as diabetic ketoacidoses and for complications such as diabetic foot disease.

Screening

One of the issues which urgently requires clarification is whether population screening for undiagnosed diabetes (almost exclusively type 2 diabetes) is effective and cost-effective. This issue is dealt with in detail below but it is mentioned briefly here, before a summary of current information on costs, because policies on screening for diabetes are closely linked to the economics of diabetes care.

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Any population-based screening programme for diabetes clearly has cost implications for the health service, those of publicising and administering the programme, taking and testing blood or urine samples, communicating the results to those screened and dealing with the resulting newly identified cases. There are also costs to the individual, not only the direct costs of attending screening sessions, which apply to all those screened, but the cost, to those found likely to have diabetes, of a diagnosis brought forward in time with its implications for lifestyle, life assurance and, in some cases, employment.

These costs may be severe for both false positives and true positives, and there are also potential costs for false negatives, unwarranted reassurance and time lost for therapeutic intervention. The latter statement implies that earlier therapeutic intervention has its benefits. This is currently not proven although accumulating indirect evidence suggests that it may be the case. Relevant observations are: (i) evidence proving the role of near-normal blood glucose control in preventing or delaying complications in both type 1 and type 2 diabetes (*see below*); and (ii) evidence that a substantial proportion of patients with type 2 diabetes already has microvascular complications at diagnosis (20%, according to the United Kingdom Prospective Diabetes Study (UKPDS) – again, *see below*).

Costs of diabetes in the UK

Information on the costs of diabetes, in particular its health care costs, is available for many countries, including the UK.^{84,91–97} The economic aspects of diabetes are currently of considerable interest internationally.^{87,98}

- In 1989 at least 4–5% of total health care expenditure, including primary, secondary and community care, was estimated to be devoted to the care of people with diabetes.⁹² This amounted to around £1 billion in the UK in that year. Of this, an estimated 3.2% (£32 million in 1986–87) was estimated to have been spent in primary care.
- More recently, Currie *et al.*⁹⁴ estimated that 8.7% of acute sector costs is spent on care for patients with diabetes. This was calculated to be an average of £2101 per year per resident with diabetes compared with £308 per year per resident without diabetes.
- In one district, people with diabetes accounted for 5.5% of hospital admissions and 6.4% of outpatient attendances.⁸⁴ The relative risk of hospital admission for diabetes-related complications in this district was around 12 for coronary heart disease and cerebrovascular disease, 16 for neuropathy and peripheral vascular disease, 10 for eye complications and 15 for renal disease.⁸⁴
- Patients with diabetes have around a fourfold increased probability of undergoing a cardiac procedure and the total cost of the hospital treatment for coronary heart disease in people with diabetes was estimated (at 1994–95 prices) to be £1.1 billion.⁹⁵
- The overall cost of hospital care for people with diabetes in one district was predicted to increase by 15% by the year 2011. This is greater than the predicted overall increase of 9.4% for all inpatient care.⁹⁴

Although the health care costs of secondary and tertiary care for people with diabetes are reasonably well quantified, the costs of primary and community care have received little attention. Costs per episode are considerably higher for secondary and tertiary care than for primary care but the number of episodes is greater in the latter. The costs per patient are likely to be lower in the short term in primary care. However, unless this care is of sufficient quality to prevent or delay complications, or at least identify them early, the long term costs are likely to be higher.

Most of the economic impact of diabetes results from its complications. Foot problems, caused by diabetic neuropathy and peripheral vascular disease, and cardiovascular disease, in particular, account for a high proportion of hospital admissions, considerable disability and, in the case of cardiovascular disease, considerable premature mortality.^{57,99} Of the currently preventable complications of diabetes, diabetic

foot disease and diabetic eye problems incur the greatest levels of service use and hence costs. Renal replacement therapy is expensive but needed less often than other services. Estimated costs, for patients with type 1 diabetes, for each of these complications are available.⁹³

The economic impact of diabetes can be categorised into direct and indirect costs. Direct costs, such as those quoted above, include the costs of preventing, diagnosing, managing and treating diabetes, including hospital costs and social services. Indirect costs result from the consequences of morbidity, disability and premature mortality and the loss of productive output for society.^{98,100} Owing to a number of methodological problems, indirect costs are difficult to estimate. When they have been estimated, e.g. Gray *et al.*,⁹³ they have been found to be at least as great as the direct costs.

6 Effectiveness and cost-effectiveness of services

In this section, where appropriate, evidence is assessed according to a scoring system outlined in Appendix VII.

Screening

Screening for diabetes

Screening ('the systematic application of a test or inquiry, to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action, among persons who have not sought medical attention on account of symptoms of that disorder'¹⁰¹) may be proactive or opportunistic. In proactive screening, members of a specific population are targeted, whereas opportunistic screening, sometimes referred to as 'case finding', is the 'invitation for testing of apparently asymptomatic individuals not otherwise seeking medical care'.¹⁰²

Although the ADA advocates 3-yearly testing for diabetes in all adults aged 45 and over, screening for diabetes in the general population is not currently advocated in the UK.² The professional advisory committee of the BDA is undecided about the benefits of screening for diabetes in the general population, describing the role and value of screening as 'unclear'.¹⁰³ The report advocates opportunistic screening 'alongside screening for other problems such as hypertension and obesity'. It also suggests that screening may take the form of 'a single-point initiative of a practice (or Health District) across a larger population'.¹⁰³ If screening is to be carried out, it recommends restricting this to adults between the ages of 40 and 75, using a rescreening frequency of 5 years and adopting the criteria listed in Box 3.

Box 3: Procedures, criteria and practice for testing asymptomatic individuals for diabetes as advocated by the professional advisory committee of the BDA.¹⁰³

If blood glucose testing is used then a 'positive' result is a FPG of > 6.6 mmol/l or a venous PG 2 h after a 75 g oral glucose load > 8.0 mmol/l.

If urine testing is used then any glucose in a sample passed 2 h after a main meal is a 'positive' result. A FPG in the range 5.5–6.6 mmol/l is an equivocal result which should be repeated in 6–12 months if there is any risk factor for diabetes (obesity, a family history of diabetes or 'Asian/African' racial origin).

If blood glucose or urine tests are 'negative' then they should be repeated in 5 years, or 3 years if any of the risk factors above are present.

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The report also summarises the elements of a diabetes screening test.¹⁰³ The sensitivity, specificity and predictive value of, for example, varying thresholds of FPG as a screening test for diabetes (as defined by the previous WHO criteria¹) are provided and are also shown in Table 5.¹⁰³

Table 5: Sensitivity, specificity and predictive value of various fasting plasma glucose (FPG) thresholds compared with 1985 WHO criteria¹ for diabetes.

FPG (mmol/l)	Sensitivity (%)	Specificity (%)	Predictive value of a positive test (%)*
> 7.8	32	100	100
> 6.7	30–60	> 90	45–55
> 5.5	70–90	around 90	20–45
> 4.5	100	< 90	< 10

Screening the general population, using a self-testing method for the detection of post-prandial glycosuria, has been reported in a study based in Ipswich.¹⁰⁴ In this study, 13,795 subjects aged between 45 and 70 years and not known to have diabetes were posted a urine testing strip with instructions and a result card. Of the 10,348 (75%) who responded, 343 (3.3%) were found to have glycosuria and diabetes was confirmed in 99 (30%) of the 330 who attended for OGTT. A further 65 had an OGTT result in the IGT range. Thus large-scale screening is possible and is relatively cheap in terms of the cost of materials, postage, etc. However, at least in this study, around 140 people had to be contacted for each true positive case detected and the short- and long term consequences of these early diagnoses were not evaluated.

The issues surrounding population screening for diabetes are complex and important, and are currently being addressed in the UK by the National Screening Committee. For this reason, screening for diabetes, particularly type 2 diabetes, has been highlighted as an issue which HAs and their equivalents need to keep in mind as a potential future development. Terminology is often used loosely. In particular, the terms screening, case-finding and opportunistic screening are often used in different senses and the screening test is sometimes endowed with a degree of certainty (either positive or negative) which even the 'gold standard' does not merit.

Greenhalgh¹⁰⁵ emphasised the last of these points in her anecdote about a patient who described symptoms of diabetes and was tested, once, for glycosuria. On being found to be negative, he was reassured that he did not have the disease. Casual (or random) testing for glycosuria is grossly insensitive (Greenhalgh quotes a sensitivity of 22%). This is improved by post-prandial testing but, as shown by Davies *et al.*,¹⁰⁴ can still remain below 30%.

Greenhalgh, quoting data from Andersson *et al.*,¹⁰⁶ provides a similar estimate of yield of true positives as did Davies *et al.*¹⁰⁴ – around 170 people need to be contacted for each true positive detected.

Screening for diabetic retinopathy

The effectiveness and cost-effectiveness of screening for diabetic retinopathy have been reviewed.^{107–110} Bachman and Nelson's comprehensive review indicates that an organised programme of early detection and treatment would be likely to reduce blindness among people with diabetes.¹¹⁰ The results of this review are summarised in Box 4.

Box 4: Screening for diabetic retinopathy.

- 'Gold standard' screening tests are stereoscopic multifield photography and direct plus indirect ophthalmoscopy performed by an ophthalmologist.
- The most widely used screening tests are direct ophthalmoscopy, performed by a variety of health professionals, and non-stereoscopic retinal photography. Individually, these tests may achieve high sensitivity and specificity under optimal conditions, with increased sensitivity when combined.
- Screening programmes reported in the UK have resulted in an overall yield of 1.2% of screening episodes leading to laser photocoagulation.
- Cost-effectiveness analyses suggest that screening by retinal photography or by an optician may be at least as efficient as retinal examination by GPs or ophthalmologists.
- Studies in the US have shown that annual screening would lead to net cost savings for people with type 1 diabetes.
- Treatment of proliferative retinopathy or maculopathy by laser coagulation has been shown to be effective. Treatment at earlier stages of retinopathy is less effective.
- For every 100 patients with treatable disease, 55 would be expected to become blind or severely visually impaired within 10 years if none were treated. This is compared with 13 if all were treated in the same period. The pick-up rate diminishes after the first round of screening.

Source: Bachman and Nelson¹¹⁰

The National Screening Committee have considered in some detail the question of population screening for diabetic retinopathy. Their recommendation is that this should be introduced and a commitment has been made for this to be a national policy from April 2000. The recommended methods are likely to be digital retinal photography with or without direct ophthalmoscopy.

Effectiveness of optimal glycaemic control

Type 1 diabetes

The DCCT reported its findings for type 1 diabetes in 1993.¹¹¹ By providing robust evidence (I-1), the DCCT confirmed the consensus opinion that improving glycaemic control in type 1 diabetes is effective in the primary and secondary prevention of retinal, renal and neurological complications. A Swedish study¹¹² (I-2), among others, came to similar conclusions and a meta-analysis (I-1), which preceded the reporting of the DCCT, found that intensive blood glucose control was effective in the secondary prevention of microvascular complications.¹¹³ The DCCT and its results are summarised in Box 5.

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Box 5: Summary of the DCCT.

- A randomised controlled trial based in the US commenced in 1986.
- 1441 patients with type 1 diabetes were randomly allocated to 'intensive insulin therapy' (IIT), or conventional therapy.
- The patients were highly motivated with 99% completing the study.
- The trial had primary and secondary prevention arms.
- The results showed that IIT delays the onset and slows the progression of diabetic retinopathy, nephropathy and neuropathy.
- Analysis of the results shows that any improvement in diabetes control will prevent complications: the better the control, the fewer the complications.
- The trial was terminated prematurely at a mean of 6.5 years due to convincing results.
- IIT increased the risk of severe hypoglycaemia threefold.

Some questions remained unanswered, such as the applicability of the results of the DCCT to patients with type 2 diabetes, patients with advanced complications and young children.¹¹⁴

Some of the implications of the DCCT for the UK are:

- 1 DCCT was a trial of efficacy (outcomes under ideal circumstances) rather than effectiveness (outcomes in 'the real world'), therefore replication of its approach may not be applicable to everyday UK clinical practice.^{115,116}
- 2 The costs of implementing the recommendations were not addressed, although subsequent economic 'modelling' has been carried out.¹¹⁷
- 3 The role of patients and patient empowerment was not addressed in the DCCT and this is seen as increasingly important in the UK.¹¹⁶
- 4 Full implementation, or a pragmatic partial implementation of the DCCT results in the UK would:
 - require increased resources in the short term, unless reorganisation of diabetes care or other activities releases existing resources
 - improve the quality of care for people with type 1 diabetes
 - be likely to result in increased efficiency of the NHS care of diabetes in the long term through the prevention or delay of microvascular complications.

Type 2 diabetes

The DCCT led to debate and speculation about the implications of its results for people with type 2 diabetes.¹¹⁸ However, two studies now provide direct evidence of the beneficial effect of improved blood glucose control on the development of complications in type 2 diabetes. These studies were already underway when the DCCT was published.

The first of these is the Kumamoto Study, published in 1995.¹¹⁹ Using a study design similar to the DCCT, Ohkubo *et al.* examined the effect of 'multiple insulin injection therapy' in patients with type 2 diabetes on the progression of microvascular complications (I-2). The study was small, involving 110 Japanese patients who did not have the characteristics typical of patients with type 2 diabetes in the UK. For example, none of the Japanese patients were obese and, as a group, had significantly lower body mass indices than most UK patients. The results were similar to those of the DCCT in that they showed that improved glycaemic control delayed the onset and progression of retinopathy, nephropathy and neuropathy. The extent to which these results could be applied to people with type 2 diabetes in the UK was uncertain, however.

Since the publication of the Kumamoto study, the results of the UKPDS have become available.¹²⁰⁻¹²⁴ The main aims of the UKPDS (I-1) were: (i) to determine whether intensive control of blood glucose would prevent complications in type 2 diabetes, (ii) to answer the same question for the tight control of

high blood pressure, and (iii) to determine whether any specific treatment (specific oral hypoglycaemic agent and/or insulin) confers particular benefit. The UKPDS is summarised in Box 6.

Editorial commentaries on the final results of the UKPDS highlighted the fact that 'intensive therapy of type 2 diabetes is beneficial, despite the associated weight gain' but that the study 'did not unequivocally show whether an intensive [blood glucose] strategy influences cardiovascular disease'.^{125–128} With regard to the latter, however, its results are reassuring in terms of the 'absence of an obvious pernicious effect [on death from cardiovascular disease] of either insulin or sulphonylureas'.¹²⁵ Orchard¹²⁶ draws attention to the benefit, in relation to survival with cardiovascular disease, of simvastatin-mediated cholesterol lowering in type 2 diabetes (the 4S study¹²⁹).

Morgensen¹²⁷ emphasised that the UKPDS demonstrated the advantages of effective control of high blood pressure in people 'even more convincingly' than the effect of tight blood glucose control. This was influential in reducing deaths from diabetes-related causes (Box 6), whereas the 'difference between the treatment regimens in their effect on haemoglobin A_{1c} concentrations (7.0% v. 7.9%) was probably not large enough to result in great differences in cardiovascular outcome'. Combination therapy was often needed to produce this effective decrease in blood pressure. The proportion of UKPDS subjects requiring three or more antihypertensive treatments to achieve effective blood pressure control was 27% and 31% respectively. This editorial also re-emphasises the 'double jeopardy' of type 2 diabetes combined with high blood pressure and the third 'bad companion' of type 2 diabetes, dyslipidaemia.

Box 6: Summary of United Kingdom Prospective Diabetes Study.

The UKPDS was a multicentre randomised controlled trial commenced in 1977 and carried out in the UK.

Initially, 4209 patients (aged 25–65 years) with newly diagnosed type 2 diabetes were randomly allocated to different therapies: 'conventional' diet and exercise therapy, or 'intensive' diet and exercise *and* oral hypoglycaemic or insulin therapy.

Over the 10 years of the study, the mean HbA_{1c} in the intensively treated group was 11% lower than in the conventionally treated group [7.0% (SD 6.2–8.2) vs. 7.9% (SD 6.9–8.8)].¹²⁰

Compared with the conventional group, the risk for any diabetes-related endpoint in the intensive group was 12% lower (95% CI: 1–21%, $p = 0.029$). This represented a reduction, in the absolute risk of death, from 46.0 events per 1000 patient years to 40.9 events per 1000 patient years.¹²⁰

The reduction in risk of diabetes-related death, in relation to this difference in glycaemic control, was not statistically significant.¹²⁰

There was a statistically significant 25% (95% CI: 7–40%, $p = 0.0099$) reduction in risk for the microvascular endpoints considered. This represented a reduction in absolute risk from 11.4 events per 1000 patient years to 8.6 events per 1000 patient years.¹²⁰

There was no significant difference in any diabetes-related endpoints between the three intensive agents (chlorpropamide, glibenclamide and insulin).¹²⁰

A statistically significant improvement in blood pressure control was achieved during the course of the study; mean blood pressure in the tightly controlled blood pressure group was 144/82 mmHg compared with 154/87 mmHg ($p < 0.0001$).

This difference was clinically significant in that the risk of death from diabetes-related causes, in relation to this difference in blood pressure, was reduced by 32%, that of stroke was reduced by 44% and that of microvascular endpoints by 37%.¹²²

There was no perceptible difference in the effectiveness of captopril and atenolol and the majority of subjects randomised to the blood pressure control groups required more than one anti-hypertensive treatment to achieve effective control.

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Watkins¹²⁸ observed that the 'use of insulin *per se* confers neither additional advantages nor disadvantages, while the use of sulphonylureas does not lead to additional risks'. He also emphasised the importance of the findings concerning blood pressure control and 'that ACE [angiotensin converting enzyme] inhibitors or β -blockers are equally effective in achieving the benefits of lowering blood pressure'. Despite the emphasis in the trial's results of the advantages of adding oral hypoglycaemic or insulin treatment to the basic dietary therapy, Watkins considered that the 'role of diet, exercise and weight reduction remain, of course, paramount in treatment of Type 2 diabetes'.

Effectiveness of risk factor modification

Although the achievement of as normal a blood glucose as possible is a contributory factor in the prevention of long term complications (and is clearly fundamental to the avoidance of hypoglycaemia and hyperglycaemia) other factors are also known to be important. Some of these are amenable to therapy or behavioural modification, for example the control of hypertension for nephropathy, cardiovascular disease and cerebrovascular disease.

The importance of smoking cessation in people with diabetes has received some attention. This suggests that smoking is associated with poor glycaemic control and increased prevalence and progression of microvascular complications.¹³⁰⁻¹³² A study in Atlanta, USA, showed that people with diabetes are as likely to smoke as those without, and that 40% of smokers with diabetes reported that their doctor had not advised or helped with cessation.¹³³ Programmes designed to encourage smoking cessation specifically in people with diabetes are rare and, where evaluated, have proved unsuccessful.¹³⁴

Effective delivery of care

The most effective setting for delivery of care for people with diabetes is open to debate. Randomised controlled trials of hospital versus primary care have been reviewed by the Cochrane Diabetes Group (I).¹³⁵ Only five trials were sufficiently robust to be included in their meta-analysis. The results suggest that 'prompted' primary care, i.e. a programme including a system of recall and regular review of diabetes, can be as good as hospital care in terms of glycaemic control. Such prompted care is better than hospital care in terms of maintaining contact with patients.

The results of this meta-analysis should be interpreted with caution, however, because of interstudy variation and statistical heterogeneity. The results are, however, consistent with an earlier review.¹³⁶ The effective element appears to be the computerised recall with prompting for patients and their family doctors. The extent to which care should be 'shared' (between the hospital team and primary care) is likely to vary from practice to practice, from patient to patient and from time to time during the natural progression of diabetes in any given patient. There will be times, e.g. during childhood, during and immediately prior to pregnancy and when complications are developing, when care by a hospital team is necessary.

Cost-effectiveness of care

Cost-effectiveness studies of diabetes care, in the UK and in countries with similar health care systems, are relatively rare. However, components of this care, such as screening for diabetic retinopathy, preventive foot care and intensive control of hypertension in people with diabetes, have received some attention. In

general, it is reasonable to follow the widely held consensus that prompt diagnosis, patient education and regular, high-quality clinical review are likely to contribute to the cost-effectiveness of local diabetes programmes.

Preventive foot care, incorporating an educational component and organised on an outpatient basis is an option which has been shown, in Australia, to reduce the need for hospital admission for lower limb complications, in the UK, to reduce amputation rates and, in the Netherlands, to reduce the cost of diabetic foot disease.^{137–139} Given the large contribution of diabetic foot disease to acute sector costs, preventive foot care would have to be either very ineffective, very costly or both not to be cost-effective.^{140–142}

Recently, the effective control of blood pressure, with ACE inhibitors or β -blockers, in people with diabetes has been shown to be cost-effective.¹²⁴ The additional resources required to achieve this control were recouped within the 10 years of the (UKPDS) trial by the cost savings associated with the reduced frequency of complications and the life years gained. This conclusion from direct observation in a trial of type 2 diabetes in the UK supports the general conclusion of a US modelling study of type 1 diabetes (based on the results of the DCCT) and the US study of type 2 diabetes (based on extrapolation of DCCT results to type 2 diabetes).^{117,143,144} Intensive therapy, directed at improved control of blood pressure or control of hyperglycaemia, although more costly than routine care, achieves significant reductions in health care costs in the long run. This 'long run' is measured in years but, ultimately, this intensive therapy is cost-effective in terms of direct health care costs and benefits.

7 Models of care

Introduction

The organisation of services for the care of people with diabetes is complex, involving hospital-based diabetes teams, community services, those working in primary care, patients and their families. The most appropriate model of care for people with diabetes is not readily apparent given the lack of effectiveness data on the relative importance of primary or secondary care.^{135,136} One thing is certain, however, as stated by Greenhalgh,¹⁴⁵ 'inadequacies in the provision of diabetes care in the UK will not be redressed simply by sounding the trumpet for a primary-care-led system, nor by the formation of political factions to protect the traditional territory of the [hospital] diabetologist'. Instead, services need to be designed from the point of view of the user, 'tailored to the individual patient' and not rigid in their adherence to district or hospital protocols.¹⁴⁵

The provision of care for people with chronic diseases, including diabetes, is shifting from secondary to primary care with the benefits of increased access to care and increased patient satisfaction because of this increased access.^{146,147} In England, PCGs soon to be primary care trusts (PCTs) are taking over from HAs as commissioners of health care.¹⁴⁸ This policy shift will lead to PCGs and PCTs (and their equivalents elsewhere in the UK) emerging as the commissioners and providers of care for people with diabetes. Specialist expertise, 'hi-tech' facilities and, in most localities, leadership are likely to remain in secondary care. Part of the role of HAs or their equivalent is to ensure health and health care needs are met appropriately and that the quality of care is monitored and maintained, for example by taking the lead in the development of local Health Improvement Programmes (HIMPs).¹⁴⁸

National guidance on the key features of a good diabetes service has been issued [NHS Executive HSG(97)45] and this emphasises the need for a process of continual improvement of diabetes services at a district level. The balance between primary and secondary care for people with diabetes can and will vary

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between districts and this is justifiable with one proviso: that nobody with diabetes should receive inexpert, unstructured care at any location. The BDA has recently issued guidance on the ways in which diabetes can feature in local HImPs (*Health Improvement Programmes – an opportunity to improve the health of people with diabetes* – available from the BDA). This document emphasises the multi-agency nature of HImP implementation with 4 of 11 designated areas for action citing the local authority as the lead organisation.

Planning district services for people with diabetes

Integrated district diabetes services have frequently been developed with support and leadership from the local hospital-based diabetes team. This team should consist of at least one consultant trained in diabetes care, the exact number will depend on the size of the district, and the prevalence of diabetes, and the appropriate number of diabetes specialist nurses, dieticians and podiatrists. Recommendations for the structure of specialist diabetes care services have been published by the BDA.¹⁴⁹

The main clinical roles of the team will be in education, specialist patient care, particularly of those with newly diagnosed type 1 diabetes, active complications, pregnant women with diabetes and diabetes of any kind which is difficult to control. Children with diabetes should be looked after by a team which includes a paediatrician with a special interest in diabetes. The hospital team will also give advice on the management of acute problems and ensure that proper clinical links are made with other hospital services such as ophthalmology, cardiology, renal medicine, medicine for the elderly, obstetrics, and general, vascular and orthopaedic surgery.

The key elements to be followed when planning service or health improvements for district residents with diabetes mellitus are shown in Box 7.

Box 7: Key elements for planning diabetes service or health improvements.

- Setting up a multidisciplinary group to exchange ideas, develop partnerships and plan and implement change. At least 60% of HAs have already set up a LSDAG or their equivalent.¹⁵⁰
- Assessing the health care needs of the local population using this health care needs assessment with additional corporate or comparative elements as appropriate.¹⁵¹ This should identify problems specific to individual districts, such as a large ethnic population, or specific local service issues, such as problems of recruiting medical staff.
- Using nationally and internationally available standards to develop and agree aims and objectives of the local diabetes service and local standards, in terms of structure, process and outcome, of care.^{80,150,152}
- Developing local protocols of care including local policies on screening for diabetes, the use of population databases, health promotion, footcare and retinal screening.
- Developing protocols on management of patients at the primary/secondary care interface.
- Ensuring the training and professional development of those caring for people with diabetes.¹⁵²
- Planning service reconfiguration where appropriate, e.g. the development of outreach clinics.
- Planning evaluation and clinical audit including economic evaluation.

The greatest current economic and organisational challenges to those involved in commissioning diabetes services are related to the four key areas (A, B, C and D) illustrated in Figure 1. Within these areas are the boundary between not having diabetes and having diabetes (A, primary prevention), between diagnosed

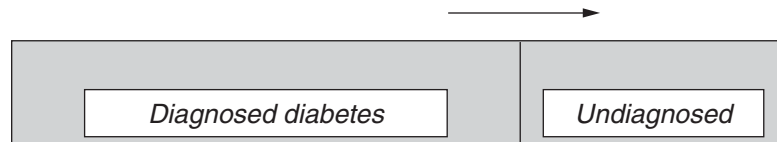
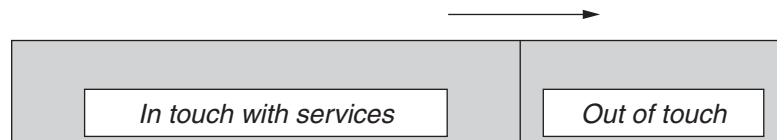
A – Primary prevention**B – Detection of undiagnosed diabetes****C – Access to services****D – Quality of care**

Figure 1: Economic and organisational challenges to those involved in commissioning diabetes services.

and undiagnosed diabetes (B, screening and early diagnosis), between being in contact and out of contact with health services (C, access to services) and between receiving effective care and receiving ineffective care (D, quality of care).

Considerable documentation and a large measure of agreement exist on the aims of diabetes care and how these might be achieved. These should include:

- opportunistic screening in those at high risk of diabetes
- involvement of all those identified in planned programmes of care
- ensuring that all those with diabetes and their carers have access to appropriate education
- maintaining optimal metabolic control to prevent or delay the development of complications
- eliminating the acute problems of hypoglycaemia and hyperglycaemia
- ensuring the early identification and treatment of complications
- improvement of glycaemic control in pregnancy, thereby reducing fetal wastage and the incidence of congenital malformations.

Planning diabetes services in the primary care setting

Many general practices have taken part in 'chronic disease management programmes' (see *The Red Book*¹⁵³) for diabetes and asthma. Practices may also have developed health promotion clinics for their diabetic patients.¹⁵⁴ As more patients with diabetes are seen predominantly in primary care, the care provided must be of the highest quality. Quality care is most likely to take place when the following are available¹⁵⁵

- trained and motivated practice personnel
- a practice-based database of patients with diabetes (linking to a district population database where possible)
- protected time for the initiation of treatment, education and follow-up
- clinical and educational audit of the practice's activities
- recognition of a practice (or district) protocol for diabetes care
- regular recall of patients for clinical review
- a curriculum for patient education
- well-defined liaison with the hospital-based team and easy access to those facilities not normally available in primary care, e.g. group education programmes, specialist nurse and dietetic advice and management of more complicated cases
- good information flow between primary and secondary care.

Revised and updated recommendations for the management of diabetes in primary care are included in a BDA publication with that title, as listed in Appendix II. The improvement of diabetes services in a primary care setting should occur as part of a district or PCG strategy. This is explored above. As a minimum, HAs, PCGs or their equivalents can encourage high-quality diabetes care at primary care level if they:

- encourage and support high-quality diabetes care in all or most general practices, but particularly those which fulfil all, or most, of the above criteria
- assist primary care teams who lack the skills or facilities to carry out high-quality diabetes care to acquire those skills and facilities
- ensure that the essential community services of dietetics and chiropody are provided to support the primary care team in their work with people with diabetes.

Tools for planning

Population databases

Developments in information technology have enabled more and more comprehensive databases of diabetes care to be established and used. These have progressed from simple card indices of individuals known to have the disorder through to sophisticated distributed databases which allow information on health care episodes occurring in many different locations to be accessed from a number of sites. Access to such data, carefully controlled and monitored to ensure confidentiality, can enhance both the care of the individual patient and the planning and monitoring of services for populations.

The work involved in establishing such population databases must not be underestimated. Particularly in inner cities, any one ascertainment source may grossly underestimate the number of people that need to be included. Burnett *et al.*,³⁵ working in inner London, found that only 40% of 4674 patients identified from multiple sources had Prescription Pricing Authority (PPA) returns. Only 43% appeared on general practice diabetes registers and only 57% could have been identified from attendances at the district

hospital. The message from this research is clear, multiple, frequently overlapping sources must be used in the compilation (and updating) of population databases on diabetes. The resource consequences of this must be identified from the outset.

Another, later study came to the opposite conclusion from Burnett *et al.* Howitt and Cheales,³⁹ based in south-east England, felt that ascertainment through general practices alone was adequate. They based this on their findings that most (41 of 43) practices approached contributed to their register and that the estimates of prevalence obtained were close to those expected from epidemiological studies carried out in other places. This is relatively weak evidence because they had no independent validation of completeness of ascertainment in their locality.

Patchet and Roberts¹⁵⁶ sounded a cautionary note about over-ascertainment (or over-diagnosis) of people included on practice-based registers. Of 112 patients listed by their practice as having diabetes, 26 had had normal HbA_{1c} concentrations in the preceding 6 months. Their conclusion was that nine of these people had been investigated by OGTT but had been found not to have diabetes. Such inflation of databases does, no doubt, occur but the net effect of over- and under-ascertainment is most likely to give an under-estimation of the numbers of people with diabetes, especially those treated with dietary therapy alone.

Recent years have seen the standardisation, both in the UK and elsewhere, of data items for inclusion on practice- and population-based diabetes data sets. The Diabetes Audit Working Group of the Research Unit of the Royal College of Physicians and the BDA,¹⁵⁷ for example, has listed and defined 101 data items which it considers should be included in a diabetes data set. This suggestion may be regarded as unnecessarily complex, especially in the context of primary care. It is more sensible, however, to advocate the use of subsets of such databases, applying the standard definitions of the items selected, rather than compiling, *de novo*, local databases that lack comparability with others elsewhere.

There is little published evidence on the effectiveness or cost-effectiveness of registers or population databases. Jones and Hedley,¹⁵⁸ in 1984, estimated that their diabetes register, when considering only the advantages it provided for retinal screening, had a benefit-to-cost ratio of 15:1. The costs of establishing such a resource are greater than the costs of maintaining it so, once established, the cost-effectiveness of such databases should increase as benefits accrue.

More recently, Elwyn *et al.*¹⁵⁹ questioned the usefulness of population databases suggesting that they may be 'more trouble than they're worth'. However, they do admit to the potential of these databases to improve the quality of individual care by prompting call and recall for regular review. Also, they acknowledge that they can facilitate local needs assessment and the monitoring of quality of care from aggregated district or regional data. Despite the fact that diabetes databases have been in use in the UK for almost three decades, they consider that, in relation to their cost-effectiveness, it may be 'too early to tell and perhaps too late to ask'. Further information about the benefits of using population databases will emerge when localities such as Salford publish longitudinal data of process and outcome. Thus far, such data are only available in abstract form.¹⁶⁰

Elwyn *et al.*¹⁵⁹ also highlight important ethical issues surrounding the compilation of these databases. They are probably correct in believing that, in most places where such databases exist, individuals with diabetes are largely ignorant of the fact that their demographic and clinical details are held in this form, in addition to the clinical record. These authors cite several items of guidance [including an NHS Executive Letter (EL (96) 72)]¹⁶¹ which emphasise that patients should 'opt-in' rather than 'opt-out' to such databases. The EL itself states that 'patients should be made aware of the existence and the purpose of a register'.¹⁶¹ In practice, it is likely that the majority of people with diabetes, given reasonable safeguards in relation to confidentiality, would not object to their personal data being held in this way. However, although some information exists on this question in relation to population databases for cervical screening, no information exists for diabetes databases.¹⁶²

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Future developments in this area will need to take account of the current NHS Information Strategy¹⁶³ and the move, as part of that strategy, towards electronic patient records. In addition, software systems, such as MIQUEST, are used for example in the extraction of data used in the DiabCare project.¹⁶⁴

Health care Resource Groups

Health care Resource Groups (HRGs) are one way of developing a system based on case-mix. 'Case-mix is a system which classifies types of patients treated, and costs each category to enable consistent pricing for each patient'.¹⁶⁵ HRGs are 'groupings of acute inpatient care episodes which are likely to consume the same amount of resource'¹⁶⁶ and are based on the patient record and inpatient events.¹⁶⁷ They are adapted from diagnosis-related groups (DRGs) which were developed in the US in the early 1980s.

HRGs have been used for contracting and are being used in commissioning, internal resource management (e.g. within a trust) and 'benchmarking'. The NHS Information Authority co-ordinates progress in the development of HRGs. Costing of surgical hospital episodes by HRGs is well developed with the extension of the use of HRGs in the acute medical specialties to be complete by 2000.^{168,169}

The allocation of a particular episode of care to a group is dependent on a number of characteristics of the episode, including:

- the age of the patient
- the primary diagnosis
- the secondary diagnosis/diagnoses
- the surgical procedure, if any
- whether the patient was alive or dead at discharge.

Although admissions and episodes for medical reasons, e.g. diabetes, are more difficult to classify into HRGs than surgical procedures, the NHS Information Authority has developed HRGs for diabetes. Costs of diabetes HRGs are being developed and preliminary figures are included in Appendix VIII.

Commissioning matrices

Health service planners and commissioners, whether based in HAs, PCGs or PCTs, should ensure that the full spectrum of health care for people with chronic diseases meets local needs and is of a high quality. Health care frameworks have been developed to assist in assessing needs, commissioning services and improving quality of care. These are, in essence, highly developed 'checklists' to ensure that the task of planning and commissioning care is approached in a logical manner and does not neglect any important area.

The 'Health Benefit Group Development Project' by the NHS Information Authority has led to the development of health care frameworks for different diseases and conditions, matching HRGs with 'Health Benefit Groups' (HBGs) and associated performance indicators.¹⁷⁰⁻¹⁷² These health care frameworks are intended to be used in drawing up local HImps and service agreements. A diabetes health care framework is being developed with emphasis on assessing need and its resource implications. A draft version of this framework is shown in Appendix IX. This health care framework is not suitable for use as a decision-making tool for individual patient care.

A condition-specific health care matrix which can be applied to different health care programmes, including care for people with diabetes has been developed and is included in Appendix X.¹⁷³⁻¹⁷⁶ This can be used as a tool for commissioning and planning services.

Although not necessarily a commissioning matrix, the National Service Framework (NSF) for diabetes will be available, in 2001, to guide the development of local services. It is one of the challenges to those

responsible for services not to delay essential improvements until that NSF is available. There is considerable evidence surrounding 'best practice' in diabetes care and there are a number of improvements that can and should be made in many localities to put this evidence into practice.

NB: HBGs and HRGs are being developed by Clinical Working Groups to NHS Information Authority (Case-mix Programme) specification. The Clinical Working Group for diabetes is chaired by Dr N. Vaughan.

8 Outcome measures

Monitoring diabetes care using measures of process and outcome occurs at two levels:¹⁷⁷

- the individual patient level, by clinicians as part of the continuing care and treatment of the patient
- the aggregated group/population level, by health care commissioners (HAs, PCGs and PCTs) and/or trust managers to ensure desired outcomes are being delivered.

A recently published Department of Health (DoH) working group report¹⁷⁸ lists 32 'candidate indicators' ranging from the prevalence of clinically diagnosed diabetes to summary measures of satisfaction with diabetes services. Among the working group's recommendations are that six of these candidate indicators should be used on a routine basis. These are listed below.

Measures of process

In its recommendations for the audit of diabetes services, the Diabetes Audit Working Group of the Research Unit of the Royal College of Physicians and the BDA¹⁵⁷ suggested a number of process measures of which the following are likely to be the most useful for evaluating diabetes services:

- 1 average waiting times in hospital clinics
- 2 average time spent with doctor, nurse or other health worker
- 3 quality of communication with primary care team
- 4 the frequency with which the following are recorded in the clinical notes:
 - body weight
 - state of optic fundi (observed through dilated pupils), visual acuity
 - blood pressure
 - concentration of urinary albumin
 - percentage of glycosylated haemoglobin
 - serum cholesterol, total and high-density lipoprotein (HDL) cholesterol
 - state of injection sites (in insulin-treated patients)
 - state of the feet
 - presence of peripheral pulses.

Measures of outcome

The outcomes of diabetes care to be measured at PCG, PCT or district level can be formulated from the aims and objectives agreed as part of the local HImP. Health care commissioners, clinicians and patients

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have different perspectives on the desired outcomes for a diabetes service (Box 8).¹⁷⁷ Chosen outcomes must achieve a balance of the different perspectives.

Box 8: Different perspectives on outcomes of diabetes care.

Health care commissioners

- Provision of high-quality, cost-effective care.
- Reduced incidence and prevalence of diabetes.
- Reduced incidence and prevalence of complications.

Clinicians

- Achievement of optimal glucose levels.
- Prevention of long term complications.
- Tailoring regimen to meet the need of the individual.

Patients

- Avoidance of short term complications, e.g. hypoglycaemia.
- Psychosocial needs, e.g. to achieve a balance between health and well-being.
- To be involved in treatment decisions

Examples of outcomes

Population health outcome indicators have been available for districts since 1993 and are shown in Table 6.¹⁷⁹ These have been developed further and a wide range of outcome measures for implementation is included in Appendix XI.

Table 6: Population health outcome indicators for diabetes.

Outcome	Indicator
Ketoacidosis and coma	Age-standardised rates for hospital episodes and coma among residents of area per 1,000,000 residents by sex
Lower limb amputation	Age-standardised rates for operations for lower limb amputations among patients with diabetes resident in the area per 1,000,000 residents by sex
Standardised Mortality Ratio (SMR)	SMR for diabetes mellitus for ages 1–44 years by sex

General, and diabetes-specific, patient-centred outcomes have been developed in recent years.^{177,180} These measure the knowledge, attitudes and beliefs of patients and the psychosocial impact of living with diabetes, for example, the quality of life measure used in the DCCT.¹⁸¹ Choice of measure depends on the research question, instrument validity and practicality, e.g. length of the questionnaire.

The collection and assessment of outcomes are limited by the difficulties of dealing with data derived from routine information systems.^{86,177,182,183} Although many data items are collected as part of the clinical review of patients, they are not always available in a standardised form which is easily collated for analysis.

Recent initiatives aim to improve the quality of diabetes care by standardising the collection and aggregation of outcome information:¹⁷⁷

- DiabCare,¹⁶⁴ monitors the achievement of the Saint Vincent targets throughout Europe
- UK Audit Feasibility study,^{157,184} development of a UK diabetes data set compatible with DiabCare
- Dialog,^{185,186} a system designed to create diabetes population databases and record information for monitoring care.

Recommendations of the DoH working group

The six indicators recommended for use on a routine basis are:

- 1 the prevalence of clinically diagnosed diabetes
- 2 the number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional expressed as a proportion of a population known to have diabetes
- 3 the number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes
- 4 SMR for death due to diabetes mellitus
- 5 years of life lost per 10 000 resident population by death due to diabetes mellitus
- 6 years of life lost by death due to diabetes mellitus.

It can be seen that knowledge of the population denominator of people with diabetes is crucial for the calculation of these indicators. This knowledge is available locally in the few districts with comprehensive diabetes population databases. For the remainder, extrapolation from published prevalence estimates must be made.

9 Information and research requirements

Some likely future developments in diabetes were mentioned at the beginning of this chapter. The following list of information and research requirements re-emphasises some of these and includes some other issues.

- There is a need for more evidence on the costs and benefits of population screening, as distinct from opportunistic screening, for type 2 diabetes. Costs and benefits need to be assessed in as wide a sense as possible – to include both financial and intangible costs and benefits affecting both the health care system and those being screened. Allied to this are issues surrounding the acceptability of screening to various groups, such as people of Asian origin, for example, in whom diabetes is already common and becoming more so.
- Primary prevention of type 1 and type 2 diabetes are goals which may be achievable within a few years. For type 1 diabetes, one avenue of exploration is the complete avoidance of cows' milk and milk products by high-risk individuals at certain immunologically crucial periods of life. Currently, the high cost of genetic investigation to identify such individuals does not make this a realistic public health strategy, even if effectiveness were proven. This might change in the future, however.
- A substantial proportion of type 2 diabetes has long been potentially preventable – that associated with obesity. Unfortunately, viable strategies for the prevention of obesity continue to elude us. A more feasible approach may be the identification of people with IGT or other risk markers for type 2 diabetes and the encouragement of lifestyle changes in them, or their treatment with oral hypoglycaemic agents as attempts to reduce the likelihood of progression to diabetes. Many therapies for obesity are

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notoriously ineffective in the long term. As new drugs appear (e.g. orlistat) they need to be evaluated thoroughly. Research is already available on these questions and further results are awaited.

- The further development of population databases, with relevant outcome measures for the assessment of the quality of care, need to be encouraged. Although the goal should be the complete ascertainment of all with diabetes in a defined population, the quality of care can be improved considerably by using currently available data to monitor the health and follow-up of those already identified. Proposed changes to the NHS such as the NHS Information Strategy¹⁶³ nationally, and HImPs locally, may well contribute to this, as will the prospective analysis of outcome data already being recorded on population databases. The development of psychosocial outcome measures suitable for routine clinical use will contribute to this area.

In addition, a number of other less wide-ranging, but nonetheless important, questions needs to be tackled including:

- the introduction of new forms of insulin, e.g. fast-acting insulin analogues and the administration of insulin intranasally
- the introduction of digital systems for the recording and interpretation of retinal photographs
- evidence relating to new methods for the treatment of leg ulcers, e.g. ketanserin and growth hormone
- demand for new, more effective treatments of erectile dysfunction, such as sildenafil (Viagra)
- further development of combination therapy (oral hypoglycaemic agents and insulin) for the treatment of type 2 diabetes.

Despite the fact that insulin has been available for more than 75 years and oral hypoglycaemic agents for almost as long, diabetes is still responsible for considerable morbidity and premature mortality in the UK. Most of these effects are the results of the complications of diabetes, many of which are potentially preventable. The delivery of continuous, effective, comprehensive care to people with diabetes is an important component in realising this potential for prevention.

Appendix I. Abbreviations

ACE	angiotensin converting enzyme
ADA	American Diabetes Association
BDA	British Diabetic Association
CVD	cerebrovascular disease
DCCT	Diabetes Control and Complications Trial
DoH	Department of Health
FPG	fasting plasma glucose
GDM	gestational diabetes mellitus
HBG	Health Benefit Group
HDL	high-density lipoprotein (cholesterol)
HImP	Health Improvement Programmes
HImP	Health Improvement Programme
HRG	Health care Resource Group
ICD	International Classification of Diseases
IDDM	insulin-dependent diabetes mellitus
IDF	International Diabetes Federation
IFG	impaired fasting glucose
IGT	impaired glucose tolerance
IIT	intensive insulin therapy
LDSAG	Local Diabetes Services Advisory Group
NHS	National Health Service
NIDDM	non-insulin dependent diabetes mellitus
NSC	National Screening Committee
NSF	National Service Framework
OGTT	oral glucose tolerance test
PCG	primary care group
PCT	primary care trust
PG	plasma glucose
PPA	Prescription Pricing Authority
PVD	peripheral vascular disease
UKPDS	United Kingdom Prospective Diabetes Study
WHO	World Health Organisation

Appendix II. Consensus documents on diabetes care

Some of the following feature as specific text references.

- Alberti KGMM, Gries FA, Jervell J, Krans HMJ for the European NIDDM Policy Group. A desktop guide for the management of non-insulin-dependent diabetes. *Diabetic Medicine* 1994; **11**: 899–909.
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- World Health Organisation (Europe) and International Diabetes Federation (Europe). Diabetes care and research in Europe: the Saint Vincent Declaration. *Diabetic Medicine* 1990; **7**: 360.

Appendix III. Data for the calculation of local estimates

Note: data similar to those below form the basis of the computer model 'Health Care Needs Assessment – Diabetes' produced by SmithKline Beecham and Abacus International, as a planning tool for HAS, PCGs and their equivalents elsewhere in the UK.

All enquiries about this model should be directed to: Dr Julia Bottomley, Head of Health Economics, SmithKline Beecham Pharmaceuticals, Mundells, Welwyn Garden City, Hertfordshire, AL7 1EY. Tel: (020) 8913 4863; Fax: (020) 8913 4689; email: julia.m.bottomley@sb.com

Note: that the data in the computer model may, in some details, differ from those listed below if more recently published studies have been incorporated into the more recent versions of the model. The model also includes additional information over and above that included here.

In the following tables, age- and sex-specific prevalences and incidence rates (as appropriate) for clinically diagnosed diabetes and its complications have been taken from various studies referenced in the above text. Using local population figures, the expected numbers of cases, and the likely maximum and minimum estimates, based on 95% CI can be calculated.

Table A1: The incidence of diabetes in childhood.²⁴

Age group (years)	Incidence
0–4	9.74 (7.93–11.55)
5–9	13.60 (12.33–14.87)
10–14	17.80 (16.94–18.66)
0–14	13.91 (13.51–14.66)

Incidence rates are per 100,000 persons per year (95% CL). **Note:** updated incidence rates from this source, with separate values for boys and girls, may be available in the near future.

Table A2: The frequency of diagnosis of new cases of diabetes in adults.²⁶

Age group (years)	Frequency of diagnosis of new cases (95% CL not available)
15–24	2.5
25–34	4.5
35–44	8.0
45–54	18.0
55–64	35.0
65–74	46.0
75–84	37.0
85 years and over	37.0

Rates are per 10,000 persons per year.

Table A3: The prevalence of clinically diagnosed diabetes in a predominantly Caucasian population (Poole, Dorset) showing the increase in prevalence between 1983²⁷ and 1996.⁴⁶

Age group (years)	Males		Females	
	1983	1996	1983	1996
0–29	2.5	2.4	2.3	2.3
30–39	4.3	8.2	3.9	4.7
40–49	8.0	13.3	7.3	7.1
50–59	16.1	22.3	9.9	18.1
60–69	24.2	54.2	16.6	37.1
70–79	41.0	66.6	31.2	35.3
80 and over	48.5	79.6	24.8	52.3
All ages	11.0	21.3	9.3	16.0

Prevalences are per 1,000 persons. Age/sex adjusted prevalences (with 95% CL). Crude prevalences have been adjusted to 1991 age and sex distribution of the UK:

All males: 10.4×10^3 (9.5–11.4) (1983); 17.4×10^3 (16.3–18.6) (1996)

All females: 8.9×10^3 (8.1–9.7) (1983); 13.7×10^3 (12.7–14.7) (1996)

Both sexes: 9.7×10^3 (9.0–10.3) (1983); 15.5×10^3 (14.8–16.3) (1996).

Table A4: The 'incidence' (I) and prevalence (P) of clinically diagnosed diabetes as assessed from the General Practice Morbidity Survey⁴⁹ together with consultation rates (C) for diabetes.⁴⁹

Age group (years)	Males			Females		
	I	P	C	I	P	C
0–4	–	0.1	0.1	0.1	0.1	0.3
5–15	0.2	0.8	1.2	0.3	0.7	1.0
16–24	0.7	2.4	5.5	0.4	1.5	3.5
25–44	1.5	4.9	11.3	0.8	3.4	8.6
45–64	5.8	21.7	54.4	4.3	15.4	39.4
65–74	10.9	42.8	105.3	9.5	33.7	85.8
75–84	12.0	47.5	116.4	10.3	37.4	93.2
85 and over	6.5	32.7	77.8	7.1	23.8	49.6

All ages prevalence = 11.9×10^3 (males) and 10.2×10^3 (females). 'Incidence' rates are per 1,000 persons per year.

Prevalences are per 1,000 persons. (**Note:** the source document gives prevalence 'per 10,000 person years at risk' which is incorrect.) Consultation rates are per 1,000 persons per year.

Table A5: The prevalence, in adults, of self-reported, clinically diagnosed diabetes and previously undiagnosed diabetes assessed by glycosylated haemoglobin concentration > 5.2%.⁴⁵

	Diagnosed diabetes	Previously undiagnosed diabetes
Men	29.8	10.0
Women	17.6	10.0
Both sexes	23.6	10.0

Prevalences are per 1,000 persons.

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Table A6: The prevalence of clinically diagnosed diabetes in adults of South Asian origin.³⁶

Age group (years)	Men		Women	
	Diagnosed	Previously undiagnosed	Diagnosed	Previously undiagnosed
20–29	2.0	8.0	–	6.0
30–39	12.5	24.1	23.7	11.3
40–49	56.3	45.7	24.5	47.5
50–59	110.3	62.5	120.3	60.0
60–69	140.0	81.2	193.7	98.7
70 and over	170.5	145.0	125.8	102.5

Prevalences are per 1000 persons. Overall, age-adjusted prevalences are 124.0×10^3 (men) and 112.0×10^3 (women).

Table A7: The prevalence of clinically diagnosed and previously undiagnosed diabetes in adults (people aged 40 and over) of Afro-Caribbean origin.⁴⁸

Men	Women	Both sexes
167.0	177.0	172.0

Prevalences are per 1,000 persons. **Note:** the ‘both sexes’ prevalence has been calculated on the assumption that the male/female ratio in this age group in the Afro-Caribbean population is 1:1. **Comment:** peer reviewed, published age- and sex-specific data for clinically diagnosed and previously undiagnosed diabetes (separately) in people of Afro-Caribbean origin are badly needed.

Table A8: The prevalence of diabetic retinopathy, maculopathy and levels of Snellen visual acuity.¹⁸⁷

Age group	Prevalence (95% CL)
People with diabetes aged 28–91 years (mean age 67.7 ± 11.9 years) Mean duration of diabetes 7.2 ± 5.8 years	Retinopathy <ul style="list-style-type: none"> • None: 48.0 (40.0–56.0) • BGR: 48.0 (39.0–56.0) • PLR: 4.0 (2.0–9.0) Maculopathy <ul style="list-style-type: none"> • None: 90.0 (85.0–95.0) • Some: 10.0 (5.0–15.0) Snellen visual acuity <ul style="list-style-type: none"> • 6/6: 33.0 (26.0–41.0) • 6/9: 22.0 (15.0–28.0) • 6/12: 21.0 (14.0–27.0) • 6/18: 12.0 (7.0–17.0) • 6/24: 3.0 (1.0–8.0) • 6/36: 3.0 (1.0–7.0) • 6/60: 1.0 (0.4–6.0) • < 6/60: 5.0 (2.0–10.0)

Prevalences are per 100 persons with clinically diagnosed diabetes. **Note:** (1) BGR is background retinopathy (Wisconsin grades 1.5–5); PLR is proliferative retinopathy (Wisconsin grades 6–8). (2) ‘Some’ maculopathy is Early Treatment of Diabetic Retinopathy Study (ETDRS) clinically significant maculopathy. (3) Retinopathy and maculopathy data above are based on combined photographic, clinical and hospital record observations ($n = 145$ for retinopathy; $n = 144$ for maculopathy). (4) Snellen visual acuity data are for people with diabetes not treated with insulin ($n = 144$).

Table A9: The prevalence of diabetic neuropathy.¹⁸⁸

Age group (years)	Prevalence (95% CL)
20–29	5.0 (2.5–6.0)
30–39	9.5 (6.0–12.5)
40–49	16.0 (13.0–18.0)
50–59	25.5 (23.5–28.0)
60–69	36.0 (34.0–38.0)
70–79	43.0 (39.5–46.0)
80–89	60.5 (54.0–67.0)

Prevalences are per 100 persons with clinically diagnosed diabetes.

Table A10: The prevalence of microalbuminuria, incidence of proteinuria and prevalence of proteinuria in people with diabetes. This table is adapted from Chattington.¹⁸⁹ The original data are from Hasslacher¹⁹⁰ and Borch-Johnsen.¹⁹¹

Complication	Type 1 diabetes	Type 2 diabetes
Prevalence of microalbuminuria	10–25	15.0–25.0
Incidence of proteinuria	0.5–3.0	1.0–2.0
Prevalence of proteinuria	15.0–20.0	10.0–25.0

Prevalences are per 100 persons with clinically diagnosed diabetes. Incidence rates are per 100 persons with clinically diagnosed diabetes per year.

Table A11: The prevalence of hypertension in adults with diabetes.¹⁹²

Age group (years)	Prevalence (95% CI)
Men	
25–34	13.5 (7.4–22.0)
35–44	28.0 (22.9–33.1)
45–54	33.8 (30.7–36.9)
55–64	40.2 (37.0–43.4)
25–64	34.7* (32.7–36.7)
Women	
25–34	16.6 (8.3–28.5)
35–44	36.5 (29.7–43.3)
45–54	43.9 (39.6–48.1)
55–64	53.4 (49.8–57.0)
25–64	46.5** (43.9–49.0)

Prevalences are per 100 persons with clinically diagnosed diabetes. *20.7% were on antihypertensive therapy, 14.0% had blood pressure > 160/90 and were untreated. **22.2% were on antihypertensive therapy, 24.3% had blood pressure > 160/90 and were untreated.

54 Diabetes Mellitus**Table A12:** The prevalence of peripheral vascular disease in adults with diabetes.¹⁹³

Age (years) [diagnostic group]	Prevalence (95% CI)	Age (years) [diagnostic group]	Prevalence (95% CI)
<i>Type 1 diabetes</i>		<i>Type 2 diabetes</i>	
Men		Men	
0–29	–	0–29	–
30–39	11.0	30–39	–
40–49	–	40–49	6.0
50–59	11.0	50–59	3.0
60–69	14.0	60–69	9.0
70–79	65.0	70–79	32.0
80 and over	–	80 and over	46.0
All ages	12.0 (6.0–19.0)	All ages	22.0 (18.0–27.0)
Women		Women	
0–29	–	0–29	–
30–39	–	30–39	–
40–49	–	40–49	–
50–59	18.0	50–59	4.0
60–69	7.0	60–69	19.0
70–79	25.0	70–79	28.0
80 and over	24.0	80 and over	45.0
All ages	5.0 (2.0–12.0)	All ages	25.0 (20.0–30.0)

Prevalences are per 100 persons with clinically diagnosed diabetes. **Note:** (1) Peripheral vascular disease was identified by a combination of palpation of pulses, blood pressure and Doppler measurements (for exact definitions see original paper); (2) prevalences were based on 213 subjects with type 1 diabetes and 864 with type 2.

Table A13: The incidence of heart disease in adults with diabetes.¹⁹⁴

Age group (years)		
35–64	Myocardial infarct	1.8
	ECG abnormality	2.2
	All IHD	4.1

Rates are per 1,000 per year.

Appendix IV. Saint Vincent Declaration⁷⁷

Representatives of government health departments and patients' organisations from all European countries met with diabetes experts under the aegis of the Regional Offices of the WHO and the IDF in St Vincent, Italy, on 10–12 October 1989. They agreed unanimously upon the following recommendations and urged that they should be presented in all countries throughout Europe for implementation.

General goals for people, children and adults, with diabetes

- Sustained improvement in health experience and a life approaching normal expectation in quality and quantity.
- Prevention and cure of diabetes and of its complications by intensifying research effort.

Five-year targets

- Elaborate, initiate and evaluate comprehensive programmes for the detection and control of diabetes and of its complications with self-care and community support as major components.
- Raise awareness in the population and among health care professionals of the present opportunities and the future needs for prevention of the complications of diabetes and of diabetes itself.
- Organise training and teaching in diabetes management and care for people of all ages with diabetes, for their families, friends and working associates and for the health care team.
- Ensure that care for children with diabetes is provided by individuals and teams specialised both in the management of diabetes and of children, and that families with a diabetic child get the necessary social, economic and emotional support.
- Reinforce existing centres of excellence in diabetes care, education and research. Create new centres where the need and potential exist.
- Promote independence, equity and self-sufficiency for all people with diabetes – children, adolescents, those in working years of life and the elderly.
- Remove hindrances to the fullest possible integration of the diabetic citizen into society.
- Implement effective measures for the prevention of costly complications.
- Reduce new blindness due to diabetes care by one-third or more.
- Reduce the numbers of people entering end-stage diabetic renal failure by at least one-third.
- Reduce by one-half the rate of limb amputations for diabetic gangrene.
- Cut morbidity and mortality from coronary heart disease in the diabetic by vigorous programmes of risk factor reduction.
- Achieve pregnancy outcome in diabetic women that approximates that of non-diabetic women.
- Establish monitoring and control systems using state of the art information technology for quality assurance of diabetes health care provision and for laboratory and technical procedures in diabetes diagnosis, treatment and self-management.
- Promote European and international collaboration in programmes of diabetes research and development through national, regional and WHO agencies, and in active partnership with diabetes patients' organisations.
- Take urgent action in the spirit of the WHO programme, 'Health for All' to establish joint machinery between WHO and IDF, European Region, to initiate, accelerate and facilitate the implementation of these recommendations.

Appendix V. What diabetic care to expect

The British Diabetic Association Patients' Charter⁷⁹

When you have been diagnosed, you should have:

- a full medical examination
- a talk with a registered nurse who has a special interest in diabetes. She will explain what diabetes is and talk to you about your individual treatment
- a talk with a state-registered dietician, who will want to know what you are used to eating, and will give you basic advice on what to eat in the future. A follow-up meeting should be arranged for more detailed advice
- a discussion on the implications of diabetes on your job, driving, insurance, prescription charges, etc. and whether you need to inform the DVLA and your insurance company, if you are a driver
- information about the BDA's services and details of your local BDA group
- ongoing education about your diabetes and the beneficial effects of exercise, and assessments of your control.

PLUS

If you are treated by insulin:

- frequent sessions for basic instruction in injection technique, looking after insulin and syringes, blood glucose and ketone testing and what the results mean
- supplies of relevant equipment
- discussion about hypoglycaemia (hypos); when and why it may happen and how to deal with it.

If you are treated by tablets:

- a discussion about the possibility of hypoglycaemia (hypos) and how to deal with it
- instruction on blood or urine testing and what the results mean, and supplies of relevant equipment.

If you are treated by diet alone:

- instruction on blood or urine testing and what the results mean, and supplies of relevant equipment.

Once your diabetes is reasonably controlled, you should:

- have access to the diabetes team at regular intervals – annually if necessary. These meetings should give time for discussion as well as assessing diabetes control
- be able to contact any member of the health care team for specialist advice when you need it
- have more education sessions as you are ready for them
- have a formal medical review once a year by a doctor experienced in diabetes.

At this review:

- your weight should be recorded
- your urine should be tested for protein
- your blood should be tested to measure long term control
- you should discuss control, including your home-monitoring results
- your blood pressure should be checked

- your vision should be checked and the back of your eyes examined. A photo may be taken of the back of your eyes. If necessary you should be referred to an ophthalmologist
- your legs and feet should be examined to check your circulation and nerve supply. If necessary you should be referred to a state-registered chiropodist
- if you are on insulin, your injection sites should be examined
- you should have the opportunity to discuss how you are coping at home and at work.

Your role:

- you are an important member of the care team so it is essential that you understand your own diabetes to enable you to be in control of your condition
- you should ensure that you receive the described care from your local diabetes clinic, practice or hospital. If these services are not available to you, you should:
 - contact your GP to discuss the diabetes care available in your area
 - contact your local community health council
 - contact the BDA or your local branch.

Appendix VI. Diabetes centres

Purpose

Diabetes centres ideally should (and some do) provide the hub of the local diabetes services, and a place where patients and their carers, and staff from the hospital and community can meet. They offer clinical advice and education on diabetes to all on a single site where most of the professional and social services required are accessible. In many cases their operational philosophy and organisation take account of the special bridging role between specialist and primary care diabetes services.

Diabetes centres should offer some or all of the following facilities:

- education services for patients and their carers, staff working in the centre and professionals from primary and secondary care
- each group requires an agreed educational curriculum
- facilities for clinical advice and regular review, including the annual review
- drop-in access for people with diabetic problems
- referrals for further diagnosis and the treatment of diabetes
- joint clinics with ophthalmologists, nephrologists and other specialists
- dietary advice – information, teaching and review by specialist dieticians
- chiropodial (podiatric) advice, education and treatment
- psychological and social advice and treatment
- a flexible outreach service
- a 24-hour telephone helpline
- a secure and effective computerised information system
- a venue for the audit of local diabetes services
- a place to house and update the diabetes register
- a meeting place for primary and secondary care staff to hold joint clinical meetings
- a focus for integrated care, providing the opportunity for creating individualised programmes of care for people, sufficiently flexible to meet their changing needs through a lifetime with diabetes
- the opportunity for people with diabetes to obtain all or a large part of the services relevant to diabetes care in one place
- children's play area
- a place where people with diabetes and their families can meet and share their problems, experiences and solutions, e.g. local BDA branch meetings
- a place where other meetings relevant to diabetes can be held, e.g. LDSAG meetings
- a place for advising groups of people with diabetes special needs, e.g. children, young adults, pre-pregnancy counselling.

Source: British Diabetic Association⁸¹

Appendix VII. Size of effect and quality of evidence

Size of effect

- A: The procedure/service has a strong beneficial effect.
- B: The procedure/service has a moderate beneficial effect.
- C: The procedure/service has a measurable beneficial effect.
- D: The procedure/service has no measurable beneficial effect.
- E: The harm of the procedure/service outweighs its benefits.

Quality of evidence

- I-1: Evidence from several consistent, or one large, randomised controlled trial.
- I-2: Evidence obtained from at least one properly designed randomised controlled trial.
- II-1: Evidence obtained from well-designed controlled trials without randomisation, or from well-designed cohort or case-control analytic studies.
- II-2: Evidence obtained from multiple time series with or without the intervention. Also, dramatic results in uncontrolled experiments.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
- IV: Evidence inadequate and conflicting.

Appendix VIII. HRG costs for diabetes (based on 1999 Schedule of Reference Costs)

HRG code	HRG label FCEs	No. of	Mean average £	Range for 50% of NHS trusts		Range for all NHS trusts	
				Minimum £	Maximum £	Minimum £	Maximum £
ELIP K11	Diabetes with hyperglycaemic emergency > 69 or with complications and co-morbidities	35	1,093	524	1,395	1,115	3,300
ELIP K12	Diabetes with hypoglycaemic emergency < 70 without complications and co-morbidities	182	618	328	779	43	1,884
ELIP K13	Diabetes with hyperglycaemic emergency > 69 or with complications and co-morbidities	15	1,458	637	1,988	117	3,242
ELIP K14	Diabetes with hyperglycaemic emergency < 70 without complications and co-morbidities	19	724	367	943	251	1,609
ELIP K15	Diabetes and other hyperglycaemic disorders > 69 or with complications and co-morbidities	438	1,154	569	1,518	143	6,599
ELIP K16	Diabetes and other hyperglycaemic disorders < 70 without complications and co-morbidities	407	768	490	1,058	124	8,167
ELIP K17	Diabetes with lower limb complications	459	1,743	806	2,285	99	8,140
ELIP Q16	Foot procedures for diabetes or arterial disease, and procedures to amputate stumps	1,011	1,453	777	1,714	112	8,002
NELIP K11	Diabetes with hypoglycaemic emergency > 69 or with complications and co-morbidities	2,120	872	561	1,220	25	8,952
NELIP K12	Diabetes with hypoglycaemic emergency < 70 without complications and co-morbidities	1,900	557	330	790	84	2,785
NELIP K13	Diabetes with hyperglycaemic emergency > 69 or with complications and co-morbidities	2,760	1,002	700	1,454	50	4,885
NELIP K14	Diabetes with hyperglycaemic emergency < 70 without complications and co-morbidities	5,304	638	453	884	55	2,239

NELIP	K15	Diabetes and other hyperglycaemic disorders > 69 or with complications and co-morbidities	6,319	1,185	830	1,638	129	9,221
NELIP	K16	Diabetes and other hyperglycaemic disorders < 70 without complications and co-morbidities	5,664	662	479	1,000	92	12,096
NELIP	K17	Diabetes with lower limb complications	4,422	1,553	912	2,024	113	9,542
NELIP	Q16	Foot procedures for diabetes or arterial disease, and procedures to amputate stumps	1,279	2,079	943	2,813	124	10,337
DC	K14	Diabetes with hyperglycaemic emergency < 70 without complications and co-morbidities	17	231	183	273	151	416
DC	K15	Diabetes and other hyperglycaemic disorders > 69 or with complications and co-morbidities	715	197	145	329	26	1,478
DC	K16	Diabetes and other hyperglycaemic disorders < 70 without complications and co-morbidities	2,938	249	156	323	33	1,480
DC	K17	Diabetes with lower limb complications	62	268	183	428	109	1,162
DC	Q16	Foot procedures for diabetes or arterial disease, and procedures to amputate stumps	305	312	265	490	103	918

ELIP, elective inpatients; NELIP, non-elective inpatients; DC, day case.

Appendix IX. HBGs/HCRGs for diabetes – summary matrix

HBGs	HRGs Prevention and health promotion	Investigation and diagnosis	Clinical management	Continuing care
<i>At risk</i> Whole population At specific risk: Type 1 diabetes Type 2 diabetes Secondary diabetes	Health promotion: Health education Primary prevention Surveillance Screening Clinical management of at risk groups			
<i>Presentation</i> Hyperglycaemia Hyperglycaemic emergencies		Clinical assessment Diagnostic investigations: Pathology Imaging Specialised tests and procedures		
<i>Confirmed disease</i> Diabetes without complications Diabetes with complications			Acute inpatient admission Medical management Surgical management Nursing Voluntary sector	
<i>Continued consequences of disease</i>				To be decided

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Appendix X. Health care programme matrix

Service level	Needs	Effective action	Location	Input	Activity targets	Output	Service outcome	Health objective
Primary prevention	Fill in this box first							Reduced incidence and prevalence of the condition
Screening and early treatment								Reduced incidence and prevalence of illness
Acute care								Reduced premature mortality
Rehabilitation and continuing care							Fill in this box last	Reduced mortality, incidence and prevalence of disability and handicap

O'Brien and Singleton.¹⁷⁶

Appendix XI. Recommendations of the Working Group on Outcomes¹⁷⁸

Recommendations for implementation were made for each indicator using the following categories

- A: To be implemented generally on a routine basis.
- B: To be implemented generally by periodic survey.
- C: To be implemented where local circumstances allow on a routine basis.
- D: To be implemented where local circumstances allow by periodic study.
- E: To be implemented following IT developments on a routine basis.
- F: To be further developed either because the link with effectiveness is not clear or the indicator specification is incomplete.

Indicators related to reducing or avoiding risk of diabetes and appropriate detection of diabetes

- 1 Prevalence of clinically diagnosed diabetes (Category A).
- 2 Percentage prevalence of retinopathy and maculopathy at the time of diagnosis of diabetes (Category E).
- 3A Prevalence of obesity in persons aged 16–64 (defined as BMI = 30.0 kg/m²) (Category B).
- 3B Proportion of people undertaking rigorous physical activity in the previous 28 days (Category F).
- 3C Proportion of people who, on average consume fruit or vegetables or salad each day, within the general population (Category F).

Indicators related to reducing risk of complications

- 4 Percentage of patients, aged 16 and over and known to have diabetes, who smoke (Category C).
- 5 Percentage of patients, aged 16–64 and known to have diabetes, who have a BMI > 30 kg/m² (Category C).
- 6 Percentage of patients known to have diabetes with elevated blood pressure: type 1 > 140/90 mmHg, type 2 > 160/90 mmHg (Category C).
- 7 Percentage of patients known to have diabetes with HbA_{1c} that was > 7.5% on a DCCT standardised assay, at time of last recording within the previous year (Category C).
- 8 Percentage prevalence of retinopathy and maculopathy within a population known to have diabetes (Category C).
- 9 Percentage prevalence of microalbuminuria within a population known to have type 1 diabetes (Category C).
- 10 Percentage prevalence of protective sensation loss within a population known to have diabetes (Category C).
- 11 Percentage prevalence of absence of both pulses in at least one foot within a population known to have diabetes (Category C).
- 12 Percentage of patients known to have diabetes where there is no record of blood pressure. The retina or the feet have been assessed within the previous year (Category C).
- 13 Percentage prevalence of symptomatic angina within a population known to have diabetes.
- 14 Percentage prevalence of claudication within a population known to have diabetes.

Indicators related to reducing impact of diabetes

- 15 Number of patients who have had at least one hypoglycaemic emergency, within the last year, that required therapeutic intervention by a health professional, expressed as a proportion of a population of patients known to have diabetes (Category A).

- 16 Number of patients who have had at least one hyperglycaemic emergency, within the last year, that required hospital admission expressed as a proportion of a population of patients known to have diabetes (Category A).
- 17 Case fatality rate associated with acute diabetic episodes treated in hospital (Category C).
- 18A SMR for death due to diabetes mellitus (Category C).
- 18B Years of life lost per 10,000 resident population by death due to diabetes mellitus (Category C).
- 18C Years of life lost by death due to diabetes mellitus (Category C).
- 19 Annual incidence of severe visual impairment (visual acuity $< 6/60$ in the better eye) within a population of patients known to have diabetes (Category C).
- 20 Annual incidence of amputation above the ankle within a population of patients known to have diabetes (Category C).
- 21 Annual incidence of amputation below the ankle within a population of patients known to have diabetes (Category C).
- 22 Annual incidence of myocardial infarction within a population of patients known to have diabetes (Category C).
- 23 Annual incidence of stroke within a population of patients known to have diabetes (Category D).
- 24 Number of patients who have started renal replacement therapy or have had a creatinine level $> 500 \mu\text{mol/l}$ recorded for the first time within the last year, expressed as a proportion of a population of patients known to have diabetes (Category C).
- 25 Rates of late stillbirth and perinatal mortality in deliveries from a population of patients known to have diabetes and who become pregnant (Category C).
- 26 The rate of delivery by Caesarean section, in deliveries from a population of patients known to have diabetes and who become pregnant (Category C).
- 27 The incidence of delivered babies with birth weight greater than the 90th centile (allowing for gestational age) from within a population of patients known to have diabetes and who become pregnant (Category C).
- 28 The incidence of occurrence of specific congenital malformations (i.e. neural tube defects, cardiac and renal malformations) in deliveries from a population of patients known to have diabetes and who become pregnant (Category C).
- 29 The rate of admission to special care baby units (and nurseries) of babies delivered from a population of patients known to have diabetes and who become pregnant (Category F).
- 30 Summary of a measure of psychological well-being within a population of patients known to have diabetes and who become pregnant (Category F).
- 31 Summary of a measure of health status/health-related quality of life within a population of patients known to have diabetes (Category F).
- 32 Summary of a measure of satisfaction with service within a population of patients known to have diabetes.

Source: Working Group on Outcome Indicators for Diabetes, Report to the Department of Health, 1997.¹⁷⁸

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