An Roinn Sláinte
Department of Health

Adult type 1 diabetes mellitus

National Clinical Guideline No. 17

Annex 2: Budget impact analysis

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

HRB Health Research Board

CICER Collaboration in Ireland for Clinical Effectiveness Reviews

Membership of the Evaluation Team

The members of the Health Research Board-Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER) and Health Information and Quality Authority (HIQA) Evaluation Team were: Mr Paul Carty, Ms Michelle O'Neill, Dr Patricia Harrington and Professor Susan Smith.

About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, the Health Information and Quality Authority (HIQA) was awarded the contract for the five-year period from 2017 to 2022. The HRB-CICER team comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups, of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the guideline development groups; provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

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Membership of the Evaluation Team

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List of abbreviations that appear in this report

BIA	Budget impact analysis
CPI	Consumer Price Index
CSO	Central Statistics Office
CUA	Cost utility analysis
DAFNE	Dose Adjusted for Normal Eating
DDP	DAFNE Doctor Programme
DEP	DAFNE Educator Programme
DKA	Diabetic ketoacidosis
DRG	Disease-related group
FSL	Free Style Libre
GDG	Guideline development group
HIQA	Health Information and Quality Authority
HRB-CICER	Health Research Board-Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
HTA	Health technology assessment
HTAG	Health Technology Assessment Group
ICD	International Statistical Classification of Diseases and Related Health Problems
ICER	Incremental cost-effectiveness ratio
IT	Information technology
LTI	Long-term illness scheme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPH	Neutral protamine Hagedorn
PCRS	Primary Care Reimbursement Service
QALY	Quality-adjusted life year
RCT	Randomised-controlled trials
PCRS	Primary Care Reimbursement Service
SMBG	Standard monitoring of blood glucose

1. Introduction

1.1 Scope of work

The completion of a budget impact analysis (BIA) is a required step in the development of National Clinical Guidelines in Ireland.[1] A BIA addresses the expected changes in the expenditure of a healthcare system after the adoption of a new intervention. In the context of guideline development, the purpose of the BIA is to quantify the resource implications of the recommendations. That is, to estimate the additional resources and costs for the healthcare system.[2] This BIA was developed to support the guideline development group (GDG), who have prepared the clinical guideline, Adult type 1 diabetes mellitus, for the Irish healthcare system. The guideline has been developed through contextualisation of the NG17 *Type 1 diabetes in adults: diagnosis and management*, published by the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK) in 2015.[3]

Three key changes resulting from implementation of the recommendations from these guidelines were identified. These were: the provision of a high-quality structured education programme; provision of short education courses for healthcare professionals involved in the delivery of care to people with Type 1 diabetes; and the standardisation of the frequency with which adults with Type 1 diabetes are offered structured reviews in consultant-led outpatient diabetes clinics, to include an assessment of glycaemic control by measurement of HbA1c levels. These changes are described in Section 2 of this report. The budget impact analysis (BIA) estimates the additional financial consequences of implementing these recommendations, taking into consideration the existing provision within the healthcare system. The methodology used for the BIA is detailed in Section 3, with the results and discussion presented in Sections 4 and 5, respectively.

1.2 Burden of disease: Type 1 diabetes

Type 1 diabetes is a chronic autoimmune disease that arises following the destruction of insulin-producing beta cells in the pancreas.[4] As a result, people with Type 1 diabetes require insulin therapy to adequately regulate blood glucose levels. Type 1 diabetes can present at any age, but is most often diagnosed in children and adolescents. Life expectancy

for people with Type 1 diabetes is generally shorter than for those without Type 1 diabetes, with most deaths due to chronic complications of the disease.[3]

In the short term, people with Type 1 diabetes may face significant challenges to daily living such as hyperglycaemia, hypoglycaemia and ketoacidosis, while long-term complications can occur in the form of both microvascular complications, such as diabetic retinopathy and neuropathy, and macrovascular complications such as stroke and coronary artery disease.[5] The additional strain placed on healthcare resources when diabetes patients are hospitalised illustrates that diabetes-related complications impose not only a significant burden on patients and the healthcare system, but can also have a substantial societal impact due to productivity losses (such as days off work because of illness). The economic burden of diabetes on the Irish healthcare system is becoming a major challenge for the Government and the Health Service Executive (HSE).

The CODEIRE study examined the cost of treating Type 2 diabetes in Ireland, and suggested that 10% of the national health budget was being consumed through treating the condition (49% on hospitalisation for complications and wages; 42% on drug costs; 8–9% on ambulatory care and attending non-diabetes specialists for diabetes-related complications).[6] This is consistent with more recent data in the UK where it is estimated that the cost of diabetes (Type 1 and Type 2) represents approximately 10% of the total annual health expenditure by the National Health Service (NHS),[7, 8] with a significant proportion (approximately 79%) of the direct costs of diabetes patient care due to the cost of treating complications. The direct and indirect costs of diabetes is expected to rise during the next 20 years due to the growing prevalence of diabetes (Type 1 and Type 2).[9]

Early detection and effective management of Type 1 diabetes and its complications are important to limit its impact. Given the loss of insulin production, people with Type 1 diabetes require regular insulin administration via injection or insulin pump (insulin replacement therapy). Maintaining blood glucose levels at close to non-diabetic levels, reduces the occurrence of microvascular complications. However, the behavioural and technical challenges of calculating appropriate doses of insulin and situational adjustment (for instance when stressed or exercising) in a way that attempts to reproduce regular

physiology are significant.[10] Structured programmes have been developed comprising consistent, evidence-based patient education that provides a platform that enables people with Type 1 diabetes to manage their blood glucose levels more effectively.

2. Description of the technologies

2.1 Structured education for adults with Type 1 Diabetes

2.1.1 Background

Successful health outcomes for Type 1 diabetes depend, to a large extent, on the individual's ability to self-manage their insulin doses. The chronic nature of Type 1 diabetes means that achieving the desired outcomes requires a daily and life-long active commitment to monitoring, determining and administering appropriate insulin doses. This entails blood testing and adjustment of insulin accordingly, including estimation relative to the amount of carbohydrates consumed, several times a day. This requires people with Type 1 diabetes to understand the effects of insulin; to possess an awareness of foods that raise blood glucose; to have the ability to recognise and treat hypoglycaemia; and to anticipate and manage blood glucose levels that enable physical activity. Hence, there is a clear need for people with Type 1 diabetes to be adequately equipped with the knowledge and technical expertise to manage day-to-day blood glucose fluctuations.

This clinical guideline recommends the provision of expert support via a high-quality structured education programme. This can be an effective means of empowering people with Type 1 diabetes to self-manage their diabetes and the external factors that can influence their blood glucose levels, such as exercise, alcohol consumption and stress.[3] Optimising blood glucose control reduces the risk of developing microvascular complications, thereby prolonging life expectancy.[8] The selection of a high-quality structured education programme will be subject to a procurement process involving internationally available and recognised structured education programmes that have been developed to improve the glycaemic control of adults with Type 1 diabetes. The Dose Adjustment for Normal Eating (DAFNE) programme is the only structured education programme currently delivered in Ireland that meets all of the criteria of the clinical recommendations outlined in this guideline. Accordingly, following discussion with the GDG, DAFNE was selected as the exemplar for a structured education programme to analyse in the BIA.

2.1.2 Description of the DAFNE programme

The DAFNE programme is a skills-based structured education programme in intensive insulin therapy and self-management for adults with Type 1 diabetes. The aim of the DAFNE programme is to help adults with Type 1 diabetes lead as normal a life as possible by improved control of blood glucose levels.

Key to the success of the programme is the empowerment of individuals to take greater control of their own health and wellbeing by providing skills that enable insulin adjustment on a meal-by-meal basis. During the course, participants are presented with the opportunity to practice the skills relevant to their own insulin management.

DAFNE training is delivered to groups of six to eight people with Type 1 diabetes by two certified educators (one diabetes specialist nurse and one diabetes dietitian). In addition, a DAFNE-trained doctor delivers between 30 minutes and one hour and 30 minutes of the programme. The course, which has a 38-hour duration, can be delivered either over five consecutive days or over one day per week for five consecutive weeks.

A two- to three-hour group follow-up session is offered to participants at 4–12 weeks after each course to consolidate the skills acquired during the course and to review targets and goals.[11] Sessions are facilitated by trained educators using a structured curriculum which includes goal setting, action planning and review of 'DAFNE diaries'. Educators receive formal training in the delivery of these follow-up sessions. It is estimated that roughly 40% of graduates will attend this initial follow-up session.

2.1.3 Description of current approach to structured self-management education for adults with Type 1 diabetes in Ireland

Structured education programmes comprise the delivery of an education-based curriculum by a trained educator to a group of individuals living with a particular condition. The structured education programmes for Type 1 diabetes that are most commonly provided in Ireland currently are the BERGER and DAFNE programmes. The BERGER programme, developed over 30 years ago, is a comprehensive diabetes self-care skills course.[12]

In 2017, acute hospitals providing diabetes services for adults were surveyed as part of the National Survey of Acute Hospital Diabetes Services and Resources. Of the 31 hospitals identified:[13]

- DAFNE education was provided across six licensed DAFNE centres to a total of seven hospitals in 2016. One additional hospital was licensed as a DAFNE centre in 2017, but is yet to deliver any courses due to limited dietitian hours dedicated to the service. Overall, it is estimated that 3,000 people attended DAFNE training in Ireland between 2005 and 2017.
- Eight hospitals provided the BERGER programme to people with Type 1 diabetes in Ireland in 2016. One other hospital started delivering the BERGER programme in 2017.
- One hospital provided BERGER between 2010 and 2015, but has been unable to deliver BERGER since 2015 due to a lack of availability of a dietitian to deliver the programme.
- Two hospitals provided carbohydrate-counting education on a one-to-one basis.
- Two hospitals provided Accu-Chek education (in 2016), which is an adapted version of the BERGER programme.
- Nine hospitals did not provide any form of structured education programme to adults with Type 1 diabetes in 2016. Seven of these hospitals cited that structured education is not provided due to a shortage of dietitians and/or trained personnel dedicated to diabetes services.

2.1.4 Insulin analogues

One of the main principles underlying DAFNE is the separation of basal (long-acting) and bolus (rapid acting or meal-related) insulin. The role of basal insulin is to keep blood glucose levels at consistent levels during periods of fasting. The basal insulin (neutral protamine Hagedorn (NPH), detemir or glargine) is generally given as two doses, one before bed and one before breakfast. The doses are kept relatively constant to maintain the blood glucose within a given target range.[8] Participants in DAFNE training are taught to adjust the basal dose as necessary every few weeks based on their glucose measurements over time.[8]

Bolus insulin (short acting), on the other hand, is specifically administered at mealtimes to control blood glucose levels following meal consumption. The calculation of the bolus insulin dose is an important skill taught in the DAFNE programme. Adjustments may be made if the pre-meal blood glucose level is above the target range or if, for example, the patient anticipates participation in sporting activities.[8] Diaries are provided, as part of the programme, to record blood glucose levels along with the carbohydrate content of meals and the insulin doses administered, with the goal of aiding reflection and refinement of future insulin doses.

One of the main advantages of a basal-bolus insulin regimen is that it allows patients to closely match how their own body would release insulin if it had the ability to do so. It also allows for mealtime flexibility as patients possess greater flexibility over their carbohydrate consumption. However, a basal-bolus regimen involves administering a greater number of insulin injections each day. Such adjustments of insulin doses and administration frequency may have financial consequences.

2.1.5 DAFNE: assumed clinical outcomes and costs

There is clinical evidence that DAFNE training is effective (compared with no education) and results in quality of life improvements in patients and a reduction in hospital admissions.[8, 14, 15] The clinical benefits of the programme can be summarised as:

- fewer long-term complications as a result of improved glycaemic control
- reduced number of episodes of self-reported severe hypoglycaemia
- reduced number of episodes of diabetic ketoacidosis (DKA) resulting in hospital admission
- psychosocial benefits
- improved quality of life.

The principal outcomes of DAFNE training from a participant perspective can be summarised as:

- improved knowledge and understanding of diabetes
- patient-empowerment through improved skills and confidence in ability to self-manage diabetes
- improved psychological adjustment to living with diabetes
- improved undertaking of diabetes self-management behaviours
- improved clinical outcomes.

In 2014, Heller et al. conducted an economic evaluation of the DAFNE programme in the UK.[8] The evaluation was designed to address some of the limitations identified in a previous economic analysis.[14] The estimated costs and quality-adjusted life years (QALYs) were extrapolated over the patient's lifetime based on short-term and longer-term follow-up data (six-month, 12-month and 44-month follow-up) from the DAFNE randomised controlled trial (RCT).[8, 16] Costs and QALYs were discounted at a rate of 3.5% and the economic evaluation was conducted from the perspective of the National Health Service (NHS). The economic analysis included additional costs for insulin therapy as there are RCT data to suggest that the total cost of insulin therapy increases following DAFNE training with people injecting more frequently and at slightly higher doses.[8, 14]

DAFNE education was predicted to reduce the incidence of nephropathy and neuropathy, but was associated with a slight increase in the incidence of retinopathy, cardiovascular events and adverse events. The authors suggested that these increases in incidence were largely due to a rise in the number of life-years lived across the entire cohort as per patient-year rates were similar between both intervention and control arms. The analysis estimated a life expectancy gain of 30 days per patient compared with no DAFNE education or usual care. In line with the findings of the previous analysis, the economic evaluation found that DAFNE education was both cost saving and more effective when compared with no DAFNE education.[8] The results, discounted over a lifetime horizon, indicated that DAFNE education would save the NHS £1,656 (€2,139) per patient when compared with no DAFNE education, despite higher annual per-patient insulin costs and the cost of the DAFNE intervention. The

reduction in long-term costs was largely due to a decrease in long-term complications and adverse events. In terms of treatment effects, DAFNE education produced a gain of 0.0585 QALYs per patient versus no DAFNE education. This resulted from improved survival, decreased incidence of some of the long-term diabetes-related complications and fewer episodes of short-term adverse events. The analysis suggested lower rates of hypoglycaemia, lower rates of DKA and fewer long-term complications in DAFNE participants.

The current BIA attempts to quantify the cost-savings which would result from the prevention of these adverse events over a five-year time horizon in Ireland. The methods employed are outlined in Section 3.6.

2.1.6 DAFNE refresher training

Following the completion of the DAFNE course which includes one structured follow-up session, no additional refresher training is specified by the DAFNE programme and instead is at the discretion of individual centres. There is evidence that refresher training is provided on an ad hoc basis; however, the frequency and duration of these sessions vary with little data on the number of participants or the extent to which refresher training is being offered. These sessions would likely be facilitated by trained educators using a structured curriculum which includes goal setting, action planning and review of 'DAFNE diaries'. The cost of implementing a group refresher session is estimated at €185 per patient.[(11)] While acknowledging this may result in an underestimation (or overestimation as refresher training may lead to further long-term cost savings) of the total budget impact, in the absence of better data, no explicit cost for refresher training has been included in the BIA. It is noted, however, that in expanding DAFNE services to new centres, the provision and administration of refresher training would most likely be provided by the staff recruited as part of the expansion (see Section 2.1.8). Therefore, assuming no additional resources are required, the majority of the costs associated with refresher training in these sites will already be accounted for in the following estimates.

2.1.7 Quality assurance of the DAFNE programme

The DAFNE programme is evidence-based, quality assured and auditable. Ultimately, being part of the DAFNE Collaborative entails access to a high-quality structured education programme that fully meets the criteria outlined in this clinical guideline. DAFNE educators are required to teach on at least one course every six months to maintain their skills and are intermittently peer-reviewed by educators from other centres who have had additional training. The DAFNE curriculum is updated at least every three years, and all participating DAFNE centres are invited to send representatives to the Network of Excellence (the annual collaborative meeting). Representation at the meeting of at least one doctor or educator from each centre is mandatory.

DAFNE centres are audited on a three-year cycle on the process of delivering the DAFNE programme and on local outcomes, particularly recorded changes in HbA1c levels. Accordingly, all Irish DAFNE centres must submit data in relation to the clinical benefits outlined in Section 2.1.5. The resources required to comply with the quality assurance requirements are considered as part of the administrative support requirements of each DAFNE centre.

2.1.8 Expansion and set-up of DAFNE services

Within a five-year time horizon, the costs associated with expansion of the provision of the DAFNE programme depend on the following factors:

- the number of additional centres
- the number of educators and doctors to be trained
- the administrative support required to coordinate and provide patient courses
- the number of patient courses that the service plans to deliver each year
- how the service decides to fund refreshments and lunches for the patients
- where the patient courses will be delivered and whether there will be a cost incurred.

As discussed in Section 2.1.3, at the time of this report, there were seven licensed DAFNE centres in Ireland and one licensed DAFNE centre that had been unable to deliver DAFNE services. Under the recommendations of this clinical guideline, the DAFNE service provision would expand. In line with the implementation plan, there will be two to three DAFNE centres in each of the adult hospital groups. At the maximum, 11 additional centres would be required, resulting in 18 licensed centres nationally. Each centre would be required to pay the central contribution to obtain a licence for the provision of the DAFNE service. The BIA aims to estimate the number of patients that would receive DAFNE education over a five-year time horizon resulting from this expansion.

In terms of training, each centre requires two trained educators (one diabetes nurse specialist and one senior dietitian) and one DAFNE-trained doctor. Therefore, it can be expected that a minimum of three individuals per centre will undergo training. It is expected that this training will take place in Ireland, although the location has yet to be finalised. The cost incurred from this training has been estimated in the BIA along with the cost of teaching resources. This estimate includes the opportunity cost for doctors who are already employed by the HSE and will be trained to provide DAFNE education in addition to their usual duties. In this instance, the opportunity cost refers to the time spent attending the DAFNE Doctor Programme (one day) and delivering the DAFNE training course (one hour and a half per course) in place of delivering their usual duties.

The cost of additional staff recruited as part of the guideline's implementation plan — for whom delivering DAFNE education falls under their regular duties — will be estimated separately as this does not incur an opportunity cost. Each centre will be required to purchase the patients' materials, such as patient diaries, from the DAFNE collaborative. There will also be a one-off purchase of replica food models for each DAFNE centre. It is assumed that the HSE will not cover the cost of purchasing lunches for DAFNE participants (that is to say, the patients) during the course or the cost of travel for course participants. Finally, administrative support will be required to coordinate the DAFNE training courses, including, for example, registering patients, organising course times, locations and information technology (IT) requirements. It is assumed that one clerical officer will be

recruited in each of the six adult hospital groups to provide administrative support for all courses within that group.

2.1.9 Summary of assumptions for BIA of DAFNE programme

The assumptions used to populate the economic model are based on the recommendations in the clinical guideline and the associated implementation plan. They are summarised as follows:

- One additional diabetes nurse specialist and one additional senior diabetes dietitian will be recruited in each of the six adult hospital groups to expand or establish access to high-quality structured education for eligible adults with Type 1 diabetes. In addition, one clerical officer will be recruited per hospital group to provide administrative support. The respective salary costs according to HSE grades have been estimated in the BIA. Other staff costs refer to the opportunity costs of existing staff delivering segments of the DAFNE programme and attending training programmes such as the DAFNE doctor programme.
- The expansion of DAFNE provision will entail the establishment of a maximum of 11 new DAFNE centres.
- There will be a cost offset to the HSE resulting from the replacement of BERGER with DAFNE. This offset was estimated based on the delivery costs of the BERGER programme.
- Each DAFNE centre will run between two and six courses per year with between six and eight patients attending each course. Based on these estimates, each centre is expected to train between 12–48 patients per annum.
- The cost of educator and doctor training (including the cost of travel and subsistence) is covered by the HSE. It is expected that this training will take place in Ireland. However, the location and logistics of this training have not been finalised, therefore an average cost of travel and subsistence has been estimated.
- The DAFNE central contribution fee is covered by the HSE. The assumed DAFNE central contribution is £4,369 (€4,893). This fee varies depending on the number of

educators in place at the centre. The mechanism and rates are detailed in Appendix 1 of this report.

- One educator from each DAFNE centre will attend the annual collaborative meeting with the cost of travel and subsistence covered by the HSE. There is no registration fee for the meeting. It is expected that one of the educators recruited as part of the implementation plan will attend this meeting. Therefore, there is no opportunity cost of attendance.
- The costs of providing patient resources at each DAFNE centre will be covered by the HSE.
- The costs of providing lunch to participants and trainers at each DAFNE centre will not be covered by the HSE.
- DAFNE training leads to cost savings in the medium to long term due to a reduction in diabetes-related complications. The reduction in complications include, amongst others, a decrease in the incidence of nephropathy and neuropathy. However, given the five-year time horizon of the BIA, only the savings resulting from a reduced incidence of severe hypoglycaemic episodes leading to inpatient admissions are estimated. The methods undertaken to calculate these savings are described in Section 3.6.6.
- After receiving DAFNE education, on average, patients inject insulin more frequently, and at slightly higher doses.[8, 14] It is estimated that this will lead to an increase in average annual per-patient insulin costs.
- There is no incremental cost from blood glucose monitoring as a result of DAFNE attendance.[14]
- One DAFNE follow-up session occurs 4–12 weeks after the initial course. This is considered an integral part of the DAFNE programme. Additional follow-up thereafter is not specified.
- In terms of the BIA from implementing the DAFNE programme, the total Type 1 diabetes population is less relevant as the programme is restricted by the number of courses run per year and the number of places available for individuals to attend each course. Assuming a range of up to six courses per centre with attendance of up

to eight patients per course, it is estimated that a maximum of 528 additional patients could be trained in a year in the 11 new DAFNE centres provided through the expansion of the current provision of the DAFNE programme. With an estimated 3,000 DAFNE graduates, it is expected that it will take over 10 years to train the remainder of the target population (at the lower bound estimate of 19,750) excluding the new entrants to the cohort such as children who transition to the adult service.

2.2 Implementation of short courses

2.2.1 Background

The guideline implementation plan proposes short courses as a means of training all staff who deliver care to people with Type 1 diabetes in Ireland. The plan states that staff should have access to training that supports patient empowerment and diabetes self-management in the form of carbohydrate counting and insulin adjustment. This is an additional training requirement and is relevant to all staff who deliver care to people with Type 1 diabetes, not just staff providing the DAFNE programme.

It is proposed that the training would occur twice a year in each adult hospital group during year two of implementation. However, training will happen less frequently from year three of implementation onwards. The training would be delivered by an experienced DAFNE educator and would last between one and two days in total. It is assumed that the attendance of course participants would be facilitated through existing arrangements for training and development.

2.2.2 Summary of assumptions for BIA of provision of short courses

The assumptions which will be used to populate the economic model are summarised as follows:

- The duration of the short course would be between one and two days.

- The cost of implementing the short courses relates mainly to the salary costs of the staff coordinating and delivering the course. In line with the implementation plan, it is assumed that the delivery and administrative support for these short courses will be provided by the three additional staff members recruited in each adult hospital group to facilitate implementation of the DAFNE programme.
- The short courses will take place twice a year in each adult hospital group beginning in the second year of implementation.
- Each course will be delivered by one educator.
- Travel and subsistence will only be covered by the HSE for the educator delivering the short course.

2.3 Standardisation of appointment frequency for adults with Type 1 diabetes at diabetes clinics

2.3.1 Background

In 2008, the HSE published a report by an expert advisory group that recommended a model of integrated care for diabetes in Ireland.[17] A National Model of Integrated Care was completed in 2012 and updated in 2017, with publication planned following its endorsement by HSE Leadership in 2018. An updated practical guide to integrated Type 2 diabetes care was published by the Irish College of General Practitioners (ICGP) with the support of the HSE in 2016.[18, 19] The updated National Model for Integrated Care and ICGP guideline specify that patients with Type 1 diabetes will be managed in secondary (specialist) care. Active management in secondary care is assumed to comprise structured reviews at least every six month in consultant-led diabetes clinics. The model specifies that patients with uncomplicated Type 2 diabetes will be actively managed with structured primary care visits, while those with complicated Type 2 diabetes will be managed through a combination of primary and secondary care services.

The clinical guideline recommends that glycaemic control should be checked by measuring HbA1c levels every three to six months in adults with Type 1 diabetes. It is assumed that HbA1c levels will be reviewed as part of the six-monthly structured reviews in the

consultant-led clinics. The National Survey of Acute Hospital Diabetes Services and Resources 2017 indicated that only 42% of services are currently offering reviews every six months to adults with Type 1 diabetes.[13] The remaining 58% of hospitals offer reviews less frequently, ranging from every seven to every 13 months. Implementation of this recommendation will lead to a standardisation of current practice.

It should be noted that the guideline's implementation plan stipulates that the staff requirement of this recommendation should be considered on a hospital-by-hospital basis. As noted above, as part of the National Model of Integrated Care initiative, it is intended that patients with uncomplicated Type 2 diabetes will be managed in primary care, thereby releasing capacity in secondary care services to accommodate adults with Type 1 diabetes and those with complicated Type 2 diabetes. To facilitate this, the Diabetes Cycle of Care initiative was launched on 1 October 2015.[20] This initiative is the first step in the reimbursement of structured diabetes care in general practice. It resources GPs to provide two structured visits each year for patients with Type 2 diabetes. Between 2015 and 2016, almost 85,000 patients were registered for the scheme, accounting for €11.25 million in payments to GPs.[21] This investment in primary care is intended to improve the provision of timely, appropriate and efficient care for patients with Type 2 diabetes while addressing the capacity constraints within diabetes specialist clinics.

If this initiative succeeds in facilitating patients with uncomplicated Type 2 diabetes to be safely discharged to primary care, then it should release capacity within the specialist clinics to allow patients with Type 1 diabetes and complex patients with Type 2 diabetes to be reviewed at an appropriate frequency without additional resources being required. That is, it is anticipated that for centres that are not currently meeting the recommended frequency of appointments, the necessary resources to provide repeat visits once every six months will be secured through the redistribution of resources, supported by the investment in primary care for type 2 diabetes. However, it is equally valid to assume that the increasing unmet need for complicated Type 2 diabetes due to an ageing population will hinder the ability to discharge patients from secondary care. In the context of a BIA, a conservative approach is taken whereby the cost of additional appointments required to ensure that all adults with Type 1 diabetes are offered appointments on a rolling basis every six months are estimated.

2.3.2 Summary of assumptions for standardising appointment frequency at diabetes clinics

The assumptions used to populate the budget impact model are summarised as follows:

- All adults with Type 1 diabetes should be offered structured appointments with a diabetes healthcare professional. These appointments would take place at consultant-led diabetes clinics every six months on a rolling basis. These appointments should include review of glycaemic control (HbA1C levels).
- Only 42% of hospital diabetes services currently offer six-monthly review appointments. The remaining hospitals offer appointments at intervals ranging from every seven months to every 13 months.
- Due to an unavailability of data, the preliminary results from the National Survey of Acute Hospital Diabetes Services and Resources were used to estimate the additional number of appointments required to achieve this recommendation. However, it should be noted that only eight of the hospitals surveyed were able to provide data considered to be accurate.
- In the preliminary survey, data were available on the re-call frequency for 30 of the 31 hospitals surveyed. Type 1 diabetes population estimates were missing on four of the hospitals. A total of 19,745 adults were reported in the finalised survey results, with 16,607 adults captured in the preliminary survey results, thus there was a missing population of 3,143 adults.
- Adults with Type 1 diabetes should be re-called for a structured review at least every six months, with a minimum of 10 reviews per patient over five years. The re-call frequencies of each hospital were used to estimate how many additional reviews per patient would be required in each hospital to meet the minimum requirement of 10 reviews over five years. Where a range was provided for the re-call time (e.g. seven to nine months), the midpoint of the range was used (e.g. eight months). The number of additional reviews (defined as the difference between current frequencies of re-call and the minimum required frequency) was then applied to the patient population reported in each hospital to estimate the total number of

additional reviews required per hospital. Of the 16,607 adults in the survey, 64% were offered the six-monthly review in 2016. The one hospital without data on re-call frequency was assumed to have met the six-monthly requirement in 2016.

- Adopting this method produced a total of 3,476 additional appointments per annum for the Type 1 diabetes population captured in the preliminary data (n=16,607).
- A base case scenario was defined by assuming the missing Type 1 diabetes population (3,143 adults) were distributed evenly across the four hospitals without a population estimate. The re-call frequency in each of these four hospitals was then applied to the estimated populations re-call to estimate the number of additional appointments required for the missing Type 1 diabetes population. Where, a hospital reported a re-call frequency of six months or less then no additional appointments were required.
- It was estimated that there would be an additional 1,459 appointments per annum from the missing population, combining these to the 3,476 extra appointments applicable to the available data produces a total of 4,935 extra appointments per annum. This was used as the base case in the analysis.

2.4 Coordinated information technology system

2.4.1 Background

Recommendation 1.2.5 in the clinical guideline entails setting up a coordinated population-based information technology (IT) system to assist with the programmed re-call of patients for annual review and assessment of complications and cardiovascular risk. The National Survey of Acute Hospital Diabetes Services and Resources 2017[13] has shown that a fragmented registry system exists at present. At the time of writing, there were 11 local registries in place in various parts of the country; however, a single coordinated system had not yet been implemented. The substantial variation around the country highlights the need for a national IT system which facilitates the integration of patient care for all those with diabetes, across all settings, including hospitals and primary care.

The absence of a coordinated system can represent a barrier to improving patient care. In other countries, national registers are maintained as part of the delivery of care and report outcomes such as HbA1c levels.[22] Monitoring the epidemiology of diabetes by generating rich patient-level data is important for service provision, resource allocation and audit. However, while implementation of such a system would provide a comprehensive information base to inform healthcare planning decisions, it would also have considerable resource and budgetary implications. Achieving the goal of developing and maintaining a national diabetes register will require commitment and buy-in from a wide range of stakeholders.

2.4.2 Considerations for future analysis

There is presently insufficient detail for the implementation strategy of a coordinated IT system to determine the cost implications that the set up of such a system would entail. Therefore, further exploration of options for implementation (such as set up costs, consensus on its function and purpose, monitoring and servicing of the system) is required to estimate the budgetary implication of this recommendation.

3. Methodology

A budget impact analysis (BIA) addresses the expected changes in the expenditure of a healthcare system when introducing a new intervention. In the case of clinical guideline development, the intervention is any recommendation that will lead to a change in the treatment pathway. In this context, the BIA aims to quantify the resource implications of any recommendation identified as representing a change to standard clinical practice. The purpose of this analysis is to estimate the likely ongoing resource and financial consequences for the Irish healthcare system of the clinical recommendations outlined in Type 1 diabetes in adults. The BIA also accounts for the costs incurred during the initial implementation phase of the guideline recommendations.

The BIA was conducted from the perspective of the publicly-funded health and social care system, the Health Service Executive (HSE). The analysis was undertaken using the Microsoft Excel 2013 software package and the annual incremental cost of the clinical recommendations over a five-year time horizon is reported. All of the analysis was conducted in accordance with the HIQA guidelines for budget impact analysis and economic evaluation in Ireland.[23, 24] An outline of the model is presented in Figure 1 of Appendix 2.

3.1 Study perspective

In line with national guidelines, costs and benefits were assessed from the perspective of the publicly-funded health and social care system, the HSE.[23, 24] As such, only direct medical costs were included. Indirect costs were excluded from the analysis, such as decreased productivity associated with morbidity, treatment or death, or out-of pocket expenses incurred by patients, for example, costs incurred attending a patient education training session.

3.2 Time horizon

The time horizon represents the time frame over which resource use is planned. According to national guidelines, the annual financial impact of a technology should be estimated for a

minimum of five years from the time of its introduction.[23] In accordance with this guideline, the BIA was estimated on a yearly basis over a five-year time horizon.

3.3 Target population

The target population is defined as all patients that are eligible for the new intervention during the time horizon of interest, given any access restrictions. Currently, there are very few reliable estimates of the size of the population with Type 1 diabetes in Ireland. Accurate epidemiological estimation is important for service provision, resource planning and allocation, and clinical audit. As such, attempts have been made to quantify the size of the adult population with Type 1 diabetes. The National Survey of Acute Hospital Diabetes Services and Resources 2017 estimated the total adult Type 1 diabetes population to be 19,745.[13] However, this estimate failed to capture the patient populations of three hospitals that were unable to provide an estimate. Estimates from only eight of the 28 hospitals providing data were considered to be accurate. The survey did not make adjustments for this uncertainty or adjustments in respect of the three hospitals which could not return data, therefore, we have assumed the estimate of 19,745 to be an underestimate of the true population.

The national paediatric register established by Roche et al. in 2008 found that the incidence of Type 1 diabetes in children under the age of 15 years stabilised at 28.8 cases per 100,000 per year in 2013.[25] Using these childhood incidence rates as the foundation for estimating adult prevalence, a model was developed to estimate the potential future Type 1 diabetic adult population in Ireland. The model accounted for age- and gender-specific incidence rates (including Scottish incidence rates of Type 1 diabetes in adults) and applied weighted mortality rates to account for the higher mortality rate in people with Type 1 diabetes. The weighted mortality rates were derived from Irish mortality rates sourced via the Central Statistics Office (CSO) database and the differential mortality rate for Type 1 diabetes identified by NICE.[3, 26] This allowed for derivation of age-specific prevalence rates. These prevalence rates were then applied to demographic information available from the CSO. The model predicted that the future adult Type 1 diabetic population could be as high as 35,000.

In the absence of a national register, it is difficult to accurately quantify the total adult Type

1 diabetic population in Ireland. However, based on the available data, it is estimated that the adult Type 1 diabetes population is somewhere between 19,750 and 35,000.

3.4 Rationale for included interventions

A BIA of a clinical guideline considers the changes to the treatment pathway arising from implementing the clinical recommendations. The BIA gives particular attention to costs or cost savings that result from changes to the standard patient journey. Therefore, routine care acts as the comparator for the BIA. There are, however, difficulties inherent with defining standard practice in the context of clinical guidelines given that the reason for the guideline may in part be due to the variation in clinical practice. Under such circumstances, it may be reasonable to restrict the description of current practice to those practices that are commonly used. The methods used to estimate the BIA for this guideline are consistent with this approach.

The provision of high-quality structured education for all adults with Type 1 diabetes was identified as one of the three key changes arising from implementation of the guideline recommendations. Such education programmes must meet defined criteria outlined in the clinical guideline. The Dose Adjustment for Normal Eating (DAFNE) programme is the only structured education programme currently delivered in Ireland that meets all of the criteria of the clinical recommendations outlined in this guideline. Accordingly, following discussion with the GDG, DAFNE was selected as the exemplar for a structured education programme to analyse in the BIA. In addition to those who have not previously been offered access to a structured education programme, those adults with Type 1 diabetes who have previously received alternative forms of education would also be offered the opportunity to attend.

The guideline implementation plan proposes short courses as a means of training all staff who deliver care to people with Type 1 diabetes in Ireland. The plan states that staff should have access to training that supports patient empowerment and diabetes self-management in the form of carbohydrate counting and insulin adjustment. This is an additional training requirement and is relevant to all staff who deliver care to people with Type 1 diabetes, not just staff providing the DAFNE programme.

The third key change arising from implementation of the guideline recommendation is the standardisation of follow-up for adults with Type 1 diabetes. The guideline recommends that glycaemic control should be checked by measuring HbA1c levels every three to six months in adults with Type 1 diabetes. It is assumed, that in line with the HSE's agreed National Model of Integrated Care, review of these HbA1C levels will happen at consultant-led diabetes clinics which should be offered to all adults with Type 1 diabetes every six months. Data from the National Survey of Acute Hospital Diabetes Services and Resources 2017 indicate that there is currently variability in this practice, with only 42% of hospital diabetes services currently offering six-monthly reviews.[13] Therefore, implementation of this recommendation would standardise current practice.

3.5 Rationale for excluded interventions

Whether or not a recommendation represented a change to routine clinical practice was identified by discussion with the GDG and with individuals involved in the provision of the DAFNE and the diabetic retinopathy screening programmes in Ireland. Expenditure on insulin through the Primary Care Reimbursement Scheme (PCRS) was reviewed and the results of the 2017 National Survey of Acute Hospital Diabetes Services and Resources were also evaluated. Finally, HSE guideline documents and reviews relating to the care of adults with Type 1 diabetes were assessed. The rationale for inclusion and exclusion of each individual recommendation is outlined in Appendix 3.

No changes to standard practice arising from the guideline recommendations were identified for any of the following categories:

- diagnosis of Type 1 diabetes
- development of individualised care plans
- referral criteria for islet or pancreas transplantation
- management of DKA
- first-line therapy for hypertension
- or management of complications in adults with Type 1 diabetes.

Continuous glucose monitoring is not routinely offered in the management of Type 1 diabetes, but it was anticipated that the number of patients affected by recommendations

1.6.21 and 1.6.22 would be negligible. The use of flash glucose monitoring would represent a change to standard practice. In January 2018, it was announced that this intervention will be reimbursed, subject to a review at 12 months, for a subgroup of those with diabetes; however, this group is yet to be defined.[27] On this basis, blood glucose monitoring techniques were not specifically considered in the BIA, but it is acknowledged that any decision by the HSE to reimburse flash glucose monitoring would have ongoing financial consequences for the budget impact of this guideline.

Recommendation 1.2.5 entails the set-up of a coordinated information technology (IT) system to assist with the programmed re-call of patients for annual review and assessment of complications and cardiovascular risk. The National Survey of Acute Hospital Diabetes Services and Resources 2017 has shown that fragmented local registries are in place in parts of the country; however, a single coordinated system has not yet been implemented. This data indicates a distinct need for a system that will provide crucial epidemiological metrics for the planning and resourcing of diabetes care and with the capacity to aid the programmed re-call of diabetes patients for review. However, there is presently insufficient detail to accurately determine the cost implications that the set-up of a coordinated IT system would entail. Therefore, the development of an IT system is currently considered to be aspirational — which warrants further exploration of options for development and implementation (such as set-up costs, consensus on its function and purpose, monitoring and servicing of the system). These factors will need to be addressed before an accurate estimation of the resource and budgetary implications of this recommendation can be made.

3.6 Costs

The BIA estimated the costs associated with the guideline recommendations that were assumed to impact standard practice. These changes were identified through a variety of resources which are described in Section 3.4 and listed in detail in Appendix 3.

The costs were applied to the model incrementally whereby the costs were considered according to the year of the time horizon in which the cost was absorbed, and consistent with the timelines specified in the guideline's implementation plan. The costs were

categorised according to seven principal headings:

- set-up of the DAFNE programme
- delivery of the DAFNE programme
- direct costs after DAFNE participation
- costs of short courses and recruitment costs for implementation
- cost offsets
- cost savings
- cost of additional structured appointments at consultant-led diabetes clinics to include review of glycaemic control (HbA1c levels).

Unit costs for the analysis were expressed in 2016 euro. Where applicable, cost were inflated to 2016 prices using the Irish Consumer Price Index for Health.[26] Costs which were sourced via direct quotation from DAFNE Central were converted from pound sterling to euro using the currency exchange rate of £1 = €1.12 valid as of 12 December 2017.[28] All costs for the analysis were derived according to the HIQA guidelines for budget impact analysis and economic evaluation in Ireland.[23, 24] The unit costs used in the analysis are presented in Sections 3.6.1 to 3.6.5 according to the categories listed above.

3.6.1 Set up of the DAFNE programme

In order to set up a DAFNE centre, a number of resources must be purchased. Some of these resources may need to be replaced over time. Additionally, each centre must pay an annual contribution fee to the central DAFNE administration based in the UK. The annual contribution can vary depending on the number of trained educators registered in the centre. The variable rates are detailed in Appendix 1.

In order to be certified to deliver DAFNE training, educators and doctors must undergo training themselves. Nurses and dietitians must attend the DAFNE Educator Programme (DEP), while doctors must attend the DAFNE Doctor Programme (DDP). There is a fee for attending these training programmes. In addition, educators and doctors attending the DEP or DDP will receive a travel allowance to cover the cost of travel and accommodation. As it is

expected that the training will take place in Ireland, but the exact location is not yet specified, an average distance was estimated. The estimate was based on the average distance between each hospital to attend the DEP in either Dublin or Cork. It was assumed that the training attendees would travel by car. An average mileage was then calculated and the HSE allowance rate applied to this.

Under the guideline implementation plan, one additional diabetes nurse specialist, one additional senior dietitian and one additional administrative person will be recruited in each adult hospital group. It is assumed that the recruited dietitians and nurses will undergo the DEP and supply the majority of the delivery of the DAFNE programme in the new DAFNE centres. The costs that apply to these recruited personnel are outlined in Section 3.6.3. A small section of the programme must be delivered by a doctor, and accordingly, it is assumed that one doctor will undergo the DDP for each of the new DAFNE centres. These doctors will comprise existing medical staff and it is assumed that they are at a hospital consultant level. The unit costs per centre for set up of the DAFNE programme are presented in Table 3.1.

Table 3.1. Unit cost per centre for set up of the DAFNE programme

Description	Details	Unit cost	Source(s)
Central contribution*	Annual fee	€4,893.19	Central DAFNE office[29]
Set-up resources*	First year only	€427.17	Central DAFNE office[29]
Patient resources*	Per patient	€5.57	Central DAFNE office[29]
Replica food models*	First year only**	€828.80	Central DAFNE office[29]
Fee for educator training course*	Two educators	€3,040.80	Central DAFNE office[29]
Fee for doctor training course*	One doctor	€319.20	Central DAFNE office[29]

Description	Details	Unit cost	Source(s)
Opportunity cost of doctor training	One day attendance based on average consultant salary	€962.46	HIQA HTA of mechanical thrombectomy[30]
Mileage	Calculated based on average rate per kilometre	€114.26	HSE motor travel rates[31]
Accommodation	Vouched accommodation overnight allowance	€133.73	HSE domestic subsistence allowance[32]
Subsistence	Domestic subsistence allowance over 10 hours	€33.61	HSE domestic subsistence allowance[32]

* Sterling prices converted to euro using the currency exchange rate of £1 = €1.12 valid as of 12 December 2017.[28]

** A depletion rate of 10% was assumed.

3.6.2 Delivery of the DAFNE programme

Once a DAFNE centre has been set up, there will be labour requirements for the delivery of each course. It is assumed that the labour requirements in terms of educator delivery and administrative support of the DAFNE programme will be provided by the additional staff recruited as part of the guideline implementation plan. The salary requirements of these recruited personnel are detailed in Section 3.6.3. Additionally, the labour requirements

include the opportunity costs attributed to doctors involved in the delivery of the training programme being unable to perform their usual duties because they are delivering DAFNE training. It is assumed that the medical doctor providing DAFNE training will be at a hospital consultant level. It should be noted that HSE hospital consultant contracts can vary significantly. Therefore, the cost of a consultant is based on the average HSE contract cost estimated in a previous HTA. This may not represent the true cost of the consultant's time, but it is a reasonable cost estimation.

It is a requirement of the DAFNE central administration that at least one educator or doctor from each DAFNE centre attends the annual collaborative meeting in the UK. The next meeting is due to take place in Manchester in 2018. As there is no registration fee, the cost of attendance is estimated based on the cost of travel and subsistence. In this BIA, it is assumed that the course will be attended by a newly recruited educator (diabetes nurse specialist or dietitian) rather than the doctor. Therefore, their attendance is part of their regular duties and does not involve the estimation of an opportunity cost. The costs per centre are presented in Table 3.2.

Under the guideline implementation plan, one additional diabetes nurse specialist, one additional senior dietitian and one administrative person will be recruited in each of the adult hospital groups. It is expected that the delivery and administrative support of the delivery of DAFNE training to adults with Type 1 diabetes will be among the primary responsibilities of these personnel. It is anticipated that the additional staff will provide sufficient capacity to expand the delivery of DAFNE training. Given that this staff recruitment is a direct consequence of the guideline implementation plan, the full salary of these personnel is included annually in the total budget impact. As such, there are no opportunity costs associated with the educators and administrative support. The annual costs related to the recruited staff are outlined in Section 3.6.3.

Table 3.2. Unit costs per centre for delivery of the DAFNE programme

Description	Details	Unit cost	Source(s)
Consultant	One hour and a half per course	€194.22	HIQA HTA of mechanical thrombectomy[30]
Attendance at annual collaborative meeting	Includes cost of return flights to Manchester, travel to city centre and overnight accommodation and subsistence	€220.28	Online airline and bus quotations; HSE domestic subsistence allowance[32]

* Salaries based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads.[23, 24]

3.6.3 Recruitment of staff

In line with the implementation plan, additional staff will be recruited in each hospital group. The additional staff will comprise one senior dietitian, one clinical nurse specialist and one clerical officer in each adult hospital group. Salary costs are based on the mid-point of the Department of Health published salary scale adjusted for pension, PRSI and overheads.[33] These staff will deliver DAFNE training in the additional centres. The unit costs for the recruitment of additional staff are presented in Table 3.3.

Table 3.3. Unit costs for staff recruitment

Description	Details	Unit cost	Source(s)
Senior diabetes dietitian	Annual cost	€77,670.26*	Senior dietitian; consolidated salary scales 2017[33]
Diabetes specialist nurse	Annual cost	€72,493.92*	Clinical nurse specialist; consolidated salary scales 2017[33]
Administrative person	Annual cost	€41,802.02*	Clerical officer; consolidated salary scales 2017[33]

* Salaries based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads.[23, 24]

3.6.4 Direct costs after DAFNE participation

A follow-up course is offered to participants six to 12 weeks after DAFNE training. The purpose is for patients to consolidate the skills that they have learned. The cost of DAFNE follow-up training includes educator and administrator time input, educational materials and consumables, post, packaging, telephone and travel expenses. The costs of educator and administrator resource requirements and associated overheads are assumed to be incurred as part of the costs of the guideline implementation plan detailed in Section 3.6.3. The materials and consumables are part of the five-day DAFNE course while it is assumed that travel expenses of patients will not be covered by the HSE. Therefore, there is no additional cost of providing the DAFNE follow-up course.

Randomised controlled trial (RCT) data suggest that after undergoing the DAFNE programme, patients inject insulin more frequently and at slightly higher doses.[8, 14, 16] On the other hand, contradictory evidence of a reduction in total daily insulin doses after DAFNE participation was found in an observational cohort study.[34] However, these data were based on insulin doses on day four of the DAFNE programme compared with baseline.

Moreover, there were no data regarding whether these changes would be maintained in the long run. Therefore, this analysis adopted a conservative approach and estimated the average annual per-patient cost increase that would occur if, consistent with the RCT data, patients' total daily insulin doses increased following DAFNE training.

Based on the original DAFNE RCT, it was assumed that the average daily insulin dose would increase by 0.03 units per kilogram (u/kg).[16] An average patient weight was assumed at 80kg. The 2016 PCRS annual report on claims and payments was reviewed to identify the most frequently prescribed insulin types.[21] Online PCRS data was then used to estimate the cost per unit of alternative formulations and brands of the insulins that comprised the majority of the prescriptions dispensed through the PCRS. Consistent with a conservative approach, the formulation with the most expensive u/kg cost was identified and this cost was applied to the assumed patient weight to get the incremental daily cost of insulin. The annual incremental per-patient cost was then found by multiplying the daily cost by 365 (365 days in a year) and applying a value-added tax (VAT) of 23%. It should be noted that this figure is a maximum estimate of the change in insulin costs directly attributable to DAFNE participation. The unit costs used in the model for calculating the changes in insulin doses are presented in Table 3.4.

Table 3.4. Direct costs after DAFNE participation

Description	Details	Unit cost	Source(s)
Flexible insulin therapy	Annual increase in insulin cost per patient	€48.49	DAFNE RCT[16]; PCRS[21]

3.6.5 Costs of short courses

Additional staff comprising one senior dietitian, one clinical nurse specialist and one clerical officer will be recruited per hospital group according to the guideline implementation plan. In addition to delivering DAFNE training, it is expected that these personnel will deliver the short courses outlined in Section 2.2. The salary costs of these personnel have been accounted for as described in Section 3.6.3. As these costs have already accounted for within the BIA, the only other costs relevant to the provision of short courses are the costs

of travel and subsistence for the educators. The location of the short courses will be decided on an ad-hoc basis, but they will be facilitated within each hospital group. Therefore, an average distance between each hospital within each hospital group was estimated. An average mileage allowance was then calculated based on HSE allowance rates. According to the implementation plan, the travel costs for course attendees will not be reimbursed. The annual unit cost of short courses in each hospital group are presented in Table 3.5.

Table 3.5. Unit costs for short courses

Description	Details	Unit cost	Source(s)
Short courses (twice a year in each hospital group)	Travel and subsistence	€738.50*	HSE mileage and subsistence rates[31, 32]

* Unit cost comprises the cost of delivering two short courses each year in one hospital group.

3.6.6 Cost offsets

It is expected that the implementation of the DAFNE programme will lead to cost offsets in the short term and potentially cost savings in both the short and long term due to the reduction in adverse outcomes for adults with Type 1 diabetes.[8] The methods for calculating the short-term cost savings due to the reduction in adverse outcomes are outlined in Section 3.6.7. In addition, consistent with the guideline recommendations, all existing education programmes that do not meet all the necessary criteria specified in the clinical guidelines (such as the BERGER programme) will be replaced by the DAFNE programme leading to a cost offset in relation to their provision.

The results of the national diabetes hospital survey indicate that there is wide variation in the delivery of BERGER in Ireland. Accordingly, a conservative approach was adopted to estimate the cost offset of replacing the BERGER programme whereby the number of BERGER centres was set at eight (the midpoint of the range).

It was assumed that four courses (average number of courses which were delivered per centre during 2015 and 2016) take place each year. The cost used to calculate the cost

offsets which result from introduction of the DAFNE programme are presented in Table 3.6.

Table 3.6. Unit costs for calculation of cost offsets

Description	Details	Unit cost	Source(s)
BERGER	Cost of standard course	€1,784.33*	Consolidated salary scales 2017[33]

* Includes the cost of the senior dietitian, nurse specialist and administrative support across two and a half days. Salaries based on mid-point of scale adjusted for pension, pay related social insurance (PRSI) and overheads.[23, 24]

3.6.7 Cost savings

In terms of estimating cost savings, the present analysis adopted a conservative approach and incorporated Irish audit data from the years following set up of DAFNE centres in Ireland and data from the peer-reviewed literature. Irish audit data found that Irish DAFNE graduates achieved a mean HbA1c reduction of 0.5% following DAFNE participation.[35] However, while these reflect improvements in glycaemic control and are associated with a reduction in long-term complications of diabetes, it is not anticipated that these will lead to a change in costs in the time frame of this BIA (five years). Therefore, the key assumptions of cost savings as a result of DAFNE education are:

- Irish DAFNE graduates, who have previously experienced episodes of severe hypoglycaemia, experience a reduction in the rate of hypoglycaemic episodes in the year following DAFNE participation.[35]
- The rate of severe hypoglycaemia reduces and results in fewer admissions to acute services in the year following DAFNE participation.[36]

Clinical audit data collected by DAFNE in Ireland has demonstrated a reduction in the rates of severe hypoglycaemia and DKA in the year following DAFNE participation. These clinical audit data were incomplete with follow-up data available for only 58% (169 out of 289) of DAFNE participants in Ireland for the period from December 2014 to January 2017.[35] An Irish-based study conducted by Dinneen et al. found that the rate of severe hypoglycaemia at 18 months' follow up reduced compared with baseline.[11] At baseline, 24% (n=433) of

trial participants reported episodes of severe hypoglycaemia in the year prior to DAFNE participation. Of these, 93% (95% CI: 82-98%) reported a decrease at 18 months following DAFNE participation. At baseline, only 2.1% reported experiencing episodes of DKA in the year preceding DAFNE. The change from baseline was not reported.

In the absence of complete clinical audit data — and given the comparable baseline rates of severe hypoglycaemia in the audit data (26%) and those reported in the larger study by Dinneen et al. (24%) — a decision was made to use the follow-up data from the Dinneen et al. study to determine the reduction from baseline in the number of episodes of severe hypoglycaemia. The BIA used the baseline rates of patients who had experienced severe hypoglycaemia in the 12 months prior to DAFNE participation from the audit data as it represented more complete baseline data. The cost savings from reductions in DKA were not estimated due to the absence of sufficiently detailed follow-up data.

Data from the Hospital In-Patient Enquiry (HIPE) database were analysed to estimate the cost savings that would accrue to the HSE from reduced admissions due to severe hypoglycaemic episodes over the five-year time horizon. International Statistical Classification of Diseases and Related Health Problems (ICD) codes were used to identify the number of inpatients with a principal diagnosis of Type 1 diabetes with an emergency admission or emergency re-admission type (ICD code E10.64). The disease-related groups (DRGs) related to these diagnoses were extracted and a cost of each relevant DRG was sourced from the HSE casemix. A weighted average was then formulated based on the relevant DRGs and the quantity of patients attributed to each across the previous two years (the ICD codes were updated in 2015 and thus not directly comparable to previous years). Finally, the likelihood that a severe hypoglycaemic episode would be avoided was applied to the cost and the number of patients attending DAFNE training. In effect, this assumes that DAFNE training will result in one episode of severe hypoglycaemia per patient in the year following DAFNE training.

In line with the method outlined above, it was assumed that the distribution of severe hypoglycaemic episodes would be constant across the five-year time horizon. It is important also to note that while 93% of patients noted a reduction in frequency of severe

hypoglycaemic episodes, it is not known what this corresponded to in terms of absolute number of episodes. Being conservative, it was assumed that on average, each patient experiences a reduction of one serious hypoglycaemic episode as a result of DAFNE training. It was also assumed that this translated into one hospital admission prevented. However, it is noted that not all severe hypoglycaemic episodes will lead to a hospital admission, rather they may lead to paramedic call out and or emergency department (ED) attendances. ED attendance and paramedic call out represent less costly use of resources. As a result of these assumptions in terms of the absolute reduction in number of episodes per patient (one per patient) and how these are managed (reduction in one inpatient admission but ignoring other costs) there is considerable uncertainty in terms of these cost savings which could conceivably lead to an under- or over-estimation of the cost savings.

The time frame of the BIA is restricted to the first five years following implementation of the DAFNE programme. It therefore excludes cost savings that may accrue arising from a reduction in long-term complications due to improved diabetes control (e.g. reduction in neuropathy, nephropathy and cardiovascular events). Furthermore, the model considers only direct cost implications relevant to the HSE and does not account for other savings including patients' out-of-pocket costs, reductions in sick leave and so on that may accrue as a result of undergoing DAFNE training. To simplify the model, it was assumed that the cost benefits of DAFNE begin to accrue one year after DAFNE participation and extrapolated across the time horizon. Therefore, the direct benefits experienced by patients translate into a cost saving one year after undergoing DAFNE training. The savings then carry through into each subsequent year. This method implicitly assumes that the cost savings accruing to each patient remains constant across the entire time horizon. The unit cost is presented in Table 3.7.

Table 3.7. Unit costs for calculation of cost offsets

Description	Details	Unit cost	Source(s)
Inpatient admission prevented	Assumes that inpatient admission is due to episodes of severe hypoglycaemia	€1,010.81	HIPE;[37] HSE casemix[38]

3.6.8 Cost of additional structured appointments at diabetes clinics to standardise the frequency of re-call and review

This guideline will standardise the frequency of patient review at diabetes specialist clinics. The guideline recommends that glycaemic control should be checked by measuring HbA1c levels at least every six months. Consistent with the National Model of Integrated Care which stipulates that patients with Type 1 diabetes should be managed in secondary care, it is assumed that HbA1c levels will be reviewed as part of six-monthly structured reviews in consultant-led clinics. Data from the National Survey of Acute Hospital Diabetes Services and Resources 2017 indicated that only 42% of hospital diabetes services are currently offering reviews at least every six months to adults with Type 1 diabetes.[13] The remaining 58% of services offer reviews at intervals ranging from every seven to 13 months.

The guideline's implementation plan stipulates that the staff requirement of this recommendation should be considered on a hospital-by-hospital basis. Moreover, it is noted that full implementation of the National Model of Integrated care, which comprises the relocation of care of people with uncomplicated Type 2 diabetes from hospital to primary care, could potentially address the capacity constraints within diabetes specialist clinics. To facilitate this, a commitment to significant investment in primary care has already been made in the form of the Diabetes Cycle of Care Programme, with almost €11.25 million paid to register and provide structured appointments for patients with Type 2 diabetes in 2015 and 2016 alone. Conceivably, therefore, it may be possible to standardise the frequency of re-call for patients with Type 1 diabetes, so that all adults are offered appointments at six-

monthly intervals without additional resources being required. However, in the context of this BIA, a conservative approach is taken to cost this recommendation within existing resource constraints. The unit cost used in this approach is presented in Table 3.8.

Due to an unavailability of data, the preliminary results from the National Survey of Acute Hospital Diabetes Services and Resources were used to estimate the additional number of appointments required to achieve this recommendation. Of the 19,745 adults with Type 1 diabetes captured in the National Survey of Acute Hospital Diabetes Services and Resources, data were unavailable on 3,143 adults. For the unaccounted 3,143 adults with diabetes, it is assumed in the base case that they are evenly distributed across four hospitals that did not provide a population estimate in the preliminary survey data. Using the reported frequency of appointment re-call of adults with Type 1 diabetes by hospital, it was then estimated that there would be an additional 4,935 appointments per annum for patients. This leads to a total of 24,675 additional appointments over a five-year time horizon.

Table 3.8. Unit costs for calculation of additional diabetes clinic appointments

Description	Details	Total cost	Source(s)
Diabetes clinic appointment	Assumes appointment takes place in consultant-led outpatient clinic	€133.33*	HSE casemix[38]

* The cost of an outpatient visit was €132 in 2013. This has been inflated to €133 using the CSO's Consumer Price Index for health.[26]

3.7 Sensitivity analysis

Two types of uncertainty are relevant to a BIA: (1) structural uncertainty; and (2) parameter uncertainty. Structural uncertainty includes the introduction of new interventions and restrictions for use. Such uncertainty is not easily incorporated into the model. Parameter uncertainty relates to the input values used in the BIA. A univariate or one-way sensitivity analysis shows how influential each parameter is by itself and how sensitive the results are to fluctuations in each input value.

For this analysis, a one-way sensitivity analysis was performed to control for the uncertainty in the parameters underpinning the model. One-way sensitivity analysis is used to identify the key model inputs and assumptions contributing most to the level of uncertainty. To do this, the main cost drivers were identified through investigation of the model results. These parameters were fixed one by one at the upper and lower bounds of their plausible values. That is, the unit costs were varied upward and downward by 20%. The parameter was fixed at the upper and lower bounds of its confidence intervals, if this was specified in the literature from which the parameter was sourced.

Best and worst case scenarios were used to estimate the uncertainty surrounding the number of additional outpatient appointments in diabetes clinics that would be required to ensure that all adults with Type 1 diabetes were offered six-monthly reviews. These scenarios were defined by using alternative methods to account for the missing population data.

In the worst case scenario, a population weighted average for the hospitals (0.58 additional appointments per year) that did not offer a six-monthly appointment according to the preliminary survey results was applied to missing data (n=3,143). This gave 1,834 extra appointments for the population that was not captured in the preliminary survey data. Combining 1,834 with 3,476 led to a total of 5,310 extra appointments per year in the worst case scenario.

In the best case scenario, a population weighted average (0.21 additional appointments per year) for the total population captured in the preliminary survey results (n=16,607) was applied to missing data (n=3,143). This gave 658 extra appointments for the population that was not captured in the preliminary survey data. Combining 658 with 3,476 led to a total of 4,133 extra appointments per year in the best case scenario.

3.8 Quality assurance

The BIA was developed in accordance with national HTA guidelines, and the model was quality assured in accordance with the HRB-CICER quality assurance framework. All inputs (including costs and population parameters) and outputs were reviewed by a second economic modeller to ensure accuracy. The structure and assumptions underpinning the

model were reviewed by a second economic modeller to ensure that these were reasonable and appropriate based on the evidence-synthesis process. The clinical and implementation assumptions underpinning the model were described in the protocol which was agreed with the chair of the GDG, programme manager and diabetes clinical programme lead prior to finalisation of the model.

4. Results

4.1 Net cost of expanding access to structured education including provision of short courses for other staff

Overall, the incremental cost of expanding the provision of structured education (DAFNE) under the guideline's recommendations was estimated at €2,934,917 over five years. This estimate includes the costs of expanding access to structured education to 11 additional DAFNE centres and the cost of hiring additional staff. As these additional staff will also provide the short education courses for people involved in the delivery of care to adults with Type 1 diabetes (as described in the implementation plan), the costs presented here represent the combined cost of both DAFNE education and the short courses for other staff. A graphical summary of the incremental cost per year is illustrated in Figure 4.1.

In line with the guideline's implementation plan, it is anticipated that recruitment of new staff will happen in year one. A phased expansion of the DAFNE programme begins in year two of the time horizon, with half of the set-up and delivery costs of the DAFNE programme introduced in year two and the rest of these costs in year three. Therefore, it is unsurprising to find that the incremental costs are highest in year two as the cost savings from the prevention of adverse health outcomes do not begin to accumulate until year three.

From Figure 4.1, it can be seen that the cumulative net cost of expanding DAFNE peaks in year four. From that point onwards, the cost offsets and savings begin to outweigh the incremental costs of delivering structured education. That is, there is a decrease in the overall costs after year four. This is because patients begin to receive the benefits of improved glycaemic control within 12 months of undergoing DAFNE training and continue to reap the reward of these benefits across the five-year time horizon. The estimated savings are due to the avoidance of hospital admissions caused by episodes of severe hypoglycaemia.

A summary of the estimated annual costs of the guideline across the five-year time horizon is presented in Table 4.1.2. These costs are categorised according to the principal headings identified in Section 3.6.

Figure 4.1. Incremental budget impact of expanding access to structured education (DAFNE) and provision of short courses across the five-year time horizon of the BIA

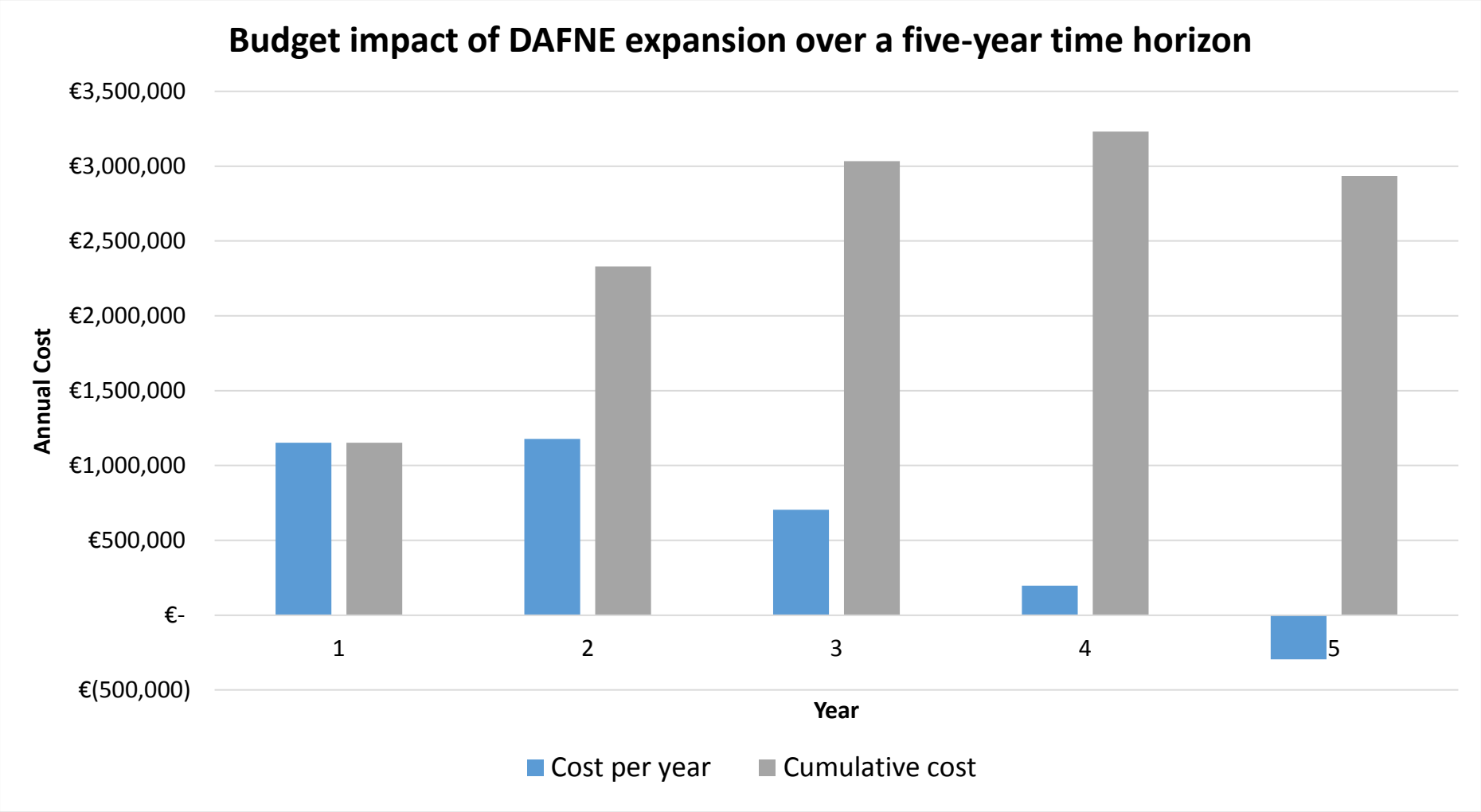


Table 4.1.2. Summary of annual costs of the principal cost categories per year

Cost	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Set-up and delivery costs (including central contribution, training of staff, patient resources, depletion of resources and staff, annual meeting attendance and opportunity cost)	€0	€67,360	€85,443	€70,091	€70,091	€292,986
Costs post-DAFNE (includes costs of insulin and DAFNE follow up)	€0	€11,637	€53,190	€94,743	€136,296	€295,865
Implementation costs (staff recruitment)	€1,151,797	€1,151,797	€1,151,797	€1,151,797	€1,151,797	€5,758,986
Implementation costs (short courses)	€0	€4,431	€4,431	€4,431	€4,431	€17,724
Cost offsets and cost savings						
Cost offsets (includes replacement of BERGER)	€0	€57,099	€57,099	€57,099	€57,099	€228,394
Cost savings (includes reduction in episodes of severe hypoglycaemia)	€0	€0	€533,708	€1,067,417	€1,601,125	€3,202,250
Net total	€1,151,797	€1,178,126	€704,055	€196,547	-€295,608	**€2,934,917**

Figures rounded to nearest euro for legibility.

Across this time horizon, it was estimated that an additional 1,824 patients would receive DAFNE education from the 11 new DAFNE centres. Over a five-year time horizon, this equates to a cost per patient of €1,599. The total net costs associated with the expansion of the DAFNE programme and the number of patients receiving DAFNE training are presented in Table 4.1.1.

Table 4.1.1. Summary of the total net costs of expanding the provision of the DAFNE programme

	Total
Net cost of expanding provision of DAFNE	€2,934,917
Number of patients receiving DAFNE training	1,824
DAFNE net cost per patient	**€1,599***

* Excludes the cost of delivering short courses to health professionals involved in the delivery of care to adults with Type 1 diabetes. These courses are not a requirement of the DAFNE programme.

4.2 Cost of standardising appointment frequency in diabetes clinics

Overall, the standardisation of care to ensure that all adults with Type 1 diabetes are offered structured appointments at six-monthly intervals to include review of HbA1c levels was estimated at €3,290,024 over five years. However, it is anticipated that no additional funding will be required in respect of this recommendation as it should be secured through the redistribution of resources, supported by the investment in primary care for patients with Type 2 diabetes.

Significant investment in primary care through the funding of a Diabetes Cycle of Care programme began in October 2015. This programme is intended to support timely, appropriate and efficient care of patients with Type 2 diabetes and to facilitate the safe discharge of patients with uncomplicated Type 2 diabetes to primary care. Ongoing engagement by patients and providers with this scheme, which will cost at least €8.5 million a year on an ongoing basis, is intended to release existing resources within the hospital

setting to ensure that centres that are not currently meeting the recommended frequency of appointments for those with Type 1 diabetes will be enabled to do so. That is, this recommendation should be resource neutral as it should be achieved through the redistribution of resources; however, consistent with the conservative approach adopted in this BIA, the potential opportunity costs of standardising follow-up of patients with Type 1 diabetes within existing resource constraints have been estimated.

The incremental costs of standardising the frequency with which adults with Type 1 diabetes are offered structured appointments is presented in Table 4.2.

Table 4.2. Summary of annual opportunity costs of standardising the appointment frequency offered to adults with Type 1 diabetes

Year 1	Year 2	Year 3	Year 4	Year 5	Total
€658,005*	€658,005*	€658,005*	€658,005*	€658,005*	**€3,290,024***

Figures rounded to nearest euro for legibility.

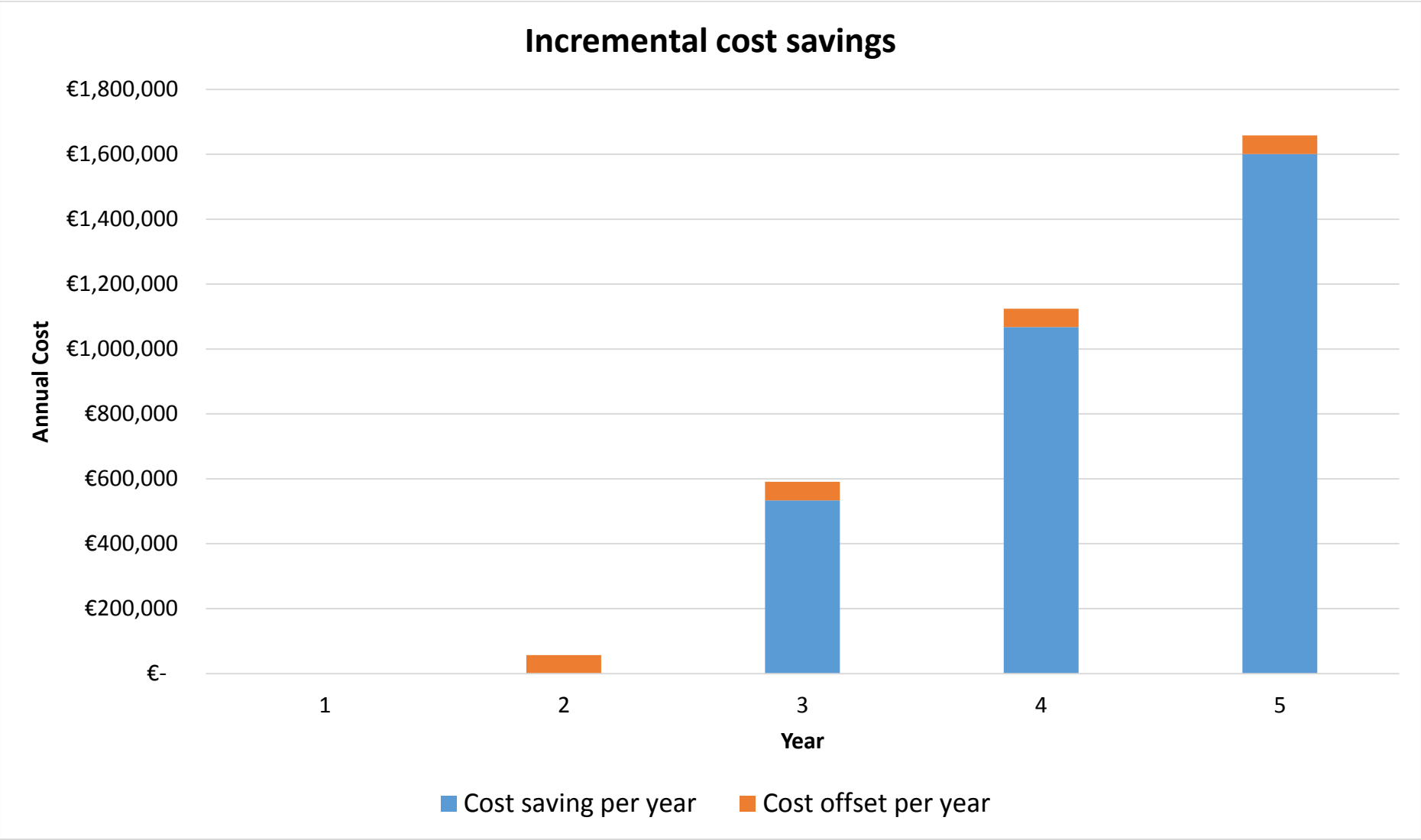
*Represents an opportunity cost, however, it is anticipated that no additional funding will be required in respect of this recommendation given the ongoing engagement of patients and providers with the Diabetes Cycle of Care programme. It is intended that the programme will release existing resources within the hospital setting secured through the redistribution of resources and supported by investment in primary care for patients with Type 2 diabetes.

4.3 Cost savings and cost offsets

Cost savings occur due to the prevention of adverse events which result from poor glycaemic control. Individuals with Type 1 diabetes that attend DAFNE training have improved management of their blood glucose, which leads to a reduction in adverse events, and thus a cost saving to the HSE due to adverse events prevented. Savings begin to accrue one year after individuals receive training. The total cost savings increase incrementally as it is assumed individuals who have undergone training continue to reap the benefits of improved glycaemic control over the time horizon.

Figure 4.3 presents the cumulative incremental increase in cost savings due to the prevention of adverse events and the cost offsets due to the replacement of other structured education programmes currently delivered in Ireland that do not meet all of the criteria outlined in the clinical guidelines (such as the BERGER programme) over the five-year time horizon. The cost offsets are due to the replacement of the BERGER programme as described in Section 3.6.5.

Figure 4.3. Cumulative incremental increase in cost offsets and savings across the five-year time horizon of the BIA



4.4 Sensitivity analysis

In line with national guidelines for the conduct of HTA, a univariate sensitivity analysis was used to assess how sensitive the results were to fluctuations in each parameter.[23, 24] Given the uncertainty around the estimated parameters, the sensitivity analysis shows how this translates into uncertainty around the results.

Through investigation of the univariate sensitivity analysis results, whereby all of the BIA parameters were fixed at their plausible lower and upper bounds, four parameters were identified as the main cost drivers in the model. These were:

- the implementation costs due to the recruitment of additional staff
- the cost saving from the prevention of episodes of severe hypoglycaemia requiring an inpatient admission
- the relative risk reduction identified in the Dinneen et al. study[36] of the occurrence of episodes of severe hypoglycaemia that require an inpatient admission
- the increase in insulin costs due to improved glucose control following DAFNE participation.

Beyond these main four parameters, the univariate sensitivity analysis did not vary the overall budget impact by more than 2%.

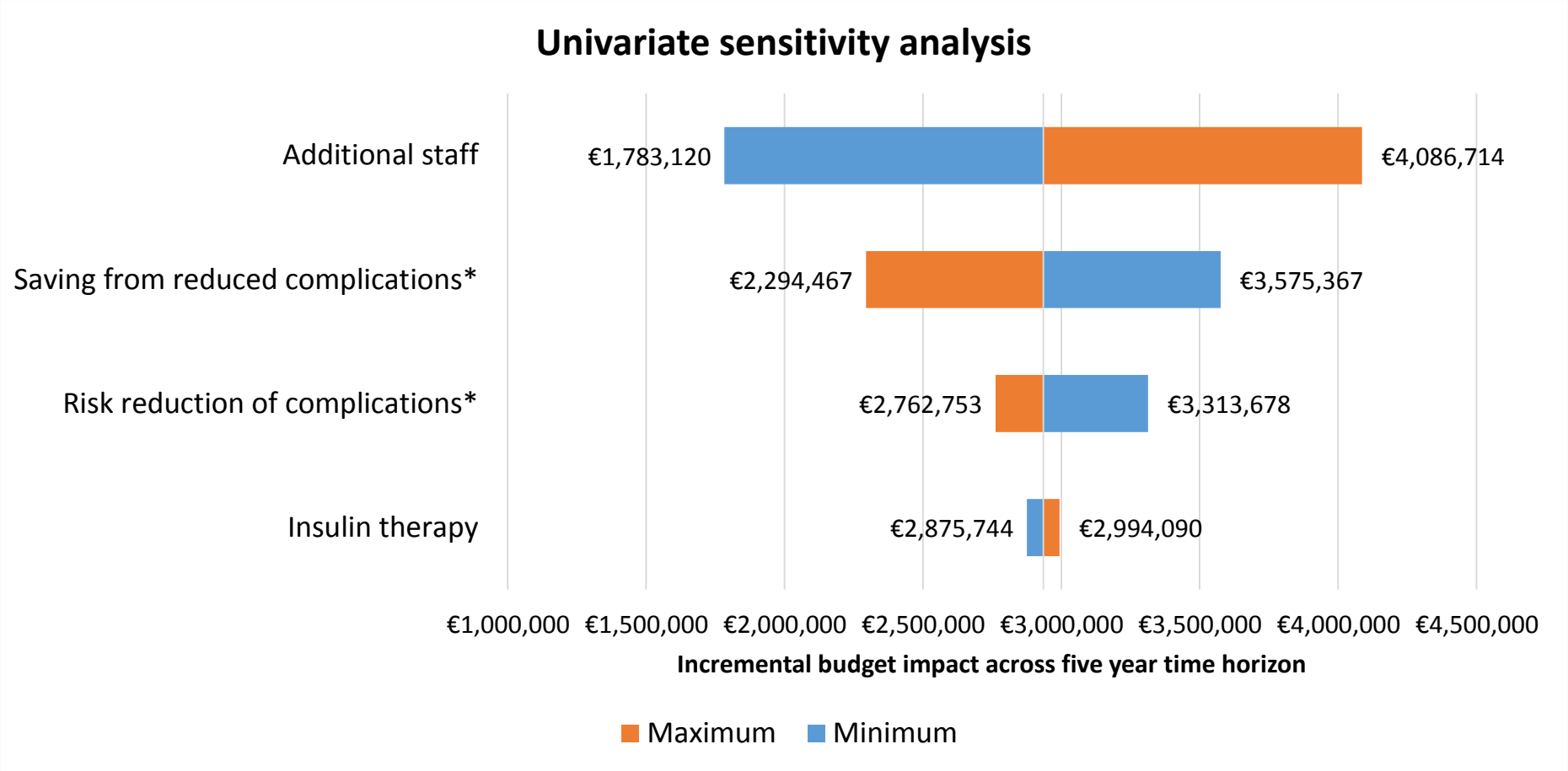
The results of the sensitivity analysis are presented in the form of a tornado plot in Figure 4.4. These results illustrate the changes to the overall costs that occur when the principal cost drivers are fixed at their upper and lower estimated plausible values. The parameters were fixed at these upper and lower values individually with all other input parameters remaining unchanged. The upper and lower cost values were defined by varying the estimated cost by 20%. The confidence intervals specified by Dinneen et al.[36] were used to define the upper and lower bounds of the relative risk of the occurrence of severe hypoglycaemia that requires an inpatient admission.

The univariate sensitivity analysis, presented in Figure 4.4 indicated that the incremental budget impact was very sensitive to variation in:

- the cost savings resulting from a reduction in episodes of severe hypoglycaemia that lead to an inpatient admission
- the implementation cost due to the recruitment of staff in each hospital group.

Changes in the estimated values for these two parameters could result in significant changes to the incremental budget impact across the five-year time horizon.

Figure 4.4. Tornado plot illustrating the sensitivity of the results for the five-year incremental BIA



Note: tornado plot presents only the four most influential parameters in the sensitivity analysis.

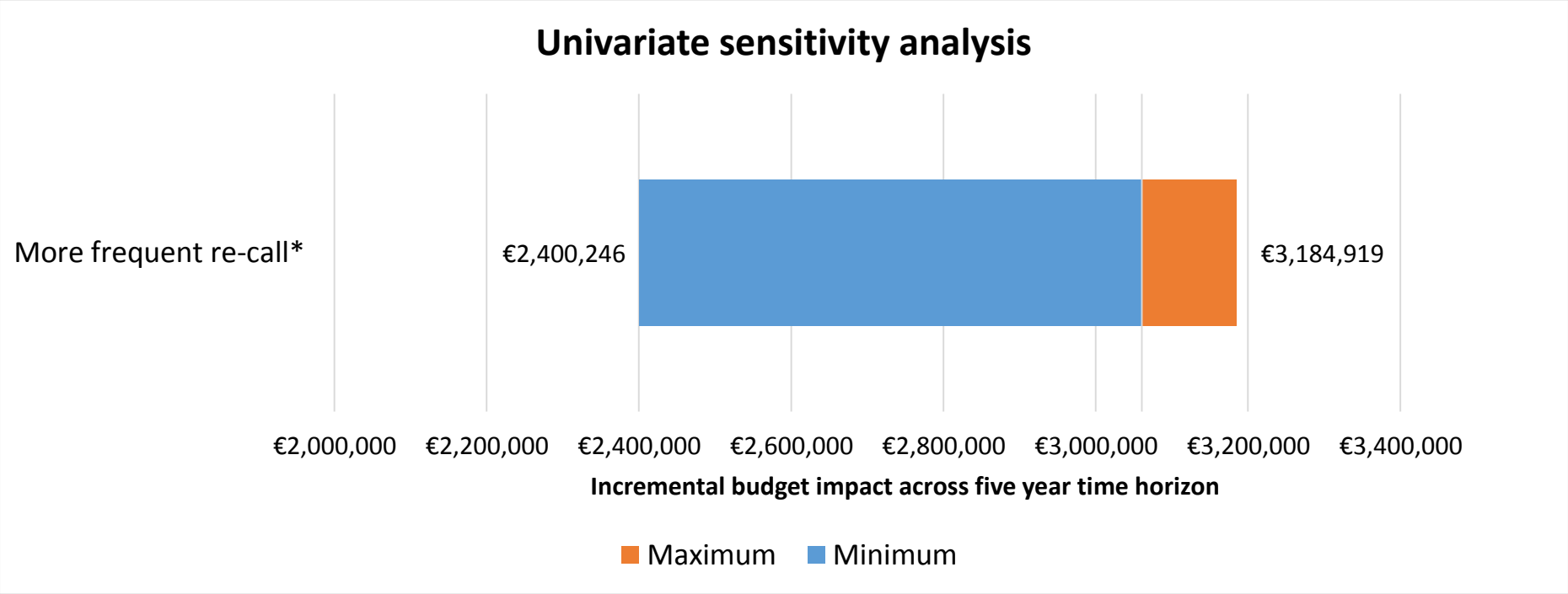
* Complications are defined here as an inpatient admission resulting from an episode of severe hypoglycaemia.

The uncertainty surrounding the potential budget impact of the additional number of appointments for structured review at diabetes clinics was also tested via a univariate sensitivity analysis. The results of the sensitivity analysis are presented in the form of a tornado plot in Figure 4.5. These results illustrate the changes to the overall costs that occur when the principal cost drivers are fixed at their upper and lower estimated plausible values. The parameters were fixed at these upper and lower values individually with all other input parameters remaining unchanged.

The upper and lower bounds of the number of structured reviews at diabetes were defined by a best and worst case scenario. The best case scenario comprised an additional 4,133 appointments per year. That is, an additional 20,666 appointments across five years. The worst case scenario comprised an additional 5,310 appointments a year. That is, an additional 26,548 across five years. These scenarios were defined using the methods outlined in Section 3.7.

The results illustrated in Figure 4.5 indicated that the incremental budget impact was very sensitive to variation in the number of additional appointments that would result from more frequent structured reviews of adults with Type 1 diabetes.

Figure 4.5. Plot illustrating the sensitivity of the results for the five-year incremental BIA.



*More frequent re-call refers to the standardisation of appointment frequency at diabetes clinics.

5. Discussion

Based on the implementation of *Type 1 diabetes in adults guideline*, this budget impact analysis identified the following changes to the treatment pathway:

- introducing and expanding access to a high-quality structured education programme, such as the DAFNE programme
- providing short courses for healthcare professionals involved in the delivery of care for patients with Type 1 diabetes
- standardising patient care to ensure that all adults with Type 1 diabetes are offered structured appointments at least every six months, to include review of glycaemic control (HbA1c levels).

As a consequence of this BIA, the net cost of expanding access to structured education and to provide short courses for healthcare professionals is estimated to be €2,935,000 over a five-year time horizon. A univariate sensitivity analysis identified the additional staff recruited under the guideline's implementation plan and the realisation of cost savings from avoiding episodes of severe hypoglycaemia that lead to hospital admission as the principal drivers of the incremental budget analysis over the time horizon. The estimate was also driven by the number of centres, courses per centres and patients attending DAFNE training. These were based on the assumptions which underpinned the analysis. A change to these assumptions will alter the results of this analysis. It is acknowledged that a budget impact analysis model can only be as strong a predictor of resource impact as the assumptions underpinning it. The limitations of the assumptions undertaken in development of this analysis have been presented transparently in Sections 2 and 3 of this report.

Recommendations 1.6.25 and 1.6.26 in the clinical guideline relate to the use of flash glucose monitoring in Ireland. The use of flash glucose monitoring would represent a change to standard practice. Given that these recommendations adopt a neutral rather than prescriptive stance on the use of flash glucose monitoring, it was decided after discussion with the GDG that flash glucose monitoring would be excluded from the BIA. That said, it is

noted that there will be an imminent change to local policy. An evaluation was conducted by the HSE's Health Technology Assessment Group (HTAG) in October 2017 to consider reimbursement of flash glucose monitoring in the form of Abbott Laboratories' FreeStyle Libre flash glucose monitoring device.

According to the published report, the incremental budget impact ranges from €2.1 million in the best case scenario to €33 million in the worst case scenario across a five-year time horizon.[39] The best case scenario assumed the HSE will reimburse a maximum of 26 sensors per annum and all replacement units would be provided free of charge by Abbott Laboratories. In comparison, the worst case scenario assumed the HSE would reimburse all sensors, with the average days per sensor being 9.3 days. Additionally, the best case scenario entails the HSE experiencing a reduction of standard monitoring of blood glucose (SMBG) of 90% versus a reduction of 80% in the worst scenario. It was also assumed that the cost of blood glucose monitoring strips suitable for use with the FreeStyle Libre reader would remain at current cost levels.

The budget impact estimate is based on uptake of the FreeStyle Libre device, rising from 30% in year one to 50% in year five of the time horizon in the total multiple daily injection diabetes population, aged over four years. However, according to a press release announcing the scheme, reimbursement will be been confined to children and young adults.[27] At this point, the definition, size and incremental budget impact of this target population is unclear, but it can be expected to be smaller than that estimated in the HTAG report. Noting the potential for a substantial budget impact, it has been recommended that any decision to reimburse this technology should be re-evaluated after one year. Furthermore, the assessment notes the potential organisational impact for the HSE in terms of IT requirements and patient support.

The relative cost of high-quality structured education relative to other therapies such as flash glucose monitoring and insulin costs is noteworthy. According to annual PCRS reports, total expenditure on insulin analogues through the Long Term Illness scheme has increased steadily from €16.81 million in 2013 to €29.03 million in 2016.[21] There are RCT data to show that DAFNE improves the health outcomes of adults with Type 1 diabetes, with

economic literature from the UK suggesting that DAFNE may be cost saving in the long term.[8, 14] Based on the RCT data, the UK evaluation estimated that per patient average insulin costs would increase by approximately 9% (from £559 to £609) following DAFNE training. Irish patients predominantly use the more expensive analogue-based insulin unlike the UK where treatment is predominantly with neutral protamine Hagedorn (NPH).[36] This could potentially impact the cost-effectiveness of the intervention. Using a conservative approach, this BIA estimated an increase in the cost of insulin therapy at a maximum of €48.49 (ranging from €38.80 to €48.49) per patient per annum. While this represents a crude estimate, a micro-costing exercise was not considered to be justified in this analysis. Instead, the analysis sought to estimate the maximum cost which may result from these changes. Additionally, cost savings associated with a reduction in paramedic call out, emergency department or primary care visits were not included in the analysis. This was due to the unavailability of data relating to these outcomes.

Apart from the direct cost implications estimated in the BIA, it is important to consider that there are significant psychological and psychosocial benefits for adults with Type 1 diabetes who undergo DAFNE training.[8, 40] As reported by previous analyses, psychosocial benefits for participants following DAFNE training include:

- a renewed sense of enthusiasm for managing their diabetes and commitment to adhering to treatment regimens
- an increased openness to discussing aspects of their condition and seeking support from family and friends.

Improved psychological outcomes include improved treatment satisfaction as measured by a variety of quality-of-life scales. These benefits are not explicitly accounted for in a BIA which only included the cost savings relating to a reduction in hospital admissions due to severe hypoglycaemia. Similarly, productivity changes relating to potential reductions in patient and/or carer time lost due to illness are not considered. This approach is consistent with the perspective of the BIA.

The net cost of expanding access to DAFNE education is estimated at €1,599 per patient

over a five-year time horizon. This may, however, underestimate the cost-savings associated with the introduction of the DAFNE programme. The analysis adopted the perspective of the HSE and thus did not consider societal costs such as improvements in productivity associated with a reduction in illness days. Similarly, given the five-year time perspective of the BIA, this method is likely to underestimate the long-term benefits experienced by patients because it does not account for long-term improvements in patient morbidity and mortality as a result of undergoing DAFNE training.

Apart from expanding access to structured education, the main cost driver in this BIA is the standardisation of patient follow-up in diabetes clinics. However, it should be noted that significant investment in primary care through the funding of a Diabetes Cycle of Care programme to facilitate discharge of patients with uncomplicated Type 2 diabetes to primary care began in October 2015. A criticism of this scheme is that it applies only to the General Medical Services scheme (GMS) patients (that is those patients who are holders of a medical card or GP visit card) and that non-GMS patients with stable Type 2 diabetes may continue to avail of free care in hospital outpatients. Assuming there are at least 190,000 adults with Type 2 diabetes in Ireland, and that consistent with national figures, 46% are GMS patients, the majority of eligible patients (87,400) have already been registered on the Diabetes Cycle of Care Programme (almost 85,000 patients registered by December 2016).

Ongoing engagement by patients and providers with this scheme, which will cost at least €8.5 million a year on an ongoing basis, should release existing resources within the hospital setting for those with Type 1 diabetes. This recommendation should therefore be resource neutral; however, consistent with the conservative approach adopted in this BIA, the potential opportunity costs of standardising follow-up of patients with Type 1 diabetes within existing resource constraints have been estimated.

Finally, the BIA did not include an estimate of resource requirements for the set up and implementation of a coordinated population-based IT system. There is a clear need for such a system in the context of resource planning and allocation as very few reliable estimates of the Type 1 diabetes population in Ireland currently exist. However, there is presently insufficient detail for the implementation strategy of a coordinated IT system to determine

the cost implications that the set up of such a system would entail. Therefore, further exploration of options for implementation (such as set-up costs, consensus on its function and purpose, methods and responsibility for monitoring and servicing of the system) is required to estimate the budgetary implications of this recommendation. Implementation of such a system is likely to have considerable resource and budgetary implications.

5.1 Conclusions

The provision of high-quality structured education can significantly benefit the treatment of adults with Type 1 diabetes in Ireland. The DAFNE (Dose Adjustment for Normal Eating) programme was used to estimate the budget impact of this guideline as it is currently the only structured education programme provided in Ireland that meets the criteria of this guideline. Over a five-year time horizon, the budget impact of the guideline recommendation on structured patient education is estimated to be approximately €2,970,000. Presently, there is insufficient evidence to claim that expanded provision of DAFNE will lead to a net cost-saving in the short term, but the international literature suggests that this will be the case in the long term. Longer term audit data and evidence of prevention of adverse events will help to determine if this finding is relevant to Ireland.

The budget impact analysis also considers the additional resources required to deliver the standardisation of appointment frequency for adults with Type 1 diabetes. In order to meet the guideline recommendations, an estimated 5,000 additional appointments would be required each year. However, it is anticipated by the GDG that the implementation of the National Model of Integrated care, which comprises the relocation of care of people with uncomplicated Type 2 diabetes from hospital to primary care, should address the capacity constraints within diabetes specialist clinics. A commitment to significant investment in primary care has already been made in the form of the Diabetes Cycle of Care Programme, with almost €11.25 million paid to register and provide structured GP appointments for almost 85,000 patients with Type 2 diabetes in 2015 and 2016 alone.

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Appendix 1: Annual contribution of DAFNE centres

The annual contribution fee for each DAFNE centre is based upon two elements to cover the projected running cost for the national programme. Firstly, there is a fixed fee to cover 95% of the running costs. That is, 95% of the running costs are divided by the number of DAFNE services expected to be part of the DAFNE consortium in the next financial year.[29]

The remaining 5% of the running costs are variable for each centre based upon the number of active educators at each centre in the previous calendar year. That is, 5% of the running costs are divided by the total number of active educators across the consortium to get an 'educator contribution'.[29] The total educator contribution per centre is calculated by multiplying the number of active educators at that centre by the educator contribution. Therefore, an individual centre's contribution fee is equal to the sum of the fixed and variable contribution. Table 1 shows the total contribution range for 2017 to 2018 according to the number of educators at each centre.

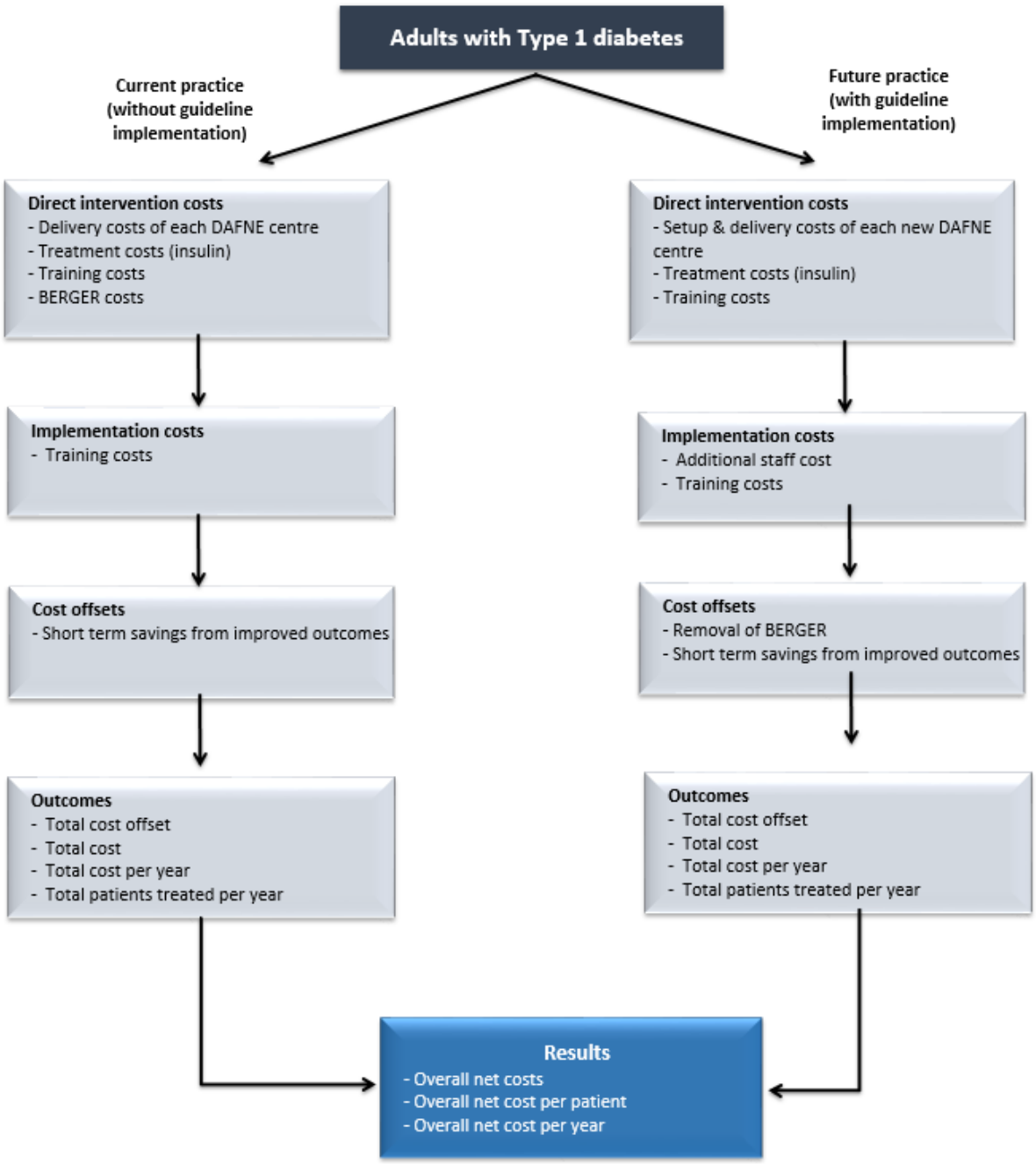
Table 1. Total contribution range for DAFNE centres according to number of educators per centre for 2017 to 2018[29]

Number of educators	Full year fee (£)	Full year fee (€)*
2	£ 4,368.92	€ 4,893.19
3	£ 4,406.85	€ 4,935.67
4	£ 4,444.78	€ 4,978.15
5	£ 4,482.71	€ 5,020.64
6	£ 4,520.64	€ 5,063.12
7	£ 4,558.57	€ 5,105.60
8	£ 4,596.50	€ 5,148.08
9	£ 4,634.42	€ 5,190.55
10	£ 4,672.35	€ 5,233.03
11	£ 4,710.28	€ 5,275.51
12	£ 4,748.21	€ 5,318.00
13	£ 4,786.14	€ 5,360.48
14	£ 4,824.07	€ 5,402.96
15	£ 4,862.00	€ 5,445.44

* Sterling prices converted to euro using the currency exchange rate of £1 = €1.12 valid as of 12 December 2017. [28]

Appendix 2: Economic model

Figure 1. Model flow



Appendix 3: List of clinical recommendations, their impact on the treatment pathway and rationale for excluded interventions

Recommendation		Change to routine care
3.1.1	Diagnose Type 1 diabetes on clinical grounds in adults presenting with hyperglycaemia, bearing in mind that people with Type 1 diabetes typically (but not always) have one or more of: • ketosis • rapid weight loss • age of onset below 50 years • BMI below 25 kg/m2 • personal and/or family history of autoimmune disease.	No — guideline development group (GDG) confirmed that the recommendations relating to the diagnosis of Type 1 diabetes do not represent a change to standard practice.
3.1.2	Do not discount a diagnosis of Type 1 diabetes if an adult presents with a BMI of 25 kg/m^2 or above or is aged 50 years or above.	No— GDG confirmed that the recommendations relating to the diagnosis of Type 1 diabetes do not represent a change to standard practice.
3.1.3	Do not measure C-peptide and/or diabetes-specific autoantibody titres routinely to confirm Type 1 diabetes in adults.	No — GDG confirmed that the recommendations relating to the diagnosis of Type 1 diabetes do not represent a change to standard practice.
3.1.4	Consider further investigation in adults that involves measurement of C-peptide and/or diabetes-specific autoantibody titres if: • Type 1 diabetes is suspected but the clinical presentation includes some atypical features (for example, age 50 years or above, BMI of 25 kg/m2 or above, slow evolution of hyperglycaemia or long prodrome) or • Type 1 diabetes has been diagnosed and treatment started but there is a clinical suspicion that the person may have a monogenic form of diabetes, and C-peptide and/or autoantibody testing may guide the use of genetic testing or	No — GDG confirmed that the recommendations relating to the diagnosis of Type 1 diabetes do not represent a change to standard practice.

Recommendation		Change to routine care
	• Classification is uncertain, and confirming Type 1 diabetes would have implications for availability of therapy (for example, continuous subcutaneous insulin infusion [CSII or 'insulin pump'] therapy).	
3.1.5	When measuring C-peptide and/or diabetes-specific autoantibody titres, take into account that: • autoantibody tests have their lowest false negative rate at the time of diagnosis, and that the false negative rate rises thereafter • C-peptide has better discriminative value the longer the test is done after diagnosis • with autoantibody testing, carrying out tests for 2 different diabetes-specific autoantibodies, with at least 1 being positive, reduces the false negative rate.	No — GDG confirmed that the recommendations relating to the diagnosis of Type 1 diabetes do not represent a change to standard practice.
3.1.6	At the time of diagnosis (or if necessary after the management of critically decompensated metabolism), the diabetes professional team should develop with and explain to the adult with Type 1 diabetes a plan for their early care. To agree such a plan will generally require: • medical assessment to: - ensure security of diagnosis of type of diabetes - ensure appropriate acute care is given when needed - review and detect potentially confounding disease and medicines - detect adverse vascular risk factors • environmental assessment to understand: - the social, home, work and recreational circumstances of the person and carers - their preferences in nutrition and physical activity - other relevant factors, such as substance use • cultural and educational assessment to identify prior knowledge and to enable optimal advice and planning about: - treatment modalities - diabetes education programmes • assessment of emotional state to determine the appropriate pace of education.	No — GDG confirmed that the recommendations to the early care of adults diagnosed with Type 1 diabetes do not represent a change to standard practice.

Recommendation		Change to routine care
	The results of the assessment should be used to agree a future care plan. Some items of the initial diabetes assessment: • acute medical history • social, cultural and educational history/lifestyle review • complications history/symptoms • long-term/recent diabetes history • other medical history/systems • family history of diabetes/cardiovascular disease • medication history/current medicines • vascular risk factors • smoking • general examination • weight/BMI • foot/eye/vision examination • urine albumin excretion/urine protein/serum creatinine • psychological wellbeing • attitudes to medicine and self-care • immediate family and social relationships and availability of informal support.	
3.1.7	Elements of an individualised and culturally appropriate plan will include: • sites and timescales of diabetes education, including nutritional advice (see Sections 1.3 and 1.4) • initial treatment modalities, including guidance on insulin injection and insulin regimens (see Sections 1.7 and 1.8) • means of self-monitoring and targets (see Section 1.6) • symptoms, risk and treatment of hypoglycaemia • management of special situations, such as driving • means and frequency of communication with the diabetes professional team • management of cardiovascular risk factors (see Section 1.13) • for women of childbearing potential, implications for pregnancy and family planning advice (see the HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period) • frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review.	No — GDG confirmed that the recommendations to the early care of adults diagnosed with Type 1 diabetes do not represent a change to standard practice.

Recommendation		Change to routine care
3.1.8	After the initial plan is agreed, put arrangements in place to implement it without inappropriate delay, and to provide for feedback and modification of the plan over the ensuing weeks.	No — GDG confirmed that the recommendations to the early care of adults diagnosed with Type 1 diabetes do not represent a change to standard practice.
3.1.9	All patients who are newly diagnosed with diabetes should be registered with the Long Term Illness Scheme and the National Diabetes Retinopathy Screening Programme	No — people with diabetes mellitus qualify for reimbursement of certain medications related to their diabetes care under the Long Term Illness Scheme. General practitioners have had the option to register patients with the Retinopathy Screening Programme since 2013.
3.2.1	Take account of any disabilities, including visual impairment, when planning and delivering care for adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to support and individualised care do not represent a change to standard practice.
3.2.2	Advice to adults with Type 1 diabetes should be provided by a range of professionals with skills in diabetes care working together in a coordinated approach. A common environment (diabetes centre) is an important resource in allowing a diabetes multidisciplinary team to work and communicate efficiently while providing consistent advice.	No — hospital survey data confirmed that the multidisciplinary approach to the provision of support and individualised care does not represent a change to standard practice.
3.2.3	Regard each adult with Type 1 diabetes as an individual, rather than as a member of any cultural, economic or health-affected group (see also recommendations 1.4.4 and 1.4.11 about the cultural preferences of individual adults with Type 1 diabetes). Set up an individual care plan jointly agreed with the adult with	No — hospital survey data indicates that annual review takes place. The GDG confirmed that the education of family members is not new

Recommendation		Change to routine care
	Type 1 diabetes, review it annually and modify it taking into account changes in the person's wishes, circumstances and medical findings, and record the details. The plan should include aspects of: • diabetes education, including nutritional advice (see Sections 1.3 and 1.4) • insulin therapy, including dose adjustment (see Sections 1.8 and 1.9) • self-monitoring (see Section 1.6) • avoiding hypoglycaemia and maintaining awareness of hypoglycaemia • management of hypoglycaemia including training of friends and/or family on glucagon administration • for women of childbearing potential, family planning, contraception and pregnancy planning (see the HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period) • cardiovascular risk factor monitoring and management (see Section 1.13) • complications monitoring and management (see Section 1.15) • psychological wellbeing of the person with diabetes • means and frequency of communicating with the diabetes professional team • frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review.	and that provision of annual reviews would not impact standard practice.
3.2.4	Use population, practice-based and clinic diabetes registers to assist programmed re-call for annual review and assessment of complications and cardiovascular risk.	Yes — development of diabetes registers would need to be part of a coordinated IT system.
3.2.5	The multidisciplinary team approach should be available to inpatients with Type 1 diabetes, regardless of the reason for admission (see Section 1.14).	No — hospital survey data confirmed that a multidisciplinary approach to the provision of support and individualised care does not represent a change to

Recommendation		Change to routine care
		standard practice.
3.2.6	At the time of diagnosis and periodically thereafter, provide adults with Type 1 diabetes with up-to-date information about diabetes support groups (local and national e.g. Diabetes Ireland), how to contact them and the benefits of membership	No — GDG confirmed that the recommendations relating to the provision of support and individualised care do not represent a change to standard practice.
3.3.1	Offer all adults with Type 1 diabetes a structured education programme of proven benefit, for example the DAFNE (dose-adjustment for normal eating) programme. Offer this programme 6–12 months after diagnosis.	Yes — GDG confirmed that this represents a change to standard practice. Provision of the DAFNE programme will be expanded.
3.3.2	If a structured education programme has not been undertaken by an adult with Type 1 diabetes by 12 months after diagnosis, offer it at any time that is clinically appropriate and suitable for the person, regardless of duration of Type 1 diabetes.	Yes — GDG confirmed that this represents a change to standard practice. Provision of the DAFNE programme will be expanded.
3.3.3	Provide an alternative of equal standard for any adult with Type 1 diabetes unable or unwilling to participate in group education.	No — no alternative of equal standard has been identified.
3.3.4	Ensure that any structured education programme for adults with Type 1 diabetes includes the following components: • It is evidence-based, and suits the needs of the person. • It has specific aims and learning objectives, and supports the person and their family members and carers in developing attitudes, beliefs, knowledge and skills to self-manage diabetes. • It has a structured curriculum that is theory-driven, evidence-based and resource-effective, has supporting materials, and is written down. • It is delivered by trained educators who have an understanding of educational theory appropriate to the age and needs of the person, and who are trained and competent to deliver the principles and content of the programme. • It is quality assured, and reviewed by trained, competent, independent assessors who measure it against criteria that	Yes — GDG confirmed that this represents a change to standard practice. Provision of the DAFNE programme will be expanded.

Recommendation		Change to routine care
	ensure consistency. • The outcomes are audited regularly.	
3.3.5	Explain to adults with Type 1 diabetes that structured education is an integral part of diabetes care.	Yes — GDG confirmed that this represents a change to standard practice. A pre-DAFNE booking meeting will take place.
3.3.6	Provide information about Type 1 diabetes and its management to adults with Type 1 diabetes at all opportunities from diagnosis onwards.	Yes — GDG confirmed that this represents a change to standard practice. Provision of the DAFNE programme will be expanded.
3.3.7	Carry out more formal review of self-care and needs annually in all adults with Type 1 diabetes. Vary the agenda addressed each year according to the priorities agreed between the healthcare professional and the adult with Type 1 diabetes.	No — hospital survey data confirmed that the annual review does not represent a change to standard practice.
3.4.1	Offer carbohydrate-counting training to adults with Type 1 diabetes as part of structured education programmes for self-management.	Yes — this will be covered during DAFNE training.
3.4.2	Consider carbohydrate-counting courses for adults with Type 1 diabetes who are waiting for a more detailed structured education programme or are unable to take part in a stand-alone structured education programme.	No — GDG confirmed that this does not represent a change to standard practice.
3.4.3	Offer dietary advice to adults with Type 1 diabetes about issues other than blood glucose control, such as weight control and cardiovascular risk management, as indicated clinically.	No — GDG confirmed that the recommendations relating to dietary advice do not represent a change to standard practice.
3.4.4	Provide nutritional information sensitive to personal needs and culture from the time of diagnosis of Type 1 diabetes.	No — GDG confirmed that the recommendations relating to dietary advice do not represent a change to standard practice.
3.4.5	Provide nutritional information individually and as part of a diabetes education programme. Include advice from health	Yes — this recommendation will be covered by DAFNE.

Recommendation		Change to routine care
	care professionals with specific and approved training and continuing accredited education in delivering nutritional advice to people with health conditions. Offer opportunities to receive nutritional advice at intervals agreed between adults with Type 1 diabetes and their advising professionals.	
3.4.6	Discuss the glycaemic effects of different foods an adult with Type 1 diabetes wishes to eat in the context of the insulin preparations chosen to match those food choices	No — GDG confirmed that this does not represent a change to standard practice.
3.4.7	Make programmes available to adults with Type 1 diabetes to enable them to make: • optimal choices about the variety of foods they wish to consume • insulin dose changes appropriate to reduce glucose excursions when taking different quantities of those foods.	Yes — this recommendation will be covered by DAFNE.
3.4.8	Agree the indication for, choice of content, timing and amount of snacks between meals or at bedtime available to the adult with Type 1 diabetes, based on informed discussion about the extent and duration of the effects of eating different food types and the insulin preparations available to match them. Modify those choices based on discussion of the results of self-monitoring tests.	Yes — this recommendation will be covered by DAFNE.
3.4.9	Make information available on: • effects of different alcohol-containing drinks on blood glucose excursions and calorie intake • use of high-calorie and high-sugar foods.	Yes — this recommendation will be covered by DAFNE.
3.4.10	Make information available about the benefits of healthy eating in reducing cardiovascular risk as part of dietary education in the period after diagnosis, and according to need and interest at intervals thereafter. Include information about fruit and vegetables, types and amounts of fat, and ways of making the appropriate nutritional changes.	Yes — this recommendation will be covered by DAFNE.
3.4.11	Modify nutritional recommendations to adults with Type 1 diabetes to take account of associated features of diabetes, including: • excess weight and obesity	No — GDG confirmed that this does not represent a change to standard practice.

Recommendation		Change to routine care
	• underweight • eating disorders • hypertension • renal failure • coeliac disease • gastroparesis.	
3.4.12	Be aware of appropriate nutritional advice on common topics of concern and interest to adults living with Type 1 diabetes, and be prepared to seek advice from colleagues with more specialised knowledge. Suggested common topics include: • body weight, energy balance and obesity management • cultural and religious diets, feasts and fasts • foods sold as 'diabetic' • sweeteners • dietary fibre intake • protein intake • vitamin and mineral supplements • alcohol • matching carbohydrate, insulin and physical activity • salt intake in hypertension • comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders • alternative diets e.g. ketogenic diet, very low calorie diet • use of peer support groups.	No — GDG confirmed that this does not represent a change to standard practice. The GDG confirmed that healthcare professionals would not require further education in terms of dietary advice.
3.5.1	Advise adults with Type 1 diabetes that physical activity can reduce their enhanced cardiovascular risk in the medium and longer term.	No — GDG confirmed that this does not represent a change to standard practice.
3.5.2	Give adults with Type 1 diabetes who choose to integrate increased physical activity into a more healthy lifestyle information about: • importance of planning activity • appropriate intensity and frequency of physical activity • role of self-monitoring of changed insulin and/or nutritional needs • effect of activity on blood glucose levels (likely fall) when insulin levels are adequate	Yes — this recommendation will be covered during DAFNE training.

Recommendation		Change to routine care
	• effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic (risk of worsening of hyperglycaemia and ketonaemia) • appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours • interactions of exercise and alcohol • further contacts and sources of information.	
3.6.1	Measure HbA1c levels every 3–6 months in adults with Type 1 diabetes.	Yes — hospital survey data indicates that would be a standardisation of current practice.
3.6.2	Consider measuring HbA1c levels more often in adults with Type 1 diabetes if the person's blood glucose control is suspected to be changing rapidly; for example, if the HbA1c level has risen unexpectedly above a previously sustained target	No — GDG confirmed that the recommendations relating to HbA1c measurement do not represent a change to standard practice.
3.6.3	Use methods to measure HbA1c that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation.	No — GDG confirmed that the recommendations relating to HbA1c measurement do not represent a change to standard practice.
3.6.4	Inform adults with Type 1 diabetes of their HbA1c results after each measurement and ensure that their most recent result is available at the time of consultation.	No — GDG confirmed that the recommendations relating to HbA1c measurement do not represent a change to standard practice.
3.6.5	If HbA1c monitoring is invalid because of disturbed erythrocyte turnover or abnormal haemoglobin type, estimate trends in blood glucose control using one of the following: • fructosamine estimation • quality-controlled blood glucose profiles	No — GDG confirmed that the recommendations relating to HbA1c measurement do not represent a change to

Recommendation		Change to routine care
	• total glycated haemoglobin estimation (if abnormal haemoglobins).	standard practice.
3.6.6	Support adults with Type 1 diabetes to consider aiming for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications.	The GDG stated that patients will be supported to achieve this target by receiving DAFNE education and healthcare professionals following the recommendations laid out in the guideline. Therefore, this recommendation will not have a resource or financial implication.
3.6.7	Agree an individualised HbA1c target with each adult with Type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia.	No — GDG confirmed that this did not represent a change to standard practice.
3.6.8	Ensure that aiming for an HbA1c target is not accompanied by problematic hypoglycaemia in adults with Type 1 diabetes.	No — GDG confirmed that this does not represent a change to standard practice.
3.6.9	Diabetes services should document the proportion of adults with Type 1 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower.	Yes — this is one of the key performance indicators recorded by the DAFNE central administration.
3.6.10	Advise routine self-monitoring of blood glucose levels for all adults with Type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.11	Support adults with Type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply: • the desired target for blood glucose control, measured by	No — GDG confirmed that the recommendations relating to blood glucose

Recommendation		Change to routine care
	HbA1c level (see recommendation 1.6.6), is not achieved • the frequency of hypoglycaemic episodes increases • there is a legal requirement to do so (such as before driving, in line with the Road Safety Authority [RSA] Sláinte agus Tiomáint Medical Fitness to Drive Guidelines) • during periods of illness • before, during and after sport • when planning pregnancy, during pregnancy and while breastfeeding (see HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period) • if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, impaired awareness of hypoglycaemia, high-risk activities).	monitoring do not represent a change to standard practice.
3.6.12	Enable additional blood glucose testing (more than 10 times a day) for adults with Type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.13	Advise adults with Type 1 diabetes to aim for: • a fasting plasma glucose level of 5–7 mmol/litre on waking and • a plasma glucose level of 4–7 mmol/litre before meals at other times of the day.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.14	Advise adults with Type 1 diabetes who choose to test after meals to aim for a plasma glucose level of 5–9 mmol/litre at least 90 minutes after eating. (This timing may be different in pregnancy — for guidance on plasma glucose targets in pregnancy, see the HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period).	No — this is standard practice since publication of the HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period in 2010.
3.6.15	Agree bedtime target plasma glucose levels with each adult	No — GDG confirmed that

Recommendation		Change to routine care
	with Type 1 diabetes that take into account timing of the last meal and its related insulin dose, and are consistent with the recommended fasting level on waking.	the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.16	Teach self-monitoring skills at the time of diagnosis and initiation of insulin therapy.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.17	When choosing blood glucose meters: • take the needs of the adult with Type 1 diabetes into account • ensure that meters meet current ISO standards.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.18	Educate adults with Type 1 diabetes about how to measure their blood glucose level, interpret the results and know what action to take. Review these skills at least annually.	No — hospital survey data indicates that formal review occurs at least annually.
3.6.19	Support adults with Type 1 diabetes to make the best use of data from self-monitoring of blood glucose through structured education	Yes — this structured education will be provided through DAFNE.
3.6.20	Monitoring blood glucose using sites other than the fingertips cannot be recommended as a routine alternative to conventional self-monitoring of blood glucose.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.21	Do not offer real-time continuous glucose monitoring routinely to adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard

Recommendation		Change to routine care
		practice.
3.6.22	Consider real-time continuous glucose monitoring for adults with Type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring: • more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause • complete loss of awareness of hypoglycaemia • frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities • extreme fear of hypoglycaemia • hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 47 and 48). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.	No — GDG stated that the number of patients impacted by this change would be negligible.
3.6.23	For adults with Type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.24	Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes.	No — GDG confirmed that the recommendations relating to blood glucose monitoring do not represent a change to standard practice.
3.6.25	Flash glucose monitoring is becoming available, but NICE has not formally evaluated its clinical and cost effectiveness. In the interim, NICE has issued a briefing, available at https://www.nice.org.uk/advice/mib110/chapter/Summary. This form of technology is not currently licensed to completely	No — the use of flash glucose monitoring represents a change to routine. However, although the FreeStyle Libre device has been

Recommendation		Change to routine care
	replace capillary blood glucose monitoring in Ireland and patients will continue to require SMBG in addition to flash monitoring.	recommended for reimbursement, the target population that will gain access to the device is not yet known. Hence, flash glucose monitoring has not been formally considered in the budget impact analysis.
3.6.26	Refer to local guidelines and protocols for patients who are using flash glucose monitoring or real-time continuous glucose monitoring as they will require education on the onset and duration of action of the different formulations of insulin and the risk of insulin accumulation or stacking after repeated insulin boluses.	No — the guideline recommendations relating to flash glucose monitoring do not represent a change to standard practice; however, it is noted that there will be an imminent change to local policy. An evaluation by the HSE Health Technology Assessment Group completed in October 2017 has recommended that reimbursement of flash glucose monitoring should be considered. Noting the potential for a substantial budget impact, it also recommends that any decision to reimburse this technology should be re-evaluated after one year. The assessment also notes the potential organisational impact for the HSE in terms of IT requirements and patient support.
3.7.1	Offer multiple daily injection basal–bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin	No — GDG confirmed that the recommendations

Recommendation		Change to routine care
	injection regimen of choice for all adults with Type 1 diabetes. Provide the person with guidance on using multiple daily injection basal–bolus insulin regimens.	relating to insulin therapy do not represent a change to standard practice.
3.7.2	Do not offer adults newly diagnosed with Type 1 diabetes non-basal–bolus insulin regimens (that is, twice-daily mixed, basal only or bolus only).	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.3	Consider offering twice-daily insulin detemir as basal insulin therapy for adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.4	Consider, as an alternative basal insulin therapy for adults with Type 1 diabetes: • an existing insulin regimen being used by the person that is achieving their agreed targets • once-daily insulin glargine or insulin detemir if twice-daily basal insulin injection is not acceptable to the person, or once-daily insulin glargine if insulin detemir is not tolerated • newer basal insulin analogues such as once daily insulin degludec (Tresiba) or once daily U300 insulin glargine (Toujeo) have not been evaluated in the NICE guideline. In the interim, NICE published advice, available at https://www.nice.org.uk/advice/esnm24/chapter/key-points-from-the-evidence and https://www.nice.org.uk/advice/esnm62/chapter/Key-points-from-the-evidence. Refer to local guidance and protocols on their use.	No — once-daily U300 insulin glargine (Toujeo) was evaluated by the National Centre for Pharmacoeconomics (NCPE) and received a positive recommendation in the Irish setting. Insulin degludec (Tresiba) did not receive a positive recommendation from the NCPE, but was subsequently approved for reimbursement by the HSE following price negotiation.
3.7.5	Consider other basal insulin regimens for adults with Type 1 diabetes only if the regimens in recommendations 1.7.3 and 1.7.4 do not deliver agreed targets. When choosing an alternative insulin regimen, take account of the person's preferences and acquisition cost.	No — GDG confirmed that the recommendations relating to insulin therapy did not represent a change to standard practice.
3.7.6	For guidance on the use of continuous subcutaneous insulin	No — GDG confirmed that

Recommendation		Change to routine care
	infusion (CSII or insulin pump) therapy for adults with Type 1 diabetes, refer to the HSE Product Evaluation Group (Insulin pumps and Consumables) guidelines.	the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.7	Offer rapid-acting insulin analogues injected before meals, rather than rapid-acting soluble human or animal insulins, for mealtime insulin replacement for adults with Type 1 diabetes	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.8	Do not advise routine use of rapid-acting insulin analogues after meals for adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.9	If an adult with Type 1 diabetes has a strong preference for an alternative mealtime insulin, respect their wishes and offer the preferred insulin.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.10	Consider a twice-daily human mixed insulin regimen for adults with Type 1 diabetes if a multiple daily injection basal–bolus insulin regimen is not possible and a twice-daily mixed insulin regimen is chosen.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.11	Consider a trial of a twice-daily analogue mixed insulin regimen if an adult using a twice-daily human mixed insulin regimen has hypoglycaemia that affects their quality of life.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.7.12	For adults with erratic and unpredictable blood glucose control (hyperglycaemia and hypoglycaemia at no consistent times), rather than a change in a previously optimised insulin regimen, the following should be considered: • injection technique • injection sites	No — GDG confirmed that this does not represent a change to standard practice.

Recommendation		Change to routine care
	• self-monitoring skills • knowledge and self-management skills • nature of lifestyle • psychological and psychosocial difficulties • possible organic causes such as gastroparesis.	
3.7.13	Give clear guidelines and protocols ('sick-day rules') to all adults with Type 1 diabetes to help them to adjust insulin doses appropriately during periods of illness.	No — GDG confirmed that this does not represent a change to standard practice.
3.7.14	Consider adding metformin to insulin therapy if an adult with Type 1 diabetes and a BMI of 25 kg/m2 (23 kg/m2 for people from South Asian and related minority ethnic groups) or above wants to improve their blood glucose control while minimising their effective insulin dose.	No — GDG confirmed that this does not represent a change to standard practice.
3.8.1	Adults with Type 1 diabetes who inject insulin should have access to the insulin injection delivery device they find allows them optimal wellbeing, often using one or more types of insulin injection pen.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.8.2	Provide adults with Type 1 diabetes who have special visual or psychological needs with injection devices or needle-free systems that they can use independently for accurate dosing.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.8.3	Offer needles of different lengths to adults with Type 1 diabetes who are having problems such as pain, local skin reactions and injection-site leakages.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.8.4	After taking clinical factors into account, choose needles with the lowest acquisition cost to use with pre-filled and reusable insulin pen injectors. (See FIT Guidelines www.fit4diabetes.com)	No — GDG confirmed that the recommendation relating to insulin therapy do not represent a change to standard practice.

Recommendation		Change to routine care
3.8.5	Advise adults with Type 1 diabetes to rotate insulin injection sites and avoid repeated injections at the same point within sites	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.8.6	Provide adults with Type 1 diabetes with suitable containers for collecting used needles and other sharps. Arrangements should be available for the suitable disposal of these containers.	No — GDG confirmed that the recommendations relating to the provision of supplies for those on insulin therapy do not represent a change to standard practice.
3.8.7	Check injection site condition at least annually and if new problems with blood glucose control occur.	No — GDG confirmed that the recommendations relating to insulin therapy do not represent a change to standard practice.
3.9.1	Consider referring adults with Type 1 diabetes who have recurrent severe hypoglycaemia that has not responded to other treatments to a centre that assesses people for islet and/or pancreas transplantation.	No — GDG confirmed that the recommendations relating to islet or pancreas transplantation do not represent a change to standard practice.
3.9.2	Consider islet or pancreas transplantation for adults with Type 1 diabetes with suboptimal diabetes control who have had a renal transplant and are currently on immunosuppressive therapy.	No — GDG confirmed that the recommendations relating to islet or pancreas transplantation do not represent a change to standard practice.
3.10.1	Assess awareness of hypoglycaemia in adults with Type 1 diabetes at each annual review	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.2	Use the Gold score or Clarke score to quantify awareness of	No — GDG confirmed that

Recommendation		Change to routine care
	hypoglycaemia in adults with Type 1 diabetes, checking that the questionnaire items have been answered correctly.	the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.3	Explain to adults with Type 1 diabetes that impaired awareness of the symptoms of plasma glucose levels below 3 mmol/litre is associated with a significantly increased risk of severe hypoglycaemia.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.4	Ensure that adults with Type 1 diabetes with impaired awareness of hypoglycaemia have had structured education in flexible insulin therapy using basal–bolus regimens and are following its principles correctly.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.5	Offer additional education focusing on avoiding and treating hypoglycaemia to adults with Type 1 diabetes who continue to have impaired awareness of hypoglycaemia after structured education in flexible insulin therapy.	No — GDG confirmed that this does not recommend a change to standard practice.
3.10.6	Avoid relaxing individualised blood glucose targets as a treatment for adults with Type 1 diabetes with impaired awareness of hypoglycaemia.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.7	If target blood glucose levels preferred by adults with Type 1 diabetes who have impaired awareness of hypoglycaemia are lower than recommended, reinforce the recommended targets (see recommendations 1.6.13-1.6.15).	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.

Recommendation		Change to routine care
3.10.8	Review insulin regimens and doses and prioritise strategies to avoid hypoglycaemia in adults with Type 1 diabetes with impaired awareness of hypoglycaemia, including: • reinforcing the principles of structured education • offering continuous subcutaneous insulin infusion (CSII or insulin pump) therapy • offering real-time continuous glucose monitoring.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.9	If impaired awareness of hypoglycaemia is associated with recurrent severe hypoglycaemia in an adult with Type 1 diabetes despite these interventions, consider referring the person to a specialist centre.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.10	Explain to adults with Type 1 diabetes that a fast-acting form of glucose is needed for the management of hypoglycaemic symptoms or signs in people who are able to swallow.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.11	Adults with Type 1 diabetes with a decreased level of consciousness as a result of hypoglycaemia and so are unable to take oral treatment safely should be: • given intramuscular glucagon by a family member or friend who has been shown how to use it (intravenous glucose may be used by healthcare professionals skilled in obtaining intravenous access) • monitored for response at 10 minutes, and call an ambulance if their level of consciousness is not improving significantly • then given oral carbohydrate when it is safe to administer it, and placed under continued observation by a third party who has been warned of the risk of relapse.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.12	Explain to adults with Type 1 diabetes that some hypoglycaemic episodes are an inevitable consequence of insulin therapy in most people using any insulin regimen, and that it is advisable that they should use a regimen that avoids or reduces the	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not

Recommendation		Change to routine care
	frequency of hypoglycaemic episodes while maintaining as optimal a level of blood glucose control as is feasible. Make advice available to all adults with Type 1 diabetes to assist in obtaining the best such balance from any insulin regimen (see Section 1.7 and Section 1.8).	represent a change to standard practice.
3.10.13	If hypoglycaemia becomes unusually problematic or of increased frequency, review the following possible contributory causes: • inappropriate insulin regimens (incorrect dose distributions and insulin types) • meal and activity patterns, including alcohol • injection technique and skills, including insulin resuspension if necessary • injection site problems • possible organic causes including gastroparesis • changes in insulin sensitivity (including drugs affecting the renin–angiotensin system and renal failure) • psychological problems • previous physical activity • lack of appropriate knowledge and skills for self-management.	No — GDG confirmed that the recommendations relating to the management of hypoglycaemia do not represent a change to standard practice.
3.10.14	Manage nocturnal hypoglycaemia (symptomatic or detected on monitoring) by: • reviewing knowledge and self-management skills • reviewing current insulin regimen, evening eating habits and previous physical activity • choosing an insulin type and regimen that is less likely to induce low glucose levels at night.	No — GDG confirmed that the recommendations relating to the management of nocturnal hypoglycaemia do not represent a change to standard practice.
3.10.15	If early cognitive decline occurs in adults on long-term insulin therapy, supplement normal investigations by the consideration or investigation of possible brain damage resulting from overt or covert hypoglycaemia, and the need to ameliorate this.	No — GDG confirmed that the recommendations relating to further investigations in those with early cognitive decline do not represent a change to standard practice.
3.11.1	Consider ketone monitoring (blood or urine) as part of 'sick-day	No — GDG confirmed that

Recommendation		Change to routine care
	rules' for adults with Type 1 diabetes, to facilitate self-management of an episode of hyperglycaemia.	the recommendations relating to ketone monitoring and the management of DKA did not represent a change to standard practice.
3.11.2	In adults with Type 1 diabetes presenting to emergency services, consider capillary blood ketone testing if: • DKA is suspected or • the person has uncontrolled diabetes with a period of illness, and urine ketone testing is positive.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to ketone monitoring and the management of DKA do not represent a change to standard practice.
3.11.3	Consider capillary blood ketone testing for inpatient management of DKA in adults with Type 1 diabetes that is incorporated into a formal protocol.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to ketone monitoring and the management of DKA do not represent a change to standard practice.
3.11.4	Professionals managing DKA in adults should be adequately trained, including regular updating, and be familiar with all aspects of its management which are associated with mortality and morbidity. These topics should include: • fluid balance • acidosis • cerebral oedema • electrolyte imbalance • disturbed interpretation of familiar diagnostic tests (white cell count, body temperature, ECG) • respiratory distress syndrome • cardiac abnormalities	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.

Recommendation		Change to routine care
	• precipitating causes • infection management, including opportunistic infections • gastroparesis • use of high dependency and intensive care units • recommendations 1.11.5 to 1.11.12 in this guideline.	
3.11.5	For primary fluid replacement in adults with DKA, use isotonic saline, not given too rapidly except in cases of circulatory collapse.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.6	Do not generally use bicarbonate in the management of DKA in adults.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.7	Give intravenous insulin by infusion to adults with DKA.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.8	In the management of DKA in adults, once the plasma glucose concentration has fallen to 10–15 mmol/litre, give glucose-containing fluids (not more than 2 litres in 24 hours) in order to allow continued infusion of insulin at a sufficient rate to clear	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed

Recommendation		Change to routine care
	ketones (for example, 6 units/hour monitored for effect).	that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.9	Begin potassium replacement early in DKA in adults, with frequent monitoring for the development of hypokalaemia.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the monitoring and management of DKA do not represent a change to standard practice.
3.11.10	Do not generally use phosphate replacement in the management of DKA in adults.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.11	In adults with DKA whose conscious level is impaired, consideration should be given to inserting a nasogastric tube, monitoring urine production using a urinary catheter and giving heparin.	No – hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to the management of DKA do not represent a change to standard practice.
3.11.12	To reduce the risk of catastrophic outcomes in adults with DKA, ensure that monitoring is continuous and that review covers all aspects of clinical management at frequent intervals.	No — hospital survey data illustrated that protocols are in place for DKA management. GDG confirmed that the recommendations relating to ketone monitoring

Recommendation		Change to routine care
		and the management of DKA do not represent a change to standard practice.
3.12.1	In adults with Type 1 diabetes who have a low BMI or unexplained weight loss, assess markers of coeliac disease.	No — GDG confirmed that the recommendations relating to the development of other conditions do not represent a change to standard practice.
3.12.2	Be alert to the possibility of the development of other autoimmune disease in adults with Type 1 diabetes (including Addison's disease and pernicious anaemia). For advice on monitoring for thyroid disease, see recommendation 1.15.40.	No — GDG confirmed that the recommendations relating to development of other autoimmune diseases do not represent a change to standard practice.
3.13.1	Do not routinely offer aspirin for the primary prevention of cardiovascular disease to adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.2	Assess cardiovascular disease risk factors annually, including: • albuminuria • smoking • blood glucose control • blood pressure • full lipid profile (including HDL and LDL cholesterol and triglycerides) • age • family history of cardiovascular disease • abdominal adiposity.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.3	For guidance on tools for assessing risk of cardiovascular disease in adults with Type 1 diabetes, refer to local standards	No — GDG confirmed that the recommendations

Recommendation		Change to routine care
	and guidelines of care.	relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.4	For guidance on the primary prevention of cardiovascular disease in adults with Type 1 diabetes, see the NICE guideline on lipid modification.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.5	Give adults with Type 1 diabetes who smoke advice on smoking cessation and use of smoking cessation services. Reinforce these messages annually for people who currently do not plan to stop smoking, and at all clinical contacts.	No — GDG confirmed that this does not represent a change to standard practice.
3.13.6	Advise young adult non-smokers never to start smoking.	No — GDG confirmed that this does not represent a change to standard practice.
3.13.7	Provide intensive management for adults who have had myocardial infarction or stroke, according to relevant non-diabetes guidelines. In the presence of angina or other ischaemic heart disease, beta-adrenergic blockers should be considered. (For use of insulin in these circumstances, see Section 15). For guidance on secondary prevention of myocardial infarction, see the NICE guideline on MI — secondary prevention.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.8	Intervention levels for recommending blood pressure management should be 135/85 mmHg unless the adult with Type 1 diabetes has albuminuria or 2 or more features of metabolic syndrome, in which case it should be 130/80 mmHg. See also recommendations 1.16.4-1.16.6.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.9	To allow informed choice by the person with hypertension, discuss the following with them: • reasons for choice of intervention level	No — GDG confirmed that the recommendations relating to cardiovascular

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	• substantial potential gains from small improvements in blood pressure control • possible negative consequences of therapy. See also recommendations 1.16.14 and 1.16.15.	disease and risk do not represent a change to standard practice.
3.13.10	Start a trial of a renin–angiotensin system blocking drug as first-line therapy for hypertension in adults with Type 1 diabetes.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.11	Provide information to adults with Type 1 diabetes on the potential for lifestyle changes to improve blood pressure control and associated outcomes, and offer assistance in achieving their aims in this area.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.13.12	Do not allow concerns over potential side effects to inhibit advising and offering the necessary use of any class of drugs, unless the side effects become symptomatic or otherwise clinically significant. In particular: • do not avoid selective beta-adrenergic blockers where indicated in adults on insulin • low-dose thiazides may be combined with beta-blockers • when calcium channel antagonists are prescribed, use only long-acting preparations • use direct questioning to detect the potential side effects of erectile dysfunction, lethargy and orthostatic hypotension with different drug classes.	No — GDG confirmed that the recommendations relating to cardiovascular disease and risk do not represent a change to standard practice.
3.14.1	Aim for a target plasma glucose level of 5–8 mmol/litre for adults with Type 1 diabetes during surgery or acute illness.	No — GDG confirmed that the recommendations relating to blood glucose control do not represent a change to standard practice.
3.14.2	Establish a local protocol for controlling blood glucose levels in adults with Type 1 diabetes during surgery or acute illness to	No — the hospital survey revealed that 23 of the 30

Recommendation		Change to routine care
	achieve the target level.	hospitals interviewed had peri-operative protocols in place.
3.14.3	Use intravenous in preference to subcutaneous insulin regimens for adults with Type 1 diabetes if: • the person is unable to eat or is predicted to miss more than 1 meal or • an acute situation is expected to result in unpredictable blood glucose levels - for example, major surgery, high-dose steroid treatment, inotrope treatment or sepsis or • insulin absorption is expected to be unpredictable, for example because of circulatory compromise.	No — GDG confirmed that the recommendations relating to insulin regimens do not represent a change to standard practice.
3.14.4	Consider continuing the person's existing basal insulin regimen (including basal rate if they are using continuous subcutaneous insulin infusion [CSII or insulin pump] therapy) together with protocol-driven insulin delivery for controlling blood glucose levels in adults with Type 1 diabetes during surgery or acute illness.	No — GDG confirmed that the recommendations relating to insulin regimens do not represent a change to standard practice.
3.14.5	Use subcutaneous insulin regimens (including rapid-acting insulin before meals) if an adult with Type 1 diabetes and acute illness is eating.	No — GDG confirmed that the recommendations relating to insulin regimens did not represent a change to standard practice.
3.14.6	Enable adults with Type 1 diabetes who are hospital inpatients to self-administer subcutaneous insulin if they are willing and able and it is safe to do so.	No — GDG confirmed that the recommendations relating to the delivery of care do not represent a change to standard practice.
3.14.7	From the time of admission, the adult with Type 1 diabetes and the team caring for him or her should receive, on a continuing basis, advice from a trained multidisciplinary team with expertise in diabetes.	No — GDG confirmed that the recommendations relating to the delivery of care do not represent a change to standard practice. A multidisciplinary approach

Recommendation		Change to routine care
		to care is currently adopted.
3.14.8	Throughout the course of an inpatient admission, respect the personal expertise of adults with Type 1 diabetes (in managing their own diabetes) and if their condition allows, routinely integrate this into ward-based blood glucose monitoring and insulin delivery.	No — GDG confirmed that the recommendations relating to the delivery of care do not represent a change to standard practice.
3.14.9	Throughout the course of an inpatient admission, the personal knowledge and needs of adults with Type 1 diabetes regarding their dietary requirements should be a major determinant of the food choices offered to them, except when illness or medical or surgical intervention significantly disturbs those requirements.	No — GDG confirmed that the recommendations relating to the delivery of care do not represent a change to standard practice.
3.14.10	Members of care teams caring for adults with Type 1 diabetes in institutions, such as nursing homes, residential homes and prisons, should follow the recommendations in this section.	Yes — under the implementation plan, short courses will be provided to all staff involved in the delivery of care to adults with Type 1 diabetes. The associated cost implications will be estimated as part of the budget impact analysis.
3.14.11	Provide optimal insulin therapy, which can be achieved by the use of intravenous insulin and glucose, to all adults with Type 1 diabetes with threatened or actual stroke. Critical care and emergency departments should have a protocol for such management.	No — GDG confirmed that the recommendations relating to the delivery of care do not represent a change to standard practice.
3.15.1	Women of reproductive age should be informed of the importance of optimising management prior to pregnancy and should have access to pre-pregnancy care. (See HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period.)	No — contained in HSE Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus from Pre-conception to the Postnatal period since 2010.
3.16.1	Start eye screening for adults newly diagnosed with Type 1 diabetes from diagnosis.	No — Diabetic Retinopathy Programme confirmed that this does not represent a

Recommendation		Change to routine care
		change to standard practice. Current practice since 2013 and therefore screening is not a direct impact of the recommendation.
3.16.2	All patients with Type 1 diabetes should be registered with the National Retinopathy Screening Programme.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.
3.16.3	Explain the reasons and success of eye screening systems to adults with Type 1 diabetes, so that attendance is not reduced by lack of knowledge or fear of outcome.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.
3.16.4	Depending on the findings, follow structured eye screening by: • routine review annually or • earlier review or • referral to an ophthalmologist.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice. Current practice is annual screen after initial screen or referral to ophthalmology specialist clinic.
3.16.5	Offer digital retinopathy screening annually to adults with Type 1 diabetes.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.
3.16.6	Use mydriasis with tropicamide when photographing the retina, after prior agreement with the adult with Type 1 diabetes after discussion of the advantages and disadvantages, including appropriate precautions for driving.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice. Diabetic Retina Screen Clinical Practice Guidelines for Treatment indicates that this is the gold standard.
3.16.7	Make visual acuity testing a routine part of eye screening programmes.	No — Diabetic Retinopathy Programme confirmed that

Recommendation		Change to routine care
		this does not represent a change to standard practice. This is part of the current assessment according to Diabetic Retina Screen Clinical Practice Guidelines for Treatment Clinics.
3.16.8	Ensure that emergency review by an ophthalmologist occurs for: • sudden loss of vision • rubeosisiridis • pre-retinal or vitreous haemorrhage • retinal detachment.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.
1.16.9	Ensure that rapid review by an ophthalmologist occurs for new vessel formation.	No — Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.
3.16.10	Refer to an ophthalmologist for: • referable maculopathy: - exudate or retinal thickening within 1 disc diameter of the centre of the fovea - circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, of a diameter the distance between the temporal border of the optic disc and the fovea) - any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea, only if associated with a best visual acuity of 6/12 or worse • referable pre-proliferative retinopathy: - any venous beading - any venous reduplication - any intraretinalmicrovascular abnormalities (IRMA) - multiple deep, round or blot haemorrhages (if cotton wool spots are present, look carefully for the above features, but cotton wool spots themselves do not define pre-proliferative retinopathy)	No — GDG and Diabetic Retinopathy Programme confirmed that this does not represent a change to standard practice.

Recommendation		Change to routine care
	• any large sudden unexplained drop in visual acuity.	
3.16.11	For guidance on managing kidney disease in adults with Type 1 diabetes, refer to local standards and guidelines of care.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.12	Ask all adults with Type 1 diabetes with or without detected nephropathy to bring in the first urine sample of the day ('early morning urine') once a year. Send this for estimation of albumin: creatinine ratio. Estimation of urine albumin concentration alone is a poor alternative. Serum creatinine should be measured at the same time.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.13	Suspect other renal disease: • in the absence of progressive retinopathy • if blood pressure is particularly high • if proteinuria develops suddenly • if significant haematuria is present • in the presence of systemic ill health.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.14	Discuss the significance of a finding of albuminuria with the person concerned.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.15	Start angiotensin-converting enzyme (ACE) inhibitors and, with the usual precautions, titrate to full dose in all adults with confirmed nephropathy (including those with moderately increased albuminuria ['microalbuminuria'] alone) and Type 1 diabetes	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.16	If ACE inhibitors are not tolerated, substitute angiotensin 2 receptor antagonists. Combination therapy is not recommended.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.17	Maintain blood pressure below 130/80 mmHg by addition of other anti-hypertensive drugs if necessary.	No — GDG confirmed that the recommendations relating to diabetic kidney

Recommendation		Change to routine care
		disease do not represent a change to standard practice.
3.16.18	Advise adults with Type 1 diabetes and nephropathy about the advantages of not following a high-protein diet.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.19	Referral criteria for tertiary care should be agreed between local diabetes specialists and nephrologists.	No — GDG confirmed that the recommendations relating to diabetic kidney disease do not represent a change to standard practice.
3.16.20	For guidance on managing chronic painful diabetic neuropathy in adults with Type 1 diabetes, refer to the HSE Integrated Model of Care for Type 2 Diabetes	No — HSE Integrated Model of Care for Type 2 Diabetes.
3.16.21	In adults with Type 1 diabetes who have unexplained diarrhoea, particularly at night, the possibility of autonomic neuropathy affecting the gut should be considered.	No — GDG confirmed that this do not represent a change to standard practice.
3.16.22	Take care when prescribing antihypertensive medicines not to expose people to the risks of orthostatic hypotension as a result of the combined effects of sympathetic autonomic neuropathy and blood pressure lowering medicines.	No — GDG confirmed that this do not represent a change to standard practice.
3.16.23	In adults with Type 1 diabetes who have bladder emptying problems, investigate the possibility of autonomic neuropathy affecting the bladder, unless other explanations are adequate.	No — GDG confirmed that this do not represent a change to standard practice.
3.16.24	When managing the symptoms of autonomic neuropathy, include standard interventions for the manifestations encountered (for example, for abnormal sweating and postural hypotension).	No — GDG confirmed that this does not represent a change to standard practice.
3.16.25	Anaesthetists should be aware of the possibility of parasympathetic autonomic neuropathy affecting the heart in adults with Type 1 diabetes who are listed for procedures under general anaesthetic and who have evidence of somatic neuropathy or other manifestations of autonomic neuropathy.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.26	Advise a small-particle-size diet (mashed or pureed food) for	No — GDG confirmed that

Recommendation		Change to routine care
	symptomatic relief for adults with Type 1 diabetes who have vomiting caused by gastroparesis.	this does not represent a change to standard practice.
3.16.27	Consider continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with Type 1 diabetes who have gastroparesis.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.28	For adults with Type 1 diabetes who have vomiting caused by gastroparesis, explain that: • there is no strong evidence that any available antiemetic therapy is effective • some people have had benefit with domperidone, erythromycin or metoclopramide • the strongest evidence for effectiveness is for domperidone, but prescribers must take into account its safety profile, in particular its cardiac risk and potential interactions with other medicines.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.29	For treating vomiting caused by gastroparesis in adults with Type 1 diabetes: • consider alternating use of erythromycin and metoclopramide • consider domperidone only in exceptional circumstances (that is, when it is the only effective treatment).	No — GDG confirmed that this does not represent a change to standard practice.
3.16.30	Refer adults with Type 1 diabetes who have gastroparesis for specialist advice if the interventions in recommendations 1.15.25, 1.15.26 and 1.15.28 are not beneficial or not appropriate.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.31	Reassure adults with Type 1 diabetes that acute painful neuropathy resulting from rapid improvement of blood glucose control is a self-limiting condition that improves symptomatically over time.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.32	Explain to adults with Type 1 diabetes that the specific treatments for acute painful neuropathy resulting from rapid improvement of blood glucose control: • have the aim of making the symptoms tolerable until the condition resolves • may not relieve pain immediately and may need to be taken regularly for several weeks to be effective.	No — GDG confirmed that this does not represent a change to standard practice.

Recommendation		Change to routine care
3.16.33	Use of simple analgesics (paracetamol, aspirin) and local measures (bed cradles) are recommended as a first step, but if trials of these measures are ineffective, discontinue them and try other measures.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.34	Do not relax diabetes control to address acute painful neuropathy resulting from rapid improvement of blood glucose control in adults with Type 1 diabetes.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.35	If simple analgesia does not provide sufficient pain relief for adults with Type 1 diabetes who have acute painful neuropathy resulting from rapid improvement of blood glucose control, offer treatment as described in the HSE Model of Integrated Care for Type 2 Diabetes. Simple analgesia may be continued until the effects of additional treatments have been established.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.36	When offering medicines for managing acute painful neuropathy resulting from rapid improvement of blood glucose control to adults with Type 1 diabetes, be aware of the risk of dependency associated with opioids.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.37	For guidance on preventing and managing foot problems in adults with Type 1 diabetes, see the HSE Model of Care for the Diabetic foot.	No — HSE Model of Care for the Diabetic foot.
3.16.38	Offer men with Type 1 diabetes the opportunity to discuss erectile dysfunction as part of their regular review.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.39	Offer a phosphodiesterase-5 inhibitor to men with Type 1 diabetes with isolated erectile dysfunction unless contraindicated. Choose the phosphodiesterase-5 inhibitor with the lowest acquisition cost.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.40	Consider referring men with Type 1 diabetes to a service offering further assessment and other medical, surgical or psychological management of erectile dysfunction if phosphodiesterase-5 inhibitor treatment is unsuccessful or contraindicated.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.41	Measure blood thyroid-stimulating hormone (TSH) levels in	No — GDG confirmed that

Recommendation		Change to routine care
	adults with Type 1 diabetes at annual review.	this does not represent a change to standard practice.
3.16.42	Members of diabetes professional teams providing care or advice to adults with Type 1 diabetes should be alert to the development or presence of clinical or subclinical depression and/or anxiety, in particular if someone reports or appears to be having difficulties with self-management.	Yes — short educational courses will be provided to healthcare professionals involved in the delivery of care to people with Type 1 diabetes.
3.16.43	Diabetes professionals should: • ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds • be familiar with appropriate counselling techniques and drug therapy, while arranging prompt referral to specialists of those people in whom psychological difficulties continue to interfere significantly with wellbeing or diabetes self-management • pathways should be established and resources provided to ensure that when required, patients with Type 1 diabetes have rapid access to mental health MDTs including clinical psychologist.	Yes — short educational courses will be provided to healthcare professionals involved in the delivery of care to people with Type 1 diabetes.
3.16.44	Members of diabetes professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and insulin dose manipulation in adults with Type 1 diabetes with: • over-concern with body shape and weight • low BMI • hypoglycaemia • suboptimal overall blood glucose control.	Yes — short educational courses will be provided to healthcare professionals involved in the delivery of care to people with Type 1 diabetes.
3.16.45	The risk of morbidity from the complications of poor metabolic control suggests that consideration should be given to early, and occasionally urgent, referral of adults with Type 1 diabetes to local eating disorder services.	No — GDG confirmed that this does not represent a change to standard practice.
3.16.46	Make provision for high-quality professional team support at regular intervals with regard to counselling about lifestyle issues and particularly dietary behaviour for all adults with Type 1 diabetes from the time of diagnosis	No — GDG confirmed that this does not represent a change to standard practice.

Glossary of terms

Some of the terms in this glossary will not be found within the body of these guidelines. They have been included here to make the glossary a more complete resource for users.

Adverse event	An undesirable effect of a health technology.
Baseline	A term used to describe the initial set of measurements taken at the beginning of a study (after a run-in period, when applicable).
Bias	Systematic (as opposed to random) deviation of the results of a study from the 'true' results.
Budget impact analysis (BIA)	A procedure for comparing only the financial costs and cost offsets of competing options, rather than comparing their clinical and economic costs and benefits.
Comorbidity	The coexistence of a disease, or more than one disease, in a person in addition to the disease being studied or treated.
Comparator	The alternative against which the intervention is compared.
Confidence interval (CI)	The computed interval with a specified probability (by convention, 95%) that the true value of a variable such as mean, proportion, or rate is contained within the interval.
Consumer Price Index (CPI)	This index measures the change in the average price levels (including all indirect taxes) paid for consumer goods and services by all private households in the country and by foreign tourists holidaying in the country.
Cost	The value of opportunity forgone, as a result of engaging resources in an activity (see opportunity cost); there can be a cost without the exchange of money; range of costs (and benefits) included in a particular economic evaluation depends on perspective taken; average costs are average cost per unit of output (that is, total costs divided by total number of units produced); incremental costs are extra costs associated with intervention compared to alternative; marginal cost is cost of producing one extra unit of output.
Cost benefit analysis (CBA)	An economic evaluation that compares the proposed technology with its main comparator(s) in which both costs and benefits are measured in monetary terms to compute a net monetary gain or loss or benefit gain or loss

Cost-effective (value for money)	A proposed technology is considered cost-effective for a specified main indication if the incremental benefits of the proposed technology versus its main comparator(s) justify its incremental costs and harms.
Cost-effectiveness analysis (CEA)	An economic evaluation in which costs are measured in monetary terms and clinical or health outcomes are measured in natural units, for example, reduced mortality or morbidity.
Cost-minimisation analysis (CMA)	An economic evaluation that finds the least costly alternative technology. For example, after the proposed technology has been demonstrated to be no worse than its main comparator(s) in terms of effectiveness and adverse events.
Cost-utility analysis (CUA)	An economic evaluation that compares the proposed technology with its main comparator(s) in which costs are measured in monetary terms and outcomes are measured in terms of extension of life and the utility value of that extension, for example, using quality adjusted life years (QALYs).
Critical appraisal	A strict process to assess the validity, results and relevance of evidence.
Deterministic decision analytic model	A method of decision analysis where the output of the model is fully determined by the parameter values without any room for random variation.
Direct costs	The fixed and variable costs of all resources (goods, services, and so on) consumed in the provision of a technology as well as any consequences of the intervention such as adverse effects or goods or services induced by the intervention. These include direct medical costs and direct non-medical costs such as transportation or child care.
Discount rate	The interest rate used to discount or adjust future costs and benefits so as to arrive at their present values, for example 5%. This is also known as the opportunity cost of capital investment.
Discounting	The process used in economic analyses to convert future costs or benefits to present values using a discount rate. Discounting costs reflects societal preference for costs to be experienced in the future rather than the present. Discounting benefits reflects a preference for benefits to be realised in the present rather than at a later date.

Economic evaluation	Application of analytical methods to identify, measure, value, and compare costs and consequences of alternatives being considered; addresses issue of efficiency to aid decision-making for resource allocation. It is an umbrella term covering CBA, CEA, CMA and CUA.
Economic model	Economic models provide a means of bringing together different types of data from a range of sources and provide a framework for decision-making under conditions of uncertainty. Modelling may be used to combine different datasets changing the information collected from a clinical trial into a form that can be used, to extrapolate short-term clinical data to longer term, to link intermediate with final endpoints, to generalise from clinical trial settings to routine practice and to estimate the relative effectiveness of technologies where these have not been directly compared in clinical trials.
Effectiveness	The extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) in routine clinical practice. (Contrast with efficacy.)
Efficacy	The extent to which a technology produces an overall health benefit (taking into account adverse and beneficial effects) when studied under controlled research conditions. (Contrast with effectiveness.)
Epidemiology	The study of the distribution and determinants of health-related conditions or events in defined populations.
Extrapolation	Prediction of value of model parameter outside measured range or inference of value of parameter of related outcome (for example, extrapolation of reduction in rate of progression to AIDS from improvement in HIV viral load).
Generalisability	The problem of whether one can apply or extrapolate results obtained in one setting or population to another; the term may also be referred to as 'transferability', 'transportability', 'external validity', 'relevance', or 'applicability'.
Grey literature	Research that is either unpublished or has been published in non-commercial form, such as government reports.
Health outcome	A change (or lack of change) in health status caused by a therapy or factor when compared with a previously documented health status using disease-specific measures, general quality of life measures or utility measures.

Health technology	The application of scientific or other organised knowledge — including any tool, technique, product, process, method, organisation or system — in healthcare and prevention. In healthcare, technology includes drugs, diagnostics, indicators and reagents, devices, equipment, and supplies, medical and surgical procedures, support systems and organisational and managerial systems used in prevention, screening diagnosis, treatment and rehabilitation.
Heterogeneity	In the context of meta-analysis, clinical heterogeneity means dissimilarity between studies. It can be because of the use of different statistical methods (statistical heterogeneity), or evaluation of people with different characteristics, treatments or outcomes (clinical heterogeneity). Heterogeneity may render pooling of data in meta-analysis unreliable or inappropriate. Finding no significant evidence of heterogeneity is not the same as finding evidence of no heterogeneity. If there are a small number of studies, heterogeneity may affect results but not be statistically significant.
Health technology assessment (HTA)	This is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient-focused and seek to achieve best value.
Incidence	The number of new cases of a disease or condition that develop within a specific time frame in a defined population at risk. It is usually expressed as a ratio of the number of affected people to the total population.
Incremental costs	The absolute difference between the costs of alternative management strategies of the same medical condition, disease or disorder.
Indirect costs	The cost of time lost from work and decreased productivity due to disease, disability, or death. (In cost accounting, it refers to the overhead or fixed costs of producing goods or services.)
Meta-analysis	Systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study. Also known as data synthesis or quantitative overview

Opportunity cost	The value of the forgone benefits because the resource is not available for its best alternative use.
Outcome	Consequence of condition or intervention; in economic guidelines, outcomes most often refer to health outcomes, such as surrogate outcomes or patient outcomes.
Perspective	This is the viewpoint from which an economic evaluation is conducted. Viewpoints that may be adopted include that of the patient, the public healthcare payer or society.
PPP	This theory states that in an efficient market, the exchange rate of two currencies results in equal purchasing power. The purchasing power indices are currency conversion rates that both convert to a common currency and equalise the purchasing power of different currencies. In other words, they eliminate the differences in price levels between countries in the process of conversion.
QALY	A unit of healthcare outcomes that adjusts gains (or losses) in years of life subsequent to a healthcare intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost utility across different technologies and health problems. Analogous units include disability-adjusted life years (DALYs) and healthy-years equivalents (HYEs).
Scenario analysis	A method of decision analysis that considers future events by considering possible alternative scenarios. It can use both one-way (variation of one variable at a time) and multi-way (two or more parameters varied at the same time) to capture the level of uncertainty in the results.
Sensitivity analysis	A means to determine the robustness of a mathematical model or analysis by examining the extent to which results are affected by changes in methods, parameters or assumptions.
Surrogate endpoint	A measure that is used in place of a primary endpoint (outcome). Examples are decrease in blood pressure as a predictor of decrease in strokes and heart attacks in hypertensive patients, and increase in T-cell (a type of white blood cell) counts as an indicator of improved survival of patients with AIDS. Use of a surrogate endpoint assumes that it is a reliable predictor of the primary endpoint(s) of interest.

Target population	In the context of a budget impact analysis, the individuals with a given condition or disease who might avail of the technology being assessed within the defined time horizon.
Technology	The application of scientific or other organised knowledge — including any tool, technique, product, process, method, organisation or system — to practical tasks. In healthcare, technology includes drugs; diagnostics, indicators and reagents; devices, equipment and supplies; medical and surgical procedures; support systems; and organisational and managerial systems used in prevention, screening, diagnosis, treatment and rehabilitation.
Time horizon or time frame	The time span used in the assessment that captures the period over which meaningful differences between costs and outcomes between competing technologies would be expected to accrue.
Tornado diagram	Diagrammatic display of the results of one-way sensitivity analysis; each bar represents the range of change in model results when the parameter is varied from its minimum to maximum values.
Transferability	A trial, study or model has transportability if it can produce unbiased inferences to another specified healthcare system (for example, from overseas to Ireland).
Uncertainty	Where the true value of a parameter or the structure of a process is unknown.
Usual care	This is the most common or most widely used alternative in clinical practice for a specific condition. This is also referred to as 'routine care' or 'current practice' or 'typical care'.
Utility	In economic evaluation, utilities are used to represent the strength of individuals' preferences for different health states. When utility values are averaged over a population of responders they can be considered to be valuations of health states. Conventionally, the valuations fall between 0 and 1, with 1 representing the valuation of a state of perfect health and 0 representing the valuation of death (non-existence).
Validity	The extent to which technique measures what it is intended to measure.
Value Added Tax	This is a tax on consumer spending. It is collected by VAT-registered traders on their supplies of goods and services to customers. Each such trader in the chain of supply from manufacturer through to retailer charges VAT on his or her sales and is

	entitled to deduct from this amount the VAT paid on his or her purchases, that is, the tax is on the added value. For the final consumer, not being VAT-registered, VAT is simply part of the purchase price.
Variability	This reflects known differences in parameter values arising out of inherent differences in circumstances or conditions. It may arise due to differences in patient population (for example, patient heterogeneity – baseline risk, age, gender), differences in clinical practice by treatment setting or geographical location.