NHS

National Institute for Clinical Excellence

Guidance on the use of patient-education models for diabetes

Technology Appraisal 60

April 2003

This document has been circulated to the following:

- PCT Chief Executives
- NHS Trust Chief Executives in England and Wales
- Local Health Group General Managers
- Strategic Health Authority Chief Executives in England and Wales
- Medical Directors in England and Wales
- Nursing Directors in England and Wales
- Clinical Governance Leads in England and Wales
- Audit Leads in England and Wales
- NHS Trust, PCT and LHG libraries in England and Wales
- NHS Director Wales
- Chief Executive of the NHS in England
- Directors of Directorates of Health and Social Care in England and Wales
- Special Health Authority Chief Executives
- Community Health Councils in England and Wales
- Patient Advocacy Groups
- Commission for Health Improvement
- NHS Clinical Governance Support Team
- Chief Medical Officers, Nursing Officers and Pharmaceutical Officers in England and Wales
- Medical Director & Head of NHS Quality - Welsh Assembly Government
- GP Prescribing Advisors and Purchase Advisors in England and Wales
- Consultant Diabetologists in England and Wales
- Consultant Endocrinologists in England and Wales
- Representative bodies for health services, professional organisations and statutory bodies, Royal Colleges

This guidance is written in the following context:
This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

National Institute for Clinical Excellence

Contents

1 Guidance

1.1   It is recommended that structured patient education is made available to all people with diabetes at the time of initial diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need.

1.2   There is insufficient evidence currently available to recommend a specific type of education or provide guidance on the setting for, or frequency of, sessions. However, to achieve maximum effectiveness some principles of good practice are clear:

- educational interventions should reflect established principles of adult learning

- education should be provided by an appropriately trained multidisciplinary team to groups of people with diabetes, unless group work is considered unsuitable for an individual

- sessions should be accessible to the broadest range of people, taking into account culture, ethnicity, disability and geographical issues, and could be held either in the community or at a local diabetes centre

- educational programmes should use a variety of techniques to promote active learning (engaging individuals in the process of learning and relating the content of programmes to personal experience), adapted wherever possible to meet the different needs, personal choices and learning styles of people with diabetes, and should be integrated into routine diabetes care over the longer term.

1.3   Multidisciplinary teams providing education should include, as a minimum, a diabetes specialist nurse (or a practice nurse with experience in diabetes) who has knowledge of the principles of patient education and a dietitian. Although not formally assessed in this appraisal, input from other disciplines, such as podiatry, has potential value. The composition of the team and the way that members interact may vary between programmes, but team functioning should be tailored to the needs of different groups of people with diabetes.

1.4   It is considered that the Dose Adjustment for Normal Eating (DAFNE) programme may be a suitable option for individuals with type 1 diabetes, being one means of enabling people to self-manage this condition.

2 Clinical need and practice

2.1   Diabetes is a chronic metabolic disorder caused by defects in insulin secretion and action. There are two major types of diabetes: type 1 and type 2.

2.2   In type 1 diabetes, the pancreas makes little or no insulin because the islet b cells, which produce insulin, have been destroyed through an autoimmune mechanism. Therefore, people with type 1 diabetes depend on insulin injections to survive.

2.3   Type 2 diabetes results from failure of insulin production to overcome reduced tissue sensitivity to insulin (known as insulin resistance). Type 2 diabetes is a progressive disease in which insulin production declines as the disease progresses.

2.4   The age-standardised prevalence of diagnosed diabetes is estimated to be 2.23 per 100 males and 1.64 per 100 females. There are just over 1 million people in England and Wales with diagnosed diabetes. Of these, about 80% have type 2 diabetes (750,000 in England and 50,000 in Wales). The incidence of diabetes has been estimated at 1.7 new diagnoses per 1000 population per year (around 85,000 per year in England and 5000 per year in Wales).

2.5   An impaired insulin effect results in increased levels of glucose in the blood (hyperglycaemia) which can, if prolonged, cause microvascular and macrovascular damage. Common complications of diabetes include visual impairment, kidney failure, angina, myocardial infarction, stroke, foot ulceration and erectile dysfunction. People with diabetes can also suffer considerable anxiety relating to their condition, its management, and uncertainties about long-term outcomes.

2.6   Two large landmark studies, the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study, have demonstrated the beneficial effects of maintaining good glycaemic control on the development and progression of diabetic complications in type 1 and type 2 diabetes, respectively.

2.7   The principal goals of treatment are to prevent acute and late complications and thus improve quality of life and avoid premature diabetes-associated death. These goals may be achieved through better control of blood glucose levels and reductions in other macrovascular risk factors, including high blood pressure.

2.8 In the assessment of diabetes management, the most important outcome measures are:

- target blood glucose levels as measured by glycated haemoglobin (HbA$_1$ and HbA$_{1c}$), which give an indication of blood glucose control over the previous 2–3 months (lower values represent better glucose control); the target should reflect individual needs, but HbA$_{1c}$ levels of between 6.5% and 7.5% are generally recommended

- pre- and post-meal blood/plasma glucose levels

- the prevention of acute episodes of hypoglycaemia and hyperglycaemia

- a reduction in other macrovascular risk factors, such as dyslipidaemia, high blood pressure, smoking and obesity

- short-term quality of life, adverse events and treatment tolerance

- long-term effects on the incidence of diabetic complications, quality of life and mortality.

Other relevant outcomes for educational interventions include diabetes-related knowledge, motivation and improvement in anxiety or depression, although many of these outcomes have not been formally or consistently measured in trials undertaken to date.

2.9 Insulin is the mainstay of treatment for type 1 diabetes. Type 2 diabetes can usually be managed through diet and exercise alone, at least in the early stages. However, it is a progressive disease, and nearly all individuals require oral antidiabetic drugs after some time. Many people with type 2 diabetes eventually need insulin to maintain satisfactory blood glucose levels. Current treatment guidelines recommend a 'step-up' policy, starting with advice on diet and exercise, adding oral antidiabetic agents, first as monotherapy and then in combination, and finally using insulin if blood glucose control deteriorates.

3 The technology

3.1   Education is considered to be a fundamental part of diabetes care. People with diabetes, whether they are using insulin or other means of achieving glycaemic control, have to assume responsibility for the day-to-day control of their condition. It is therefore critical that they understand the condition and know how to treat it, whether this is through an appreciation of the basis of insulin replacement therapy and its optimal use, or through lifestyle management, including nutrition and physical activity. The aim of education for people with diabetes is to improve their knowledge and skills, enabling them to take control of their own condition and to integrate self-management into their daily lives. The ultimate goal of education is improvement in the following areas:

- control of vascular risk factors, including blood glucose, blood lipids and blood pressure

- management of diabetes-associated complications, if and when they develop

- quality of life.

3.2   The National Service Framework for Diabetes proposes a 'supported self care service model' for diabetes and recognises the importance of education in facilitating self-management as the cornerstone of diabetes care. The expert patient programme initiative, which is now being piloted in over 50 primary care trusts and as yet has not been evaluated, involves the introduction and evaluation of self-management training programmes for people living with long-term medical conditions, including diabetes. The programmes are lay-led and focus on areas such as developing individuals' confidence to access services, and are therefore complementary to and not an alternative to diabetes education.

3.3   Most people with diabetes in England and Wales are offered education, at least at the time of their diagnosis. However, the length, content and style of educational options varies greatly between services; some of the educational programmes offered are unstructured, very few have been formally evaluated, and few individuals who deliver education have been formally trained for this purpose.

3.4 Dose Adjustment for Normal Eating (DAFNE) is a structured educational programme for people with type 1 diabetes that teaches individuals to adjust their insulin to match carbohydrate intake and lifestyle on a meal-by-meal basis, thereby allowing enhanced dietary freedom. It is currently available in a number of diabetes centres across England as part of a national evaluation project. The programme consists of 5 days of intensive training delivered to groups of six to eight individuals on an outpatient basis. The programme is based on the Diabetes Treatment and Teaching Programmes, developed in Europe in the 1970s, and often referred to as the Geneva-Düsseldorf model of education. In the context of this appraisal, DAFNE was recognised as being both a treatment and an educational package.

3.5 The cost of patient education for diabetes depends on the type of programme offered. Current estimates of cost range from £66 per person attending a diabetes centre-based teaching programme spread over three afternoons, to £545 for DAFNE.

4 Evidence and interpretation

The Appraisal Committee (Appendix A) considered evidence from a number of sources (Appendix B).

4.1 Clinical effectiveness

4.1.1 Education for people with type 1 diabetes

4.1.1.1 Four studies were found: two randomised controlled trials (RCTs) and two controlled clinical trials (CCTs). Three of the studies tested the effect of intensified insulin treatment that included an educational component, and the other assessed the effect of education alone. The aim of intensified insulin treatment was to help individuals learn how to self-treat with generally more frequent insulin doses that were specifically related to variations in energy consumption and demand. The two CCTs were based on the Geneva-Düsseldorf model of patient education.

4.1.1.2 The RCT that tested education alone showed no significant difference in glycated haemoglobin HbA_1, although the trial was very small (n = 37). The second RCT, the Swedish Diabetes Intervention Study (SDIS), showed a significant

difference in HbA_{1c} between groups after the 7.5-year study period and at 10-year follow-up. HbA_{1c} levels in the intensified treatment group at 7.5 and 10 years were 2.4% and 2.3% lower, respectively, than at the start of the study; in the control group, the mean HbA_{1c} values had decreased by 0.9% and 1.1% after 7.5 and 10 years, respectively. To put this in context, a 0.5% reduction in HbA_{1c} can reduce long-term complications by 15–20%. The intensive insulin groups in the two CCTs had lower levels of HbA_1 at the end of the studies compared with control groups (9.3% vs 12.8%, $p < 0.01$; 9.4% vs 12.3%, no p value provided).

4.1.1.3   There is evidence from these studies that severe hypoglycaemic events may be more frequent among people receiving intensified treatment, although there were fewer incidents of ketoacidosis and hospitalisation among this group. Longer-term complications were reported in the SDIS study: the group using intensified insulin treatment experienced fewer cases of retinopathy, nephropathy and neuropathy at the end of the study (though for neuropathy the difference was not significant). Knowledge of diabetes was assessed in the two CCTs using a questionnaire that rated knowledge on a scale of 0–37, and was found to be higher in the intervention groups at the end of the studies (32 vs 24, $p < 0.01$; 25 vs 11, p value not provided). While increased knowledge of diabetes may reflect an improved ability to self-manage, there is little evidence that knowledge alone predicts better metabolic outcomes.

4.1.1.4   The study of DAFNE in the UK (see Section 3.4) did not meet the inclusion criteria for the Assessment Group's systematic review as there was a concurrent control group only for the first 6 months, after which time the members attended a 'delayed DAFNE' training course. The results of the study show that HbA_{1c} levels fell by 1% in the first 6 months in the initial DAFNE group, and remained 0.5% lower than baseline at 12 months ($p = 0.004$). HbA_{1c} levels in the control group remained constant for the first 6 months but were 0.7% lower than baseline at 12 months (that is, 6 months after the group had attended the DAFNE training course). There was no evidence to suggest that improved glycaemic control was achieved at the expense of an increase in episodes of severe hypoglycaemia. However, it should be noted that one participant in the DAFNE group was 'found dead in bed' 6 months after the course; such deaths are usually assumed to relate to a hypoglycaemic event. Quality of life improved significantly after DAFNE training, with 77% of patients recording an improvement in wellbeing and 95% recording an improvement in treatment satisfaction.

4.1.1.5   In summary, only one study of a purely educational intervention was found and this did not demonstrate any beneficial effects of education, although the sample size was very small. The other three studies reviewed, and the results from the DAFNE study, suggest that intensive insulin treatment is effective in reducing HbA_{1c} and complications, both in the short and long term, albeit at the possible expense of increased hypoglycaemic episodes in some individuals.

4.1.2   General self-management education for type 2 diabetes

4.1.2.1   Eight trials – six RCTs and two CCTs – were found that focused on educating individuals on a wide range of components of self-management for type 2 diabetes.

4.1.2.2   Only three of the studies, all RCTs, reported significant differences in HbA_{1c} levels between the intervention and control groups, with education either reducing or preventing a worsening in HbA_{1c} levels. These three studies involved education delivered over a long period, and had the shortest time between the end of the intervention and follow-up; this overall pattern of results suggests that effects may not be long lasting, that education should be delivered over long intervals, or both.

4.1.2.3   Significant differences in body mass index (BMI) or weight loss in favour of the education group were reported in four studies. Both CCTs reported significant differences in the use of medications, with fewer people in the education group receiving insulin or hypoglycaemic drugs at the end of the studies. Few studies recorded outcomes reflecting diabetic endpoints, and those that did showed no significant differences, although follow-up periods were too short to obtain meaningful results. Only one study reported on quality of life using a validated scale; here, quality of life was found to improve in the education group but to deteriorate in the control group. Three studies reported results for diabetes knowledge, and two of these demonstrated significantly better knowledge in the intervention groups.

4.1.2.4   In summary, the evidence suggests that general self-management education has a limited impact on clinical outcomes, although few long-term data were available. The effect of education on glycaemic control was more evident for longer-term interventions with shorter follow-up periods.

4.1.3 Focused self-management education for people with type 2 diabetes

4.1.3.1 Eight trials were found – seven RCTs and one CCT – that focused on one or two aspects of self-management (for example, diet and/or exercise). One RCT compared a diet intervention with a weight-loss intervention; as there were no differences in outcomes between the groups it was not discussed further in the Assessment Report.

4.1.3.2 Two trials combining exercise with dietary education reported significant differences in HbA_{1c} levels compared with controls ($p < 0.05$ in both); in one trial, this effect was relatively long lasting (18 months). One other study combining dietary education with exercise found a significant difference in the percentage of people with $HbA_{1c} \leq 7.0\%$ in favour of the intervention group ($p < 0.05$).

4.1.3.3 For the studies that reported them, no significant differences were found in the outcomes of blood pressure (except in the CCT), BMI or weight, or cholesterol and triglyceride levels. One study reported significantly fewer individuals taking glucose-lowering drugs in the intervention group, whereas another study reported no significant decreases in medication use between individuals educated in weight control and those educated in self-monitoring. Only one study reported on quality of life using a validated measure, and showed significantly better quality of life in the group taking exercise and receiving dietary education ($p < 0.05$).

4.1.3.4 In summary, the evidence suggests that focused self-management education may have some effect in reducing or maintaining HbA_{1c} levels, but there is little evidence of impact on other clinical outcomes, partly because of short study durations.

4.1.4 Education for people with type 1 or type 2 diabetes

4.1.4.1 Four trials of educational interventions – three RCTs and one CCT – were found that included people with type 1 or type 2 diabetes.

4.1.4.2 Two studies reported significantly lower HbA_{1c} levels in the education groups compared with controls at the end of the study. However, there were no significant differences between the different education groups in either of these studies (intensive group education vs passive education through provision of written materials; education vs education plus social support).

4.1.4.3 One study focused on diet and reported no significant differences in BMI, although cholesterol levels were significantly lower in the education group. The other studies did not report on other clinical outcomes. Only one study reported on quality of life using a validated measure, and this showed significant improvements in a group receiving education and social support compared with an education-only group and a usual care group. Knowledge of diabetes was assessed in two studies, and both suggested that interventions (education in one study, education and support in the other) significantly improved knowledge scores.

4.1.4.4 In summary, the results of these studies are similar to those reporting results for type 1 and type 2 diabetes separately. There is some evidence to suggest that education may improve glycaemic control and quality of life, but little evidence about the longer-term benefits of education.

4.2 Cost effectiveness

4.2.1 Two published economic evaluations were found; both were from the USA and both were limited in their applicability and generalisability. The DAFNE Study Group submission included a detailed cost–utility analysis of DAFNE. The Assessment Group did not develop their own cost-effectiveness model but re-analysed the DAFNE model using more conservative assumptions.

4.2.2 Of the published evaluations, one found that a behavioural intervention addressing diet plus exercise was more cost effective than a general educational intervention in adults with type 2 diabetes, with significant improvements in quality of life at a cost of $10,870 per well year (calculated at 1986 prices). The other evaluation found that dietary self-management improved intermediate health outcomes (dietary fat consumption, saturated fat consumption, serum cholesterol) compared with usual care in adults with both type 1 and type 2 diabetes at a cost of US$137 per participant.

4.2.3 The DAFNE cost–utility analysis compares DAFNE with conventional treatment in people with type 1 diabetes over a 10-year period. Improved metabolic control, as measured by HbA_{1c}, is assumed to delay the onset of microvascular complications, but is conservatively assumed to have no effect on macrovascular disease. HbA_{1c} levels are based on European trial data and are assumed to reduce by 0.9% with DAFNE and to be sustained over a 4-year period, reducing to 0.26% thereafter; these results are better than those seen in the UK DAFNE study. Utility values are based on those from

the CODE-2 study of people with type 2 diabetes and are adjusted for patient characteristics and complications. However, the validity of extrapolating utility values from people with type 2 diabetes to those with type 1 diabetes is uncertain.

4.2.4   The results of the model suggest that DAFNE dominates conventional treatment (that is, it is associated with more quality-adjusted life years [QALYs, 0.11] and a net cost saving over 10 years [£2679]). DAFNE becomes cost saving after 4 years, and the results are robust to the sensitivity analyses undertaken.

4.2.5   The Assessment Group re-analysed the DAFNE model using more conservative assumptions, including: no effect of DAFNE on ketoacidosis; no difference in outpatient reviews; initial reduction in HbA_{1c} of 0.53%; reduced annual probability of progression to end-stage renal disease; and reduced annual probability of first amputation. On the basis of these assumptions, DAFNE still dominates conventional treatment, but the net benefits (0.063 QALYs) and net cost savings (£536) are reduced.

4.2.6   In summary DAFNE, and the intensified insulin treatment it inherently involves, appears to be cost effective. There is very little evidence regarding the cost effectiveness of patient education in general but, given the relatively small costs associated with educational programmes, only small improvements in terms of morbidity or health-related quality of life are needed to make educational interventions cost effective.

4.3 Consideration of the evidence

4.3.1   The Committee reviewed the evidence available on the clinical and cost effectiveness of patient-education models for diabetes, having considered evidence on the nature of the condition and the value placed by users on the benefits of educational opportunities from people with diabetes, those who represent them, and clinical experts. It was also mindful of the need to take account of the efficient use of NHS resources.

4.3.2   Whilst it is recognised that much work has been carried out researching educational principles and theory, considering such evidence was outside the scope of this appraisal. Similarly, education for family and carers is recognised as being important, but was not considered as part of this appraisal.

4.3.3   The Committee noted that many of the reviewed studies had practical limitations, were underpowered, and rarely met the standards for high-quality RCTs. Length of follow-up was generally too short to detect differences in the rates of diabetic complications, and the number of withdrawals was high in many studies. The majority of studies were carried out in white British or North American populations, and there were few trials in other ethnic groups. The Committee also noted the significant number of trials that did not meet the inclusion criteria for this appraisal but that have been included in other published systematic reviews. Many of these trials did not include a control group or did not impose a requirement for long-term follow-up. In addition, the Committee noted the lack of published evidence regarding the cost effectiveness of patient-education models for diabetes and, in particular, the lack of quality-of-life information available.

4.3.4   Despite the limitations of the studies, the Committee was convinced of the importance of patient education in improving glycaemic control and quality of life, while reducing the rate of complications associated with diabetes. The Committee also recognised that, given the relatively small costs of education, only small improvements in terms of morbidity or quality of life would be needed to make educational programmes cost effective.

4.3.5   After considering the evidence available, the Committee concluded that all individuals with diabetes should be offered structured patient education at the time of initial diagnosis and ongoing patient education as required, based on a formal, regular assessment of need, recognising that needs change over time. In this context, structured patient education is defined as being a planned and graded programme that is comprehensive in scope, flexible in content, responsive to an individual's clinical and psychological needs, and adaptable to his or her educational and cultural background. However, the Committee also noted the importance of informal education and support provided by health professionals as part of an individual's continuing treatment and care, which reinforces and enables learning over time.

4.3.6   The Committee noted that changes in outcomes from educational programmes cannot be measured in isolation from changes in other variables. The Committee also noted that the lack of a consistent relationship between outcomes and type, length and frequency of intervention, team composition and setting, particularly in studies involving

people with type 2 diabetes, made it difficult to identify the characteristics that would make an educational programme successful. It was therefore unable to provide recommendations on specific approaches to education. However, the Committee was convinced by the anecdotal evidence supporting:

• the use of established principles of adult education

• a multidisciplinary approach to education, with teams including, as a minimum, a diabetes specialist nurse (or a practice nurse with experience in diabetes) and a dietitian, and with appropriate training provided to the educators

• the use of group education sessions, which enable individuals to support one another and which are generally less costly and allow staff to use time devoted to patient education more efficiently

• the provision of educational opportunities that are accessible to the broadest range of people taking into account culture, ethnicity, disability and geographical issues, and which could be held either in the community or at a local diabetes centre

• the value of educational programmes based on a variety of learning techniques, adapted to meet the varying needs of people with diabetes and integrated into routine diabetes care over the longer term.

In order to determine the characteristics that would maximise the impact of patient education, further evaluation in clinical trials and qualitative studies is recommended.

4.3.7 The Committee considered the DAFNE programme to be one means by which people with type 1 diabetes can manage their condition, and to be particularly useful for those people in whom a multiple dose insulin regimen is being used or considered. Although the DAFNE study did not meet the inclusion criteria for the systematic review, the Committee noted that the study was specifically designed to test the feasibility of introducing the Geneva-Düsseldorf model of education into the UK setting. As such, the DAFNE study meets the good practice criteria set out by the Medical Research Council for the evaluation of complex interventions.

5 Further research

5.1   The DAFNE evaluation has been expanded and extended for a further 12 months to include seven more centres and up to 1000 more participants, with the aim of learning more about implementation issues across the NHS. Work is also underway to develop new DAFNE programmes for children with type 1 diabetes and for adults with type 2 diabetes. Such programmes should be evaluated in well-designed clinical trials with long follow-up intervals.

5.2   Further evaluation should be undertaken of other available models of education for people with type 1 diabetes. Such programmes, as with DAFNE, should also be evaluated in well-designed clinical trials.

5.3   The paucity of high-quality trials of the effectiveness of patient-education models for diabetes, particularly those for people with type 2 diabetes, reveals a need for more research. Further research should involve RCTs with designs based on explicit hypotheses and educational theory, and include a range of outcomes evaluated after long follow-up intervals. Studies should aim to determine the characteristics, in terms of type, length and frequency of intervention, team composition and setting, that would maximise the impact of patient education in both the short and longer term. Such studies should also include qualitative evaluation of the educational intervention itself, and research to identify the characteristics of education that are most important for different stages of the disease, and that best match different cultural and social needs. Such research is inherently complex and may require collaboration between different disciplines.

6 Implications for the NHS

6.1   Successful implementation of structured educational programmes will depend on the availability of an appropriately trained workforce. Evidence submitted to the Committee suggests that there is a shortage of both diabetes specialist nurses and dietitians. There is a need for rigorous, ongoing training for all educators in the principles of both diabetes and education, and educators should be accredited by a nationally recognised procedure. While some accredited training programmes exist, others will need to be developed. To enable future developments in patient education to be fully evaluated, trusts need to establish robust audit and quality-assurance processes.

6.2   The impact of patient education for diabetes on the NHS budget will depend on the incidence and prevalence of diabetes in the target population and the cost of the educational programme offered. For type 2 diabetes, the impact of this guidance will vary at a local level depending on the extent to which structured education programmes are already available. Although significant, and increasing, numbers of people are eligible for education, the cost of providing education may be offset by reduced healthcare costs brought about by improved glycaemic control.

6.3   For type 1 diabetes, the impact of this guidance will depend to a large extent on the uptake of the DAFNE programme.

6.3.1   In the submission from the DAFNE study group, it is estimated that 113,500 and 6700 people with type 1 diabetes in England and Wales, respectively, would be suitable for DAFNE, with a further 5513 newly diagnosed patients in England and 324 in Wales becoming eligible each year. These figures are based on the following assumptions:

• a prevalence rate of type 1 diabetes of 0.366 per 100 people and an incidence rate of 0.017 per 100 people

• 80% of people with type 1 diabetes being suitable for DAFNE

• an adult population of 38.7 million and 2.3 million in England and Wales, respectively.

6.3.2   The budget impact calculation also makes the following assumptions:

• the 'stock' of eligible people will be trained within 10 years, although there is no provision for follow-up training

• each of the ten existing DAFNE centres can train a further 1.5 new centres each year

• each centre trains 120 patients per year

• each centre costs £64,500 per year to run, with an initial capital investment of £9000 which includes the costs of staff training.

6.3.3   The results from the DAFNE study group suggest that, in England,160 centres could be established by 2005 to train those people who are currently eligible, with 46 centres required from 2014 to maintain a steady state of provision. The maximum cumulative capital required would be £19 million in 2006/07. The roll out would be self-financing by 2009 and potentially could generate savings in subsequent years. In Wales, nine centres could be established by 2006 to train those people who are currently eligible, with three centres required from 2015 to maintain a steady state. The maximum cumulative capital required would be £1 million in 2007/08. The roll out would be self-financing by 2010 and potentially could generate savings in subsequent years. However, it is unlikely that such savings would be realised in terms of 'cash' for two reasons: the estimates represent amounts of resources that would remain within the system (but might nevertheless be redeployed); and the estimates are based on average costs (for example, of days in hospital avoided), some of which are fixed costs and therefore will not be saved.

7 Implementation and audit

7.1   NHS organisations and all clinicians who provide care for people with diabetes, including general practitioners, practice nurses, consultants treating people with diabetes, diabetes specialist nurses and dietitians, should review local practice and policies regarding education for people with diabetes to take account of the guidance set out in Section 1.

7.2   Local guidelines or care pathways that refer to the care of people with diabetes should incorporate the guidance in Section 1.

7.3   NHS trusts, primary care organisations and general practices should ensure that responsibility is clearly defined for offering and providing educational programmes for people with diabetes and for considering referral to the DAFNE programme as one option for people with type 1 diabetes.

7.4   Arrangements should be made in NHS organisations for:

- multidisciplinary teams, including at least a diabetes specialist nurse (or a practice nurse with experience in diabetes) who has a knowledge of the principles of patient education and a dietitian, to be available to provide structured education for people with diabetes

- the teams to receive appropriate training
  - in the use of a variety of techniques to promote active learning to meet the different needs, personal choices and learning styles of people with diabetes
  - in the formal, regular assessment of individuals' learning needs

- sessions to be provided to groups of individuals in accessible locations.

7.5   To measure compliance locally with the guidance, the following criteria can be used. Further details on suggestions for audit are presented in Appendix D.

7.5.1   People initially diagnosed with diabetes are offered structured education that is:

- provided by an appropriately trained multidisciplinary team

- provided to groups of people with diabetes, unless group work is considered unsuitable for an individual

- held in a location accessible to individuals who want to participate.

7.5.2   People with diabetes are assessed formally and regularly for their needs for education on managing diabetes, and further structured education is offered to meet those needs.

7.5.3   The DAFNE programme is considered an option for people with type 1 diabetes.

7.6   Local clinical audits on the care of people with diabetes could also include criteria for the management of diabetes based on the standards in the National Service Framework for Diabetes.

8 Related guidance

8.1   The Institute has issued guidance on the use of rosiglitazone, pioglitazone and long-acting insulin analogues for diabetes. All issued guidance and details of appraisals and guidelines in progress are available on the NICE website (www.nice.org.uk).

- National Institute for Clinical Excellence (2000) Guidance on rosiglitazone for type 2 diabetes mellitus. *NICE Technology Appraisal Guidance* No. 9. London: National Institute for Clinical Excellence.

- National Institute for Clinical Excellence (2001) Guidance on the use of pioglitazone for type 2 diabetes mellitus. *NICE Technology Appraisal Guidance* No. 21. London: National Institute for Clinical Excellence.

- National Institute for Clinical Excellence (2002) Guidance on the use of long-acting insulin analogues for the treatment of diabetes – insulin glargine. *NICE Technology Appraisal Guidance* No. 53. London: National Institute for Clinical Excellence.

8.2   The Institute is also publishing a series of guidelines on the management of type 2 diabetes.

- National Institute for Clinical Excellence (2002) Management of type 2 diabetes: retinopathy – screening and early management. *Inherited Clinical Guideline* E. London: National Institute for Clinical Excellence.

- National Institute for Clinical Excellence (2002) Management of type 2 diabetes: renal disease – prevention and early management. *Inherited Clinical Guideline* F. London: National Institute for Clinical Excellence.

- National Institute for Clinical Excellence (2002) Management of type 2 diabetes: management of blood glucose. *Inherited Clinical Guideline* G. London: National Institute for Clinical Excellence.

- National Institute for Clinical Excellence (2002) Management of type 2 diabetes: management of blood pressure and blood lipids. *Inherited Guideline* H. London: National Institute for Clinical Excellence.

8.3   The following technology appraisals and clinical guidelines are part of the Institute's ongoing work programme.

- Technology appraisal on insulin pumps: due to be issued early 2003.

- Technology appraisal review on glitazones: due to be issued early 2003.

- Clinical guideline on management of type 2 diabetes: foot care (update of an existing guideline published by the Royal College of General Practitioners): due to be issued late 2003.

- Clinical guideline on type 1 diabetes: diagnosis and management of type 1 diabetes in primary and secondary care: due to be issued early 2004.

9 Proposed date for review of guidance

9.1   The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.

9.2   The guidance on this technology will be reviewed in February 2006.

Andrew Dillon
Chief Executive
April 2003

Appendix A

Appraisal Committee members

> **NOTE** The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month other than in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and topics are not moved between the branches.
>
> Committee members are asked to declare any interests in the technology to be appraised. If there is a conflict of interest, the member is excluded from participating further in that appraisal.
>
> The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declaration of interests, are posted on the NICE website.

Dr Jane Adam
Radiologist, St George's Hospital, London

Dr Sunil Angris
General Practitioner, Waterhouses Medical Practice, Staffordshire

Dr Darren Ashcroft
Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical sciences, University of Manchester

Professor David Barnett (Chair)
Professor of Clinical Pharmacology, University of Leicester

Professor Mike Campbell
Statistician, Institute of General Practice & Primary Care, Sheffield

Dr Mike Davies
Consultant Physician, University Department of Medicine & Metabolism, Manchester Royal Infirmary

Dr Cam Donaldson
PPP Foundation Professor of Health Economics, School of Population and Health Sciences & Business School, Business School – Economics, University of Newcastle upon Tyne

Professor Jack Dowie
Health Economist, London School of Hygiene

Dr Paul Ewings
Statistician, Taunton & Somerset NHS Trust, Taunton

Professor Trisha Greenhalgh
Professor of Primary Health Care, University College London

Miss Linda Hands
Clinical Reader in Surgery, University of Oxford

Professor Philip Home
Professor of Diabetes Medicine, University of Newcastle upon Tyne

Ms Ruth Lesirge
Lay Representative, previously Director, Mental Health Foundation, London

Dr George Levvy
Lay Representative, Chief Executive, Motor Neurone Disease Association, Northampton

Dr Gill Morgan
Chief Executive, NHS Confederation, London

Professor Philip Routledge
Professor of Clinical Pharmacology, College of Medicine, University of Wales, Cardiff

Dr Stephen Saltissi
Consultant Cardiologist, Royal Liverpool University Hospital

Professor Andrew Stevens (Vice-Chair)
Professor of Public Health, University of Birmingham

Professor Mary Watkins
Professor of Nursing, University of Plymouth

Dr Norman Waugh
Senior Lecturer and Public Health Consultant, University of Southampton

Appendix B

Sources of evidence considered by the Committee

The following documentation and opinions were made available to the Committee:

A   **Assessment Report** Rapid Reviews Team, Southampton Health Technology Assessment Centre, University of Southampton: *Patient education models for diabetes,* August 2002

B   The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, assessment report and the appraisal consultation document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination.

I. Manufacturer/sponsors:
- DAFNE study group

II Professional/specialist and patient/carer groups:
- Association of Diabetes Specialist Nurses
- British Dietetic Association
- British Geriatrics Society
- Diabetes UK
- Department of Health and Welsh Assembly Government
- Long Term Medical Conditions Alliance
- National Collaborating Centre for Chronic Conditions
- NHS Quality Improvement Scotland
- Primary Care Collaborating Centre, ScHARR, University of Sheffield
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians (on behalf of Royal College of Physicians, the Specialist Care Section of Diabetes UK, and the Association of British Clinical Diabetologists)
- Society of Chiropodists and Podiatrists

C   The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on the clinical effectiveness and cost effectiveness of glitazones for the treatment of type 2 diabetes by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the ACD.

- Dr Helen Cooper, Lecturer in Health Care Education, Liverpool University
- Dr John Day, Consultant Physician Emeritus, The Ipswich Hospital NHS Trust
- Two people with diabetes from Diabetes UK
- Dr Wendy Gatling, Consultant Physician, Poole Hospital NHS Trust
- A person with diabetes from Avon Health Authority
- Mr Simon O'Neill, Patient Advocate, Head of Care Developments, Diabetes UK

Appendix C

Patient-education models for diabetes

Understanding NICE guidance - information for people with diabetes and the public

The information in this appendix has been designed to support the production of your own information leaflets. You can download it from our website at www.nice.org.uk where it is available in English and Welsh. If you would like printed copies of the leaflets please ring the NHS Response Line on 0870 1555 455 and quote reference number N0215 for the English version and N0216 for the version in English and Welsh.

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance for both the NHS and patients on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures and under what circumstances they should be used.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance. Each appraisal takes about 12 months to complete.

NICE was asked to look at the available evidence on patient-education models for diabetes, which are designed to help people with diabetes manage their condition from day to day. NICE was asked to provide guidance that will help the NHS in England and Wales decide whether such patient-education models should be used.

What is diabetes?

Diabetes is a condition in which the body does not produce enough insulin, or produces insulin but can't use it properly. Insulin is a substance that controls the amount of glucose (sugar) in the blood. If there isn't enough insulin or it isn't having the proper effect, the level of glucose in the blood increases and this can have harmful effects. There are two types of diabetes: type 1 and type 2.

Type 1 diabetes occurs when there is a severe lack of insulin in the body because most or all of the insulin-producing cells in the pancreas (the organ that produces insulin) have been destroyed. This type of diabetes usually appears in people aged under 40, often during childhood. People with type 1 diabetes need daily insulin injections and also have to be careful about their diet.

Type 2 diabetes develops when the pancreas can make some, but not enough, insulin or the insulin doesn't work properly (this is also known as insulin resistance). This type of diabetes usually appears in people over the age of 40. People with type 2 diabetes usually start to manage their glucose levels by making changes to their diet and lifestyle. But many people with type 2 diabetes eventually have to start taking one or more medicine and may need to use insulin.

What are patient-education models for diabetes?

People with diabetes have to make sure their condition is properly managed all the time. This is true, whether or not they are using insulin or glucose-lowering medicines. So they need to understand diabetes and know how to treat it. This includes knowing about the effect of lifestyle, including diet and exercise, on their condition, and when relevant the way insulin is used. Educating people with diabetes about their condition and its treatment helps them to manage it better and more conveniently, and so helps them to avoid other health problems related to diabetes and to lead fuller, more enjoyable lives.

The DAFNE (short for Dose Adjustment For Normal Eating) training course is one example a patient-education model for people with type 1 diabetes. A DAFNE course lasts 5 days and teaches groups of people to tailor their insulin doses according to the amount of starchy foods they eat and their lifestyle. DAFNE is a 'structured' programme. A 'structured' programme is one that is planned and that covers all the important topics and can also be adapted to each person's needs, education and culture.

What has NICE recommended?

NICE has recommended that all people with diabetes should be offered structured education, provided by a trained specialist team of health professionals. NICE considers the team should include a diabetes specialist nurse (or a GP practice nurse who has experience in diabetes) and a dietitian (someone who can give specialist advice on diet). Other health professionals should join the team if needed.

Education about diabetes should start when people are first told they have the condition and should then become part of their long-term routine care.

NICE concluded that there was not enough evidence available to make recommendations about specific types of education. But NICE does offer the following general advice.

• People with diabetes generally should be taught in groups, although one-to-one teaching should also be available.

• Teaching sessions should use a variety of different methods to help people learn.

• Educational programmes should meet the needs of the broadest possible range of people with diabetes. People from different cultures and ethnic groups, and those who have disabilities or who live in more remote areas, all need to be considered. Sessions could take place either in the community or at a local diabetes centre.

The Dose Adjustment for Normal Eating (DAFNE) course may be one suitable education programme for people with type 1 diabetes.

What should I do?

If you or someone you care for has diabetes, you should discuss this guidance with your doctor.

Will NICE review its guidance?

Yes. The guidance will be reviewed in February 2006.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on patient-education models for diabetes that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0213. If you would like to read the NICE guidance on patient-education models for diabetes, you can request it from the NHS Response Line by quoting reference N0215 for the patient version.

If you have access to the Internet, you can find more information about diabetes on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 08 45 46 47.

Appendix D

Detail on criteria for audit of the use of patient-education models for diabetes

Possible objectives for an audit

An audit on patient education for diabetes could be carried out to ensure that structured education is offered to all people with diabetes.

Possible people to be included in an audit

An audit could be carried out on any or all of the following groups:

- all people who are newly diagnosed with diabetes in a given time period (for example, in the last 6 months or 1 year)

- a reasonable sample of people who have been previously diagnosed with diabetes; for example, 10% or 25% of people stratified by age group, either in a general practice or in a diabetes service offered by a specialist consultant or diabetes specialist nurse, who have had the diagnosis of diabetes for a specified time period (for example, 6 months or 1 year)

- all people with type 1 diabetes currently registered in a general practice or being seen by a consultant specialising in diabetes.

Measures that could be used as a basis for audit

The measure that could be used in an audit of education for people who are newly diagnosed with diabetes is as follows.

Criterion	Standard	Exception	Definition of terms
1. The person is offered structured education that is consistent with all of the following:	100% of people newly diagnosed with diabetes	A. For 1b, group work is considered unsuitable for an individual	For audit purposes, teams will have to agree locally on the following:
a. provided by an appropriately trained multidisciplinary team			• what constitutes structured education
b. provided to a group of people with diabetes			• how the offer of education is documented
c. held in a location that is accessible to the individuals involved			• the individuals for whom it is considered that group work is unsuitable
			• how the accessibility of location for providing education is to be measured.
			A multidisciplinary team is defined as a minimum of a diabetes specialist nurse (or a practice nurse with experience in diabetes) who has knowledge of the principles of patient education and a dietitian

The measures that could be used in an audit of education for people who have previously been diagnosed with diabetes are as follows.

Criterion	Standard	Exception	Definition of terms
1. The person is assessed formally and regularly for his or her needs for education on managing diabetes	100% of people who have an established diagnosis of diabetes	None	For audit purposes, teams will have to agree locally on what constitutes a formal assessment of a person's needs for education and how regularly the assessment is to be carried out
2. The person is offered further structured education to meet his or her identified educational needs	100% of people who have an established diagnosis of diabetes	A. Formal, regular assessment has not identified any need for further structured education	See 1 above for definition of terms for audit purposes

The measure that could be used in an audit of education for people with type 1 diabetes is as follows.

Criterion	Standard	Exception	Definition of terms
1. The person is considered for referral to a DAFNE programme	100% of people with type 1 diabetes	A. The person is unable to participate in the programme B. There is no DAFNE programme currently available in the area C. A suitable alternative programme has been selected	For audit purposes, teams will have to agree locally on how consideration for referral to a DAFNE programme is documented

Calculation of compliance with the measures

Compliance (%) with each measure described in the tables above is calculated as follows.

$$\frac{\text{Number of people whose care is consistent with the criterion } \textit{plus} \text{ the number of people who meet any exception listed}}{\text{Number of patients to whom the measure applies}} \times 100$$

Clinicians should review the findings of measurement, identify whether practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.