



An Roinn Sláinte  
Department of Health

# Adult type 1 diabetes mellitus

National Clinical Guideline No. 17

June 2018



**NATIONAL  
CLINICAL  
EFFECTIVENESS  
COMMITTEE**

This National Clinical Guideline for adults with type 1 diabetes has been developed by the Guideline Development Group, supported by the HSE National Clinical Programme for Diabetes. Part of the process of developing this guideline involved contextualising (for Ireland) the **National Institute for Health and Care Excellence (NICE) NG17 “Type 1 diabetes in adults: diagnosis and management” guideline**, published in 2015.

### Using this National Clinical Guideline

This National Clinical Guideline applies to adults (aged 18 years and older) with type 1 diabetes in Ireland. It does not apply to children living with type 1 diabetes, adults living with type 2 diabetes or individuals living with monogenic (or other rarer forms of) diabetes.

This National Clinical Guideline is relevant to all healthcare professionals working in healthcare settings delivering care to people living with type 1 diabetes.

Readers should note that sections of the guideline relating to the National Institute for Health and Care Excellence (NICE) contextualisation are denoted by a blue background and border.

### Disclaimer

NCEC National Clinical Guideline do not replace professional judgment on particular cases, whereby the clinician or health professional decides that individual guideline recommendations are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation should be appropriately recorded in the patient’s healthcare record.

Users of NCEC National Clinical Guideline must ensure they have the current version (hardcopy or softcopy) by checking the relevant section in the National Patient Safety Office on the Department of Health website: <http://health.gov.ie/national-patient-safety-office/>

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### Membership of the Guideline Development Group (GDG)

The GDG was chaired by Dr Kevin Moore, Consultant Endocrinologist. This National Clinical Guideline is supported by the HSE National Clinical Programme (NCP) for Diabetes. Membership nominations were sought from a variety of clinical and non-clinical backgrounds so as to be representative of people living with type 1 diabetes and all key stakeholders involved in the care of people living with type 1 diabetes. Members of this group are listed in table 1. Membership was sought from primary care and feedback was requested during consultation after a substantive draft was completed. All sections relating to diabetic retinopathy were contextualised by Mr David Keegan, clinical lead of the National Diabetic Retinal Screening Programme. Refer to appendix 1 terms of reference for the GDG.

Membership of the NICE Guideline Development Groups are listed in tables 2, 3 and 4. The Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER) team is listed in Annex 1.

**Table 1:** Members of the Guideline Development Group

Name	Job title and affiliation
Dr Kevin Moore (Chair)	Consultant Endocrinologist
Prof Sean Dinneen	Clinical lead NCP Diabetes/Consultant Endocrinologist
Niamh Smyth	NCP-Diabetes Programme Manager
Tony McPoland	Patient Representative
Shane O'Donnell	Patient Representative
Anna Clarke	Health Promotion and Research Manager Diabetes Ireland
Dr Ronan Canavan	Consultant Endocrinologist
Dr Diarmuid Smith	Consultant Endocrinologist
Dr Mensud Hatunic	Consultant Endocrinologist
Dr Colin Davenport	Consultant Endocrinologist (Specialist Registrar Endocrinologist at start of development process)
Margaret Humphreys	Clinical Specialist Diabetes Dietitian /National HSE Structured Patient Education Co-ordinator
Cathy Breen	Senior Dietitian Diabetes
Mary Finn	Senior Dietitian Diabetes
Karen Townsend	Clinical Nurse Specialist Diabetes
Pauline O'Hanlon	Clinical Nurse Specialist Diabetes
Mary O'Scannail	Clinical Nurse Specialist Diabetes
Helen Twamley	Clinical Nurse Specialist Diabetes Integrated Care
Prof Brian McGuire	Professor of Clinical Psychology
Eilis Kearney	Clinical Pharmacist

### Membership of the NICE Guideline Development Groups

**Table 2:** Members of NICE Guideline Contextualisation Quality Assurance Team

Name	Job title and affiliation
Christine Carson	Programme Director
Phil Alderson	Clinical Advisor
Rachel O'Mahony	Technical Advisor
Andrew Gyton	Programme Manager

The Guideline Development Group members listed in table 3 are those for the 2015 update. For the composition of the previous Guideline Development Group, see the full guideline (<https://www.nice.org.uk/Guidance/NG17/Evidence>)

**Table 3:** Members of the NICE Guideline Development Group

Name	Job title and affiliation
Stephanie Amiel	Professor of Diabetic Medicine, King's College London
Augustin Brooks	Consultant Diabetologist, Bournemouth Hospital
Arthur Durrant	Patient member
Michael Flynn	Consultant Physician, Kent and Canterbury Hospital
Roger Gadsby	Visiting Professor, Institute of Diabetes in Older People, University of Bedfordshire; GP; and Principle Teaching Fellow, University of Warwick
Peter Hammond	Consultant Physician, Harrogate District Hospital
Michael Kendall	Patient member
Vibhuti Mistry	Lead Diabetes and Obesity Dietitian, Homerton University NHS Foundation Trust
Henrietta Mulnier	Lecturer in Diabetes Nursing, King's College London
Victoria Ruszala	Specialist Pharmacist, Diabetes and Endocrinology, North Bristol NHS Trust
Stuart Smellie	Consultant in Chemical Pathology, Durham and Darlington NHS Foundation Trust
Perdy van den Berg	Clinical Lead, Oxfordshire Diabetes Service
Jill Cobb	Information Scientist
Dalia Dawoud	Health Economist
Bernard Higgins	Clinical Director
Elisabetta Fenu	Health Economics Lead
Bethany King	Document Editor/Process Assistant
Rachel O'Mahony	Senior Research Fellow
Nancy Pursey	Senior Project Manager

**Table 4:** Members of the NICE Project Team

<b>Name</b>	<b>Job title and affiliation</b>
Christine Carson	Guideline Lead
Phil Alderson	Clinical Adviser
Clifford Middleton	Guideline Commissioning Manager
Jennifer Wells	Guideline Coordinator
Nichole Taske	Technical Lead
Bhash Naidoo	Health Economist
Lyn Knott	Editor

### Credits

The role of the NCEC is to prioritise, quality assure and recommend clinical guideline to the Chief Medical Officer for endorsement by the Minister for Health. It is intended through Ministerial endorsement that full implementation of guidelines will occur through the relevant service plans.

The NCEC and the Department of Health acknowledge and recognise the Chair and members of the Guideline Development Group (GDG) for development of the guideline. The NCEC and Department of Health wish to express thanks and sincere gratitude to all persons contributing to this National Clinical Guideline; especially those that give of their time on a voluntary basis.

### Acknowledgments

As chair of the GDG, I wish to acknowledge the support of all members of the GDG as contributors to the development of this National Clinical Guideline. In particular I wish to thank and acknowledge the contributions of Prof. Sean Dinneen and Niamh Smyth.

I also want to acknowledge NCEC for their support throughout the process of generating the clinical guideline. The GDG would like to thank NICE for facilitating us to contextualise their guideline. In addition, I would like to highlight the excellent and efficient work of HRB-CICER in putting together the budget impact analysis.

Finally, I would like to express my thanks to those who took the time to share their expertise and provide feedback during the external consultation process.

Dr Kevin Moore  
Chair, Guideline Development Group, February 2018

## National Clinical Guidelines

Providing standardised clinical care to patients in healthcare is challenging. This is due to a number of factors, among them variations in environments of care and complex patient presentations. It is self-evident that safe, effective care and treatment are important in ensuring that patients get the best outcomes from their care.

The Department of Health is of the view that supporting evidence-based practice, through the clinical effectiveness framework, is a critical element of the health service to deliver safe and high quality care. The National Clinical Effectiveness Committee (NCEC) is a Ministerial committee set up in 2010 as a key recommendation of the report of the Commission on Patient Safety and Quality Assurance (2008). The establishment of the Commission was prompted by an increasing awareness of patient safety issues in general and high profile health service system failures at home and abroad.

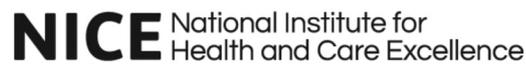
The NCEC on behalf of the Department of Health has embarked on a quality assured National Clinical Guideline development process linked to service delivery priorities. Furthermore, implementing National Clinical Guidelines sets a standard nationally, to enable healthcare professionals to deliver safe and effective care and treatment while monitoring their individual, team and organisation's performance.

The aim of NCEC Clinical Guidelines is to reduce unnecessary variations in practice and provide an evidence base for the most appropriate healthcare in particular circumstances. As a consequence of Ministerial mandate, it is expected that NCEC National Clinical Guidelines are implemented across all relevant services in the Irish healthcare setting.

The NCEC is a partnership between key stakeholders in patient safety. NCEC's mission is to provide a framework for national endorsement of clinical guidelines and clinical audit to optimise patient and service user care. The NCEC has a remit to establish and implement processes for the prioritisation and quality assurance of clinical guidelines and clinical audit so as to recommend them to the Minister for Health to become part of a suite of National Clinical Guidelines and National Clinical Audit. The aim of the suite of National Clinical Guidelines is to provide guidance and standards for improving the quality, safety and cost-effectiveness of healthcare in Ireland. The implementation of these National Clinical Guidelines will support the provision of evidence-based and consistent care across Irish healthcare services.

## NCEC Terms of Reference

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish standards for clinical practice guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC work streams.
10. Publish an annual report.

**National Institute for Health and Clinical Excellence**

The UK's National Institute for Health and Care Excellence (NICE) provides evidence-based guidance and advice to improve health and social care.

NICE's Centre for Guidelines develops guidance on the promotion of good health; the prevention of ill health; the appropriate treatment and care for people with specific diseases and conditions; social care and service delivery. The guidelines are evidence-based recommendations for health and care in England on a wide range of topics, from preventing and managing specific conditions to planning broader services and interventions to improve the health of communities; and are used by those working in the UK National Health Service, local government, social care, patients and their families. NICE has published over 250 guidelines since 2002.

Since 2014, NICE has worked with international clients wishing to rapidly contextualise NICE guidelines for their local populations and health care context infrastructure. The process involves a local guideline committee who consider and contextualise NICE's original recommendations before consultation with relevant stakeholders. NICE quality assures the contextualisation process to ensure the published guidelines meet internationally-recognised standards of best practice, and are also relevant to local contexts.

In 2017 an agreement was reached between NICE and the National Patient Safety Office's Clinical Effectiveness Unit, on behalf of the NCEC to work together on the contextualisation of NICE's clinical guideline, (NG17) Type 1 diabetes in adults: diagnosis and management (2015).



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## 1

**National Clinical Guideline summary****1.1 Key recommendations<sup>1</sup>**

The full list of recommendations are in section 3.

**Education and information**

- 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.

**Blood glucose management**

- Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications.
- 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.
- 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 HbA1c level (see recommendation 3.6.6), 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) (2014) Sláinte agus Tiomáint Medical Fitness to Drive Guidelines
  - during periods of illness
  - before, during and after vigorous physical activity
  - when planning pregnancy, during pregnancy and while breastfeeding, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)
  - 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).
- 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.

1 Refer to section 2.9 for a description on the strength of recommendations made

**Insulin therapy**

- Offer multiple daily injection basal–bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin 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.

**Awareness and management of hypoglycaemia**

- Assess awareness of hypoglycaemia in adults with type 1 diabetes at each annual review.

**Care of adults with type 1 diabetes in hospital**

- 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.

**1.2 Key priorities for implementation**

- To provide access to high quality structured patient education programme for eligible adults with type 1 diabetes in Ireland 6 – 12 months after diagnosis or at another appropriate time.
- Measure HbA1c levels every 3–6 months in adults with type 1 diabetes. To facilitate implementation provide access to a minimum of 2 consultations with a diabetes healthcare provider per year for all adults with type 1 diabetes.

**2****Development of the National Clinical Guideline****2.1 Background**

Type 1 diabetes is an autoimmune condition that causes destruction of the insulin producing cells in the pancreas. As a result of the loss of insulin production, people with type 1 diabetes must administer subcutaneous insulin in order to manage their blood glucose. Type 1 diabetes is a challenging condition to manage. Successful management of diabetes requires motivation, education, knowledge, frequent glucose monitoring and careful insulin administration. In addition to administering insulin, people with type 1 diabetes must monitor their blood glucose concentrations, and regulate their intake of carbohydrates accordingly. A key goal of diabetes management is to maximise the time spent with near normal glucose concentrations, while avoiding problems such as hypoglycaemia or ketosis. Given the complexity of maintaining tight glucose control, successful outcomes depend, perhaps more than with any other long-term condition, on full engagement of the adult with type 1 diabetes in life-long day-to-day self-management. In order to support this, the health service needs to provide informed, expert support, education and training as well as a range of other more conventional biomedical services and interventions for the prevention and management of long term complications. Patients with type 1 diabetes require significant input from their diabetes multidisciplinary team in order to ensure that they have the necessary knowledge and skills required to successfully manage their condition and avoid the potential complications of diabetes. A hospital diabetes multidisciplinary team should comprise, at the minimum, of a consultant diabetologist, diabetes specialist nurse (clinical nurse specialist/advanced nurse practitioner), a diabetes dietitian and a diabetes podiatrist. There should also be access to a diabetes psychologist.

It is estimated that there are 20,000 adults with type 1 diabetes living in the Republic of Ireland. The care of these patients with type 1 diabetes has been delivered by diabetes multidisciplinary teams located in secondary and tertiary care centres across the country. Heretofore, Ireland has not had a clinical guideline for the management of adult patients with type 1 diabetes and there is very limited knowledge of the quality of care or the clinical outcomes for patients with type 1 diabetes living in Ireland. We hope that the development of a national clinical guideline will provide the diabetes multidisciplinary team, patients and the HSE with a framework that will ensure that adults with type 1 diabetes have equitable access to high quality care, thus improving patient's outcomes and reducing diabetes complications.

**2.2 Clinical and financial impact of type 1 diabetes**

The complications of type 1 diabetes can result in disability: including vision loss, kidney failure and foot ulceration leading to amputation, as well as premature heart disease and stroke. The morbidity associated with these complications can have a devastating impact on quality of life and generate a significant cost to the state.

A systematic review and meta-analysis which included studies with people living with type 1 diabetes in Ireland showed the prevalence of diabetes complications ranged widely depending on study population and methodology used (6.5–25.2 % retinopathy; 3.2–32.0 % neuropathy; 2.5–5.2 % nephropathy) (Tracey et al, 2016). However this review highlighted a number of limitations in interpretation of available data due to inconsistencies in reporting, limited availability of objective data and standardisation in diagnostic criteria (Tracey et al, 2016). Another Irish study showed the average glycaemic control in a population of young adults (18–25 years old) with type 1 diabetes was poor at 81mmols/mol and diabetes related complications were present in 32% of this young adult population (Casey et al, 2014).

In 2016, the Hospital In-Patient Enquiry Scheme (HIPE) reported 1,959 hospital discharges for type 1 diabetes-associated complications including hyperosmolarity, ketoacidosis, kidney complications, ophthalmic and neurological conditions. The association between having diabetes and psychiatric disorder is strong and consistent across different settings (Thomas et al, 2003; Golden et al, 2008). Depression is a common finding among people with diabetes, with an average prevalence of 10%, and increases in incidence as the burden and disability from diabetes complications progresses. When individuals with poor glycaemic control are formally assessed by liaison mental health teams, previously undiagnosed psychiatric disorders such as depression, borderline personality traits, and eating disorders emerge (Doherty et al, 2016).

Data from the UK estimates 10% of the entire health budget is spent on diabetes and related complications, this is projected to rise to around 17% in 2035/2036 (Hex et al, 2012). The true costs in Ireland are unknown; a similar estimate to the UK would appear reasonable. The CODEIRE study assessed the cost of type 2 diabetes in Ireland and, in keeping with international literature, demonstrated that diabetes is costly and that much of the cost relates to managing the complications of diabetes (Nolan et al, 2006). It is over 20 years since the publication of the Diabetes Control and Complications Trial (DCCT), which proved beyond doubt that intensive glucose control in people living with type 1 diabetes reduces the risk of microvascular and neuropathic complications. Realising this goal remains challenging at the level of the individual patient and across the health service. If the recommendations in the Guideline are implemented, then Ireland should be closer to achieving improved control and improved quality of life for individuals living with type 1 diabetes.

### 2.3 Rationale for this National Clinical Guideline

In the absence of a National Diabetes Register it is estimated that there are 20,000 adults in Ireland living with type 1 diabetes, representing approximately 10% of adults diagnosed with diabetes.

People living with type 1 diabetes need to be provided with the necessary knowledge and tools in order to successfully self-manage their condition. The HSE National Framework and Implementation Plan for Self-management Support for Chronic Conditions: COPD, Asthma, Diabetes and Cardiovascular Disease published in 2017 supports a collective shift in emphasis toward creating enabling, supportive and transformative environments that put the patient first, realising the value of active participation and effective collaborative interactions between patients and healthcare staff. It acknowledges that supporting people to self-manage their health conditions through systematic provision of education and supportive interventions increases their skills and confidence and improves outcomes for patients (HIQA 2015, Panagioti et al, 2014).

In many health services (including Germany and the UK) care for individuals living with type 1 diabetes incorporates the delivery of high quality self-management education, usually in a group setting. Many of these self-management education programmes have demonstrated improvement in diabetes control, quality of life and diabetes knowledge. Despite an awareness of the importance of group education, only 409 adults with type 1 were recorded as having attended such programmes in Ireland in 2016, with only 159 having attended a programme which meets international standards (HSE NCP National Survey of Diabetes Care Delivery by Acute Hospitals, 2017-unpublished).

Current evidence shows the care of people with diabetes varies across Ireland. Care may be limited, unstructured and ad-hoc in some locations with limited access to specialist expert diabetes opinion in secondary care. Only 42% of hospital diabetes services are currently offering adults with uncomplicated type 1 diabetes the recommended six monthly review appointments. Instead many patients are offered only infrequent appointments focused on annual review (HSE NCP National Survey of Diabetes Care Delivery by Acute Hospitals Diabetes, 2017-unpublished).

As previously stated Ireland has not had clinical guidelines for the management of adult patients with type 1 diabetes. The National Clinical Programme for Diabetes together with the NCEC recognised that the NICE guideline (NG17) *Type 1 diabetes in adults: diagnosis and management (2015)* offered an opportunity to work with an up-to-date, well prepared guideline. This would allow the development of an Irish guideline that was created with a similar patient population and health system in mind. It is hoped that the publication of this guideline will be a driver to standardise care nationally and as a result patient outcomes will improve and the incidence of diabetes related complications will decrease. The development of a guideline will allow a structured review and evaluation against explicit standards of care to identify gaps in service and help targeted improvements in patient care and outcomes.

## 2.4 Aim and objectives

The aim of this guideline is to provide evidence-based, practical advice on the steps necessary to support adults with type 1 diabetes to live full lives and avoid the acute and long-term complications of both the disease and its treatment. This evidence-based clinical guideline will provide a practical approach to promote the implementation of cost-effective evidence-based care nationally. This will improve health outcomes for patients, reduce variation in practice and improve the quality of clinical decisions that patients and healthcare staff make together. A National Clinical Guideline will inform patients about the care they should be receiving and assist them to make healthcare choices based on best available information.

## 2.5 Guideline scope

### Groups that will be covered

- Adults (aged 18 years and older) with type 1 diabetes.

### Groups that will not be covered

- Children with type 1 diabetes. This is addressed in the HSE (2015) Model of Care for All Children and Young Adults with Type 1 Diabetes and HSE Transition from Paediatric to Young Adult Diabetes Care Guidelines (awaiting publication).
- Adults with type 2 diabetes. This is addressed in the HSE (2018) Model of Integrated Care for Type 2 Diabetes (awaiting publication) and the ICGP (2016) Practical Guide to Integrated Type 2 Diabetes Care.
- Diabetes in pregnancy. This is addressed in the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).
- Monogenic and other rarer forms of diabetes.

### Healthcare setting

All settings in which people living with type 1 diabetes is receive care.

## 2.6 Conflict of interest statement

The guideline development group adhered to the conflict of interest policy set out by NCEC. All members of the group completed the required Conflict of Interest Declaration form which were submitted to the NCP Diabetes Programme Manager and reviewed by the chair. No interests stated were deemed to be conflicts in relation to the recommendations of this guideline.

## 2.7 Sources of funding

The NICE contextualisation process was funded by the Department of Health as a pilot to facilitate guideline development. The economic review and the budget impact analysis for the guideline was carried out by the Health Research Board Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER).

## 2.8 Guideline methodology

A literature search for international guidelines for type 1 diabetes was conducted on the Guidelines International Network, International Guideline Library database in October 2016. 21 international guidelines were identified that met the search criteria. Guidelines were excluded if they were not yet published, if they were over 5 years old, related only to type 2 diabetes or were not available in English. When this exclusion criteria was applied only two sets of guidelines were eligible for consideration:

- NICE 2015 Type 1 diabetes in adults: diagnosis and management guideline
- Type 1 diabetes through the life span: a position statement of the American Diabetes Association 2014.

The programme convened a Guideline Development Group (GDG) of recognised experts and clinical leaders having invited representation from the main professional bodies of the diabetes multidisciplinary team. After discussion with the GDG and following a wider consultative consensus day with all stakeholders involved it was agreed to develop a National Clinical Guideline through the Department of Health's NCEC. To demonstrate the high quality and reporting of the NICE guideline a quality assessment was conducted using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) (Brouwers et al, 2010) tool by two members of the GDG. The NICE guideline ranked very highly with appraiser scores in all domains, overall percentages were 86-90%, and both appraisers recommended this guideline for use. The NCEC prioritised this clinical guideline in February 2017 following submission of a proposal document by the GDG in December 2016. The ADAPTE (2009) and NICE contextualisation processes were considered. The programme together with the NCEC recognised the potential value of contextualising the NICE guideline *Type 1 diabetes in adults: diagnosis and management (NG17)* to an Irish guideline and engaged with NICE. This is the first time NCEC have undertaken a contextualisation process and only the second time NICE have worked with a country outside of the United Kingdom.

NICE contextualisation is a process whereby an external agency can contextualise certain NICE guidelines for a different jurisdiction. A licensing agreement was required and was negotiated between NICE and the NCEC. Funding was provided by the Department of Health. The GDG were responsible for reviewing the NICE guideline and recommending to the NICE Guideline Contextualisation Quality Assurance Team any change deemed necessary for the Republic of Ireland context. The evidence base for the guideline being contextualised was not reviewed and/or updated. Where changes / updates were felt to be necessary / beneficial and have been agreed with the NICE Guideline Contextualisation QA Team, the appropriate references are included. The guideline provides recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

The next stage in the development process was a public consultative process, which is described in section 2.12. Following this consultation period, feedback was reviewed by the GDG and incorporated into the document if deemed appropriate to produce a guideline relevant to the Irish population, which we hope will be welcomed by those who manage and experience diabetes care in Ireland. This guideline describes methods for achieving optimal outcomes for adults with type 1 diabetes to inform service design and delivery. Its intended audience includes healthcare professionals involved in delivering services to adults with type 1 diabetes, service managers and commissioners, and adults with type 1 diabetes and their families.

The implementation plan and budget impact analysis (BIA) were developed independent of NICE. The BIA was developed by HRB-CICER in conjunction with members of the GDG (see Section 2.15). The development of the implementation plan was the sole responsibility of the GDG. To assist with this process members of the GDG attended training and follow up workshops provided by the Centre for Effective Services (CES) through the NCEC (see Section 2.14).

## **2.9 Strength of NICE recommendations**

Some recommendations can be made with more certainty than others. The NICE Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the NICE Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation). For further detail refer to <https://www.nice.org.uk/guidance/ng17/chapter/About-this-guideline>.

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care' section 2.10).

### **Interventions that must (or must not) be used**

NICE usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally NICE use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

### **Interventions that should (or should not) be used – a 'strong' recommendation**

NICE use 'offer' (and similar words such as 'refer' or 'advise') when they are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. NICE use similar forms of words (for example, 'Do not offer...') when they are confident that an intervention will not be of benefit for most patients.

### **Interventions that could be used**

NICE use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## **2.10 Patient centred care**

This guideline offers best practice advice on the care of adults with type 1 diabetes. Patients and healthcare professionals have rights and responsibilities as set out in the Health Information and Quality Authority (HIQA) National Standards for Safer Better Healthcare (2012). Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Healthcare professionals should follow the HSE National Consent Policy 2017 for advice on consent. If someone does not have capacity to make decisions, healthcare professionals should follow the Assisted Decision-Making (Capacity) Act 2015 and the HSE (2017) Guide for Health and Social Care Professionals.

## 2.11 Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.

It is important to recognise that the licensing process for drugs regulates the marketing activities of pharmaceutical companies, and not prescribing practice. Use of unlicensed drugs by prescribers is often appropriate and guided by clinical judgment. This practice is safeguarded in legislation in accordance with Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. 540/2007) as amended. Furthermore, drugs prescribed outside license can be dispensed by pharmacists and administered by nurses or midwives.

## 2.12 Consultation summary

The public consultation of the guideline was advertised on the Royal College of Physicians of Ireland Website, via the HSE, Patient Advocacy Groups and Social Media. Individuals and organisations identified as key stakeholders in the care of type 1 diabetes were also invited to review the guideline and provide feedback. The guideline was made available on line on the website of the Royal College of Physicians of Ireland and feedback was submitted on the recommended NCEC template. The consultative period ran from December 18<sup>th</sup> 2017 until January 12<sup>th</sup> 2018. Feedback was reviewed by the GDG and the guideline was amended where appropriate, refer to appendix 3.

## 2.13 External review

Working with NICE has ensured that clinical expertise of UK experts was incorporated into the guideline's development. Further international peer review was not undertaken.

## 2.14 Implementation summary

A national survey was undertaken to assess current adult type 1 diabetes care delivery by the 31 acute hospitals providing inpatient and ambulatory diabetes services in Ireland. A 100% response rate was achieved and the findings have informed the implementation plan. It was found that many of the guideline recommendations, such as diagnosis, clinical monitoring of glucose control, insulin regimens, and treatment and monitoring of specific complications are already established as part of routine care for patients with type 1 diabetes in Ireland. There were two key recommendations that are not yet established as routine care and are currently not widely available in Ireland. The guideline recommends that high quality structured patient education must be incorporated into routine care for all people living with type 1 diabetes. It also recommends the measurement of HbA1c levels every 3–6 months in adults with type 1 diabetes. To facilitate implementation of this guideline there is a requirement to ensure access to high quality structured patient education and access to a minimum of 2 consultations with a diabetes healthcare provider per year for all adults with type 1 diabetes. These recommendations are the primary focus of this guideline implementation plan. A full plan for implementation of this guideline is outlined in Appendix 4 and Logic Model. Funding for implementation of this guideline is subject to service planning and estimates process.

## 2.15 Summary budget impact analysis

A review of the economic literature underpinning the 2015 NICE guideline was undertaken. The full economic evidence review is presented in Annex 1. The review, in line with NICE contextualisation methodology, was constrained to literature identified in the systematic review that informed the 2015 NICE guideline and economic evidence available from within the Irish healthcare context. The evidence presented in the NICE guideline was considered transferrable to the Irish setting, and no conflicting Irish evidence was identified in a full systematic literature search for national evidence.

The full budget impact analysis (BIA) is presented in Annex 2. There are three key changes to service delivery that will occur as a result of implementation of the guideline recommendations and these were considered within the budget impact analysis. Firstly, the national provision of a high-quality structured patient education programme to empower people with type 1 diabetes to effectively manage their diabetes and the external factors that can influence their blood glucose levels such as exercise and stress. The Dose Adjustment for Normal Eating (DAFNE) programme is the only structured education programme that is currently available in Ireland that meets all of the criteria of the clinical recommendations regarding structured patient education. There are currently seven DAFNE centres in Ireland. The expansion of DAFNE provision would entail the establishment of a maximum of 11 new DAFNE centres following successful implementation, at an estimated cost of €2.9 million over a five year period. This estimate includes the anticipated recruitment costs for additional staff to deliver the programme as well as ongoing running costs and the potential savings due to improved outcomes. Of note, an economic evaluation of the DAFNE programme was performed in the United Kingdom in 2014. The economic evaluation found that DAFNE education was both cost saving and more effective when compared with no DAFNE education. The results, discounted over a lifetime horizon, indicated that DAFNE education would save the National Health Service £1,656 (€2,139 when converted in equivalent Irish Euros) per patient when compared with no DAFNE education. DAFNE education was predicted to reduce the incidence of severe long-term complications such as nephropathy and neuropathy. The results of this economic evaluation were considered to be transferable to the Irish setting. As such, it is anticipated that delivery of the DAFNE programme in Ireland would be a cost-effective use of resources.

Secondly, to ensure implementation of the guideline, short courses for all staff who deliver care to people with type 1 diabetes in Ireland will be provided. The training would be delivered by the staff recruited to deliver the DAFNE programme, and attendance of course participants would be facilitated through existing arrangements for training and development. The estimated budget impact for the short course was approximately €18,000 over five years.

Finally, the guideline recommends the standardisation of patient follow-up in diabetes clinics where patients are re-called at least every six months. Survey data has indicated that there is substantial variation to practice, with only 42% of hospitals currently offering re-call appointments at this frequency. In order to meet the guideline recommendations an estimated additional 5,000 appointments would need to be provided each year, with an opportunity cost of €3.2 million over five years. However, it is anticipated that the implementation of the HSE (2018) National Model of Integrated Care for Type 2 Diabetes (awaiting publication) and the ICGP (2016) A Practical Guide to Integrated Type 2 Diabetes 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. 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.

## 2.16 Monitoring, evaluation and audit

Ireland does not have a National Diabetes Register. It is recognised at present that ICT systems are not in place in Ireland to easily monitor the implementation of the recommendation made in this guideline. Such deficits represent a significant barrier to improving diabetes care for individuals living with diabetes in Ireland. In other countries where registers are maintained as part of care delivery reporting of outcomes of care such as average levels of HbA1c happens routinely (McKnight et al, 2015). Achieving the goal of developing and maintaining a National Diabetes Register will require commitment and buy-in from many stakeholders.

The National Clinical Programme for Diabetes is keen to demonstrate the benefits of developing and maintaining a register for individuals living with type 1 diabetes. Most individuals living with type 1 diabetes attend hospital services for their care. In a recent National Survey of Diabetes Care Delivery by Acute Hospitals the programme established that although 18 out of 31 hospitals reported having a diabetes register of existing patients or a diabetes management system that would allow them to generate a list of diabetes patients, only 8 of 31 acute hospitals reported that the number of type 1 diabetes patients attending their service were based on accurate figures.

Qualitative data collected as part of the recent National Survey would suggest that there is frustration among hospital teams that do not have access to a diabetes information system. The experience in other countries would strongly suggest that if a National Register/Audit of Care can be initiated then the resultant data will generate many important questions for future audit, research and most importantly improvements in patient care. While we wait for the necessary ICT infrastructure and national diabetes audit, progress can be monitored in individual diabetes units. Each unit will be encouraged to conduct annual audits of attendance, clinical outcomes such as HbA1c and rates of screening for complications. The expansion of structured patient education programmes will be co-ordinated by the NCP Diabetes with the assistance of the National Patient Education Co-ordinator. The National Structured Patient Education Database due to be launched in 2018 will be used to collate and analyse data relating to SPE programmes. Administrative staff will be required to co-ordinate the expansion of structured patient education programmes across the country and part of their role will be to maintain and submit all of the relevant data. A National Diabetes Register when developed will use this National Clinical Guideline to set the standard of care for people living with type 1 diabetes, refer to appendix 5.

## 2.17 Plan to update this National Clinical Guideline

The guideline will be updated three years from publication as per the process outlined by NCEC. Responsibility for update of the guideline will rest with the HSE National Clinical Programme for Diabetes (or the equivalent depending on the governance structures at the time). If there is a major change in evidence prior to this, a rapid update may be conducted as per NCEC procedures. Due to the contextualisation process, ongoing engagement with NICE will ensure compatibility with its update/review procedures.

## 3

## National Clinical Guideline recommendations

The following guidance is based on the best available evidence. The NICE [full guideline \(https://www.nice.org.uk/Guidance/NG17/Evidence\)](https://www.nice.org.uk/Guidance/NG17/Evidence) gives details of the methods and the evidence used to develop the guidance.

**Blood glucose and plasma glucose**

This guideline refers frequently to circulating glucose concentrations as ‘blood glucose’. A lot of the evidence linking specific circulating glucose concentrations with particular outcomes uses ‘plasma’ rather than ‘blood’ glucose. In addition, patient-held glucose meters and monitoring systems are all calibrated to plasma glucose equivalents. However, the term ‘blood glucose monitoring’ is in very common use, so in this guideline we use the term ‘blood glucose’, except when referring to specific concentration values.

**3.1 Diagnosis and early care plan****Diagnosis**

- 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/m<sup>2</sup>
  - personal and/or family history of autoimmune disease.
- 3.1.2** Do not discount a diagnosis of type 1 diabetes if an adult presents with a BMI of 25 kg/m<sup>2</sup> or above or is aged 50 years or above.
- 3.1.3** Do not measure C-peptide and/or diabetes-specific autoantibody titres routinely to confirm type 1 diabetes in adults.
- 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/m<sup>2</sup> 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**
  - 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.

### Early care plan

- 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.

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 3.3 and 3.4)
  - initial treatment modalities, including guidance on insulin injection and insulin regimens (see sections 3.7 and 3.8)
  - means of self-monitoring and targets (see section 3.6)
  - 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 3.13)
  - for women of childbearing potential, implications for pregnancy and family planning advice, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)
  - frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review.
- 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.
- 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.

## **3.2 Support and individualised care**

- 3.2.1** Take account of any disabilities, including visual impairment, when planning and delivering care for adults with type 1 diabetes.
- 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 to work and communicate efficiently while providing consistent advice.
- 3.2.3** Provide adults with type 1 diabetes with:
- open-access services on a walk-in and telephone-request basis during normal working hours of Diabetes Day Centre
  - contact information for these services.
- 3.2.4** 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 3.4.4 and 3.4.12 about the cultural preferences of individual adults with type 1 diabetes).

- 3.2.5** Set up an individual care plan jointly agreed with the adult with 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 3.3 and 3.4)
  - insulin therapy, including dose adjustment (see sections 3.8 and 3.9)
  - self-monitoring (see section 3.6)
  - avoiding hypoglycaemia and maintaining awareness of hypoglycaemia
  - management of hypoglycaemia including training of friends and / or family on glucagon administration
  - sick day rules, ketone monitoring
  - for women of childbearing potential, implications for pregnancy and family planning advice, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)
  - cardiovascular risk factor monitoring and management (see section 3.13)
  - complications monitoring and management (see section 3.16)
  - 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.
- 3.2.6** Use population, practice-based and clinic diabetes registers to assist programmed recall for annual review and assessment of complications and cardiovascular risk.
- 3.2.7** The multidisciplinary team approach should be available to inpatients with type 1 diabetes, regardless of the reason for admission (see section 3.14).
- 3.2.8** 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.

### 3.3 Education and information

- 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.
- 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.
- 3.3.3** Provide an alternative of equal standard for any adult with type 1 diabetes unable or unwilling to participate in group education.

- 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 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.
- 3.3.6** Provide information about type 1 diabetes and its management to adults with type 1 diabetes at all opportunities from diagnosis onwards.
- 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.
- 3.3.8** Provide women of childbearing potential with information on the risks associated with pregnancy and the importance of adequate contraception and pre-conception planning. See the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).

## **3.4 Dietary management**

### **Carbohydrate counting**

- 3.4.1** Offer carbohydrate-counting training to adults with type 1 diabetes as part of structured education programmes for self-management (see section 3.3).
- 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.

### **Dietary advice**

- 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.
- 3.4.4** Provide nutritional information sensitive to personal needs and culture from the time of diagnosis of type 1 diabetes.

- 3.4.5** Provide nutritional information individually and as part of a diabetes education programme (see section 3.3). Include advice from a CORU registered dietitian 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 healthcare 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.
- 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.
- 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.
- 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.
- 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.
- 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
  - underweight
  - eating disorders
  - hypertension
  - coeliac disease
  - gastroparesis
  - renal failure.
- 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.

### **3.5 Physical activity**

**3.5.1** Advise adults with type 1 diabetes that physical activity can reduce their enhanced cardiovascular risk in the medium and longer term.

**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
- 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 Blood glucose management**

#### **HbA1c measurement and targets**

##### **Measurement**

**3.6.1** Measure HbA1c levels every 3–6 months in adults with type 1 diabetes.

**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.

**3.6.3** Use methods to measure HbA1c that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation.

**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.

**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
- total glycated haemoglobin estimation (if abnormal haemoglobins).

### Targets

**3.6.6** Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications.

**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.

**3.6.8** Ensure that aiming for an HbA1c target is not accompanied by problematic hypoglycaemia in adults with type 1 diabetes.

**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.

### Self-monitoring of blood glucose

#### Frequency of self-monitoring of blood glucose

**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.

**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 HbA1c level (see recommendation 3.6.6), 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) (2014) *Sláinte agus Tiomáint Medical Fitness to Drive Guidelines*
- during periods of illness
- before, during and after vigorous exercise
- When planning pregnancy, during pregnancy and while breastfeeding, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)
- 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).

- 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.

### **Blood glucose targets**

- 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.
- 3.6.14** Advise adults with type 1 diabetes who chose 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 (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).
- 3.6.15** Agree bedtime target plasma glucose levels with each adult 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 (see recommendation 3.6.13).

### **Empowering people to self-monitor blood glucose**

- 3.6.16** Teach self-monitoring skills at the time of diagnosis and initiation of insulin therapy.
- 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.
- 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. Patients should be aware of potential sources of blood glucose meter errors, appropriate quality control techniques and need for meter replacement every 2 years.
- 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 (see recommendations 3.3.1 and 3.3.2).

### **Sites for self-monitoring of blood glucose**

- 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.

### **Continuous glucose monitoring**

- 3.6.21** Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes.
- 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/litre [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 3.6.11 and 3.6.12). 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.

**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.

**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.

**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>. It is noted that this technology does not completely replace capillary blood glucose monitoring. Patients will continue to require SMBG in addition to flash monitoring.

**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.

## 3.7 Insulin therapy

### Insulin regimens

**3.7.1** Offer multiple daily injection basal–bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin 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.

**3.7.2** Do not offer adults newly diagnosed with type 1 diabetes non-basal–bolus insulin regimens (twice-daily mixed, basal only or bolus only).

### Long-acting insulin

In 2015 NICE recommended the following as the most cost-effective option based on network meta-analysis and modelling:

**3.7.3** Offer twice-daily insulin detemir as basal insulin therapy for adults with type 1 diabetes.

**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.

Since 2015 a number of alternative long-acting insulins have become available in Ireland.

- 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

**3.7.5** Consider other basal insulin regimens for adults with type 1 diabetes only if the regimens in recommendation 3.7.3 and 3.7.4 do not deliver agreed targets. When choosing an alternative insulin regimen, take account of the person's preferences and acquisition cost.

### **Continuous subcutaneous insulin infusion (CSII or insulin pump) therapy**

**3.7.6** For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, refer to the HSE (2018) Product Evaluation Group (Insulin pumps and Consumables) guidelines.

### **Rapid-acting insulin**

**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.

**3.7.8** Do not advise routine use of rapid-acting insulin analogues after meals for adults with type 1 diabetes.

**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.

### **Mixed insulin**

**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.

**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.

### Optimising insulin therapy

**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
- 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.

### Adjuncts

**3.7.14** Consider adding metformin to insulin therapy if an adult with type 1 diabetes and a BMI of 25 kg/m<sup>2</sup> (23 kg/m<sup>2</sup> for people from South Asian and related ethnic minority groups) or above wants to improve their blood glucose control while minimising their effective insulin dose.

## 3.8 Insulin delivery

**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.

**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.

**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.

**3.8.4** After taking clinical factors into account (See FIT Ireland Recommendations [www.fit4diabetes.com/ireland](http://www.fit4diabetes.com/ireland)) choose needles with the lowest acquisition cost to use with pre-filled and reusable insulin pen injectors.

**3.8.5** Advise adults with type 1 diabetes to rotate insulin injection sites and avoid repeated injections at the same point within sites.

**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.

**3.8.7** Check injection site condition at least annually and if new problems with blood glucose control occur.

### 3.9 Referral for islet or pancreas transplantation

- 3.9.1** Consider referring adults with type 1 diabetes who have recurrent severe hypoglycaemia that has not responded to other treatments (see section 3.10) to a centre that assesses people for islet and/or pancreas transplantation.
- 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.

### 3.10 Awareness and management of hypoglycaemia

#### Identifying and quantifying impaired awareness of hypoglycaemia

- 3.10.1** Assess awareness of hypoglycaemia in adults with type 1 diabetes at each annual review.
- 3.10.2** Use the Gold score or Clarke score to quantify awareness of hypoglycaemia in adults with type 1 diabetes, checking that the questionnaire items have been answered correctly.
- 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.

#### Strategies for managing impaired awareness of hypoglycaemia

- 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.
- 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.
- 3.10.6** Avoid relaxing individualised blood glucose targets as a treatment for adults with type 1 diabetes with impaired awareness of hypoglycaemia.
- 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 3.6.13–3.6.15).
- 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.
- 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.

### Preventing and managing hypoglycaemia

- 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.
- 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.
- 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 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 sections 3.7 and 3.8).
- 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.
- 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.
- 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.

## 3.11 Ketone monitoring and management of diabetic ketoacidosis (DKA)

### Ketone self-monitoring for prevention of DKA

- 3.11.1** Consider ketone monitoring (blood or urine) as part of ‘sick-day rules’ for adults with type 1 diabetes, to facilitate self-management of an episode of hyperglycaemia.

### **Ketone monitoring in hospital**

- 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.
- 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.

### **Management of DKA**

- 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
  - precipitating causes
  - infection management, including opportunistic infections
  - gastroparesis
  - use of high dependency and intensive care units
  - recommendations 3.11.5 to 3.11.12 in this guideline.

Management of DKA in adults should be in line with local clinical governance.

- 3.11.5** For primary fluid replacement in adults with DKA, use isotonic saline, not given too rapidly except in cases of circulatory collapse.
- 3.11.6** Do not generally use bicarbonate in the management of DKA in adults.
- 3.11.7** Give intravenous insulin by infusion to adults with DKA.
- 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 ketones (for example, 6 units/hour monitored for effect).
- 3.11.9** Begin potassium replacement early in DKA in adults, with frequent monitoring for the development of hypokalaemia.
- 3.11.10** Do not generally use phosphate replacement in the management of DKA in adults.

**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.

**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.

### 3.12 Associated illness

**3.12.1** In adults with type 1 diabetes who have a low BMI or unexplained weight loss, assess markers of coeliac disease.

**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 3.16.41.

### 3.13 Control of cardiovascular risk

#### Aspirin

**3.13.1** Do not offer aspirin for the primary prevention of cardiovascular disease to adults with type 1 diabetes.

#### Identifying cardiovascular risk

**3.13.2** Assess cardiovascular 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.

**3.13.3** For guidance on tools for assessing risk of cardiovascular disease in adults with type 1 diabetes, refer to local standards and guidelines of care and NICE guideline on [lipid modification CG181](#).

#### Interventions to reduce risk and manage cardiovascular disease

**3.13.4** For guidance on the primary prevention of cardiovascular disease in adults with type 1 diabetes refer to NICE guideline on [lipid modification CG181](#).

**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 if there is a prospect of the person stopping.

**3.13.6** Advise young adult non-smokers never to start smoking.

**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 3.14). For guidance on secondary prevention of myocardial infarction, see NICE guideline on [lipid modification CG181](#).

### **Blood pressure management**

**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 3.16.14–3.16.16.

**3.13.9** To allow informed choice by the person with hypertension, discuss the following with them:

- reasons for choice of intervention level
- substantial potential gains from small improvements in blood pressure control
- possible negative consequences of therapy.

See also recommendations 3.16.14 and 3.16.16.

**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.

**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.

**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.

## **3.14 Care of adults with type 1 diabetes in hospital**

### **Blood glucose control**

**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.

**3.14.2** Establish a local protocol for controlling blood glucose levels in adults with type 1 diabetes during surgery or acute illness to achieve the target level.

- 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.
- 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.
- 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.
- 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.

### Delivery of care

- 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 and access to a trained multidisciplinary team with expertise in diabetes.
- 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.
- 3.14.9** Throughout the course of an inpatient admission, the hospital catering service should provide a good choice of nutritious meals that can accommodate patients’ specific dietary requirements. All patients should have a choice of food, including those on a texture-modified diet, therapeutic diet, ethical or cultural diets. This includes patients in emergency departments who are deemed to be admitted to the hospital, but who remain in the emergency department while waiting for a hospital inpatient bed to become available (HIQA 2016).
- 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.
- 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.

### 3.15 Pre-pregnancy care

Women of reproductive age should be informed of the importance of optimising management of their diabetes prior to pregnancy and should have access to pre-pregnancy care. See the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).

## **3.16 Managing complications**

### **Eye disease**

- 3.16.1** Start eye screening for adults newly diagnosed with type 1 diabetes from diagnosis.
- 3.16.2** All patients with type 1 diabetes should be registered with the National Retinopathy Screening Programme
- 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.
- 3.16.4** Depending on the findings, follow structured eye screening by:
- routine review annually by digital photographic screening via RetinaScreen or by clinical exam **or**
  - earlier review **or**
  - referral to an ophthalmologist if indicated.
- 3.16.5** Offer digital retinopathy screening annually to adults with type 1 diabetes.
- 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.
- 3.16.7** Make visual acuity testing a routine part of eye screening programmes.
- 3.16.8** Ensure that emergency review by an ophthalmologist occurs for:
- sudden loss of vision
  - rubeosis iridis
  - pre-retinal or vitreous haemorrhage
  - retinal detachment.
- 3.16.9** Ensure that rapid review by an ophthalmologist occurs for new vessel formation.
- 3.16.10** Refer to an ophthalmologist/Diabetic Retinal Treatment Clinic 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 for any of the following:
    - multiple deep, round or blot haemorrhages
    - venous beading
    - venous reduplication

- intraretinal microvascular abnormalities (IRMA)  
(Cotton wool spots are not diagnostic of pre-proliferative retinopathy but should promote a careful search for other lesions)
- any large sudden unexplained drop in visual acuity.

### Diabetic kidney disease

- 3.16.11** For guidance on managing kidney disease in adults with type 1 diabetes, refer to local standards and guidelines of care.
- 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.
- 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.
- 3.16.14** Discuss the significance of a finding of albuminuria with the person concerned.
- 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.
- 3.16.16** If ACE inhibitors are not tolerated, substitute angiotensin 2 receptor antagonists. Combination therapy is not recommended.
- 3.16.17** Maintain blood pressure below 130/80 mmHg by addition of other anti-hypertensive drugs if necessary.
- 3.16.18** Advise adults with type 1 diabetes and nephropathy about the advantages of not following a high-protein diet.
- 3.16.19** Referral criteria for tertiary care should be agreed between local diabetes specialists and nephrologists.

### Chronic painful diabetic neuropathy

- 3.16.20** For guidance on managing chronic painful diabetic neuropathy in adults with type 1 diabetes, refer to HSE (2018) Integrated Care Model for Type 2 diabetes (awaiting publication) and the ICGP (2016) Practical Guide to Integrated Type 2 Diabetes Care.

### Autonomic neuropathy

- 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.

- 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.
- 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.
- 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).
- 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.

### Gastroparesis

- 3.16.26** Advise a small-particle-size diet (mashed or pureed food) for symptomatic relief for adults with type 1 diabetes who have vomiting caused by gastroparesis<sup>2</sup>.
- 3.16.27** Consider continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes who have gastroparesis.
- 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<sup>3</sup>, erythromycin<sup>4</sup> or metoclopramide<sup>5</sup>
  - the strongest evidence for effectiveness is for domperidone<sup>3</sup>, but prescribers must take into account its safety profile, in particular its cardiac risk and potential interactions with other medicines.
- 3.16.29** For treating vomiting caused by gastroparesis in adults with type 1 diabetes:
- consider alternating use of erythromycin<sup>4</sup> and metoclopramide<sup>5</sup>
  - consider domperidone<sup>3</sup> only in exceptional circumstances (that is, when it is the only effective treatment) and in accordance with European Medicine Agency and Irish Medicines Board guidance.

2 Diagnosis of gastroparesis needing specific therapy can only be made in the absence of hyperglycaemia at the time of testing, because hyperglycaemia induces a physiological delay in gastric emptying.

3 European Medicines Agency and the Health Products Regulatory Authority (HPRA) (2014) notes that domperidone is associated with a small increased risk of serious cardiac side effects. Domperidone is now contraindicated in certain groups in whom the risk of cardiac effects is higher; its marketing authorisations have also been restricted to its use in the relief of nausea and vomiting only, at the lowest effective dose and for the shortest possible time (usually not more than 1 week). They advise that prescribers should take into account the overall safety profile of domperidone, and in particular its cardiac risk and potential interactions with other medicines (such as erythromycin), if there is a clinical need to use it at doses or durations greater than those authorised. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. Refer to HPRA <https://www.hpra.ie/homepage/site-tools/search?query=domperidone>

4 Refer to HPRA <https://www.hpra.ie/homepage/site-tools/search?query=erythromycin>

5 HPRA (2014) notes that metoclopramide has well-known risks of neurological effects such as short-term extrapyramidal disorders and tardive dyskinesia. It advises that metoclopramide should be prescribed only for short-term use (up to 5 days) at a maximum dose of 0.5mg per kg body weight in 24 hours. Refer to HPRA <https://www.hpra.ie/homepage/site-tools/search?query=metoclopramide>

**3.16.30** Refer adults with type 1 diabetes who have gastroparesis for specialist advice if the interventions in recommendations 3.16.26, 3.16.27 and 3.16.29 are not beneficial or not appropriate.

### **Acute painful neuropathy of rapid improvement of blood glucose control**

**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.

**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.

**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.

**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.

**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 (2018) *Integrated Model of Care for Type 2 diabetes*. Simple analgesia may be continued until the effects of additional treatments have been established.

**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.

### **Diabetic foot problems**

**3.16.37** For guidance on preventing and managing foot problems in adults with type 1 diabetes, see the HSE (2012) *Model of Care for the Diabetic foot* and HSE (2018) *National Best Practice and Evidence based guidelines for Wound Management*.

### **Erectile dysfunction**

**3.16.38** Offer men with type 1 diabetes the opportunity to discuss erectile dysfunction as part of their regular review.

**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.

**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.

### **Thyroid disease monitoring**

**3.16.41** Measure blood thyroid-stimulating hormone (TSH) levels in adults with type 1 diabetes at annual review.

### **Psychological and Mental Health problems**

**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.

**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
- Diabetes healthcare professionals should collaborate with Mental Health Services (including Clinical Psychology as part of a Liaison Mental Health Team and/or Community Mental Health Services) to establish pathways to ensure that when required, patients with type 1 diabetes have rapid access to Mental Health Services.

### **Eating disorders**

**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.

See HSE Model of Care for Eating Disorders, available at <http://www.hse.ie/eng/about/Who/cspd/ncps/mental-health/eating-disorders/>

**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.

**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 (see sections 3.3 and 3.4).

## 4 Appendices

### Appendix 1: Terms of reference for the guideline development group

Membership of the guideline development group is outlined at the beginning of this document.

#### **Terms of reference**

To develop a national evidence-based clinical guideline for the diagnosis and management of people with type 1 diabetes. To do this by contextualising the NICE Type 1 diabetes in adult guideline, developing a budget impact analysis in conjunction with HRB-CICER and finally completion of a guideline implementation plan.

## Appendix 2: Recommendations from NICE NG17 that have been contextualised

Recommendations listed in the table below are those which changes were made to the NICE clinical guideline to ensure they are appropriate for the Republic of Ireland with the rationale for these changes outlined.

\*Recommendations that have been contextualised following feedback received from the external consultation process

**Table 5:** Recommendations from NICE NG17 that have been contextualised

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
1	<p>Recommendation 1.1.1 - 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:</p> <ul style="list-style-type: none"> <li>• ketosis</li> <li>• rapid weight loss</li> <li>• age of onset below 50 years</li> <li>• BMI below 25 kg/m<sup>2</sup></li> <li>• personal and/or family history of autoimmune disease.</li> </ul>	<p>Recommendation 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 (<u>but not always</u>) have one or more of:</p> <ul style="list-style-type: none"> <li>• ketosis</li> <li>• rapid weight loss</li> <li>• age of onset below 50 years</li> <li>• BMI below 25 kg/m<sup>2</sup></li> <li>• personal and/or family history of autoimmune disease.</li> </ul>	Emphasis the “but not always” based on external consultation feedback*.
2	<p>Recommendation 1.1.7 - Elements of an individualised and culturally appropriate plan will include:</p> <ul style="list-style-type: none"> <li>• sites and timescales of diabetes education, including nutritional advice (see sections 1.3 and 1.4)</li> <li>• initial treatment modalities, including guidance on insulin injection and insulin regimens (see sections 1.7 and 1.8)</li> <li>• means of self-monitoring and targets (see section 1.6)</li> <li>• symptoms, risk and treatment of hypoglycaemia</li> <li>• management of special situations, such as driving</li> <li>• means and frequency of communication with the diabetes professional team</li> <li>• management of cardiovascular risk factors (see section 1.13)</li> </ul>	<p>Recommendation 3.1.7 - Elements of an individualised and culturally appropriate plan will include:</p> <ul style="list-style-type: none"> <li>• sites and timescales of diabetes education, including nutritional advice (see sections 1.3 and 1.4)</li> <li>• initial treatment modalities, including guidance on insulin injection and insulin regimens (see sections 1.7 and 1.8)</li> <li>• means of self-monitoring and targets (see section 1.6)</li> <li>• symptoms, risk and treatment of hypoglycaemia</li> <li>• management of special situations, such as driving</li> <li>• means and frequency of communication with the diabetes professional team</li> <li>• management of cardiovascular risk factors (see section 1.13)</li> </ul>	Reference to Irish guidelines.

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
	<ul style="list-style-type: none"> <li>for women of childbearing potential, implications for pregnancy and family planning advice (see the NICE guideline on diabetes in pregnancy)</li> <li>frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review.</li> </ul>	<ul style="list-style-type: none"> <li>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 and NICE guidelines on diabetes in pregnancy)</li> <li>frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review.</li> </ul>	
3	Not applicable	Recommendation 3.1.9 - All patients who are newly diagnosed with diabetes should be registered with the Long Term Illness (LTI) scheme and the National Diabetes Retinopathy Screening Programme.	Addition of this recommendation as all people with diabetes in Ireland are eligible for a LTI card. Patients also should be register on diagnosis for annual retinal screening.
4	<p>Recommendation 1.2.3 - Provide adults with type 1 diabetes with:</p> <ul style="list-style-type: none"> <li>open-access services on a walk-in and telephone-request basis during working hours</li> <li>a helpline staffed by people with specific diabetes expertise on a 24-hour basis</li> <li>contact information for these services.</li> </ul>	<p>Recommendation 3.2.3 - Provide adults with type 1 diabetes with:</p> <ul style="list-style-type: none"> <li>open-access services on a walk-in and telephone-request basis during normal working hours of Diabetes Day Centre</li> <li>contact information for these services.</li> </ul>	Agreement of GDG to clarify working hours of Diabetes Day Centre. Agreement to remove 24 hour basis contact information as there is no such service available in Ireland and no plan to establish.
5	<p>Recommendation 1.2.5 - Set up an individual care plan jointly agreed with the adult with 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:</p> <ul style="list-style-type: none"> <li>diabetes education, including nutritional advice (see sections 1.3 and 1.4)</li> <li>insulin therapy, including dose adjustment (see sections 1.8 and 1.9)</li> <li>self-monitoring (see section 1.6)</li> <li>avoiding hypoglycaemia and maintaining awareness of hypoglycaemia</li> </ul>	<p>Recommendation 3.2.5 - Set up an individual care plan jointly agreed with the adult with 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:</p> <ul style="list-style-type: none"> <li>diabetes education, including nutritional advice (see sections 1.3 and 1.4)</li> <li>insulin therapy, including dose adjustment (see sections 1.8 and 1.9)</li> <li>self-monitoring (see section 1.6)</li> <li>avoiding hypoglycaemia and maintaining awareness of hypoglycaemia</li> </ul>	GDG wanted to strengthen recommendation on education of a family member on administration of glucagon and taking into account physiological wellbeing when setting up an individualised care plan. Ketone monitoring and sick day rules added following external consultation feedback*. Reference to Irish guidelines.

	<b>Original wording from NICE NG17</b>	<b>Recommendation following contextualisation for this guideline</b>	<b>Rationale for Contextualisation</b>
	<ul style="list-style-type: none"> <li>for women of childbearing potential, family planning, contraception and pregnancy planning (see the NICE guideline on diabetes in pregnancy)</li> <li>cardiovascular risk factor monitoring and management (see section 1.13)</li> <li>complications monitoring and management (see section 1.15)</li> <li>means and frequency of communicating with the diabetes professional team</li> <li>frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review.</li> </ul>	<ul style="list-style-type: none"> <li>management of hypoglycaemia including training of friends and / or family on glucagon administration</li> <li>sick day rules, ketone monitoring</li> <li>For women of childbearing potential, implications for pregnancy and family planning advice, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)</li> <li>cardiovascular risk factor monitoring and management (see section 1.13)</li> <li>complications monitoring and management (see section 1.15)</li> <li>psychological wellbeing of the person with diabetes</li> <li>means and frequency of communicating with the diabetes professional team</li> <li>frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review.</li> </ul>	<p>GDG wanted to strengthen recommendation on education of a family member on administration of glucagon and taking into account physiological wellbeing when setting up an individualised care plan. Ketone monitoring and sick day rules added following external consultation feedback*. Reference to Irish guidelines.</p>
6	<p>Recommendation 1.2.8 - 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), how to contact them and the benefits of membership.</p>	<p>Recommendation 3.2.8 - 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.</p>	<p>GDG agreed should be reference to main Irish advocacy group i.e. Diabetes Ireland.</p>
7	<p>Recommendation 1.3.7 - Consider the Blood Glucose Awareness Training (BGAT) programme for adults with type 1 diabetes who are having recurrent episodes of hypoglycaemia.</p>	<p>Removed based on feedback received at consensus conference and following discussion at GDG meeting.</p>	<p>This recommendation removed from guideline, GDG agreed this training is not available in Ireland and there is no plan to establish BGAT training in Ireland.</p>
8	<p>Not applicable</p>	<p>Recommendation 3.3.8 - Provide women of childbearing potential with information on the risks associated with pregnancy and the importance of adequate contraception &amp; pre-conception planning. See the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).</p>	<p>Addition made to emphasis importance of education on pre- pregnancy care based on external consultation feedback*.</p>

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
9	Recommendation 1.4.3 - Do not advise adults with type 1 diabetes to follow a low glycaemic index diet for blood glucose control.	Removed based on feedback received at consensus conference and following discussion at GDG meeting.	This recommendation was removed as the GDG did not want GI diets to be singled out for recommendation. This area only forms very small part of dietary management in Ireland. Agreement very limited evidence for low GI diets in glycaemia management in type 1 but lower GI, higher fibre CHO foods may have other health benefits, low GI / high fat meals have the potential to cause delayed postprandial hyperglycaemia. Also the principles of GI are an important part of dietary education for type 1 as in DAFNE and other programmes. Agreement that rather than amend would remove recommendation.
10	Recommendation 1.4.6 - Provide nutritional information individually and as part of a diabetes education programme (see section 1.3). Include advice from 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.	Recommendation 3.4.5 - Provide nutritional information individually and as part of a diabetes education programme (see section 1.3). Include advice from a CORU registered dietitian 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 healthcare professionals.	All dietitians working in the Irish health service executive in Ireland must be CORU registered based on external consultation feedback*.
11	Recommendation 1.4.7 - Discuss the hyperglycaemic 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.	Recommendation 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.	Agreement to change to glycaemic effects to cover hypo and hyper effects of different foods , both of which would be covered in education.

	<b>Original wording from NICE NG17</b>	<b>Recommendation following contextualisation for this guideline</b>	<b>Rationale for Contextualisation</b>
12	Recommendation 1.4.9 - Agree the 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.	Recommendation 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.	Agreement to add the indication for snacking as snacking may not be recommended for all people with type 1 diabetes.
13	Recommendation 1.4.10 - Make information available on: <ul style="list-style-type: none"> <li>• effects of different alcohol-containing drinks on blood glucose excursions and calorie intake</li> <li>• use of high-calorie and high-sugar 'treats'.</li> </ul>	Recommendation 3.4.9 - Make information available on: <ul style="list-style-type: none"> <li>• effects of different alcohol-containing drinks on blood glucose excursions and calorie intake</li> <li>• use of high-calorie and high-sugar foods.</li> </ul>	Avoid use of word "treats" in all Irish healthy eating literature.
14	Recommendation 1.4.12 - Modify nutritional recommendations to adults with type 1 diabetes to take account of associated features of diabetes, including: <ul style="list-style-type: none"> <li>• excess weight and obesity</li> <li>• underweight</li> <li>• eating disorders</li> <li>• hypertension</li> <li>• renal failure.</li> </ul>	Recommendation 3.4.11 - Modify nutritional recommendations to adults with type 1 diabetes to take account of associated features of diabetes, including: <ul style="list-style-type: none"> <li>• excess weight and obesity</li> <li>• underweight</li> <li>• eating disorders</li> <li>• hypertension</li> <li>• renal failure</li> <li>• coeliac disease</li> <li>• gastroparesis.</li> </ul>	Addition of coeliac disease and gastroparesis as both also require modification of nutritional recommendations.

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
15	<p>Recommendation 1.4.13 - 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:</p> <ul style="list-style-type: none"> <li>• body weight, energy balance and obesity management</li> <li>• cultural and religious diets, feasts and fasts</li> <li>• foods sold as 'diabetic'</li> <li>• sweeteners</li> <li>• dietary fibre intake</li> <li>• protein intake</li> <li>• vitamin and mineral supplements</li> <li>• alcohol</li> <li>• matching carbohydrate, insulin and physical activity</li> <li>• salt intake in hypertension</li> <li>• comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders</li> <li>• use of peer support groups.</li> </ul>	<p>Recommendation 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:</p> <ul style="list-style-type: none"> <li>• body weight, energy balance and obesity management</li> <li>• cultural and religious diets, feasts and fasts</li> <li>• foods sold as 'diabetic'</li> <li>• sweeteners</li> <li>• dietary fibre intake</li> <li>• protein intake</li> <li>• vitamin and mineral supplements</li> <li>• alcohol</li> <li>• matching carbohydrate, insulin and physical activity</li> <li>• salt intake in hypertension</li> <li>• comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders</li> <li>• alternative diets e.g. ketogenic diet, very low calorie diet</li> <li>• use of peer support groups.</li> </ul>	<p>Include alternative diets in list to be aware of increasing usage of ketogenic and very low calorie diets in Ireland.</p>
16	<p>Recommendation 1.5.2 - Give adults with type 1 diabetes who choose to integrate increased physical activity into a more healthy lifestyle information about:</p> <ul style="list-style-type: none"> <li>• appropriate intensity and frequency of physical activity</li> <li>• role of self-monitoring of changed insulin and/or nutritional needs</li> <li>• effect of activity on blood glucose levels (likely fall) when insulin levels are adequate</li> <li>• effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic (risk of worsening of hyperglycaemia and ketonaemia)</li> <li>• appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours</li> <li>• interactions of exercise and alcohol</li> <li>• further contacts and sources of information.</li> </ul>	<p>Recommendation 3.5.2 - Give adults with type 1 diabetes who choose to integrate increased physical activity into a more healthy lifestyle information about:</p> <ul style="list-style-type: none"> <li>• importance of planning activity</li> <li>• appropriate intensity and frequency of physical activity</li> <li>• role of self-monitoring of changed insulin and/or nutritional needs</li> <li>• effect of activity on blood glucose levels (likely fall) when insulin levels are adequate</li> <li>• effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic (risk of worsening of hyperglycaemia and ketonaemia)</li> <li>• appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours</li> <li>• interactions of exercise and alcohol</li> <li>• further contacts and sources of information.</li> </ul>	<p>Agreement of GDG to strengthen importance of planning of physical activities by patients with type 1 diabetes as the starting point to taking into account all of the areas listed.</p>

	<b>Original wording from NICE NG17</b>	<b>Recommendation following contextualisation for this guideline</b>	<b>Rationale for Contextualisation</b>
17	<p>Recommendation 1.6.11 - 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:</p> <ul style="list-style-type: none"> <li>the desired target for blood glucose control, measured by HbA1c level (see recommendation 41), is not achieved</li> <li>the frequency of hypoglycaemic episodes increases</li> <li>there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] At a glance guide to the current medical standards of fitness to drive)</li> <li>during periods of illness</li> <li>before, during and after sport</li> <li>when planning pregnancy, during pregnancy and while breastfeeding</li> <li>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).</li> </ul>	<p>Recommendation 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:</p> <ul style="list-style-type: none"> <li>the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved</li> <li>the frequency of hypoglycaemic episodes increases</li> <li>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)</li> <li>during periods of illness</li> <li>before, during and after vigorous exercise</li> <li>when planning pregnancy, during pregnancy and while breastfeeding, see the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3)</li> <li>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).</li> </ul>	<p>Reference to Irish guidelines. Replace sport with vigorous exercise based on feedback from external consultation*.</p>
18	<p>Recommendation 1.6.14 - 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 NICE guideline on diabetes in pregnancy.)</p>	<p>Recommendation 3.6.14 - Advise adults with type 1 diabetes who chose 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 (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).</p>	<p>Reference to Irish guidelines.</p>

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
19	Recommendation 1.6.18 - 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.	Recommendation 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. Patients should be aware of potential sources of blood glucose meter errors, appropriate quality control techniques and need for meter replacement every 2 years.	Education should include education on blood glucose meters, quality control of these and replacement every 2 years based on external consultation feedback*.
20	Not applicable	Recommendation 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 <a href="https://www.nice.org.uk/advice/mib110/chapter/Summary">https://www.nice.org.uk/advice/mib110/chapter/Summary</a> . It is noted that this technology does not completely replace capillary blood glucose monitoring. Patients will continue to require SMBG in addition to flash monitoring.	Include reference to use of flash glucose monitoring which are now available on the Irish market.
21	Not applicable	Recommendation 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.	As above.

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22	<p>Recommendations 1.7.3, 1.7.4. and 1.7.5</p> <ul style="list-style-type: none"> <li>• Offer twice-daily insulin detemir as basal insulin therapy for adults with type 1 diabetes.</li> <li>• 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.</li> <li>• 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.</li> </ul> <p>When choosing an alternative insulin regimen, take account of the person's preferences and acquisition cost.</p>	<p>Recommendation 3.7.3,3.7.4 and 3.7.5 - In 2015 NICE recommended the following as the most cost-effective option based on network meta-analysis and modelling:</p> <ul style="list-style-type: none"> <li>• Offer twice-daily insulin detemir as basal insulin therapy for adults with type 1 diabetes.</li> <li>• Consider, as an alternative basal insulin therapy for adults with type 1 diabetes: <ul style="list-style-type: none"> <li>• an existing insulin regimen being used by the person that is achieving their agreed targets</li> <li>• 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.</li> </ul> </li> </ul> <p>Since 2015 a number of alternative long-acting insulins have become available in Ireland.</p> <ul style="list-style-type: none"> <li>• 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 <a href="https://www.nice.org.uk/advice/esnm24/chapter/key-points-from-the-evidence">https://www.nice.org.uk/advice/esnm24/chapter/key-points-from-the-evidence</a> and <a href="https://www.nice.org.uk/advice/esnm62/chapter/Key-points-from-the-evidence">https://www.nice.org.uk/advice/esnm62/chapter/Key-points-from-the-evidence</a>. Refer to local guidance and protocols on their use</li> <li>• Consider other basal insulin regimens for adults with type 1 diabetes only if the regimens in recommendation 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.</li> </ul>	<p>Acknowledge the use of newer basal insulins in Ireland. Clarify timing of NICE recommendations based on external consultation feedback*.</p>
23	<p>Recommendation 1.7.6 - For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, see Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (NICE technology appraisal guidance 151).</p>	<p>Recommendation 3.7.6 - For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, refer to the HSE Product Evaluation Group (Insulin pumps and Consumables) guidelines.</p>	<p>Reference to Irish insulin pump procurement process and care pathways within this process.</p>

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
24	Recommendation 1.14.7 -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.	Recommendation 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 and access to a trained multidisciplinary team with expertise in diabetes.	Include “access to” diabetes multidisciplinary team during an adult with type 1 diabetes inpatient stay to strengthen importance of review by members of the diabetes multidisciplinary team based on external consultation feedback*.
25	Recommendation 1.14.8 -Throughout the course of an inpatient admission, respect the personal expertise of adults with type 1 diabetes (in managing their own diabetes) and routinely integrate this into ward-based blood glucose monitoring and insulin delivery.	Recommendation 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.	Agreement of GDG to clarify 'if condition allows' as may not always be appropriate for a patient to continue to self-manage their diabetes in hospital.
26	Recommendation 1.14.9 -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.	Recommendation 1.14.9 - Throughout the course of an inpatient admission, the hospital catering service should provide a good choice of nutritious meals that can accommodate patients' specific dietary requirements. All patients should have a choice of food, including those on a texture-modified diet, therapeutic diet, ethical or cultural diets. This includes patients in emergency departments who are deemed to be admitted to the hospital, but who remain in the emergency department while waiting for a hospital inpatient bed to become available (HIQA 2016).	Reference to Irish recommendations based on external consultation feedback*.
27	Not applicable	Recommendation 3.15 - Women of reproductive age should be informed of the importance of optimising management of their diabetes prior to pregnancy and should have access to pre-pregnancy care. See the HSE (2010) Guidelines for the Management of Pre-gestational and Gestational Diabetes Mellitus and the NICE (2015) Guideline Diabetes in pregnancy: management from preconception to the postnatal period (NG3).	Include recommendation on importance of pre-pregnancy care for all women of reproductive age with diabetes as part of type 1 diabetes care*.

	<b>Original wording from NICE NG17</b>	<b>Recommendation following contextualisation for this guideline</b>	<b>Rationale for Contextualisation</b>
28	Not applicable	Recommendation 3.16.2 - All patients with type 1 diabetes should be registered with the National Retinopathy Screening Programme.	Eye disease section amended based on recommendation of Irish National Retinal Screening Programme/ RetinaScreen.
29	<p>Recommendation 1.15.2 -Depending on the findings, follow structured eye screening by:</p> <ul style="list-style-type: none"> <li>• routine review annually or</li> <li>• earlier review or</li> <li>• referral to an ophthalmologist.</li> </ul>	<p>Recommendation 3.16. 4 -Depending on the findings, follow structured eye screening by:</p> <ul style="list-style-type: none"> <li>• routine review annually by digital photographic screening via RetinaScreen or by clinical exam or</li> <li>• earlier review or</li> <li>• referral to an ophthalmologist if indicate.</li> </ul>	Eye disease section amended based on recommendation of Irish National Retinal Screening Programme/ RetinaScreen.
30	<p>Recommendation 1.15.9 - Refer to an ophthalmologist for:</p> <ul style="list-style-type: none"> <li>• referable maculopathy: <ul style="list-style-type: none"> <li>- exudate or retinal thickening within 1 disc diameter of the centre of the fovea</li> <li>- 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)</li> <li>- 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</li> </ul> </li> <li>• referable pre-proliferative retinopathy: <ul style="list-style-type: none"> <li>-any venous beading</li> <li>-any venous reduplication</li> <li>-any intraretinal microvascular abnormalities (IRMA)</li> <li>-multiple deep, round or blot haemorrhages.</li> </ul> </li> </ul> <p>(If cotton wool spots are present, look carefully for the above features, but cotton wool spots themselves do not define pre-proliferative retinopathy).</p>	<p>Recommendation 3.16.10 - Refer to an ophthalmologist/Diabetic Retinal Treatment Clinic for:</p> <ul style="list-style-type: none"> <li>• referable maculopathy: <ul style="list-style-type: none"> <li>- exudate or retinal thickening within 1 disc diameter of the centre of the fovea</li> <li>- 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)</li> <li>- 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</li> </ul> </li> <li>• referable pre-proliferative retinopathy for any of the following: <ul style="list-style-type: none"> <li>-multiple deep, round or blot haemorrhages</li> <li>-venous beading</li> <li>-venous reduplication</li> <li>-intraretinal microvascular abnormalities (IRMA).</li> </ul> </li> </ul> <p>(Cotton wool spots are not diagnostic of pre-proliferative retinopathy but should promote a careful search for other lesions).</p>	Eye disease section amended based on recommendation of Irish National Retinal Screening Programme/ RetinaScreen.

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
31	Recommendation 1.15.10 - For guidance on managing kidney disease in adults with type 1 diabetes, see the NICE guideline on chronic kidney disease.	Recommendation 3.16.11 - For guidance on managing kidney disease in adults with type 1 diabetes, refer to local standards and guidelines of care.	Reference Irish guidelines.
32	Recommendation 1.15.19 - For guidance on managing chronic painful diabetic neuropathy in adults with type 1 diabetes, see the NICE guideline on neuropathic pain – pharmacological management.	Recommendation 3.16.20 - For guidance on managing chronic painful diabetic neuropathy in adults with type 1 diabetes, refer to HSE (2018) Integrated Care Model for Type 2 diabetes and ICGP (2016) Practical Guide to Type 2 Diabetes.	Reference Irish guidelines.
33	Recommendation 1.15.28 - For treating vomiting caused by gastroparesis in adults with type 1 diabetes: <ul style="list-style-type: none"> <li>consider alternating use of erythromycin and metoclopramide</li> <li>consider domperidone only in exceptional circumstances (that is, when it is the only effective treatment) and in accordance with MHRA guidance.</li> </ul>	Recommendation 3.16.29 - For treating vomiting caused by gastroparesis in adults with type 1 diabetes: <ul style="list-style-type: none"> <li>consider alternating use of erythromycin and metoclopramide</li> <li>consider domperidone only in exceptional circumstances (that is, when it is the only effective treatment) and in accordance with European Medicine Agency and HPRA.</li> </ul>	Reference Irish guidelines.
34	Recommendation 1.15.34 - 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 NICE guideline on neuropathic pain – pharmacological management. Simple analgesia may be continued until the effects of additional treatments have been established.	Recommendation 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 (2018) Integrated Model of Care for Type 2 Diabetes and ICGP (2016) Practical Guide to Type 2 Diabetes. Simple analgesia may be continued until the effects of additional treatments have been established.	Reference Irish guidelines.
35	Recommendation 1.15.36 - For guidance on preventing and managing foot problems in adults with type 1 diabetes, see the NICE guideline on diabetic foot problems.	Recommendation 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 and HSE National Best Practice and Evidence Based Guidelines for Wound Management.	Reference Irish guidelines. Reference to HSE National Best Practice and Evidence Based Guidelines for Wound Management based on external consultation feedback*.
36	Recommendation 1.15.41 - Psychological problems.	Recommendation 3.16.42 Psychological and Mental Health problems.	Based on external consultation feedback from Mental Health Services*.

	Original wording from NICE NG17	Recommendation following contextualisation for this guideline	Rationale for Contextualisation
37	<p>Recommendation 1.15.42 - Diabetes professionals should:</p> <ul style="list-style-type: none"> <li>ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds</li> <li>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.</li> </ul> <p>See also the NICE guidelines on common mental health disorders, generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults and depression in adults with a chronic health problem.</p>	<p>Recommendation 3.16.43 - Diabetes professionals should:</p> <ul style="list-style-type: none"> <li>ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds</li> <li>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</li> <li>Diabetes healthcare professionals should collaborate with Mental Health Services(including Clinical Psychology as part of a Liaison Mental Health Team and/or Community Mental Health Services) to establish pathways to ensure that when required, patients with type 1 diabetes have rapid access to Mental Health Services.</li> </ul>	<p>Agreement of GDG that there was a need to include recommendation on access when required to mental health MDT's. Wording changed following external consultation feedback from Mental Health Services*.</p>
38	<p>Recommendation 1.15.43 -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. See also the NICE guideline on eating disorders.</p>	<p>Recommendation 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:</p> <ul style="list-style-type: none"> <li>over-concern with body shape and weight</li> <li>low BMI</li> <li>hypoglycaemia</li> <li>suboptimal overall blood glucose control.</li> </ul> <p>See HSE Model of Care for Eating Disorders, available at <a href="http://www.hse.ie/eng/about/Who/cspd/ncps/mental-health/eating-disorders/">http://www.hse.ie/eng/about/Who/cspd/ncps/mental-health/eating-disorders/</a></p>	<p>Reference to Irish guideline based on external consultation feedback from Mental Health Services*.</p>

## Appendix 3: Consultation process

The representative groups and bodies listed below were given notice of the consultation and sent the requisite details on how to make a submission. They were asked to bring the consultation to the attention of people living with type 1 diabetes, their respective professional bodies and all healthcare professionals working in healthcare settings which care for people with type 1 diabetes is received or commissioned.

<b>List of groups or representative bodies who were invited to participate in the consultation process</b>
Department of Health, Deputy Chief Medical Officer
Diabetes Ireland
Dr Colm Henry, HSE National Clinical Advisor and Group Lead for Acute Hospital Division
Dr Orlaith O'Reilly, HSE National Clinical Advisor and Group Lead for Health and Wellbeing
Dr Philip Dodd, HSE National Clinical Advisor and Group Lead for Mental Health
Dr David Hanlon, HSE National Clinical Advisor and Group Lead for Primary Care
HSE National Clinical Advisor and Group Lead for Social Care
Irish College of General Practitioners
Dr Velma Harkins, author of ICGP Guidelines A Practical Guide to Integrated Type 2 Diabetes Care
Irish Diabetes Nurse and Midwife Specialist Association
Irish Nutrition and Dietetic Institute
National Clinical Programme Clinical Advisory Group including all hospital endocrinologists
National Clinical Programme for Diabetes Working Group which includes representatives from physiotherapy, hospital and community pharmacy, podiatry, dietetics, hospital and community nursing, medical and academia
Office of Health and Social Care Professionals
Office of the Nursing and Midwifery Services Director
Society of Chiropodists and Podiatrists Ireland
Psychologists in Diabetes Care Group

The template for consultation asked for comments about user friendliness, the content and the implementation plan outlined in the draft guideline. The following are the questions reviewers were asked to comment on;

**1. User friendliness**

- a) Is the draft guideline easy to read?
- b) Do you think the guideline will be easy to use in practice?

**2. Content**

- a) Do the recommendations cover the scope of the draft guideline?
- b) Do the recommendations clearly link to the evidence presented?
- c) Does the draft guideline consider the views and needs of this population group?
- d) Does the draft guideline consider gaps in the current evidence?

**3. Implementation**

- a) Do any recommendations change current practice substantially? If so, do you consider that the reasons given in the draft guideline explain why the change is necessary?
- b) Which areas do you think may be difficult to put into practice? Please explain why.
- c) What would help users to implement the guideline? (For example, useful checklists, patient information leaflets etc.).

Extensive consultation feedback was received from patients, patient advocacy groups, healthcare professionals, professional groups and industry. Healthcare professional groups that provided feedback included hospital consultants, nursing, dietetics, podiatry, clinical psychology and mental health services. Please refer to appendix 2, table 5 which outlines under the rationale for contextualisation, the recommendations that have been contextualised following this feedback received from the external consultation process, which were marked with an asterisk (\*).

## Appendix 4: Implementation plan

### 1. Introduction

The following implementation plan is designed to provide a framework to guide the actions required to promote and support effective implementation locally and nationally of the Adult type 1 diabetes mellitus National Clinical Guideline in Ireland. The national implementation of cost-effective evidence-based care will ultimately improve health outcomes for patients, reduce variation in practice and improve the quality of clinical decisions that patients and healthcare staff have to make. This guideline will also inform patients about the care they should be receiving and assist them to make healthcare choices based on best available information.

Following completion of a national survey of Acute Hospital Adult Diabetes Services by the National Clinical Programme (NCP) for Diabetes in 2017 it was found that many of the guideline recommendations, such as diagnosis, clinical monitoring of glucose control, insulin regimens, and treatment and monitoring of specific complications are already established as part of routine care for patients with type 1 diabetes. As part of the National Pancreas Transplantation Programme, which was established in St Vincent's Hospital in 2016, planning has commenced to establish an endocrinology led islet transplant service for patients with type 1 diabetes within Ireland. However, there are two key recommendations that are not yet established as routine care and are currently not widely available in Ireland. The guideline recommends that high quality structured patient education must be incorporated into routine care for all people with diabetes. It also recommends the measurement of HbA1c levels every 3–6 months in adults with type 1 diabetes. To facilitate implementation of this guideline there is a requirement to ensure access to high quality structured patient education (SPE) and access to a minimum of 2 consultations with a diabetes healthcare provider per year for all adults with type 1 diabetes. These recommendations will be the primary focus of this guideline implementation plan.

Outside of the scope of this implementation plan, but an area which the NCP for Diabetes acknowledge as a deficit in current care is access to mental health services for all people living with diabetes. It is recommended that clinicians have a high index of suspicions for co-morbid mental illnesses such as depression and eating disorders especially where there is chronic hyperglycaemia, low body mass index or recurrent diabetic ketoacidosis (DKA). Current international guidelines specifically recommend that a psychiatric opinion is sought where a patient presents with two or more episodes of DKA without any clear precipitant such as infection (JBDS & RCPsych, 2018). High quality structured patient education has been shown to improve the psychological adjustment to living with type 1 diabetes. However the NCP for Diabetes recognise the need to develop a strategy in collaboration with colleagues in mental health services to increase the psychological knowledge of the diabetes healthcare professionals in the secondary care setting, while also providing a clearer path of referral for rapid access to mental health professionals when required.

## 2. Baseline survey of acute hospital services adult type 1 diabetes care

Summary of baseline survey of acute hospital services adult type 1 diabetes care	
Estimated numbers of patients with type 1 diabetes	19748*
<b>Percentage of diabetes services providing access to speciality type 1 diabetes clinics</b>	
Transition Clinic	35%
Young Adult Clinic	52%
Type 1 Diabetes Clinic	45%
Insulin Pump Clinic	39%
<b>Percentage of diabetes services meeting recommended recall time for adults with uncomplicated type 1 diabetes</b>	
4 – 6 months	42%
<b>Percentage of diabetes services meeting recommended recall time for young adults with uncomplicated type 1 diabetes</b>	
4-6 months	65%
<b>Structured patient education provision in 2016</b>	
<ul style="list-style-type: none"> <li>• 58% of hospital services provide access to a structured patient education programme</li> <li>• 19% of hospital services provide access to a structured education programme which meets the standards set out in the guideline</li> <li>• A total of 409 patients completed a programme in 2016, 158 patients completed a programme which meets the standards set out in the guideline</li> </ul>	

\* Only 8 of 31 hospital sites indicated that numbers were based on actual figures, 20 provided estimated figures, and 3 were unable to provide an estimate of the number of people with type 1 diabetes attending their service.

## 3. Strategic aims

The core objectives of this implementation plan are as follows:

- Outline the framework to provide access to a high quality SPE programme for eligible adults with type 1 diabetes in Ireland 6-12 months after diagnosis or at another appropriate time.
- To provide access to a minimum of 2 consultations with a diabetes healthcare provider per year for all adults with type 1 diabetes.

## 4. Approach to implementation

The implementation of an adult type 1 diabetes NCG are dependent on a range of factors, most importantly the engagement by all relevant stakeholders in the process. For successful implementation, there are significant facilitators but there will also be potential barriers which have to be considered and overcome (see fig 1 Logic Model) some of which have been identified below.

### Facilitators to implementation

- Patient need and desire
- Current outcomes for Irish patients with type 1 diabetes, data suggests suboptimal level of diabetes control and elevated HbA1c's (Casey et al, 2014)
- Appropriately qualified dedicated diabetes healthcare professionals
- Current practice in many diabetes units

- The evidence from clinical research which forms the basis for these guideline recommendations. This guideline has been developed in conjunction with the NICE in the UK. Ireland is only the second country NICE have facilitated to contextualise one of their guidelines
- Patient representatives and representatives of all healthcare professionals involved in the care of people with type 1 diabetes on the guideline development group
- Support from the outset was sought and received from senior policy and service decision makers within the NCEC, DOH and HSE. Ministerial endorsement of the guideline will follow final sign off by these organisations.
- Hospital group network
- National HSE Structured Patient Education Co-ordinator
- HSE Database for Structured Patient Education which is currently under development and will allow collection of data electronically on education programmes.

### **Potential barriers to implementation**

- Lack of awareness by people with diabetes and healthcare professionals of the guideline
- Resistance to change work practices or acceptance that the status quo is adequate
- Capacity of hospital groups to implement due to staffing deficits
- Financial resources to allow procurement of a national structured patient education programme, to facilitate ongoing training and to purchase resources
- Lack of awareness by people with diabetes of the benefit and importance of attendance at structured patient education programmes
- Lack of awareness by healthcare professionals of the benefit and importance to refer people with diabetes, and encourage attendance at structured education programmes
- The requirement for hospital sites within hospital groups to work together to reach a hospital group target
- Lack of information and communications technology (ICT) systems to facilitate sharing of information across sites
- Lack of ICT systems to facilitate an annual national diabetes audit.

### **Activities and outputs**

This plan designed by the GDG will be implemented through the following approaches to harness the facilitators and overcome the barriers;

- Create awareness and generate buy-in for implementation through a comprehensive communication strategy for all relevant stakeholders including patients, diabetes healthcare providers, DOH, HSE Acute Hospital Division, hospital groups and professional bodies. The process of generating awareness will commence at the start of guideline development and be maintained every step of the way, including after the guideline has been implemented and the care is being delivered.
- Patients and all healthcare providers involved in the provision of care for patients with type 1 diabetes were invited to review the guideline during the consultation process.
- Full guideline including budget impact analysis and implementation plan will be easily accessible on the DOH NCEC website.
- Once the guideline has been published, representatives from the guideline development group and from the National Clinical Programme for Diabetes will visit key personnel from each hospital group in order to assist in assessment of individual hospital group needs, fit, feasibility, capacity and readiness.
- Effective implementation through development of local action plans based on local structures and arrangements.
- Identifying hospital group clinical leads for type 1 diabetes care.
- Determining and arranging staff training and support requirements for effective implementation.

- Effective monitoring and evaluation through the development of an audit dataset to assess the implementation of the guideline to include HbA1c measurements, recall times for uncomplicated adult with type 1 diabetes and access and attendance at SPE programmes, refer to appendix 5.
- Analysis and feedback of audit data.

**Strategic Aim 1 - To provide access to high quality structured patient education (SPE) programme for eligible adults with type1 diabetes in Ireland 6-12 months after diagnosis or at another appropriate time**

**Proposed roll out of high quality SPE programme for type 1 diabetes nationally**

A proposed model to ensure equity of access to high quality SPE for type 1 diabetes is for;

- A National procurement process for a SPE programme which meets criteria outlined in the guideline. This procurement process will be conducted through HSE procurement.
- Information sessions to be arranged in each Hospital Group emphasising a Hospital Group-wide approach to guideline implementation. The location of education delivery within each hospital group should be agreed between the hospitals within the group. The education could be delivered on one site, however it is likely that the education will be delivered across several sites. The education does not have to be delivered in the hospital setting if suitable alternative arrangements can be found. Each group will require a minimum of 6-8 educators per hospital group depending on population and geographical distribution. It is hoped that staff from multiple hospitals within each group will participate in delivering structured education.
- Patients with type 1 diabetes must be entitled to health leave for the purpose of attending the education programme.
- Each hospital group should aim to deliver 50 courses annually to a minimum of 6 patients per course. This level of activity would result in approximately 1800 patients being trained on a yearly basis. With an estimated 20,000 patients with type 1 diabetes living in Ireland, the majority of whom have not yet attended structured education, it would still take approximately 10 years for all adult patients with type 1 diabetes in Ireland to receive structured education.
- Each hospital group should have a clinical lead to oversee all aspects of type 1 diabetes care, including delivery of structured education.
- Educators must be facilitated by the hospital group to work across multiple hospital sites within that hospital group, this includes travel costs, flexible hours to allow delivery of education outside normal working hours and online supports. The governance and indemnity issues will have to be addressed to facilitate people working across sites. It must also ensure that patients who have completed high quality SPE have access to structured follow-up and appropriate clinics.
- Develop an education module to train all health care professionals working with people with type 1 diabetes that supports CHO counting, insulin adjustment and promotes diabetes self-management.
- Develop key performance indicators and thereafter annual audit of key performance indicators relating to delivery of high quality structured patient education across each hospital and each hospital group.

**Workforce requirements**

In order for a hospital group to establish high quality SPE for type 1 diabetes they must identify a minimum of 6 educators per hospital group at any given time (3 Diabetes Specialist Nurses and 3 Senior Diabetes Dietitians). The majority of educators will come from existing staff but a minimum of one additional diabetes nurse specialist and one additional senior dietitian must be resourced within each hospital group. Educators may come from any of the hospitals within the group resulting in an 'educator pool'. Each hospital group must also identify at least 1 doctor per centre to attend the doctor training programme.

To support the sizable administrative workload associated with scheduling, course preparation, follow up data entry, reporting nationally and ordering of supplies for delivery, 1 WTE administrative person to provide clerical support must be resourced within each hospital group.

### **Training and resource costs for service**

Set up costs for a SPE programme in a hospital group not currently delivering, consists of staff training costs, plus purchase of a set of teaching resources. Given the scale of education required and the number of staff members who will require education, to improve accessibility and affordability training courses will need to be available in Ireland.

In addition to the training of the SPE educators, all staff who deliver care to people with type 1 diabetes should have access to training that supports patient empowerment and diabetes self-management – CHO counting and insulin adjustment. This will necessitate availability of short courses being available for all staff on a rolling basis to ensure all healthcare professionals are SPE aware. This will allow ongoing support for patients on return to their base hospital.

On-going educational updates for staff will require regular regionalised short courses for staff and core training for educators to be available in Ireland annually.

### **Staff costs**

- A minimum of 1 additional Diabetes Specialist Nurse and 1 additional Senior Diabetes Dietitian are required per hospital group to expand or establish access to high quality structured education programme for eligible adults with type 1 diabetes in Ireland based on current staffing numbers from National Survey of Acute Hospital Diabetes Services and Resources 2017.
- 1 administrative person to provide clerical support within each hospital group.

### **Information and communication technology (ICT)**

Each diabetes unit should have access to the necessary ICT resources in order to facilitate audit of the care of patients with type 1 diabetes.

### **Lead for implementation**

The overall responsibility for monitoring and optimising the delivery of SPE will rest with the NCP for Diabetes working with the National Structured Patient Education Co-ordinator and Hospital Groups. The programme will ensure that annual audit is conducted, reported and evaluated. High quality SPE programme for type 1 diabetes will be delivered by hospital staff only within secondary care. The NCP will work with hospital groups that are challenged to establish or maintain KPIs relating to SPE in order to optimise outcome. The NCP will work closely with the National Structured Patient Education Co-ordinator, to ensure that the implementation plan succeeds.

### **Timeline**

Implementation will take place over the next 4 years. Successful implementation of this plan will be dependent on securing resources outlined above.

- Year 1- completion of procurement process, recruitment of additional staff and establishment of hospital group based strategies for delivery of education.
- Year 2- training of educators. Training of all diabetes health care professionals. Commencement of education programmes. Inaugural type 1 diabetes SPE annual audit.
- Year 3- expansion of education programmes, audit type 1 diabetes SPE.
- Year 4- each hospital group delivering over 50 group education programmes per year, audit type 1 diabetes SPE.

**Strategic Aim 2 - To provide access to a minimum of 2 consultations with your diabetes healthcare provider per year for all adults with type 1 diabetes.**

The National Clinical Programme for Diabetes promote a model of integrated care for delivery of diabetes care in Ireland. In this model of care, people with uncomplicated type 2 diabetes will have their care managed in primary care only. People with complicated type 2 diabetes will be managed between primary and secondary care. People with type 1 diabetes will be managed in secondary care only. This Model of Care is fully aligned with the ICGP (2016) Guidelines, A Practical Guide to Integrated Type 2 Diabetes Care.

People with type 1 diabetes, represent approximately 10% of adults diagnosed with diabetes. People with type 1 diabetes need education and support from healthcare professionals with specific expertise in nutrition, physiology and therapeutics to manage their diabetes effectively and should have access to a minimum of 2 consultations annually with the specialist diabetes team.

**Workforce requirements**

Staff requirement to provide access to a minimum of 2 consultations per year needs to be reviewed on a hospital by hospital basis. This will be supported by the National Clinical Programme for Diabetes working with the hospital groups and individual hospitals. Services must be encouraged to evaluate and modify some aspects of their current activity. Adequate resources are required in primary care to support the transition towards integrated diabetes care, which relocates care of people with uncomplicated type 2 diabetes from hospital to primary care. The introduction of the Cycle of Care for Diabetes 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. 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. Expansion and consolidation of this level of service in primary care should be addressed through the GP contract. Full implementation of the National Model of Integrated Care for Type 2 Diabetes and the ICGP diabetes guidelines will increase capacity within diabetes specialist clinics to ensure that patients with type 1 diabetes and those complex patients with type 2 diabetes can be reviewed with appropriate frequency. It is anticipated that for centres that are not currently meeting the recommended frequency of appointments, the necessary resources to provide twice yearly visits will be secured through the redistribution of resources, supported by the investment in primary care for type 2 diabetes.

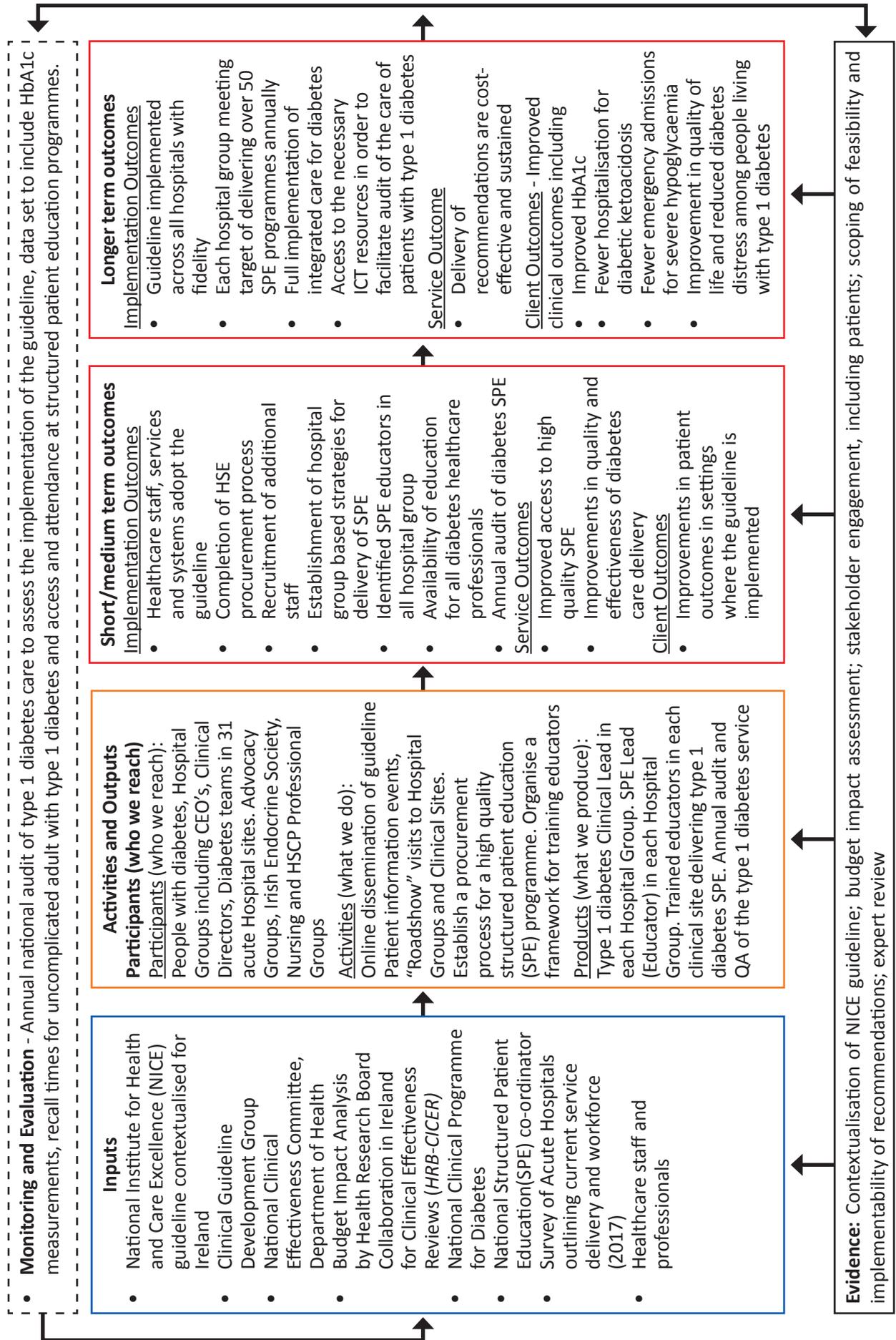
**Evaluation and monitoring**

Recall times for adult with uncomplicated type 1 diabetes should be included as part of an audit of diabetes care.

**Information and communication technology (ICT)**

Each diabetes unit should have access to the necessary ICT resources in order to facilitate audit of the care of patients with type 1 diabetes.

Figure 1: Logic Model – Implementation of Adult Type 1 Diabetes Guideline



## Appendix 5: Monitoring, evaluation and audit

The key objective of this NCEC National Clinical Guideline is to improve outcomes of care for people living with type 1 diabetes in Ireland over the next five years, provided that funding is secured through the annual service planning and estimates process. Critical to evaluating quality of care is the development of a system of audit of both the processes and outcomes of care to enable comparison with the National Guideline to help drive service developments and improved care delivery. A national diabetes register and audit when developed will use this NCEC National Clinical Guideline to set the standard of care for people living with type 1 diabetes.

It is recognised at present that ICT systems are not in place in Ireland to easily monitor the implementation of the recommendations made in this guideline. In the interim while we wait for the necessary ICT for a National Diabetes Register and audit, progress can be monitored in individual diabetes units. Collecting data is frequently challenging. However, meaningful and consistent reporting of outcomes inform clinicians and managers in their efforts to drive quality improvement in terms of identifying the potential for improvement and monitoring the results of new initiatives. Audit and monitoring criteria data are outlined in Table 6.

**Table 6: Audit and monitoring criteria**

Criteria	Target	Audited/monitored by	Possible source of data
HbA1c measurements	7.5% or less	Individual service/ NCP Diabetes	Patient notes, Laboratory ICT system
Total cholesterol	A level of below 5mmol/l	Individual service/ NCP Diabetes	Patient notes, Laboratory ICT system
Blood Pressure	Reading of less than 140/80mm/ Hg1	Individual service/ NCP Diabetes	Patient notes, Laboratory ICT system
Rates of complications (including severe hypoglycaemia)	Aim to see an annually reduction in complications	Individual service/ NCP Diabetes	Patient notes, ICT systems, HIPE
Attendance rates for uncomplicated adult with type 1 diabetes	Attendance at 2 appointments a year. Target >42%	Individual service/ NCP Diabetes	Patient notes, ICT systems
Access to high quality structured patient education	Within 1 year of diagnosis or at another appropriate time	Individual service/ NCP Diabetes/ National Structured Patient Education Co-ordinator	National Database for Structured Patient Education
HbA1c levels, hypoglycaemia rates and hospital admission due to diabetic ketoacidosis pre and post attendance at SPE	Aim to see a reduction in parameters post attendance at SPE	Individual service/ NCP Diabetes/ National Structured Patient Education Co-ordinator	National Database for Structuring Patient Education
Hospital discharges for type 1 diabetes-associated complications including diabetic ketoacidosis, kidney complications, ophthalmic and neurological conditions.	Less than number of discharges in 2016, less than 1959 discharges	HSE Business Intelligence Unit	HIPE

## Appendix 6: Abbreviations

The following abbreviations are used in this document:

ACE	Angiotensin-converting enzyme
AGREE II	Appraisal of Guidelines for Research and Evaluation II
BIA	Budget Impact Assessment
BMI	Body Mass Index
CES	Centre for Effective Services
CHO	Carbohydrate
CSII	Continuous Subcutaneous Insulin Infusion
DAFNE	Dose-adjustment for normal eating
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic ketoacidosis
DOH	Department of Health
ECG	Electrocardiography
EDI	Euro Diabetes Index
FIT	Forum for Injection Technique
GDG	Guideline Development Group
HbA1c	Haemoglobin A1c
HDL	High Density Lipoprotein
HIPE	Hospital In-Patient Enquiry
HIQA	Health Information and Quality Authority
HPRA	Health Products Regulatory Authority
HRB-CICER	Health Research Board-Collaboration in Ireland for Clinical Effectiveness Reviews
HSE	Health Service Executive
ICGP	Irish College General Practitioners
ICT	Information and Communication Technology
IDF	International Diabetes Federation
IFCC	International Federation of Clinical Chemistry
IRMA	Intraretinal microvascular abnormalities
ISO	International Organisation for Standardisation
LDL	Low Density Lipoprotein
MI	Myocardial infarction
NCEC	National Clinical Effectiveness Committee
NCP	National Clinical Programme
NG	National Guideline
NHQRS	National Healthcare Quality Reporting System
NICE	National Institute for Health and Clinical Excellence
OCED	Organisation for Economic Co-operation and Development
RSA	Road Safety Authority
SMBG	Self-monitoring of blood glucose
SPE	Structured Patient Education
TSH	Thyroid-stimulating hormone
UK	United Kingdom
WTE	Whole time equivalent

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**An Roinn Sláinte**  
Department of Health

Department of Health, Hawkins House, Hawkins Street, Dublin 2, D02 VW90, Ireland  
Tel: +353 1 6354000 • Fax: +353 1 6354001 • [www.health.gov.ie](http://www.health.gov.ie)