
*The National Collaborating Centre
for Chronic Conditions*

Funded to produce guidelines for the NHS by NICE

TYPE 1 DIABETES IN ADULTS

National clinical guideline for diagnosis
and management in primary and secondary care

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Preface

It is a pleasure to introduce this national guideline on Type 1 diabetes in adults, commissioned by the National Institute for Clinical Excellence (NICE) to identify best practice for the NHS in the management of Type 1 diabetes. It is the fourth such guideline to be prepared by the National Collaborating Centre for Chronic Conditions (NCC-CC) based at the Royal College of Physicians of London.

Type 1 diabetes can, if poorly controlled, produce devastating problems in both the short and the long term. Good control of blood glucose levels reduces the risk of these problems arising, but can be very difficult for patients and carers to achieve. This guideline emphasises that the NHS should provide all patients with the means – and the necessary understanding – to control their diabetes, and that it should help patients integrate the disease management with their other activities and goals. It argues that every person with diabetes should be able to develop their own care plan and utilise effective treatment in a way agreeable to them. The input of various health professionals may be needed to achieve this, and should be readily available. A system of regular monitoring, so that any complications which do develop are picked up at an early stage and treated appropriately, should also be provided.

In common with all NICE guideline recommendations, those for Type 1 diabetes have been developed using a rigorous, evidence-based methodology. An extensive search identified the relevant medical literature, and papers were carefully assessed to ensure that recommendations were based on treatment and practice of proven benefit. This process was carried out by a guideline development group (GDG), a small team from the NCC-CC working together with patients and health professionals with wide expertise in Type 1 diabetes. They have used the available evidence to produce guidance that is clinically relevant as well as methodologically sound. The availability of clinical expertise also allowed recommendations to be made in areas for which there is inadequate evidence, but which are important to patients and carers. At the same time the need for further research in these areas was identified.

It goes without saying that the members of the GDG deserve enormous thanks for their efforts. The technical team at the NCC-CC, the GDG Lead, the Clinical Advisor and the rest of the group have all worked incredibly hard over the past two years, and have been most generous with their time. Thanks are also due to all those who commented on the guideline at various stages of development. Since I have assumed the directorship of the NCC-CC only at the very end of this process, I can say without any self-aggrandisement that they have done a magnificent job. This full guideline is both an excellent clinical reference work and a practical working document which will improve the care of those with Type 1 diabetes.

Bernard Higgins MD FRCP
Director, National Collaborating Centre for Chronic Conditions

Glossary

ACE inhibitor	Angiotensin-converting enzyme inhibitor.
ADA	American Diabetes Association.
AER	Albumin excretion rate; a measure of kidney damage due to diabetes (and other conditions) and a risk factor for arterial disease.
Albuminuria	The presence of albumin and other proteins in urine.
Alpha-glucosidase inhibitors	Group of drugs which inhibit the digestion of complex carbohydrates in the gut, and thus flatten the post-meal blood glucose excursion.
AMIDA	Active meal-time insulin dose adjustment (see DAFNE).
Autoimmune disease	Condition in which a person's own tissues become the target of attack by their immune system.
Basal-bolus insulin regimen	A meal-time + basal insulin regimen, in which short- or rapid-acting insulin is given before meals, and an extended-acting insulin to cover requirements at night and sometimes between meals.
BGAT	Blood glucose awareness training.
BMI	Body mass index; an index of body weight corrected for height.
CDA	Canadian Diabetes Association.
CGMS	Continuous glucose monitoring systems.
CMAP	Compound muscle action potential.
Cochrane review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Concordance	Concordance is a concept reflecting the extent to which a course of action agreed between clinicians and a person with diabetes is actually carried out; often but not solely used in the sense of therapeutic interventions or behavioural changes.
COPD	Chronic obstructive pulmonary disease.
Cost-effectiveness	Comparative analysis of the costs and health benefits of the treatment or care. In cost effectiveness analysis, the outcomes of different interventions are converted into health gains for which a cost can be associated, for example, cost per diabetic complication prevented.
C-peptide	Biologically inactive part of proinsulin molecule, secreted in equal molar quantities with insulin. C-peptide level gives information on endogenous insulin secretion.
CRG	Consensus Reference Group.
CSII	Continuous subcutaneous insulin infusion; insulin therapy delivered by a pump rather than injection.
DAFNE	Dose adjustment for normal eating; a recent adaptation of a system of self-adjustment of meal-time insulin dose requirement based on assessment of intended food intake.
DCCT	Diabetes Control and Complications Trial; a landmark study of the effects of intensification of diabetes care on development of microvascular complications.
Deep subcutaneous fat	Layer of subcutaneous fat into which insulin has to be injected for optimal effect.
Diabetes centre	A generic term for a source of a unified multidisciplinary diabetes service.

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Diabetes mellitus	Chronic condition characterised by elevated blood glucose levels. Diabetes is of diverse aetiology and pathogenesis, and should not be regarded as a single disease. Predominant types are Type 1 diabetes and Type 2 diabetes, diabetes secondary to other pancreatic disease or other endocrine disease, and diabetes of onset in pregnancy.
Diabetes register	A database, at practice, clinic or regional level, including all people diagnosed with diabetes, and containing information on outcomes, complication recall and surveillance, and treatments.
Diabetes UK	Self-help charity for people with diabetes in the UK, and a professional organisation for diabetes care.
DKA	Diabetic ketoacidosis.
DSME	Diabetes self-management education.
ECG	Electrocardiogram.
Education	In the context of this guideline, patient education in self-management of everyday diabetes issues like insulin therapy, dietary changes, self-monitoring of glucose level, physical exercise, foot care, coping with concurrent illness, how to avoid hypoglycaemia, complications, arterial risk control, jobs and travel.
ELISA	Enzyme-linked immunosorbent assay.
EmAb	Anti-endomysial antibodies.
FBG	Fasting blood glucose level or concentration.
Framingham equation	A widely known and used calculation of arterial risk, derived from a long-term study in Framingham, Massachusetts. Not valid in people with Type 1 or Type 2 diabetes.
Fuzzy logic	A logical computing technique, here as used to control insulin infusion on the basis of degrees of certainty of measurements.
GA	Anti-gliadin antibodies; used in the detection of coeliac disease.
GDG	Guideline Development Group.
GFR	Glomerular filtration rate; a measure of kidney function.
GHb	Glycated haemoglobin, see HbA _{1c} .
Glucose excursions	Change in blood glucose levels especially after meals.
Grade (of recommendation)	A code (eg A, B, C) linked to a guideline recommendation, indicating the strength of the evidence supporting that recommendation. The grading does not indicate the importance of the recommendation, nor the certainty of it being true.
HbA_{1c}	The predominant form of glycated haemoglobin, present in red blood cells, and formed when the normal haemoglobin A reacts non-enzymatically with glucose. As the reaction is slow and only concentration dependent, the amount of HbA _{1c} formed is proportional only to the concentration of HbA and glucose. As HbA remains in the circulation for around three months, the amount of HbA _{1c} present, expressed as a percentage of HbA, is proportional to the glucose concentration over that time.
HPLC	High performance liquid chromatography; one method used in the measurement of HbA _{1c} .
HTA	Health technology assessment; funded by the NHS Research and Development Directorate.
ICA	Islet cell antibodies (see islet B cells).
IDF	International Diabetes Federation; a global federation of diabetes associations.
IgA	Immunoglobulin A.
IGT	Impaired glucose tolerance; a condition of hyperglycaemia less marked by diabetes but association with a high risk of arterial damage.

Insulin analogues	A derivative of human insulin in which change of the amino-acid sequence alters duration of action after injection.
Insulin regimen	A therapeutic combination of different insulin preparations, including time of injection and frequency during a day.
ISDN	Isosorbide dinitrate.
Islet B-cell; sometimes β-cells	Located in the islets of Langerhans of the pancreas, the cells which produce insulin.
Isophane insulin	A synonym for NPH (neutral protamine Hagedorn) insulin.
ISPAD	International Society for Paediatric and Adolescent Diabetes.
Lente insulin	A basal insulin, made by combining insulin with large amounts of zinc; first available in 1951.
MCV	Motor conduction velocity.
MDI	Multiple daily injections (<i>see</i> basal-bolus insulin regimen).
Metabolic syndrome	Overweight (abdominal adiposity), insulin insensitivity, higher blood pressure, abnormal blood fat profile.
Methodological limitations	Features of the design or reporting of a clinical study which are known to be associated with risk of bias or lack of validity. Where a study is reported in this guideline as having significant methodological limitations, a recommendation has not been directly derived from it.
Microalbuminuria	A low but clinically significant level of albumin and other proteins in the urine.
MNCV	Motor nerve conduction velocity.
MODY	Maturity onset diabetes in the young, a dominant gene disorder, not to be confused with Type 1 diabetes, and not insulin dependent.
Multidisciplinary team	Team of people of differing expertise; for diabetes care with expertise in patient education, prevention, therapy, management of complications, foot care, diet, counselling and the like.
NCC-CC	The National Collaborating Centre for Chronic Conditions, set up in 2000 to undertake commissions from NICE to develop clinical guidelines for the NHS.
NHS	National Health Service. This guideline is written for the NHS in England and Wales.
NICE	National Institute for Clinical Excellence; a special health authority set up within the NHS to develop appropriate and consistent advice on health care technologies, and to commission evidence-based guidelines.
NPH insulin	Neutral protamine Hagedorn insulin, a basal insulin, named after the Danish researcher Hans Christian Hagedorn, and developed in the 1940s. Synonymous with isophane insulin.
NPT	Near patient testing.
NSC	National Screening Committee (UK).
NSF	National Service Framework; a nationwide initiative designed to improve delivery of care for a related group of conditions.
OGTT	Oral glucose tolerance test; a diagnostic test sometimes used in people with equivocal diabetes.
PDE5 inhibitors	Phosphodiesterase type 5 inhibitors, a class of drugs developed in recent years to treat erectile dysfunction.
PPAR-γ agonists	A group of drugs which improve insulin sensitivity in people with reduced sensitivity to their own or injected insulin; presently the licensed drugs are both of the chemical group known as thiazolidinediones (trivially 'glitazones').

PROCAM	Prospective Cardiovascular Münster Heart Study – an epidemiological study performed in Germany.
Proteinuria	The presence of protein in the urine.
QALY	Quality-adjusted life year; a measure of a person’s quality of life, used here in the sense of loss of quality through disease, and gain in quality through health care interventions.
RCT	Randomised clinical trial; a trial in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or control group) receiving an alternative treatment, a placebo (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. Such trial designs help minimise experimental bias.
RDW	Red cell distribution width.
Rigiscan	An instrument used in research to measure penile tumescence and rigidity.
SIGN	Scottish Intercollegiate Guidelines Network.
SNAP	Sensory nerve action potential.
SWM	Semmes-Weinstein monofilament.
Technology appraisal	Formal ascertainment and review of the evidence surrounding a health technology, restricted in the current document to appraisals undertaken by NICE.
Type 1 diabetes	Insulin-deficiency disease, developing predominantly in childhood, characterized by hyperglycaemia if untreated, and with a consequent high risk of vascular damage using developing over a period of decades.
Type 2 diabetes	Diabetes generally of slow onset mainly found in adults and in association with features of the metabolic syndrome. Carries a very high risk of vascular disease. While not insulin-dependent, many people with the condition eventually require insulin therapy for optimal blood glucose control.
UKDIABS	A large study/initiative of the collection of outcomes and process data from diabetes care services throughout the UK.
UKPDS	United Kingdom Prospective Diabetes Study – a landmark study of the effect of different diabetes therapies on vascular complications in people with Type 2 diabetes.
VO ₂ max	The oxygen consumption of a person exercising maximally.
VPT	Vibratory perception threshold.
WHO	World Health Organization.

THE DEVELOPMENT OF THE GUIDELINE

1 Introduction

The word ‘diabetes’ refers to a group of disorders with a number of common features, of which raised blood glucose is the most evident. In England and Wales the three most common types of diabetes are:

- Type 1 diabetes
- Type 2 diabetes
- gestational diabetes (diabetes of pregnancy).

This guideline is concerned only with Type 1 diabetes. The underlying disorder is that of a pure hormone deficiency disease: lack of insulin. Because hormone replacement with insulin therapy is suboptimal, and despite the implementation of lifestyle and disease management measures, acute and long-term complications are endemic.

In people whose diabetes is untreated, glucose metabolism may be sufficiently disturbed to cause symptoms, typically of polyuria, thirst, weight loss and fatigue. With further worsening, diabetic coma (ketoacidosis) may occur due to disturbed fat metabolism.

Because insulin therapy, problematically, can give rise to high and low blood glucose levels, people with diabetes have to engage in a high level of self-care to contain the risk of acute and late complications.

The main complications of diabetes in the longer term are:

- eye, kidney, and nerve damage
- arterial disease affecting the heart, brain and feet.

In many people with Type 1 diabetes, abnormalities of blood pressure and blood lipids also develop, particularly in association with diabetic kidney damage. In such people there is a very high risk of premature arterial disease.

1.1 Definition

The Guideline Development Group (GDG, see 2.2) worked to the World Health Organization (WHO) definition of Type 1 diabetes,

a condition of deficiency of insulin secretion from the pancreas, usually due to auto-immune damage of the insulin producing cells. However the clinical condition is generally recognised on the basis of diabetes (high blood glucose levels) occurring in mainly younger and thinner people in the absence of other precipitating causes.⁸

The GDG were, however, conscious that some people with evident Type 1 diabetes and thus absolute insulin deficiency, also have insulin insensitivity in the context of the metabolic syndrome (overweight, insulin insensitivity, higher blood pressure, abnormal blood fat profile).

It was noted that Type 2 diabetes in the young, and the condition known as maturity onset diabetes in the young (MODY), should not be confused with Type 1 diabetes. This is mainly an issue of definition of Type 2 diabetes or MODY rather than Type 1 diabetes. Some conditions of pancreatic damage have a similar phenotype to Type 1 diabetes, but these are usually obvious and of little consequence to the management of the diabetes, so are not considered further.

1.2 Health and resource burden

Type 1 diabetes can result in a wide range of complications, and these affect both the individual patient and the National Health Service. The economic impact of the disease includes:

- direct cost to the NHS
- indirect cost to the economy, including the effects of early mortality
- personal impact of diabetes and subsequent complications on patients and their families.

The direct cost of Type 1 diabetes to the NHS was estimated to be £96m in 1992 prices,¹ which corresponds to approximately £167m at 2001 prices and population levels. The GDG adjusted this figure, using more recent data and expert judgement, to correct for the underestimate of some components^{2,3} and to reflect changes in standard treatment, and arrived at a figure of £212m in 2001 prices. The figure includes:

- renal replacement therapy costs of £38m
- outpatient support costs of £50m
- hospitalisation costs of £65m.

Whilst the indirect costs of diabetes are difficult to quantify, in 1992 the costs in terms of lost productivity were estimated to be slightly higher than the direct costs of Type 1 diabetes.¹

1.3 Scope

The recommendations in the guideline are subject to a number of limitations. The sponsoring authority, NICE, is primarily concerned with health services in England and Wales, so the guideline only indirectly refers to:

- social services
- the voluntary sector
- employers
- services supplied by secondary and tertiary specialties for the late complications of diabetes (for example renal, cardiological, urological and ophthalmological services)
- the education sector (including schools and universities)
- others concerned with an individual's health, rather than healthcare.

Nonetheless, the importance of other agencies must not be ignored, and in each locality the aim should be to integrate care for people with Type 1 diabetes across all relevant sectors.

A pre-agreed scope (see Appendix C) defined the remit of the guideline and specified which aspects of Type 1 diabetes would be included and excluded. The scope had been through stakeholder consultation in accordance with processes established by NICE⁴ before the development of the guideline began, and covered both a children's guideline and this guideline for adults. It specified that the groups to be covered were to include babies, children, adolescents, adults, and older people with Type 1 diabetes.

Because NICE is considering developing a separate guideline on diabetes in pregnancy, the scope did not cover:

- the management of women with diabetes who wish to conceive or who are pregnant
- the management of women who develop diabetes during pregnancy.

The guideline scope covered the following health settings:

- care received from primary and secondary healthcare professionals who have direct contact with and advise on the care of people with Type 1 diabetes
- the interface between community and specialist care, including the circumstances in which people should be referred or admitted to specialist care both within diabetes care and to other specialties
- the interface between children's and adult services
- support/advice that the NHS should offer to crèches, nurseries, schools and other institutions.

The scope also details the aspects of clinical management to be addressed (see Appendix C).

1.4 Other relevant work

This guideline has been developed with the knowledge that other national work on diabetes has been completed or is in progress. Work on diabetes not commissioned by NICE includes:

- the National Service Framework for diabetes, developed by the Department of Health (www.dh.gov.uk)
- an information strategy, developed by the NHS Information Authority (www.nhsia.nhs.uk/phsmi/datasets/pages/diabetes.asp)
- guidance on health outcome indicators, developed by the National Centre for Health Outcomes Development⁵
- a system of national clinical audit, set up by the Commission for Health Improvement (www.nhsia.nhs.uk/ncasp/pages/default.asp)
- a report for HM Treasury which aims to provide an evidence-based assessment of long-term resource requirements for the NHS, and includes information on diabetes (Chapter 6). *Securing our future health: taking a long-term view*, also known as the First Wanless Report, is available from (www.hm-treasury.gov.uk/consultations_and_legislation/wanless/consult_wanless_final.cfm)

NICE has commissioned these other guidelines on diabetes:

- Type 2 diabetes (completed):
 - guideline E, retinopathy
 - guideline F, renal disease prevention and early management
 - guideline G, blood glucose management and patient education
 - guideline H, blood pressure and blood lipid management
 - guideline 10, foot care (updated).

NICE has commissioned the following technical appraisals relevant to diabetes:

- Type 1 and Type 2 diabetes (completed):
 - appraisal 53, long-acting insulin analogues
 - appraisal 57, insulin pump therapy
 - appraisal 60, patient education models

- Type 2 diabetes (completed):
 - appraisal 9, rosiglitazone
 - appraisal 21, proglitazone
 - appraisal 63, glitazones
- Type 1 and Type 2 diabetes (completed):
 - appraisal 71, coronary artery stents
 - appraisal 73, myocardial perfusion scintigraphy
- Type 1 and Type 2 diabetes (in development):
 - coronary events: statins.

2 Methodology

2.1 Aims and principles

This chapter describes the resources and techniques used to reach the clinical recommendations in this guideline.

Clinical guidelines have been formally defined as ‘systematically developed statements to assist both practitioner and patient decisions in specific circumstances’.⁶ This guideline aims to offer the best practice advice on the care of adults (defined as those aged 18 years or older) with Type 1 diabetes. It gives guidance on the management, monitoring and support of people with Type 1 diabetes. The context of the intended guidance is the primacy of the needs of the individual with diabetes, reflecting the difficulties of reconciling the problems of insulin replacement therapy with personal lifestyles.

The current guideline is aimed at helping all healthcare professionals provide optimal services for people with Type 1 diabetes by:

- providing healthcare professionals with a set of explicit statements on the best known ways to assist people with diabetes with their most common clinical problems, while maximising the effectiveness of the service in supporting the population with Type 1 diabetes
- giving commissioning organisations and provider services specific guidance on the best way to provide complex services in a way that maximises efficiency and equity (service organisation is, however, outside the scope of this clinical guideline)
- informing people with diabetes of the optimal methods for helping them self-manage their diabetes.

Others, including the general public, may find the guideline of use in understanding the global and clinical approach to Type 1 diabetes. Separate short-form documents for the public and for healthcare professionals are available; they summarise the recommendations without giving full details of the supporting evidence.

The main principles behind the development of this guideline are that it should:

- consider all the most important issues in the management of people with Type 1 diabetes using published evidence wherever this is available
- be useful to and usable by all professionals
- take full account of the perspectives of the person with Type 1 diabetes and their carers
- indicate areas of uncertainty or controversy needing further research.

2.2 The developers

- ▷ The National Collaborating Centre for Chronic Conditions

The National Collaborating Centre for Chronic Conditions (NCC-CC) is housed by the Royal College of Physicians (RCP) but governed by a multiprofessional partners board, which includes patient groups and NHS management. It was set up in 2000 to undertake commissions from the National Institute for Clinical Excellence (NICE) to develop clinical guidelines for the NHS in England and Wales.

▷ The technical team

The technical team consisted of:

- an information scientist
- a health services research fellow
- a clinical advisor
- a health economist
- the chair of the Guideline Development Group (GDG)
- a project manager

and was supported by administrative personnel. It took part in the GDG meetings, and also met separately each month.

▷ The Guideline Development Group

The GDG met monthly for 10 months to review the evidence identified by the technical team, to comment on its completeness and to develop and refine clinical recommendations based on that evidence and other considerations.

Editorial responsibility for this guideline rests solely with the GDG.

Nominations for group members were invited from various stakeholder organisations, which were selected to ensure an appropriate mix of clinical professions and patient groups. These made up the Consensus Reference Group (CRG, see below) and from their members the GDG was selected to represent the groups involved in the day-to-day management of Type 1 diabetes. It included two representatives of people with Type 1 diabetes. Each nominee was expected to serve as an individual expert in their own right and not as a mandated representative, although they were encouraged to keep their parent organisation informed of the process. Group membership details can be found at the front of this document.

All group members made a formal 'declaration of interests' at the start of the guideline development and provided updates throughout. The NCC-CC and the GDG Chair monitored these.

▷ The Consensus Reference Group

The larger Consensus Reference Group (CRG) met twice during the process, once early in the development to ensure the aims and clinical questions (see Appendix A) were appropriate, and again at the end of the process to review the validity of the recommendations drafted by the GDG. The formal consensus technique used for this purpose was developed by the NCC-CC and is a modification of the RAND Nominal Group Technique.

▷ Involvement of people with Type 1 diabetes

The NCC-CC believes that the views of people with diabetes and their carers are an integral part of the development process of a guideline on Type 1 diabetes. Patient organisation representation (Diabetes UK) was secured on the Guideline Development Group and included a non-healthcare professional with Type 1 diabetes. People with diabetes were also present as part of the GDG and CRG and were involved at every stage of the guideline development process.

2.3 Searching for the evidence

There were four stages to evidence identification and retrieval:

- 1 The technical team set out a series of specific clinical questions (see Appendix A) that covered the issues identified in the project scope. The CRG met to discuss, refine and approve these questions as suitable for identifying appropriate evidence from within the published literature.
- 2 A total of 74 questions were identified. The technical team and project executive agreed that a full literature search and critical appraisal process could not be undertaken for all of these areas due to the time limitations of the guideline development process. The technical team identified questions where it was felt that a full literature search and critical appraisal were essential. Reasons for this included an awareness of new or unclear evidence, or a particular clinical need for evidence-based guidance in the area.
- 3 The information scientist, with the assistance of the clinical advisor, developed a search strategy for each question to identify the available evidence. Identified titles and abstracts were reviewed for relevance to the agreed clinical questions and full papers obtained as appropriate. These were assessed for inclusion according to predefined criteria as developed by the Scottish Intercollegiate Guidelines Network (SIGN).
- 4 The full papers were critically appraised by the health services research fellow and the pertinent data entered into evidence tables. These were then reviewed and analysed by the GDG as the basis upon which recommendations were formulated.

Due to the large amount of literature potentially relevant to Type 1 diabetes, the inclusion criteria aimed to limit the included studies to those of a higher level (see 2.6) conducted primarily in people with Type 1 diabetes. Where these were not available, lower-level studies, well-conducted studies outside Type 1 diabetes (in Type 2 diabetes or in the non-diabetic population), or more methodologically-limited studies in people with Type 1 diabetes, were included.

Limited details of the databases and constraints used in the searches can be found in Appendix A. No formal contact was made with the authors of identified studies. Additional contemporary articles identified by the GDG on an *ad hoc* basis, and further published evidence identified by national stakeholder organisations, were incorporated where appropriate after having been assessed for inclusion by the same criteria as evidence provided by the electronic searches.

Searches were rerun at the end of the guideline development process, thus including evidence published and included in the literature databases up to 27 May 2003. Studies recommended by stakeholders or GDG members that were published after this date were not considered for inclusion. The date should be the starting point for searching for new evidence for future updates to this guideline.

2.4 Synthesising the evidence

Abstracts of articles identified by the searches were screened for relevance, and hard copies were ordered of papers that appeared to provide useful evidence relevant to each clinical question. Using a validated appraisal tool, each paper was assessed for its methodological quality against pre-defined criteria. Papers that met the inclusion criteria were then assigned a level according

to the evidence hierarchy given under 2.6. Owing to practical limitations, selection, critical appraisal and data extraction were undertaken by one reviewer only. Evidence was, however, considered carefully by the GDG for accuracy and completeness.

Each clinical question dictated the study design that was prioritised in the search strategy. In addition, certain topics within any one clinical question at times required different evidence types to be considered. Randomised control trials (RCTs) were the most appropriate study design for some clinical questions as they lend themselves particularly well to research into medicines. They were not, however, appropriate for all clinical questions, for example the evaluation of diagnostic tests.

RCTs are difficult to perform in areas such as rehabilitation and lifestyle, where interventions are often tailored to the needs of the individual. As a consequence, pharmaceutical interventions tend to be placed higher in the evidence hierarchy than other, equally important, interventions. This should not be interpreted as a preference for a particular type of intervention or as a reflection of the quality of the evidence, particularly for those clinical areas where non-RCT evidence is valid and most appropriate.

Where available, evidence from well-conducted systematic reviews was appraised and presented. Trials included within these reviews are listed in the evidence table but were not critically appraised. Studies identified in addition to those included in the systematic review were included in the appraisal process.

At times, evidence was not available from studies that included a Type 1 diabetes population. Where a Type 2 or mixed diabetes population, or non-diabetes population, is considered, it is indicated in the relevant evidence statement.

On occasion the group identified a clinical question that could not be appropriately answered through undertaking a rigorous literature review (because the evidence was scarce, or conflicting). These questions were addressed by group consensus, and the group considered a summary of the area in an expert-drafted discussion paper. In these instances there was no formal assessment of the studies cited.

Finally, national and international evidence-based guidelines were referred to during the development process. These were not formally appraised because of the consistency of process and of evidence base can be difficult to ascertain across such documents.

The evidence statements should be read with the following caveats in mind:

- all comparisons discussed are statistically significant unless otherwise stated
- where evidence is available from a good quality systematic review or meta-analysis, then individual studies are not reviewed and referenced. Any additional RCT evidence presented relates to studies published since the completion of systematic review(s) included or those considered relevant to this guideline, but which may not have been suitable for inclusion in the systematic review(s)
- unless explicitly stated, all studies relate to diabetes populations. The inclusion of studies of Type 1, Type 2 or mixed Type 1 and Type 2 diabetes populations varies between questions (see Appendix A)
- descriptions of studies of poor methodological quality in evidence statements include details on all relevant interventions in a specified question. However, no positive recommendations have been based solely on such studies

- evidence statements in this guideline derived from one systematic review may be graded with different hierarchy of evidence in different places, due to some topics within the review being based on a synthesis of the outcomes of well-conducted randomised controlled trials and others being based on a synthesis of non-randomised studies, prevalence studies and diagnostic studies, or on consensus
- when other guidelines are reviewed, some of their recommendations are presented here as evidence statements. These may not necessarily reflect the recommendations made in this guideline and are clearly labelled
- where individual trials are referred to in the evidence statements as small, medium, or large, this equates to the following number of participants (at baseline): small, less than 50; medium, from 50 to 200; large, greater than 200. Exact numbers for each trial can be found in the online evidence tables.

2.5 Health economic evidence

While evidence on cost-effectiveness was extracted from the clinical literature searches wherever it existed, this was rare. As such, a separate search was conducted to isolate the health economic evidence that attempted to identify the cost of, and the benefits accruing from, each strategy or intervention. An *a priori* study design criterion was not imposed, so information may come from sources other than RCTs and formal economic evaluations.

As the management of diabetes is complex, many of the areas covered by this guideline have little economic evidence; within clinical trials it is not always clear which of a range of interventions and strategies actually improves health. The GDG therefore expected the useful cost-effectiveness evidence to fall within a limited range of areas. Where searching produced either no evidence or insufficient evidence for a substantive health economic evidence statement, this fact is indicated.

The health economist presented the economic evidence to the GDG alongside the clinical evidence. There is no standard measure to assess the quality of the economic evidence, and reported costs and benefits experienced in other healthcare systems may not apply in the UK. The GDG had to assess not only the results but also their applicability.

Health economic analysis can provide a framework for combining information from a variety of sources to form a standard comparison of cost and benefits. However, the task of producing these estimates is complex and labour intensive, and requires a level of clinical evidence that is not always readily available. Evidence on the costs and benefits of a broad range of interventions was presented to the GDG, but the issue of cultured human dermis for foot ulceration was identified as a particularly important area for further economic analysis. The choice was made on the grounds that:

- this treatment does not have good quality economic evidence attached
- it has a potentially large health benefit
- if made available, the treatment could have a large effect on NHS resources given the prevalence of diabetic foot ulcers
- there are uncertainties surrounding both the benefits and resources, and an absence of cost-utility studies.

2.6 Drafting recommendations

Evidence for each topic was extracted into tables and summarised in evidence statements. The GDG reviewed the evidence tables and statements at each meeting and reached a group opinion. Recommendations were explicitly linked to the evidence supporting them and graded according to the level of the evidence upon which they were based, using the grading system in the table below.

It should be noted that it is the level of evidence that determines the grade assigned to each recommendation. The grade does not necessarily reflect the clinical importance attached to the recommendation.

Hierarchy of evidence		Typical grading of recommendations	
Ia	Evidence from meta-analysis of randomised controlled trials.	A	Based on category I evidence.
Ib	Evidence from at least one randomised controlled trial.		
IIa	Evidence from at least one controlled study without randomisation.	B	Based on category II evidence or extrapolated from category I.
IIb	Evidence from at least one other type of quasi-experimental study.		
III	Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case control studies.	C	Based on category III evidence or extrapolated from category I or II.
IV	Evidence from expert committee reports or opinions and/or clinical experience of respected authorities.	D	Directly based on category IV evidence or extrapolated from category I, II or III.
DS	Evidence from diagnostic studies.	DS	Evidence from diagnostic studies.
NICE	Evidence from NICE guidelines or health technology appraisal programme.	NICE	Evidence from NICE guidelines or health technology appraisal programme.

2.7 Agreeing recommendations

Once the evidence review had been completed and an early draft of the guideline produced, a one-day meeting of the CRG was held to finalise the recommendations. This included a pre-meeting vote on the recommendations and a further vote at the CRG meeting, where the group was asked to consider the draft guideline in two stages:

- 1 Are the evidence-based statements acceptable and is the evidence cited sufficient to justify the grading attached?
- 2 Are the recommendations derived from the evidence justified and are they sufficiently practical so that those at the clinical front line can implement them? Three types of recommendation were considered:
 - a) A recommendation from the GDG based on strong evidence, usually non-controversial unless there was important evidence that had been missed or misinterpreted

- b) A recommendation that was based on good evidence but where it was necessary to extrapolate the findings to make it useful in the NHS. The extrapolation was approved by consensus
- c) Recommendations for which no evidence existed but which address important aspects of care, and for which a consensus on best practice could be reached.

This formal consensus method has been established within the NCC-CC, drawing on the knowledge set out in a health technology appraisal,⁷ the work of the Royal College of Nursing Institute¹ and practical experience. It approximates to a modification of the RAND Nominal Group Technique and will be fully described in future publications.

2.8 Writing the guideline

The draft version of the guideline was drawn up by the technical team in accordance with the decisions of the guideline groups. Prior to publication, it was circulated to stakeholders according to the formal NICE stakeholder consultation and validation phase.

Modifications were made to this document in response to comments received. Changes were approved by the Guideline Development Group, who retain the final editorial authority for the content.

2.9 Structure of the guideline

The part of this document which contains recommendations (chapter 4 onwards) is divided into sections, each of which covers a set of related topics. For each topic the layout is the same:

- the **rationale** for including the topic is provided in one or two paragraphs that simply set the recommendations in the context of their clinical importance
- the **evidence statements**, both clinical and health economic, are then given, summarising the evidence (more detail can be found in the **evidence tables**, available on the web at www.rcplondon.ac.uk/pubs/books/dia/index.asp) Specific health economic evidence statements also follow the clinical evidence when available. The evidence statements and tables aim to contextualise and explain each recommendation
- the evidence statements are followed by a **consideration** that reflects the thinking of the GDG in making the recommendations. This is intended to explain how the evidence was used to formulate the recommendations
- the **recommendations** follow. These are graded to indicate the level of the evidence behind the recommendation, rather than how valid the GDG believes them to be. In some sections of the guideline, additional text providing more detailed guidance is contained within the recommendations.

3 Key messages of the guideline

3.1 Key recommendations

Patient-centred care

- 1 The views and preferences of individuals with Type 1 diabetes should be integrated into their healthcare. Diabetes services should be organised, and staff trained, to allow and encourage this.

Multidisciplinary team approach

- 2 The range of professional skills needed for delivery of optimal advice to adults with diabetes should be provided by a multidisciplinary team. Such a team should include members having specific training and interest to cover the following areas of care:
 - education/information giving
 - nutrition
 - therapeutics
 - identification and management of complications
 - foot care
 - counselling
 - psychological care.

Patient education

- 3 Culturally appropriate education should be offered after diagnosis to all adults with Type 1 diabetes (and to those with significant input into the diabetes care of others). It should be repeated as requested and according to annual review of need. This should encompass the necessary understanding, motivation and skills to manage appropriately:
 - blood glucose control (insulin, self-monitoring, nutrition)
 - arterial risk factors (blood lipids, blood pressure, smoking)
 - late complications (feet, kidney, eye, heart).

Blood glucose control

- 4 Blood glucose control should be optimised towards attaining DCCT-harmonised HbA_{1c} targets for prevention of microvascular disease (7.5% or lower) and, in those at increased risk, arterial disease (6.5% or lower) as appropriate, while taking into account:
 - the experiences and preferences of the insulin user, in order to avoid hypoglycaemia
 - the necessity to seek advice from professionals knowledgeable of the range of available mealtime and basal insulins and of optimal combinations thereof, and their optimal use.

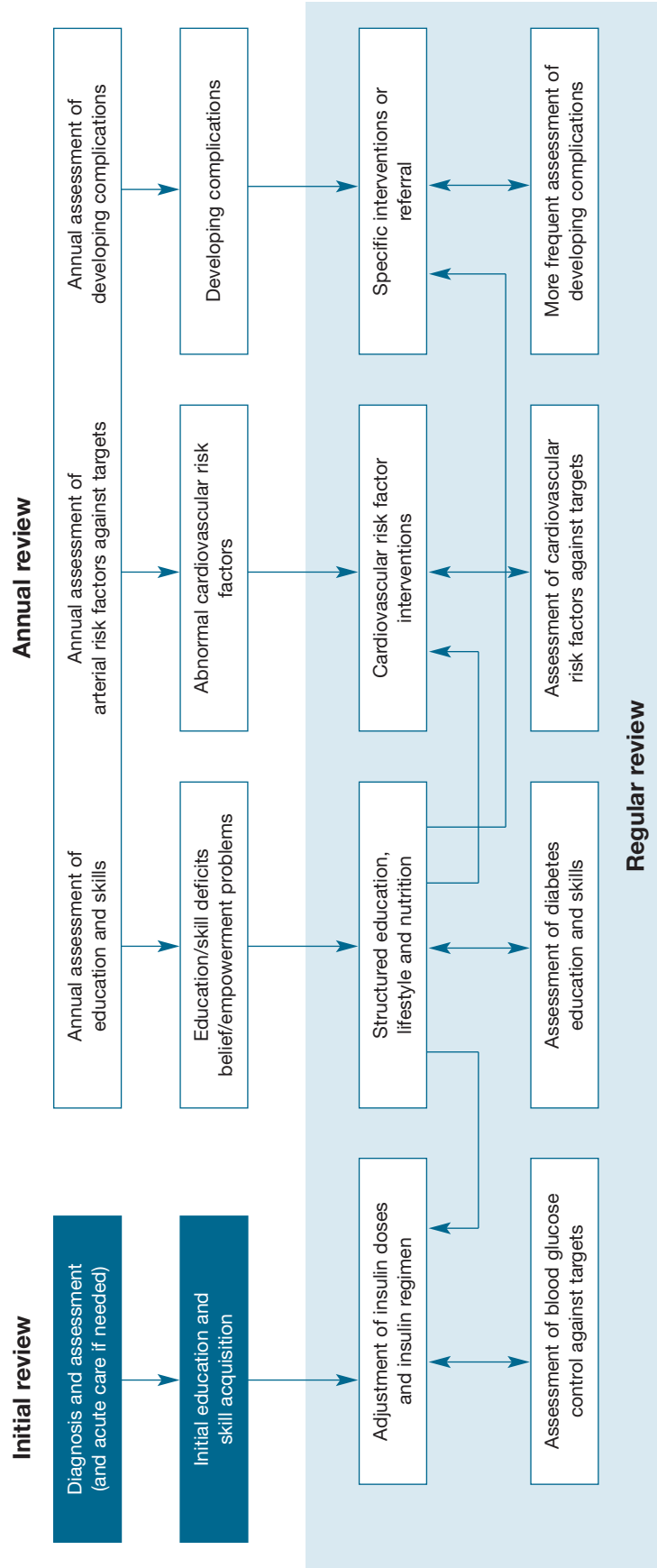
Arterial risk factor control

- 5** Adults with Type 1 diabetes should be assessed for arterial risk at annual intervals. Those found to be at increased risk should be managed through appropriate interventions and regular review. Note should be taken of:
- microalbuminuria, in particular
 - the presence of features of the metabolic syndrome
 - conventional risk factors (family history, abnormal lipid profile, raised blood pressure, smoking).

Late complications

- 6** Adults with Type 1 diabetes should be assessed for early markers and features of eye, kidney, nerve, foot, and arterial damage at annual intervals. According to assessed need, they should be offered appropriate interventions and/or referral in order to reduce the progression of such late complications into adverse health outcomes affecting quality of life.

3.2 An outline Type 1 diabetes care algorithm



3.3 Audit criteria

The audit criteria shown below are linked to the key messages in 3.1. These are intended to be suggestions to aid and monitor the implementation of this guideline at the level of an NHS trust or similar scale healthcare provider.

Table 1: Audit criteria for key messages

Key message	Audit criterion	Exceptions	Definition
Patient-centred care			
1. The views and preferences of individuals with Type 1 diabetes should be integrated into their healthcare. Diabetes services should be organised, and staff trained, to allow and encourage this.	Method: Structured records should show evidence, for every individual with diabetes, that their agenda and views are being incorporated into agreed clinical decisions. Measure: Percent with such evidence within the previous 12 months.	None.	Structured record fields may show evidence of responses to open questions, the person's views on taking an agreed decision recorded, and/or the person's personal targets noted.
Multidisciplinary team approach			
2. The range of professional skills needed for delivery of optimal advice to adults with diabetes should be provided by a multidisciplinary team. Such a team should include members having specific training and interest to cover the following areas of care: <ul style="list-style-type: none"> ● education/information giving ● nutrition ● therapeutics ● identification and management of complications ● foot care ● counselling ● psychological care. 	The diabetes service should include, working together as a team, people with specific and maintained training in medical, educational, dietetic, and foot-care aspects of diabetes care. Method: Record whether each aspect is present. Measure: Percent with such evidence within the previous 12 months.	None.	The professional members of the care 'team' are the people who habitually work together to help individual people with diabetes. 'Training' means formal training where that exists for the healthcare professional type, or otherwise training by suitable experience with expert colleagues. 'Training' implies that continuing professional education is undertaken by all team members.

continued

Table 1: Audit criteria for key messages – continued

Key message	Audit criterion	Exceptions	Definition
Patient education			
3. Culturally appropriate education should be offered after diagnosis to all adults with Type 1 diabetes (and to those with significant input into the diabetes care of others). It should be repeated as requested and according to annual review of need. This should encompass the necessary understanding, motivation, and skills to manage appropriately: <ul style="list-style-type: none"> ● blood glucose control (insulin, self-monitoring, nutrition) ● arterial risk factors (blood lipids, blood pressure, smoking) ● late complications (feet, kidney, eye, heart). 	<p><i>Newly diagnosed</i> Method: The medical notes should record within the six months after diagnosis progress through a culturally-appropriate structured education programme designed for people with Type 1 diabetes and covering lifestyle and medical topics. Measure: Percent of records with such evidence. <i>Subsequent years</i> Method: The medical notes should record within the previous 14 months an assessment of agreed and culturally-appropriate educational needs, and delivery of education to meet those needs. Measure: Percent of records with such evidence.</p>	None.	An education programme is a structured activity involving health-care professional trained in the principles of adult education. 'Culturally appropriate' implies that attention is paid to beliefs, education attainment, desires, lifestyle, and language in devising and delivering the programme to the individual.
Blood glucose control			
4. Blood glucose control should be optimised towards attaining DCCT-harmonised HbA _{1c} targets for prevention of microvascular disease (7.5% or lower) and, in those at increased risk, arterial disease (6.5% or lower) as appropriate, while taking into account: <ul style="list-style-type: none"> ● the experiences and preferences of the insulin user, in order to avoid hypoglycaemia ● the necessity to seek advice from professionals knowledgeable of the range of available mealtime and basal insulins and of optimal combinations thereof, and their optimal use. 	<p><i>General glucose control</i> Method: The medical record should note those with Type 1 diabetes diagnosed longer than one year who have HbA_{1c} $\geq 7.5\%$ measured with a DCCT-harmonised assay, and recorded at last annual review within the previous 14 months or if no annual review at last regular review within 12 months. Measure: Percentage 7.5% or lower, with statistical trend to improvement in recent years or in best quartile when benchmarked against equivalent other services. <i>Hypoglycaemia</i> Method: Patient records should note episodes of severe hypoglycaemia. Measure: Percentage experiencing one or more episodes of severe hypoglycaemia within the last 12 months.</p>	People with haemoglobinopathies or abnormalities of erythrocyte turnover.	DCCT-harmonisation means traceability of the assay standardisation to NGSP reference standards (or to the IFCC standard, with adjustment to the DCCT norm), and participation in a national quality assurance scheme.

continued

Table 1: Audit criteria for key messages – continued

Key message	Audit criterion	Exceptions	Definition
<p>Arterial risk factor control</p> <p>5. Adults with Type 1 diabetes should be assessed for arterial risk at annual intervals. Those found to be at increased risk should be managed through appropriate interventions and regular review. Note should be taken of:</p> <ul style="list-style-type: none"> ● microalbuminuria, in particular ● the presence of features of the metabolic syndrome ● conventional risk factors (family history, abnormal lipid profile, raised blood pressure, smoking). 	<p>Assessment</p> <p>Method: The medical record should give a structured record of assessment of cardiovascular risk factors within the previous 14 months. Measure: Percentage of records with such records.</p> <p>Subsequent management</p> <p>Method: The medical record should plan for management where microalbuminuria diagnosed, smoker, LDL cholesterol >2.6 mmol/l, triglycerides >2.3 mmol/l, systolic or diastolic blood pressure >135/85 mmHg, and change in first degree family history of cardiovascular events, or any previous personal cardiovascular event or history. Measure: Percent with such plans.</p>	None.	Non-glucose cardiovascular risk factors include: abnormal albumin excretion rate (albumin/creatinine ratio or sometimes urinary albumin concentration), smoking, blood pressure, full lipid profile (including HDL and LDL cholesterol and triglycerides), age, family history of cardiovascular disease (CVD) and abdominal adiposity.
<p>Late complications</p> <p>6. Adults with Type 1 diabetes should be assessed for early markers and features of eye, kidney, nerve, foot, and arterial damage at annual intervals. According to assessed need, they should be offered appropriate interventions and/or referral in order to reduce the progression of such late complications into adverse health outcomes affecting quality of life.</p>	<p>Method: Medical record of people with Type 1 diabetes should record assessments of eye, kidney, nerve, foot, and arterial damage (all these) within the last 14 months. Measure: Percent with such assessment recorded.</p> <p>Method: Where evidence of eye, nerve, kidney or arterial damage is found, evidence of a plan for management of the condition within the medical record. Measure: Percent with such a plan recorded.</p>	A record of agreed none acceptance of surveillance by the person concerned.	<p>Eye surveillance by digital photography or examination by an ophthalmologist; kidney assessment is a measure of albumin excretion rate and serum creatinine; foot assessment includes skin condition (ulceration), sensation, foot pulses and deformity as minimum; arterial damage includes questioning on claudication, angina, and occurrence of cardiac arterial, cerebrovascular or limb arterial events. Retinal damage means any grade of retinopathy including macular change; kidney damage means albumin:creatinine ratio over 2.5 mg/mmol for men or 3.5 mg/mmol for women, or proteinuria, or creatinine >130 µmol/l; nerve</p>

continued

Table 1: Audit criteria for key messages – continued

Key message	Audit criterion	Exceptions	Definition
Late complications – continued	<p>Outcome measures</p> <p>Method: In people with Type 1 diabetes, prevalence of:</p> <ul style="list-style-type: none"> ● diabetes retinal damage ● abnormality of monofilament sensory detection ● abnormality of albumin excretion rate or serum creatinine ● absence of both pulses in at least one foot ● symptomatic angina ● claudication. <p>Measure: Statistically significant trend to improvement between years, or in best quartile when benchmarked against equivalent other services.</p>		<p>damage means abnormality of response to 10 g monofilament or non-traumatic pin prick (Neurotip); arterial damage means presence or experience of limb claudication, angina, cardiac vascular event, or cerebrovascular event (TIA or stroke).</p>