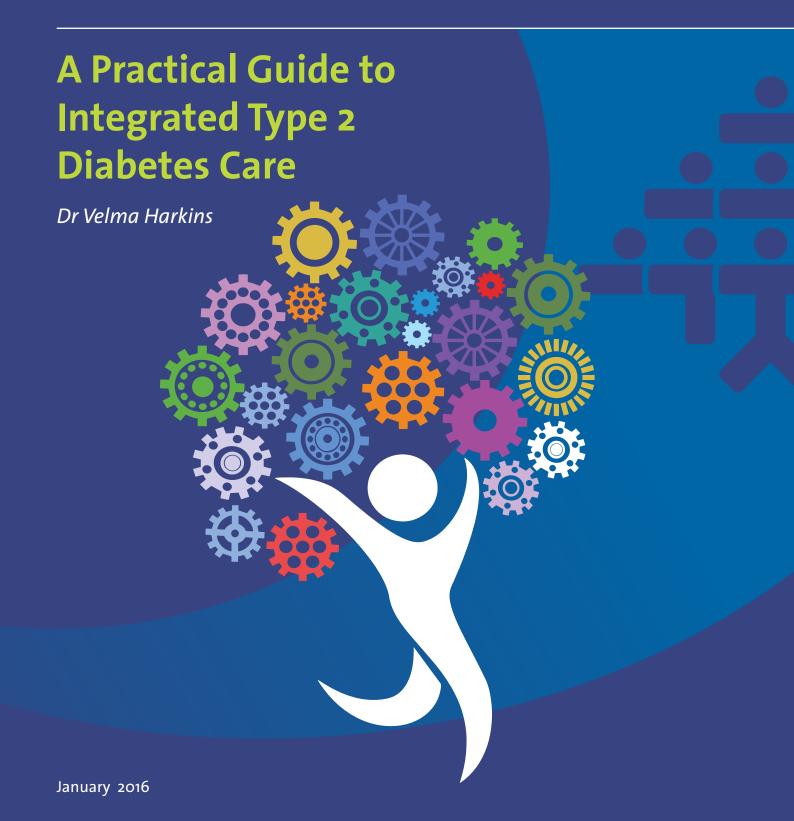
Irish College of General Practitioners











Foreword

The explosion in the prevalence of diabetes mellitus, predominantly Type 2, has led to the recognition that the adequate care of such individuals requires a formal and more structured involvement of primary and secondary care sectors together.

In the past the care of diabetes has often been unstructured and sometimes delivered in an opportunistic manner, not reflecting the requirements of those with a chronic disease. This is partly because care was delivered primarily in hospitals which themselves were developed over the decades to deal with infectious disease and trauma. As the population has aged, the majority of interactions are with people with chronic diseases who require a more pro-active model of care and this requires flexibility to deal with the diverse demands of people at different stages of their disease.

This has led to the concept of "INTEGRATED CARE" which espouses the joint involvement of all levels of care, primary, secondary and tertiary levels of care, to optimise outcomes in people with diabetes mellitus. In practical terms this means that both primary and secondary care centres assume joint responsibility for the patients and that funding of resources for both going forward will take place according to their relative needs.

The publication of these original guidelines in April 2008 and the collaboration which led up to their publication fuelled an already existing interest in the provision of Integrated Care for patients with Type 2 Diabetes in Ireland. In 2010 the work of the Expert Advisory Group in Diabetes of the HSE was completed and this led onto the formation of the National Clinical Programme for Diabetes (NCPD). The aim of the National Clinical Programme for Diabetes is to ascertain and reduce the prevalence of diabetes in Ireland and to reduce the burden of diabetes on both affected individuals and the State by reducing the morbidity and mortality associated with Diabetes.

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Dr Velma Harkins

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Introduction

It is estimated that there are approximately 190,000 people in Ireland with diabetes, with type 2 diabetes accounting for approximately 90% of all cases¹. In 2010, the Institute of Public Health in the report 'Making Chronic Conditions Count' revised their previous prevalence forecast upwards and now predict a 62% (up from 37%) increase in the number of people with diabetes by 2020. It also predicts that the prevalence of diabetes will increase from 4.5% in 2007 to 5.9% of the population in 2020². The overall prevalence of type 2 diabetes among adults aged 50 years and over in Ireland is 8.5% and is increasing in line with global trends, driven primarily by rising levels of obesity and ageing populations³. The true prevalence of Type 2 is underestimated and many cases are undiagnosed because hyperglycemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes. Recent data shows 5.5% adults aged 50 years and over in Ireland have pre-diabetes, placing them at increased risk of developing type 2 diabetes in the future⁴. It's known that active intervention will greatly delay or reverse pre diabetes and should be a major focus of maintaining health and well being.

Aims and Objectives of this Document

Diabetes care aims to enable people with diabetes to achieve a quality of life and life expectancy similar to that of the general population by reducing the complications of diabetes. Primary diabetes care aims to deliver integrated, quality care uniformly to all affected people and their families. In order to provide a high quality of care it needs to be clearly understood that there are funding implications. This quality of care cannot be implemented without the appropriate allocation of resources to practices involved in its delivery.

How to use this Document

The guidance presented here is derived from previously developed full process guidelines, with updated evidence to support local implementation.

The level of evidence is used as a basis for the grade of recommendations. Therefore it should be remembered that the grade of recommendation reflects the strength of the evidence (quality of the study methods) and not the clinical importance.

The grading of recommendations involves assessment of evidence and processes of interpretation and consensus. A graded recommendation is made in the guideline, following considered judgement of the design and quality of each study and the consistency, clinical relevance and external validity of the whole body of evidence.⁵

This is general guidance for those involved in the care of patients with Type 2 diabetes. It should be applied in the context of the local health system and using clinical expertise and judgment when applied to individual patients. See Appendix 1 for levels of evidence.

Section 1: Classification, Screening and Diagnosis

Classification

Type 2 is the commonest type of diabetes and is characterised by disorders of insulin action and secretion, either of which may be the predominant feature. Both are usually present at the time that type 2 diabetes is clinically manifest. The specific reasons for the development of these abnormalities are not yet known.⁶

Type 2 diabetes has a long pre-clinical phase and may be asymptomatic until well after long term microvascular and macrovascular complications have occurred. Type 2 diabetes can be detected before the onset of symptoms and clinical signs by identifying people who are at risk, and performing diagnostic testing.

Screening

The onset of Type 2 diabetes is subtle and early detection in general practice requires clinical suspicion combined with systematic and opportunistic case-finding, as diagnosis is frequently delayed until complications appear. None of the major diabetes guidelines currently recommend general screening for Type 2 diabetes. Many recommend targeted screening in certain predefined groups⁷ while others recommend screening in those patients who have been risk assessed and subsequently identified at high risk^{8,9}.

The approach recommended here is in line with ADA 2015 recommendations7.

Early identification of patients and initiation of treatment can reduce the development of complications of diabetes and therefore testing for diabetes in asymptomatic patients with risk factors associated with the development of diabetes is recommended.

CRITERIA FOR TESTING FOR DIABETES IN ASYMPTOMATIC ADULT INDIVIDUALS

- Testing for diabetes should be considered in all adults who are overweight (BMI ≥ 25kg/m²) and who have one or more additional risk factors:
 - Physical inactivity
 - First-degree relative with diabetes
 - Are hypertensive (≥140/90mmHg) or on therapy for hypertension
 - Dyslipidaemia HDL< o.9 and/or triglycerides >2.82
 - Have established arterial disease (IHD, CVA, PVD)
 - High-risk ethnicity (e.g. African, Asian, Hispanic etc.)
 - Members of the Travelling Community
 - Have delivered a baby weighing >4.1kgs or have a history of gestational diabetes mellitus (GDM)
 - On previous testing had Impaired Glucose Tolerance (IGT) or impaired Fasting Glucose (IFG)
 - Have other clinical conditions associated with insulin resistance (e.g. polycystic ovary syndrome, acanthosis nigricans, long-term steroid use or severe obesity).
- 2. In the absence of the above additional risk factors, testing for diabetes should begin at age 45 years
- 3. If the results are normal, testing should be repeated at least at 3 year intervals. Patients with IFG or IGT should be tested annually

(Adapted from the ADA Clinical Practice Recommendations 2015 Diabetes Care) Source: National Clinical Programme- Diabetes Working Group

Diagnosis

In 2011 WHO⁶ approved HbA1c as a diagnostic test for diabetes and some international guidelines have updated to reflect this ^{7,11}. To aid screening and early detection of diabetes the HbA1c can now also be used to diagnose diabetes.

For diagnosis of Type 2 diabetes probably the best combination of specificity and sensitivity is afforded by the first test being fasting blood glucose. If this is above 5.6mmol/L, the second test should be HbA1c or 75g OGTT. This will allow for identification of impaired fasting glucose, impaired glucose tolerance, and Type 2 diabetes.

CRITERIA FOR DIAGNOSIS

Diabetes is diagnosed using one of the following criteria

Symptoms of diabetes plus random plasma glucose concentration > 11.1 mmol/L.

Random is defined as any time of day without regard to time since last meal.

The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

or

Fasting plasma glucose ≥ 7.0 mmol/L.*

Fasting is defined as no caloric intake for at least 8 hours7.

or

2-hr plasma glucose > 11.1 mmol/L during a 75g Oral Glucose Tolerance Test.

The test should be performed as described by W.H.O., using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

or

A HbA1c \geq 48mmol/mol (\geq 6.5%)* †

The test should be performed using a standardised assay.

*In the absence of unequivocal hyperglycemia, the result should be confirmed by repeat testing on a different day. †A HbA1c value of < 6.5% (IFCC < 48mmol/mol) does not exclude diabetes diagnosed using the other glucose tests.

The following conditions will interfere with the HbA1c assay and exclude its use as a test to diagnose diabetes – plasma glucose criteria should be used instead to diagnose diabetes in the following conditions:

- 1. Haemoglobinopathies
- 2. Sickle cell disease
- 3. Haemolytic anaemia
- 4. Recent blood transfusion
- 5. Recent blood loss
- **6.** Iron deficiency anaemia.

How to perform a 75g Oral Glucose Tolerance Test (OGTT)

The test should be done in the morning after an overnight fast of at least 8 hours and after at least 3 days of unrestricted diet (> 150g carbohydrate per day) and unlimited physical activity. Blood should be drawn, then immediately after the person drinks 75g glucose within 5 minutes. Blood is drawn again two hours later. The person should remain seated and should not smoke throughout the test.

To prepare a 75-g Oral Glucose drink

Use 113 ml of Polycal™ (available on GMS) diluted up to 200ml with water (for taste).

100mls of water should be given 5 minutes after original mixture is consumed to aid absorption of glucose load. Oral Lucozade™ can be used but it must be 410ml of the 70kcal/100ml formulation Lucozade™ Energy Original from GSK. It cannot be any other Lucozade™ preparation.

INTERPRETATION OF RESULTS ON OGTT

If fasting plasma glucose ≥ 7.0 mmol/L and/or 2 hour plasma glucose ≥ 11.1 mmol/L – diagnosis is Diabetes

If fasting plasma glucose is between 6.1 and 6.9mmol/L and 2 hour plasma glucose is ≤ 7.8 mmol/L – diagnosis is Impaired Fasting Glucose (IFG)

If fasting plasma glucose is any reading < 7.0mmol/L but 2 hour plasma glucose is between 7.8 and 11.0 mmol/L – **diagnosis is Impaired Glucose Tolerance (IGT)**

Prevention/Delay of Type 2 Diabetes (T2DM)

There is now substantial evidence that the development of Type 2 diabetes can be prevented or delayed. Individuals at high risk of developing diabetes can be identified easily. Knowledge of the early stages of hyperglycemia and research into the prevention of Type 2 diabetes clearly show that individuals at high risk can be identified and diabetes delayed, if not prevented. The American Diabetes Association (ADA) note that the cost- effectiveness of intervention strategies is unclear, but the huge burden resulting from the complications of diabetes and the potential ancillary benefits of some of the interventions suggest that an effort to prevent diabetes may be worthwhile.¹²

Studies have shown that in patients with pre-diabetes, IFG or IGT or both, their risk of developing Type 2 diabetes can be significantly reduced by following intensive lifestyle modification programmes. Medications, including metformin, have been shown to reduce the risk of diabetes in people with pre-diabetes.

Thus individuals at high risk for developing diabetes and particularly those with IGT or IFG should be made aware of the many benefits of modest weight loss and regular physical activity and should be counselled and instructed in these areas. Follow up counselling and monitoring for the development of diabetes by glucose tolerance testing should be performed every 1-2 years.

Screening for undiagnosed or new (gestational) diabetes in pregnancy

Gestational diabetes mellitus (GDM) is defined as the onset or first recognition of glucose intolerance during pregnancy. GDM is associated with increased risks for mother and baby during pregnancy and longer term risk of diabetes in both mother and baby.

Women known to be at high risk of developing gestational diabetes include those who:

- Have had previous gestational diabetes,
- Have had a baby weighing over 4.5kilos,
- Have a strong family history (parent or sibling with diabetes),
- Are overweight or obese
- Are members of a population group with a high prevalence of diabetes
- Have a macrosomic foetus, polyhydramnios or glycosuria in their current pregnancy.

RISK ASSESSMENT FOR GDM SHOULD BE UNDERTAKEN AT THE FIRST ANTE-NATAL VISIT⁷

At their first ante-natal visit, women found to be at high risk of GDM, should be:

- » Provided with healthy lifestyle advice (nutrition and physical activity)
- » Proceed to 75g OGTT at 24-28 weeks.

If diabetes is suspected at any gestation – perform 75g OGTT immediately

Diagnosis of Gestational Diabetes with 75g OGTT

A diagnosis of gestational diabetes is made when one or more values are met or exceeded

Fasting Glucose	5.1mmol/L
1 hour post-prandial glucose	10.0mmol/L
2 hour post-prandial glucose	8.5mmol/L

Negative OGTT result in an antenatal patient:

If negative between 24–28 weeks continue routine antenatal care and repeat OGTT if GDM suspected later on in pregnancy.

Positive OGTT result (See also section on pre-conceptual care / care in pregnancy):

- 1. Refer for combined Diabetes-Obstetric Secondary Care
- 2. Educate regarding diet, lifestyle modification and diabetes management
- 3. Monitor glycaemia control
- **4.** Plan of care as for patient with Type 1 or Type 2 diabetes once on insulin therapy.

For further information please see <u>HSE Guidelines for the Management of Pre Gestational and Gestational Diabetes Mellitus from pre-conception to post-natal period.</u>

Section 2: Diabetes Care

For most people diagnosed with Type 2 diabetes their condition is life-long and while new types of medication and medical devices are constantly being produced, the basic foundation for good diabetes care still focuses on healthy eating and physical activity, monitoring blood glucose levels and taking medication. The management of Type 2 diabetes involves behavioural change best achieved through integrated care and education. General practice is increasingly providing this service supported by current national policy.¹³

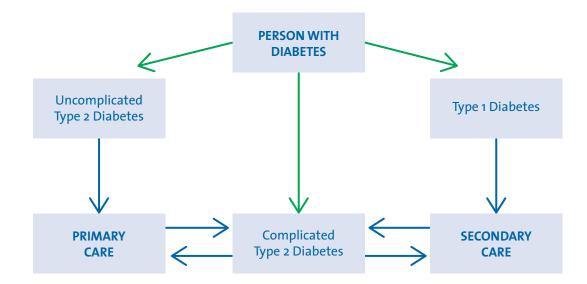
Integrated Care

Three of the key components of a comprehensive diabetes service are patient registration, recall and regular review. Integrated care also includes allocation of protected time and adherence to a standard management protocol. An annual and comprehensive review is regarded as the crucial element of integrated diabetes care. Routine integrated care involves the patient, GP, practice nurse, diabetologist, clinical nurse specialist in diabetes, dietitian, ophthalmologist and podiatrist. All patients with Type 2 diabetes should have access to specialist services such as endocrinology, vascular, cardiology, nephrology and psychology as needed. Care provision begins with initial assessment and follows with regular review that includes a comprehensive annual review.

In order to provide this level of care, protected time is required and this has funding implications for all levels of service (primary, secondary and tertiary care).

National Integrated Model of Care

Under a proposed National Integrated Model of Care patients with uncomplicated T2DM will be seen 3 times a year in primary care in a structured fashion. The visits will be every 4 months with an annual review occurring every 12 months. Patients who develop complications will be referred from primary to secondary or tertiary care for an expert specialist opinion and their care will become shared between primary and secondary or tertiary care. These patients will be seen at least once a year in secondary care for their annual review or more frequently according to the severity of the diabetes related complication and up to twice a year in primary care at 4-monthly intervals.



Patients with uncomplicated T2DM managed by primary care only

Uncomplicated patients with T2DM are defined as follows

Type 2 diabetes patients not on insulin but on diet only or on 2 glucose lowering agents (not insulin) with a HbA1c (<58mmol/mol or <7.5%) in patients with

- · Low risk or moderate risk diabetic feet
- No active diabetic eye disease
- Controlled CV risk factors
- Normal hypoglycaemia awareness
- Patients with T2DM and satisfactory renal function defined as a serum creatinine
 <150umol/l or eGFR >60ml/min or albuminuria <70mmol/ml or PCR < 100mg/mmol
- No symptoms of autonomic neuropathy (with the exception of erectile dysfunction)

If patients become complicated as defined below, then patients should be referred to secondary care diabetes service for a specialist opinion.

Complicated T2DM patients who will be managed between Primary & Secondary Care

The following patients will have their care shared between primary and secondary care. They will have at least 1 visit per year in secondary care, "the annual review", or will be seen more frequently according to the severity of the diabetes related complication and will have visits up to twice a year in primary care at 4-monthly intervals.

- Type 2 diabetes patients requiring insulin*
- Failing HbA1c (>58mmol/mol or 7.5%)on 2 or more glucose lowering agents (not insulin)
- Active or history of foot ulcer
- History of lower limb amputation
- High risk foot (as per national model of foot care)
- Renal failure (Creatinine >150umol/l or eGFR <60ml/min)
- Albuminuria with normal serum creatinine (ACR on 2 occasions >70mmol/ml or PCR > 100mg/mmol)
- Painful peripheral neuritis
- Symptoms of autonomic neuropathy (except for erectile dysfunction)
- Diabetic eye disease with active proliferative retinopathy/maculopathy or recent laser therapy (last 24 months)
- Uncontrolled CV risk factors (refractory hypertension or dyslipidaemia)
- Steroid induced hyperglycemia (can be referred back once off steroids or blood glucose levels settle)
- Recurrent hypoglycaemia
- Hypoglycaemia unawareness
- Weight loss + osmotic symptoms +/- ketones

*patients with type 2 diabetes on insulin may be managed appropriately in the community depending on local primary care expertise or availability of integrated care diabetes nurse specialist

Patients to be managed in secondary care only

The following patients are to have their diabetes related care managed in secondary care. Currently these patients are only seen once or twice a year in secondary care due to the lack

of consultant endocrinologist, diabetes nurse specialist and dietician resource within the secondary diabetes service.

- All patients with Type 1 diabetes
- Pregnancy and diabetes
- Diabetes and patients on Continuous Subcutaneous Insulin Infusion (CSII) therapy
- Paediatric and Adolescent diabetes
- Mature Onset Diabetes of the Young (MODY diabetes)
- Cystic Fibrosis Related Diabetes
- Secondary causes of diabetes (Diabetes due to endocrinopathies, pancreatitis, post pancreatic surgery etc.)
- Post-Transplant diabetes
- Genetic causes of diabetes (Turners, Klinefelters, syndromes of insulin resistance etc.)
- Diabetes in adults <30 years of age
- Complicated Type 2 diabetes (refer to section 2.2)
- Type 2 diabetes patients on insulin*

*patients with type 2 diabetes on insulin may be managed appropriately in the community depending on local primary care expertise or availability of integrated care diabetes nurse specialist

A National Model of Integrated care will increase the space within diabetes specialist clinics to see these complex diabetes patients more frequently at least 2 to 3 times per year in the secondary care setting.

Source: National Clinical Programme Diabetes

Organising Diabetes Care in the Practice

Roles within the practice

The GP and the practice nurse are key to the success of the delivery of Integrated Care. They are the primary care givers to their patients. They make the diagnosis of diabetes, are the first health professionals the patient sees on receiving their diagnosis and are involved in the delivery of their diabetes and non-diabetes care over the life time of the patient.

Role of the General Practitioner

The GP will carry overall responsibility and leadership in the running of integrated diabetes care in the practice. Responsibilities will include:

- Ensuring that the practice staff members have been familiarized with the agreed programme models of care, including algorithms, patient information, guidelines etc.
- Ensuring that all members of the team are aware of their roles and responsibilities in relation to delivery of diabetes care
- Ensuring that such patients are treated in accordance with this guideline
- Agreeing to strive to achieve the national targets as set out by the guidelines
- Maintenance of an up to date register of patients with Type 2 diabetes
- Ensuring that regular register management takes place
- Being willing to adapt to new guidelines as they are developed
- Referring complicated T2DM patients to secondary or tertiary care as per guidelines.

Role of the Practice Nurse

The practice nurse (PN) is a valuable member of the integrated care team and will in most practices carry out the day to day care of patients with diabetes in the practice.

The Practice Nurse will have responsibilities to:

- Provide regular routine care in the practice to patients with diabetes as per visits set out in guidelines
- Maintain practice diabetes register
- Set targets with patients
- Provide patient education re. diet / lifestyle / exercise etc. (See appendices 3,4 and 6)
- Carry out initial and annual foot assessment as per national model
- Refer patients to community diabetes nurse specialist, and refer patients for retinal screening, dietetics and podiatry as per guidelines.

Primary Care Diabetes Initiatives currently in existence around Ireland have shown that high quality diabetes care can be delivered to patients with T2DM in the community. Many of these initiatives already deliver diabetes care in the community in a similar model to the National Model of Integrated Care for Patients with Type 2 Diabetes.

The Role of the Integrated Care Diabetes Nurse Specialist

The Integrated Care Diabetes Nurse Specialist (DNS) is the health care professional who will ensure successful integration of patient care between primary and secondary care. The nurse specialist will work 80% of the time in primary care and 20% in secondary care. The CNS (Diabetes- Integrated Care) will have a clinical reporting relationship with the GP whose patient they are seeing in primary care and with the Consultant Endocrinologist in secondary care.

The Integrated Care Diabetes Nurse Specialist will

- See individual patients referred to him / her by the GP/PN
- Provide training and support to Practice Nurses within the GP practice to set up and deliver integrated care
- Deliver education programmes, in conjunction with the local nursing education units, for example the HETAC Certificate in Diabetes, along with annual multidisciplinary master classes
- Carry out research and audit, including using audit data to influence the delivery of integrated care at practice level

These Nurses are highly skilled, and have specialist post graduate training in diabetes care.

The Role of the Community Dietitian:

The Community Dietitian is responsible for:

- One to one dietetic interventions, delivered within the primary care setting and supporting the integrated care pathway. Clients receive individually tailored assessment and interventions supported by collaborative goal setting and management techniques.
- Delivery of diabetes structured patient education via an accredited group programme.
 The programme should include education on diet, weight management, alcohol, smoking, physical activity, medication and other lifestyle factors. Dietetic led programmes aim to empower participants to develop self-management skills.
- Involvement in the multidisciplinary primary care team (PCT) regular liaison facilitating optimum integrated patient care.

- Regular liaison with the acute dietetic and secondary care diabetes services to support the patient in the integrated care pathway
- Continuous Professional Development via training and resource development
- On-going audit and evaluation as part of care provision.
- Supporting nutrition health promotion initiatives and education to health professionals

The Role of the Community Podiatrist

The role of the Community Podiatrist in the integrated care pathway is:

- To deliver foot care as per the national model of foot care
- To identify patients as low, moderate, high risk or active foot disease
- To see patients with moderate risk foot disease at least once per year as per the national model of foot care
- To refer patients with high risk and active foot disease to the specialist secondary care services
- To liaise closely with the foot protection teams and specialist foot services in the secondary care centres
- To support practice nurses in their identification, examination and management of the diabetic foot
- Commitment to on-going Continuous Professional Development via training and resource development
- Commitment to on-going audit and evaluation as part of care provision.

Diabetes Register

A practice-based diabetes register facilitates the provision of quality diabetes care through improved processes of care. To expedite and facilitate integrated care, information using a standard format should be shared between the primary care and allied secondary or tertiary care centre to enable sharing of information for the benefit of the patient. Such a register would also allow collection of data at local, regional or national levels to allow audit and planning for resource allocation.

The register should contain:

- · Patient's name
- Address and other contact details
- Type of diabetes or related hyperglycaemic condition (including GDM, IFG and IGT)
- Other details such as the presence of complications only as required to facilitate audit and care planning.

A disease register carries responsibilities relating to patient consent and the Data Protection Act.

First Patient Visit – Initial Assessment after Diagnosis includes the following elements

Collect Demographic details	YES	NO
Patient name/ address/DOB/gender/ ethnicity		
Type of Diabetes – Uncomplicated Type 2 / Complicated Type 2/ Other		
Smoker		
Alcohol		

Diagnosis of Diabetes		YES	NO
Date (year) of Diagno	osis		
 Osmotic symptoms 			
 Random plasma glud 	cose		
 Fasting plasma gluco 	ose		
• 2hour OGTT			
 Fasting plasma gluco 	ose		
• HbA1c			
 Current medications 	& compliance history		
Family History of Diabet	res		
Gestational Diabetes			
Past Medical History:	Coronary Artery Disease		
	• MI		
	• CVA		
	• TIA		
	• PAD		
	Erectile dysfunction		
	Thyroid disease		
	• Other		
Examination			
Weight/Height – calcula	ate BMI		
Blood Pressure			
Foot examination (as pe	r National Model of Foot-Care)		
 Foot pulses 			
 10gm monofilament 			
 Vibration sensation 			
Waist circumference			
Investigation			
HbA1c			
Fasting Lipid Profile			
Full Blood Count			
	Creatinine, Urine Albumin Creatinine Ratio (ACR), eGFR		
Thyroid Function Tests	, , , , , , , , , , , , , , , , , , , ,		
Liver Function Tests			
	ansferrin saturation (if ferritin raised)		
12 lead ECG			
Referral			
Practice nurse education	٦		
Structured education pr	ogramme		
Exercise advice			
Dietitian*			
Podiatry			
Retinal screening			
Self Monitoring Blood glucose			
Clinical Nurse Specialist			
	register and give follow-up appointment		
Nominate Secondary Ce			
*If not suitable for group structured education programme at time of diagnosis refer for individual			
session with dietitian			

Regular/On-going Care

It is now accepted that regular review is needed every four months or more frequently during efforts to bring risk factors under control. The aim of regular review is prevention, early detection and management of complications associated with Type 2 diabetes.

Regular review includes the following elements	Yes	No
Medications		
Hypoglycaemia/hyperglycemia		
Smoking Status		
Dietary Habits		
Physical activity		
Assess injection sites if on insulin		
Recent life-events / new symptoms		
Other medical conditions and therapy affecting diabetes, psychological, lifestyle and social aspects		
Examination		
Weight/Height – calculate BMI		
Blood pressure		
Foot examination as per National Model of Foot care		
Foot pulse		
• 10gm monofilament		
 Vibration sensation 		
Investigations		
HbA1c		
Recheck Lipids if raised at first or preceding review		
Urinalysis and ACR, calculate eGFR (if raised at first or preceding review)		
Blood pressure		
Referral follow-up		
Practice nurse education		
Structured education programme		
Retinal screening		
Podiatry		
Exercise advice		
Exercise advice Dietitian		
Exercise advice Dietitian Podiatry		
Exercise advice Dietitian Podiatry Smoking Cessation		
Exercise advice Dietitian Podiatry		

Annual Review

Along with all of the areas monitored at regular review, surveillance of the following should also be carried out annually:

Symptoms: ischaemic heart disease, peripheral vascular disease - neuropathy, erectile dysfunction. All patients with symptoms that might reflect vascular disease, particularly ischaemic heart disease, should be investigated.

Feet: footwear, deformity/joint rigidity, poor skin condition, ischaemia, ulceration, absent pulses, sensory impairment.

Eyes: visual acuity and retinal review by ophthalmologist/retinal screening programme.

Kidney: renal damage, albumin excretion, serum creatinine and calculate eGFR

Arterial risk: blood glucose, blood pressure, blood lipids, and smoking status, ECG

Attendances: podiatry / dietitian / other as indicated.

Non routine or emergency visits to hospital:

Agreed mechanisms should be set in place to allow the "fast tracking" of patients requiring urgent assessment and care within the nominated diabetes centre. Such assessment will be carried out by a specialist consultant or registrar.

For added protection:

The ADA guidelines⁷ recommend that the flu vaccination is offered annually to all patients with diabetes and that pneumococcal vaccine should also be offered. Encourage adequate health protection, including vaccinations, prior to foreign travel.

Diabetes Patient Education - See Appendix 6

Diabetes is a complex disease. Due to the importance of lifestyle changes and the many aspects of care that impact on its management and progression, patient education is recognised as an integral part of management.

Education at all stages of the integrated care pathway should involve collaborative goal setting, patient empowerment and self-management support.

Practice Nurse Education Session: Appendix 6 outlines an overview of the education components for first and review consultations for people with Type 2 diabetes.

Structured Group Education for Type 2 diabetes.

Structured diabetes patient education is "a planned and graded process that facilitates the knowledge, skills and ability for diabetes self-management and empowers individuals to live healthily, to maintain and improve their quality of life and assume an active role in their diabetes care"¹⁶.

Programmes should have a philosophy, curriculum, trained educators, be quality assured and regularly audited and evaluated. Currently in Ireland there are three programmes for people with type 2 diabetes that aspire to these standards: X-PERT – a specifically designed dietetic structured patient education programme provided by the HSE, CODE – Community Orientated Diabetic Education and DESMOND – Diabetes Education and Self-Management for On-going and Newly Diagnosed diabetes.

There is very good evidence that education, including culturally-appropriate education improves blood glucose control in patients with Type 2 diabetes¹⁷.

Regional variation occurs in the availability of courses, Patients and their families / carers can register online for a structured <u>diabetes education course</u>.

The following table is a comprehensive list of areas to be covered and facilitates the tailoring of a structured education programme to the patient's individual needs.

TOPICS TO BE COVERED WITH PATIENT

- What is Diabetes
- Eye and Foot Care
- Motivation Strategies
- Aims of Diabetes Care

- Dietary Management
- Behaviour modification
- Complications
- · Why self-monitoring may be needed

KEY SELF-CARE ISSUES TO BE COVERED WITH PATIENT

- Medications: Uses and Side-Effects
- Hypoglycaemia
- Hyperglycaemia
- Sick-Days

- · Self-Monitoring, if indicated
- Allowances, Entitlements
- Membership of Diabetes Ireland

ADDITIONAL ISSUES AS APPROPRIATE FOR SPECIFIC PATIENT

- Lifestyle: smoking, alcohol, exercise, weight control
- Cardiovascular Status: Hypertension, Hyperlipidaemia, Micro-albuminuria
- Managing Insulin
- Travel Advice
- Encouraging Self-care
- Discussion with Carers
- Family Planning or Pre-Conception Advice

- Employment, Insurance, Driving issues
- New Symptoms:

Nocturia: frequency

Dry mouth

Chest pain: Sensation, Dyspepsia

Visual disturbance Foot problems Impotence

Source: Midland Diabetes Structured Care Programme Patient Education Guideline

Lifestyle Management

The main lifestyle management issues for people with Type 2 diabetes are healthy eating and physical activity and there is ample evidence (of varying levels) to support this.

The Scottish Intercollegiate Guideline Network (SIGN) recommend that

- Patients with diabetes should be offered lifestyle interventions based on a valid theoretical framework
- Education programmes, computer assisted packages and telephone prompting should be considered as part of a multidisciplinary lifestyle-intervention programme.¹⁸

Diet - See Appendix 2

Nutritional advice and information is an essential component of the overall management of Type 1 and Type 2 diabetes. The aim is to keep blood glucose, cholesterol, triglycerides and weight within a normal range. Healthy eating is recommended as it is encouraged for the entire population. Some of the most successful programmes for long-term weight control have involved combinations of diet, exercise and behaviour modification.¹⁹

Patients should be advised to maintain a healthy weight in order to maintain a BMI of between 20 and 25 kg/m².

The following are general recommendations in relation to referral to the dietetic service

- » Ideally all newly diagnosed patients need to be advised by a dietician within 4 weeks of diagnosis.²⁰
- » It is advisable that all people with type 2 diabetes should have an annual dietetic review.20
- » All patients with diabetes should be offered a structured diabetes education programme

Physical Activity

Along with diet and medication, exercise has long been considered as a key component of diabetes management. There is consistent evidence that programmes of increased physical activity and modest weight loss reduce the incidence of Type 2 diabetes in individuals with IGT.^{21,22,23,24} Physical activity also helps those diagnosed with Type 2 diabetes to maintain a healthy weight and reduce the risk of CVD.

Before beginning a programme of physical activity more vigorous than brisk walking, people with diabetes should be assessed for conditions that might be associated with increased likelihood of CVD or that might contraindicate certain types of exercise or predispose to injury, such as severe autonomic neuropathy, severe peripheral neuropathy, and pre-proliferative or proliferative retinopathy. The patient's age and previous physical activity level should be considered.²⁵

The universal recommendation with regard to physical activity is that all individuals should aim to accumulate at least 30 minutes of moderate intensity physical activity on most days of the week.²⁶ This has been adopted as the minimum requirement for health benefits. However, 30 minutes spread over the entire day is equally beneficial as one 30-minute walk. Activities of daily living such as housework and using stairs are valuable in increasing physical activity.²⁷

SIGN 55 recommend that exercise and physical activity involving aerobic and/or resistance training, should be performed on a regular basis. They also recommend that advice about exercise and physical activity should be individually tailored and diabetes specific and should include implications for glucose management.¹⁸

The 2015 ADA recommend

- Adults with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate), spread over at least 3 days/week with no more than 2 consecutive days without exercise.
- Evidence supports that all individuals, including those with diabetes, should be encouraged to reduce sedentary time, particularly by breaking up extended amounts of time (>90 min) spent sitting.
- In the absence of contraindications, adults with type 2 diabetes should be encouraged to perform resistance training at least twice per week.

Achieving Glycaemic Control

Type 2 Diabetes is a progressive disease with worsening glycaemia over time; therefore the addition of medications is the rule, not the exception, if treatment goals are to be met. The limited long-term success of lifestyle programmes to maintain glycaemic goals suggests that a majority of patients require medication. Baseline glycaemia, duration of diabetes, previous therapy and other factors affect the glucose-lowering effectiveness of individual therapies and combinations. ²⁸ Tight control of blood glucose with diet, physical activity and/or medication reduces long term diabetes related complications and is central to the overall management of diabetes.

Targets 7,11

- The target HbA1c for the majority of patients with Type 2 diabetes should be ≤53mmol/ mol (≤7.0%)
- Targets should be set in consultation with the patient. The targets should be seen as
 guides, as a patient's individual circumstances need to be considered when setting and
 agreeing targets.
- More stringent A1C goals such as < 48mmol/mol (<6.5%) may be considered for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, type 2 diabetes treated with lifestyle or metformin only, long life expectancy, or no significant cardiovascular disease (CVD).
- Consider relaxing the target HbA1c level such as < 58mmol/mol (<8%) on a case by case basis, with particular consideration for people who are older or frail for adults with type 2 diabetes;
 - Who are unlikely to achieve longer term risk reduction benefits, for example, people with reduced life expectancy
 - For whom tight blood glucose control poses a high risk of the consequences of hypoglycaemia, for example, people who are at risk of falling, people who have impaired awareness of hypoglycaemia and people who drive or operate machinery a part of their job
 - For whom intensive management would be appropriate, for example people with significant co-morbidities

Clinical Monitoring

• The HbA1c should be checked four monthly and treatment adjusted as appropriate if the target HbA1c is not achieved.

Self-Monitoring see Appendix 7 for Guide to Blood Glucose Testing

NICE recommend that self-monitoring should not be considered as a stand-alone intervention but used in conjunction with appropriate therapy as part of integrated self-care and that it should be taught if the need/purpose is clear and agreed with the patient.¹¹

Treatment

Diet and exercise are the cornerstones of type 2 diabetes management but frequently patients require medications to be added in. The following are medications recommended for patients who are having difficulty meeting the HbA1c agreed targets:

The ADA recommend (E)

- Achievement and maintenance of normal glycaemic goals
- Initial therapy with lifestyle interventions and metformin
- Rapid addition of medications and transition to new regimens when target glycaemic goals are not achieved or sustained
- Early addition of insulin therapy in patients who do not meet target goals.28

Treatment/Control with Oral Agents

Many organisations recommend that the patient is started on a single oral agent. The ADA, IDF and NICE recommend metformin as an option for first-line or combination therapy.

• In addition NICE ²⁹ also recommend metformin both for those who are overweight (BMI >25.0kg/m²) and not overweight as the first-line glucose-lowering therapy where blood glucose is inadequately controlled using lifestyle interventions alone (A)

Metformin is contraindicated in those with renal impairment (eGFR <30ml/min), and with end stage cardiac and hepatic failure. Metformin should be stopped in patients with eGFR <30ml/min and at possibly higher values in patients prone to dehydration.

It should be noted that glitazones are under suspicion of precipitating acute cardiac events and current recommendations contraindicate the use of glitazones in patients with a history ischaemic heart disease.

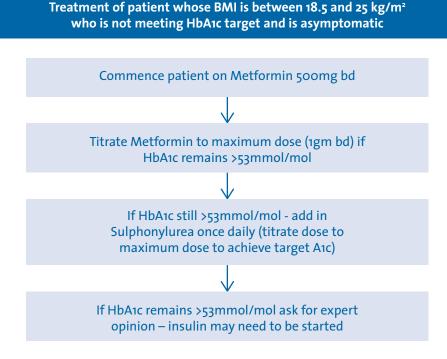
MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First line therapy - Metformin Biguanide — Inhibits hepatic gluconeogenesis Maximum dose – typically 1g twice daily – with food – breakfast and evening meal	Effective for managing glucose targets Promotes weight loss No hypoglycaemia Reduces CVD events Long term data available for its efficacy	Nausea, flatulence, diarrhoea – titrate dose slowly Review dose if serum creatinine ≥ 130 umol/L or eGFR < 45ml/min. Stop metformin if eGFR <30ml/ min – risk of Lactic Acidosis Can cause B12 deficiency
Other therapy – Sulphonylurea Stimulate insulin secretion Medications in this class include: Gliclazide MR Glimepiride Glipizide	Effective Lowers micro vascular risk Long term efficacy and safety data	Hypoglycaemia Weight gain May accelerate beta cell failure Caution in patients with hepatic cirrhosis and renal impairment – increased risk of hypoglycaemia
Other therapy: DPP 4 Inhibitors Work through the incretin pathway Medications in this class include: Sitagliptin 50mg BD (available in combination with metformin), Vildagliptin 50mg BD (available in combination with metformin), Saxagliptin 5mg OD, Lingliptin 5mg OD	Weight neutral No hypoglycaemia Well tolerated May preserve pancreatic beta cell function (speculation currently) Cardiac safety shown in trials	Can cause nausea, abdominal bloating, diarrhoea, immune reactions No long-term safety data Avoid use in patients with previous history of pancreatitis or medullary thyroid cancer Some agents may exacerbate established heart failure

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
Other therapy: GLP 1 Agonist Given as a S/C Injection – Medications in this class include: Exenatide BD S/Cut injection; Liraglutide OD S/Cut injection; Exenatide LAR 2mg once weekly	Weight loss No hypoglycaemia when used on its own Lowers glucagon levels Reduces post-prandial hyperglycemia Reduces some cardiovascular risk factors Delays gastric emptying May preserve pancreatic beta cell function (speculation currently)	Nausea, bloating, diarrhoea, skin rash, hypersensitivity reactions Subcutaneous injection Increases heart rate Pancreatitis (rare) but avoid in patients with history of pancreatitis Avoid in patients with history of medullary thyroid cancer No long-term safety data In combination with sulphonylurea, may need to reduce the dose of sulphonylurea to prevent hypoglycaemia
Other therapy – Pioglitazone – Thiazolidenedione – insulin sensitizer Starting dose is 15mg once daily, increased to 45mg a day. Can be used in combination with metformin or sulphonylurea or insulin or DPP-4.	No hypoglycaemia Some data suggests cardiovascular benefit May preserve pancreatic beta cell function	Weight gain Fluid overload NOT TO BE USED IN HEART FAILURE Increased risk of bone fracture – avoid in patients with metabolic bone disease Drop in haemoglobin Bladder pathology –avoid in patients with history of bladder cancer
Other therapy -SGLT2 - sodium—glucose co- transporter (SGLT) 2 inhibitors Medications in this class include: Dapagliflozin Canagliflozin Empagliflozin	Reduction in HbA1c Weight loss Reduces blood pressure No hypoglycaemia Effective at all stages of Type 2 diabetes Cardiac outcome trials ongoing, results to date show safe cardiac outcomes	No long term safety data available. Genitourinary infections Polyuria Volume depletion/ hypotension/dizziness Increases LDL – Cholesterol Increases creatinine (transient)

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
Other therapy – Acarbose Alpha-Glucosidase Inhibitor	No hypoglycaemia Reduce post-prandial hyperglycemia Small reduction in HbA1c when compared to other therapies	Significant GI upset Flatulence Diarrhoea
Other therapy – Meglitinides Stimulate insulin secretion, act on the same β cell receptor as Sulphonylureas Medications in this class include: Repaglinide Nateglinide	Reduce post prandial hyperglycemia Dosing flexibility	Hypoglycaemia Weight gain

Source: National Clinical Programme Diabetes

PLEASE NOTE: The risks of prescribing oral hypoglycaemic drugs should be carefully considered in women of childbearing age who may be contemplating pregnancy. (See Section on Pregnancy) (E)



Source: National Clinical Programme Diabetes

Treatment of patient whose BMI is between 18.5 and 25 kg/m² who is not meeting HbA1c target and is symptomatic (polyuria &/or polydipsia may be present)

Commence on Sulphonylurea once daily (Titrate dose to maximum dose if blood glucose remains elevated)

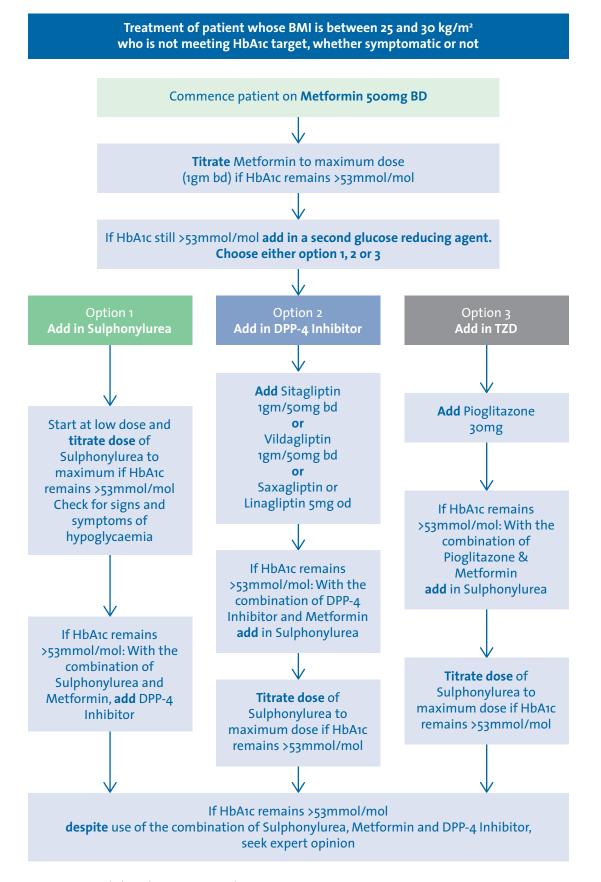
If HbA1c remains >53mmol/mol



Urgent referral to Local
Diabetes Day Centre if: HbA1c
> 53mmol/mol and patient
remains symptomatic with
weight loss or ketones –
suggests need for insulin

If HbA1c > 53mmol/mol and weight stable and no ketones – commence Metformin and titrate to maximum dose Contact Local Diabetes Day Centre if HbA1c remains > 53mmol/mol - suggests need for insulin

Source: National Clinical Programme Diabetes



Source: National Clinical Programme Diabetes

Treatment of patient whose BMI is >30 kg/m² who is not meeting HbA1c target, whether symptomatic or not

Commence patient on Metformin 500mg BD

 Ψ

Titrate Metformin to maximum dose (1gm bd) if HbA1c remains >53mmol/mol

If HbA1c still >53mmol/mol add in a second glucose reducing agent. Choose either option 1, 2, 3, 4 or 5

Option 1 **Add in GLP-1**Injection Preferred
option if BMI >35kg/m



Add Liraglutide OD Injection or Exenatide BD Injection or Exenatide LAR once weekly



If HbA1c remains >53mmol/mol **add** in Sulphonylurea



Titrate dose of Sulphonylurea to maximum dose if HbA1c remains >53mmol/mol. Check for signs and symptoms of hypoglycaemia



If HbAtc remains >53mmol/mol despite combination of GLP-1 Injection, Sulphonylurea and Metformin, contact Local Diabetes Day Centre or Integrated Care Diabetes Nurse Specialist Option 2
Add in DPP-4
Inhibitor



Add Sitagliptin 100mg OD [Sitagliptin + Metformin available BD] or Vildagliptin 50mg BD [Vildagliptin+

Metformin available BD] or

Saxagliptin 5mg OD [Sitagliptin + Metformin available BD] or

Linagliptin 5mg OD [Linagliptin + Metformin available BD]



If HbA1c remains >53mmol/mol, add Sulphonylurea (continue DPP-4) or GLP-1 Injection (Stop DPP-4)



If adding
Sulphonylurea Titrate
to maximum dose if
HbA1c remains
>53mmol/mol. Check
for signs and
symptoms of
hypoglycaemia



If HbA1c remains
>53mmol/mol despite
combination of GLP-1
Injection,
Sulphonylurea and
Metformin, and/or
DPP-4 Inhibitor,
contact Local Diabetes
Day Centre or
Integrated Care
Diabetes Nurse
Specialist

Option 3 Add in Sulphonylurea

Titrate dose of Sulphonylurea to maximum dose if HbA1c remains >53mmol/mol. Check for signs and symptoms of

hypoglycaemia

If HbA1c remains
>53mmol/mol
with the
combination of
Sulphonylurea
and Metformin,
add GLP-1
injection or oral
DPP-4 inhibitor



If HbA1c remains
>53mmol/mol
despite
combination of
Sulphonylure,
Metformin and
DPP-4 Inhibitor or
GLP-1, contact Local
Diabetes Day
Centre or
Integrated Care
Diabetes Nurse
Specialist

Option 4
Add TZD





If HbA1c remains >53mmol/mol with the combination of Pioglitazone and Metformin, add in GLP-1 Injection



If HbA1c remains
>53mmol/mol
despite combination
of GLP-1 Injection,
Metformin and
Pioglitazone, contact
Local Diabetes Day
Centre or Integrated
Care Diabetes Nurse
Specialist

SGLT2
Inhibitor



Add Dapagliflozin 10mg [Dapagliflozin + Metformin available]

or Canagliflozin 100mg [Canagliflozin + Metformin available]

or Empagliflozin 10mg [Empagliflozin + Metformin available]



If HbA1c remains >53mmol/mol add GPL1 or Sulphonylurea or Pioglitazone



If HbA1c remains
>53mmol/mol
despite combination
of 3 agents, contact
Local Diabetes Day
Centre or Integrated
Care Diabetes Nurse
Specialist

Treatment/Control with Insulin

The ADA in their consensus statement on the management of hyperglycemia in Type 2 diabetes²⁸ note that insulin:

- Is recognised as the most effective therapy for lowering blood-glucose
- Can, when used in adequate doses, decrease any level of elevated HbA1c to, or close to, the required target
- Unlike other blood-glucose lowering medication, has no maximum dose beyond which a therapeutic effect will not occur, except in insulin resistant patients
- Therapy has beneficial effects on triglyceride and HDL cholesterol levels
- Is associated with weight gain of 2-4kgs, probably proportional to the correction of glycaemia and owing to the reduction of glycosuria, but potential for weight gain may be more than this.

The IDF Guidelines 2012 make the following suggestions about insulin therapy30:

- » Do not unduly delay the commencement of insulin
- » Consider every initiation or dose increase of insulin as a trial, monitoring the response
- Explain to the person with diabetes from the time of diagnosis that insulin is one of the options available to manage their diabetes, and that it may turn out to be the best, and eventually necessary, way of maintaining glucose control, especially in the longer term
- » Explain that starting doses of insulin are low, for safety reasons, but that eventual dose requirement is expected to be 30-100 units/day
- » Aim for pre-meal glucose levels of <6.5mmol/L.

In those people with type 2 diabetes failing all therapy, virtually all studies have shown that combination therapy using the addition of insulin to sulphonylureas has many advantages over insulin alone. Thus in general, control is better and there is an insulin-sparing effect, with the result that less weight gain is seen using combination therapy rather than insulin alone. Sulphonylureas have the greatest insulin sparing effect of all the oral agents and thus potentially the greatest weight sparing effect when used with insulin.

The addition of insulin to oral agents may be either basal insulin therapy or prandial insulin therapy. Both have advantages. Basal insulin therapy will only be effective if there is a relative insulin deficiency. As progressive insulinopenia continues the addition of prandial insulin becomes necessary.

It is generally recommended that a dietitian reviews the person in the month prior to proposed insulin initiation. The patient / carer must understand and be willing to perform home glucose monitoring. A senior dietitian should instruct the patient where basal/bolus regime is proposed. IDF 2012 state patients with type 2 diabetes on insulin should be offered education on assessment of carbohydrate content of different types of food.

As the patient is the key player in the diabetes care team it is essential that they are trained and empowered to treat hypoglycaemia and all patients on insulin should be supplied with a Glucagon Hypokit and be familiar with its use.

Insulin initiation is usually carried out in a diabetes day care centre; however Insulin Initiation in General Practice is considered feasible once the practice has established its integrated diabetes service, including education of the Practice Nurses and GPs and the availability of the Community Diabetes Nurse Specialists.

Starting a patient on insulin requires a series of consultations and follow-up to monitor patient acceptance of the treatment plan and in order to titrate the insulin dose.

Patient education is a key factor in achieving overall success. The individual must be informed about the actions of insulin, the impact of food and physical activity on blood glucose, the importance of self-monitoring of blood glucose, and the importance of overall blood glucose control.

Some experts recommend that insulin as a treatment option should be brought into the conversation early in order to overcome the psychological insulin resistance experienced by some patients. Diabetes should be presented as a progressive disease and that eventually most people with Type 2 diabetes will require insulin to achieve normal blood glucose. The emphasis should not be on staying off insulin but rather the achievement of as near to normal blood glucose levels as possible³².

THERE ARE 3 PRIMARY INSULIN REGIMENS FOR TYPE 2 DIABETES:33

- 1. Basal insulin once daily
- 2. Basal + bolus insulin
- 3. Premixed insulin twice daily

THERE ARE 3 IMPORTANT PRINCIPLES TO REMEMBER WHEN DOSING INSULIN:33

- 1. Whatever starting dose you select will be wrong.
- 2. Titration is the key to success.
- 3. There is no maximum dose of insulin.

The patient should have adequate visual acuity and manual dexterity to be able to perform blood glucose testing. Group education is the preferred method when initiating patients on insulin.³⁴

Note re new insulins not yet licensed (due in 2016): if moving care to newer agents, refer to secondary care.

For further information and most recent guidelines on diabetes care please refer to the Amercian Diabetes Association (ADA) <u>www.diabetes.org</u> and the European Association for the Study of Diabetes (EASD) <u>www.easd.org</u> websites.

Pre-Conceptual Care and Care in Pregnancy

With increasing numbers of women around the world developing Type 2 diabetes and doing so at a younger age, and with women in many cultures tending to delay starting a family, the issue of diabetes complicating pregnancy has become increasingly important. Diabetes is the most common medical problem in pregnant women and is associated with less satisfactory outcomes for the mother and infant when compared with the non-diabetic population, with an increased risk of congenital malformation, perinatal morbidity and mortality in the offspring. ³⁵

The issue of screening for GDM is already dealt with in a previous section. We focus on the pre-conceptual care of women who already have Type 2 diabetes. In T2DM the situation is made worse by the fact that the women are often older, more obese, of non-Caucasian background, are frequently of higher parity and are more likely to have chronic hypertension and be treated with medications associated with congenital abnormalities.

Planned pregnancies greatly facilitate preconception diabetes care.

Standard Care

To minimize the occurrence of congenital malformations, standard care for all women with diabetes who have childbearing potential should include:

- » Education about the risk of malformations associated with unplanned pregnancies and poor metabolic control
- " Use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive
- » The possibility of pregnancy should be discussed at each diabetes consultation
- » All women with diabetes who are contemplating pregnancy should be referred to a secondary care diabetes centre.

Pre-Conceptual Care

Pre-conceptual care is associated with significantly improved pregnancy related outcomes, lower rate of congenital anomalies, earlier ante-natal booking with lower HbA1c at booking and reduced premature deliveries. Despite the benefits of pre-conceptual care, many women with T2DM are not aware of the significance of the importance of glycaemic control at the time of conception or there is no pre-conceptual care service for them to access.

Aim of Pre-Conceptual Care

- 1. Achieve excellent glycaemic control prior to conception HbA1c <48mmol/mol (<6.1%) without significant hypoglycaemia
 - a. Change diet
 - **b.** Increase exercise activity
 - c. Insulin de-novo may be needed or switch other hypoglycaemic agents to insulin
- 2. High dose folic acid (5mg) for a minimum of 12 weeks of treatment
- 3. Alter anti-hypertensive therapy (expert advice required)
- 4. Stop medications that are potentially teratogenic such as; statin, ACE, ARB, GLP1, DPP4, SGLT2.
- **5.** Identify, evaluate, and treat long-term diabetic complications such as retinopathy, nephropathy, neuropathy, hypertension and cardiovascular disease.⁶
- **6.** Assure effective contraception until stable and acceptable glycaemia is achieved.

Women contemplating pregnancy need to be seen frequently by a multidisciplinary team experienced in the management of diabetes before and during pregnancy. This team may vary but must include a diabetologist, general practitioner, obstetrician, diabetes nurse specialist and senior dietician.

Antenatal Care for women with T2DM or diagnosed with GDM

Although management of diabetes in pregnancy has been improving, women and their infants remain at higher risk for a number of complications compared with the non-diabetic pregnancy.

- 1. Refer for specialist multi-disciplinary care
- 2. Screen for diabetes complications
- 3. Self-monitoring of blood glucose 7 times a day
- 4. Maintain normo-glycaemia.

Postnatal care

- 1. Discuss future pregnancies and contraception
- 2. Discuss diet and lifestyle
- **3.** At 6–12 weeks postnatally, women with gestational diabetes should be reviewed and screened with a 75gm OGTT, if non-diabetic, they should be advised about healthy lifestyles, their risk about developing future diabetes, their need to plan future pregnancies and exclude diabetes before future pregnancies, and should be screened with an OGTT or HbA1c and FPG every 1–2 years.

ISSUES TO BE COVERED BY GP OR PN AT CONSULTATION WITH WOMAN WITH TYPE 2 DIABETES WHO ARE ACTIVELY CONSIDERING PREGNANCY

- Discuss current contraception use (see next page)
- · Discuss the need to discontinue smoking
- Discuss implications of alcohol to foetus
- Discuss implications of obesity in pregnancy
- Review of current medications
- Update on diet and refer to dietician
- Update diabetes education and the link between diabetes and pregnancy outcome
- Initiate daily 7 point glucose measurements
- · Recognition and treatment of hypoglycaemia
- · Discuss the use of the glucagon kit
- Discuss hypoglycaemia and driving
- Ensure recent retinopathy screen and screen for diabetic renal disease
- Encourage early booking to antenatal care
- Refer to specialist diabetes centre for pre-pregnancy care.

ADVICE ON CONTRACEPTION

Planning a pregnancy is essential and therefore contraception is required until appropriate HbA1c level is achieved. By the time most women discover they are pregnant organogenesis is complete and therefore congenital anomalies due to high glucose or drugs will have occurred. All forms of contraception are suitable for women with diabetes.

Contraception pill

The combined Oral Contraceptive Pill (OCP) and the Progestogen-only Pill (POP) can be used by most women with diabetes and are 99% effective if used correctly. They must be taken at the same time each day. There may be a temporary increase in blood sugar levels when initiated but this can be offset by making changes to diabetes medication. Blood pressure may increase and should be monitored as in a woman without diabetes. The POP can be used when breast feeding and is more suitable when diabetes complications exist.

Long acting contraception

Long acting contraception in the form of progestogen injection or an etonogestrel 68mg implant has the advantage that compliance is not an issue. They too are 99% effective. The progestogen injection may be associated with menorrhagia and weight gain and cannot be removed if side effects develop.

Intrauterine coil

The levonorgestrel intrauterine systems are also 99% effective and last from three to five years. An advantage is that they do not affect blood glucose levels. They are suitable for those where the pill is contraindicated or has been associated with side effects.

Barrier Methods

Barrier methods of contraception have no side effects generally. They are less effective (95%) when used correctly and cannot be used in those with latex allergy.

Co-existing illness

The primary care team's role involves coordinating diabetes care in the context of the patient's life which includes managing co-existing illness, both acute and chronic.

Chronic illness and diabetes

Consider:

- Combined risks
 - Mobility problems coupled with hypoglycaemia, failing sight or postural hypotension
 - Varicose veins/ haemosiderin and peripheral vascular disease
 - Nutritional problems of specific population subgroups e.g. disadvantaged, ethnic minorities, elderly etc.
- Drugs adversely affecting glucose control and other risks
 - Corticosteroids
 - Beta-adrenergic blockers in the presence of peripheral vascular disease
 - Many drugs in deteriorating renal function.
- Social and psychological adjustments
 - Effects of changing living circumstances
 - Denial

- Anxiety, for example regarding hypoglycaemia
- Influence of depression or dependency on capacity for diabetes self- management
- Loss of independence with failing sight or polypharmacy.

Acute illness

Be alert in cases where patients with diabetes present with acute illness:

- » Always consider worsening hyperglycemia, particularly in elderly patients
- » If home monitoring advise more frequent glucose monitoring
- » Ensure each patient has access to urine testing for ketones
- » Maintain a low threshold for admission for patients with diabetes at all ages
- » Prevent chest infections with pneumococcal and annual influenza vaccines.

End of Life Diabetes

Prescribing may be modified in patients with advanced life-limiting illness. Clinicians should provide individualised care that maximises patient comfort. Please see Appendix 8

Provision of a painless and symptom-free death

- Tailor glucose-lowering therapy and minimise diabetes-related adverse treatment effects
- Avoid metabolic de-compensation and diabetes-related emergencies e.g. frequent and unnecessary hypoglycaemia, diabetic ketoacidosis, hyperosmolar hyperglycaemic state, persistent symptomatic hyperglycemia
- Avoidance of foot complications in frail, bed-bound patients with diabetes
- Avoidance of symptomatic clinical dehydration
- Provision of appropriate level of intervention according to stage of illness, symptom profile, and respect for dignity
- Supporting and maintaining the empowerment of the individual patient (in their diabetes self-management) and their carers to the last possible stage

Emergencies

Hypoglycaemia

Hypoglycaemia can occur in any patient using insulin or sulphonylureas but not in those using metformin, incretins and rarely when using PPAR γ -agonists.

Hypoglycaemia is particularly hazardous for elderly patients (reduced awareness) or those living alone. Prevention includes using metformin or acarbose, shorter-acting sulphonylureas and/or titrated doses of long acting insulins.

Recurrent hypoglycaemia at a particular time or times of day implies a mismatch of glucose-lowering therapy to meal pattern and/or physical activity:

- » Review whether a repeated change in meal or activity behaviour is occurring; if so, advise on a specific adjustment for that change
- » Consider change in underlying insulin sensitivity (age / renal / endocrine)
- » The possible role of alcohol in hypoglycaemia should be addressed
- » The GP is encouraged to obtain urgent specialist referral in the case of severe hypoglycaemia.

Hypoglycaemia unawareness

Repeated hypoglycaemia can induce hypoglycaemia unawareness. Consider (by self-testing) the possibility of undetected night-time or other hypoglycaemia, especially if HbA1c is lower than average and

- Use adjustment of insulin doses or food intake to ameliorate such problems
- Encourage more frequent self-testing and increased self-awareness
- Ensure glucose and glucagon are available at all times
- Avoid glucose falling to < 4.0 mmol/L
- Ensure that friends and colleagues are made aware of the signs and treatment of hypoglycaemia
- Provide education and training in recognising early cognitive dysfunction for people with the problem and their carers
- Provide counselling on any resultant life-style problems; caution re driving.

Nocturnal hypoglycaemia

Nocturnal hypoglycaemia can be improved by careful attention to glucose-lowering therapy: Consider:

- taking a bed-time snack
- using shorter-acting sulphonylureas or repaglinide
- ensure that insulin dose and regime are appropriate.

Specialist Referral

Many GPs may wish to refer those with unrecognised hypoglycaemia, nocturnal hypoglycaemia and severe hypoglycaemia to their agreed specialist partner in the integrated care system. In this model a priority appointment will be fast tracked to the patient.

Early hypoglycaemia treatment

When treating early hypoglycaemic attack use 1 glass of glucose drink or mineral (not diet or sugar-free) or 85-100mls of LucozadeTM or 4-6 glucose tablets. Follow this with a longer acting snack e.g. slice of bread if meal is not due within a half an hour. A severe hypo may require double carbohydrate intake i.e. 30gms.

Hypoglycaemic coma / fitting

If the hypoglycaemic episode has progressed to coma and/or fitting, give up to two doses of 50 mls of 20% glucose IV if unconscious, or 2 doses of 1 mg glucagon IM (fifteen minutes apart). Beware of poor glucagon effect in the starved or inebriated patient. Follow with oral carbohydrate and review for possible relapse.

Train carers to use glucagon if hypoglycaemia is a recurrent problem and ensure supplies remain in date.

Note: Glucagon needs to be refrigerated and has a short shelf life

Hyperglycaemia

Severe hyperglycaemia (diabetic ketoacidosis or non-ketotic hyperglycaemic coma)

- » is life-threatening
- » may mimic hypoglycaemia
- » complicates concurrent illness (such as UTI in elderly patients)

- » can develop in less than a day
- » may not always be accompanied by ketones, when onset is gradual (non-ketotic hyperglycaemia)
- » requires immediate admission and consider the need for pre-hospital IV hydration (non-glucose crystalline solution)

Assessment includes:

- immediate glucometer reading
- urinalysis for ketones
- assessment of hydration status.

Driving

For information on driving and testing of blood glucose refer to Guide to Blood Glucose (Sugar) Testing (Appendix 7) and the *Road Safety Authority of Ireland (RSA)*

Section 3: Prevention, Early Detection and Management of Complications

Diabetes places a significant burden of care on the individual, health care professionals and the wider health system^{1,36}. Individuals with diabetes are two to four times more likely to develop cardiovascular disease relative to the general population and have a two- to five-fold greater risk of dying from these conditions³⁷. Diabetes is a significant cause of blindness in adults, non-traumatic lower limb amputations and end-stage renal disease resulting in transplantation and dialysis^{1,37}.

In patients with diabetes

- » Life expectancy may be reduced by five to ten years, mainly because of premature cardiovascular disease.
- The risk of myocardial infarction and stroke is two to five times higher than in the general population
- » Pre-menopausal women lose their protection against macrovascular disease
- » It is the most common cause of non-traumatic lower limb amputation
- » It is the most common cause of blindness in adults of working age
- » It is the single most common cause of end-stage renal disease
- » About 30% of patients will develop overt kidney disease
- » Impotence may affect up to 50% of men with longstanding diabetes³⁸

The vascular complications of diabetes include:

MICROVASCULAR COMPLICATIONS	MACROVASCULAR COMPLICATIONS
 Retinopathy 	Cerebrovascular disease
 Nephropathy 	 Ischaemic heart disease
 Neuropathy 	 Peripheral arterial disease

The risk of developing **microvascular complications** varies according to:

- » Duration of diabetes
- » Glycaemic control
- » Hypertension

The risk of developing macrovascular complications varies according to:

- » Smoking
- » Glycaemic control
- » Hypertension
- » Lipids
- » Albuminuria

Prevention – setting targets

A range of measures will prevent or delay the development of vascular complications in patients with diabetes. They are summarised in the table below.

RISK	TARGET TARGETS/GOALS SHOULD BE INDIVIDUALISED.
	HbA1c ≤ 53mmol/mol (≤7.0%) is appropriate for the majority of patients with T2DM and has been shown to reduce diabetes related complications
Glucose Control	HbA1c ≤ 58mmol/mol (≤8%) or less stringent A1c goals may be appropriate for patients with a history of severe hypoglycaemia, limited life expectancy, advanced micro vascular or macrovascular complications, extensive co-morbid conditions or where social circumstance may prevent tight glucose control.
	More stringent A1C goals such as < 48 mmol/mol (<6.5%) may be considered for selected individual patients if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, type 2 diabetes treated with lifestyle or metformin only, long life expectancy, or no significant cardiovascular disease (CVD).
	Systolic ≤ 140 mm/Hg (A) Diastolic < 80 mm/Hg ¹¹
	Hypertension should be treated aggressively with lifestyle modification and drug therapy
Blood Pressure	Measure blood pressure annually and at every routine practice visit if found to be above target level.
	Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate. Refer to section on blood pressure management
	Primary target is the LDL cholesterol.
	Patients should be treated with a statin* with the aim to reduce
	» LDL Cholesterol: ≤ 2.5mmol/L (A) for patients without overt cardio- vascular disease
Lipid	» LDL Cholesterol: ≤ 1.8mmol/L for patients with history of overt cardio- vascular disease
Management and statins	*except for patients <40 years with low risk of CVD, patients planning pregnancy or pregnant.
	In patients treated with maximum dose statins who do not reach target LDL, a reduction of 30–40% in LDL cholesterol from baseline is an alternative therapeutic goal.
	HDL cholesterol levels of \geq 1.0mmol/L in men and 1.3mmol/L in women and fasting serum triglycerides of \leq 1.7mmol/L are desirable, but the LDL cholesterol is primary target.
Anti-Platelet Agents	Do not offer antiplatelet therapy for patients with type 2 diabetes without cardiovascular disease. Anti-platelet therapy should be offered to all patients with T2DM (secondary prevention) who have a previous history of a cardiovascular or a cerebrovascular event.
Lifestyle	Patients should be encouraged to lose weight if necessary, exercise regularly, eat healthily (see section on lifestyle management) and all patients should be encouraged to stop smoking and given access to prescription medications which encourage smoking cessation.
Renal Disease	Serum creatinine, and urine albumin:creatinine ratio (ACR) should be measured and eGFR calculated at diagnosis and annually thereafter.

RISK	TARGET TARGETS/GOALS SHOULD BE INDIVIDUALISED.
Foot Care	All patients should have feet checked at each visit and classified as either low, moderate, high risk or active according to National Model of Foot Care (see appendix 5).
Eye Care	All patients with diabetes should have eyes examined at diagnosis and regularly thereafter by Diabetic RetinaScreen - The National Diabetic Retinal Screening Programme
Flu Vaccination	All patients with diabetes should be offered flu vaccination annually and offered pneumovax .

Early Detection of Complications

The key to the management of complications is early detection and prompt intervention. Therefore systematic screening for complications forms part of a diabetes integrated care programme. The management of the risk factors associated with the development of these complications has already been outlined.

Detection of Macrovascular Complications

The risk of cardiovascular disease is increased 2- 4 fold in patients with diabetes.³⁹ It is the main cause of death in Type 2 diabetes with excess mortality seen in all age groups, especially younger age groups. The underlying pathology is usually atherosclerosis which develops insidiously over many years and is usually advanced by the time symptoms occur.⁴⁰

COMPLICATION	TO DETECT	
Cardiovascular disease	A full clinical history including history of CVD should be taken at initial diagnosis and once a year. (D)	
	The 10-year risk of CVD should be estimated annually for all patients without overt CVD using risk assessment charts.(C)	
	At initial diagnosis:	
	 Inquire about symptoms of peripheral vascular disease 	
	 Ask about previous foot ulceration or amputation 	
	 Ask about physical or visual difficulty in self-management of foot care 	
	 Feet will be assessed and classified according to National Foot Assessment Protocol (Appendix 5) 	
Peripheral	 Inspect feet for evidence of deformity, neuropathy, ischaemia or infection. 	
arterial disease	Detect neuropathy with a 10g monofilament	
	 Assess arterial circulation by measuring dorsalis pedis and posterior tibial foot pulses; measure doppler ankle: brachial pressure ratio if available.⁴³ 	
	At every visit	
	Review foot care education principles with patient	
	Examine feet at intervals according to Foot Protocol	
	(see section on foot care Page 50 and Appendix 5)	

Detection of Microvascular Complications

Delaying microvascular complication together with halting their progress, when they occur, is possible through tight glycaemic and blood pressure control along with the management of risk factors. Early detection is the key to preventing and delaying their progression.

COMPLICATION	TO DETECT
Retinopathy	Patients with diagnosed diabetes, aged 12 and over should be referred to the National Diabetic Retinal Screening Programme. All international evidence and research shows that there is no advantage to screening for retinopathy before the age of 12. This is due to the link between retinopathy and puberty. Subsequent retinal screening examinations will be repeated annually.
	Screening will be carried out using digital retinal photography. There will be timely referral, assessment and treatment of abnormalities discovered.
Nephropathy	Serum creatinine and urine albumin:creatinine ratio (ACR) should be measured and eGFR calculated at diagnosis and annually thereafter. The urine ACR should be measured on an early morning specimen. Two out of three urine ACR results need to be positive over a 6 month period to
	indicate nephropathy.
Neuropathy	See section on Painful Peripheral Neuropathy Page 56 Please refer to Model of Care for the Diabetic Foot for foot screening

Please refer also to further guidance on eye care and renal care. (Pages 52 and 53).

Hypertension

Tight control of blood pressure reduces diabetes related micro- and macrovascular complications and is central to the overall management of diabetes.

In their review of hypertension in Type 2 diabetes Vijan and Hayward 44 found that

- Studies of hypertension control in diabetes show a clear and consistent effect,
- Improved control of blood pressure leads to substantially reduced risks for cardiovascular events and death.
- In patients with diabetes, aggressive blood pressure control also reduces the risk for microvascular events, including end-stage functional impairment (such as decreased visual acuity and end-stage renal disease),
- The risk reduction seen with hypertension control in patients with diabetes is substantially greater than that seen in persons in the general population who have similar blood pressure levels,
- It is also clear that blood pressure targets for patients with diabetes should be more aggressive.

Monitoring

Blood pressure should be measured at each visit in an adult with type 2 diabetes. For an adult with type 2 diabetes on antihypertensive drug treatment when diabetes is diagnosed, review blood pressure control and medications used. Make changes only if there is poor control or if current drug treatment is not appropriate because of microvascular complications or metabolic problems¹¹.

Target

Target Blood Pressure for patients with Type 2 diabetes should be <140/80 mmHg and stricter (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage). Targets should be set in consultation with the patient. These targets should be seen as guides and a patient's individual circumstances need to be considered when setting and agreeing targets. Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate.

Treatment of Hypertension¹¹

Repeat blood pressure measurements within;

- 1 month if blood pressure is higher than 150/90 mmHg
- 2 month if blood pressure is higher than 140/80 mmHg
- 2 months if blood pressure is higher than 130/80 mmHg and there is kidney, eye or cerebrovascular damage

Provide lifestyle advice (diet and exercise) at the same time. Add medications if lifestyle advice does not reduce blood pressure to below 140/80 mmHg (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage).

Monitor blood pressure every 1–2 months, and intensify therapy if the person is already on antihypertensive drug treatment, until the blood pressure is consistently below 140/80 mmHg (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage).

Non-Pharmacotherapy

Low salt diet, reduced alcohol intake, exercise and weight loss are all beneficial in reducing blood pressure and should be instituted whenever appropriate in all patients with high blood pressure but should not delay commencement of pharmacotherapy (A).¹⁸

Pharmacotherapy

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First line therapy - ACE Inhibitors (ACEI)	Effective blood pressure lowering agents	Cough (switch to ARB) Angioedema
Vasodilators	Reno-protective effect	Hyperkalaemia
	Reduce cardiovascular morbidity and mortality Long term data available for	If prescribing in patients with renal failure – check U&E 2 weeks after starting
	its efficacy	Caution in patients with renal artery stenosis
		Teratogenic – do not use in patients planning pregnancy.
		Do not use as first line therapy in African or Caribbean family origin – risk of angioedema

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First line therapy – Angiotensin Receptor Blockers (ARB) Vasodilators	Effective blood pressure lowering agents Reno-protective effect Reduce cardiovascular morbidity and mortality Long term data available for its efficacy	Hyperkalaemia Check U&E 2 weeks after starting Caution in patients with renal artery stenosis
Second line therapy – Calcium Channel Blockers Vasodilators	Effective blood pressure lowering agents Reduce cardiovascular morbidity and mortality Long term data available for its efficacy	Leg oedema Constipation
Second line therapy – Diuretic therapy (thiazide diuretic) Diuretic Natriuresis	Effective blood pressure lowering agents Reduce cardiovascular morbidity and mortality Long term data available for its efficacy	Hyponatraemia Dehydration Gout Hyperkalaemia Avoid high dose thiazide diuretics such as bendrofluazide 5mg as this dose is associated with hyperglycemia Caution in elderly patients with low BMI – increased risk of hyponatraemia
Third Line Therapy*- Beta-Blockers Reduce heart rate Reduce myocardial contractility *Cardio-selective beta-blockers should be used	Effective blood pressure lowering agents Reduce cardiovascular morbidity and mortality Long term data available for its efficacy *Beta-blockers should be used as first line BP agents in patients with co-existing angina	Bradycardia Fatigue Cold peripheries Dizziness

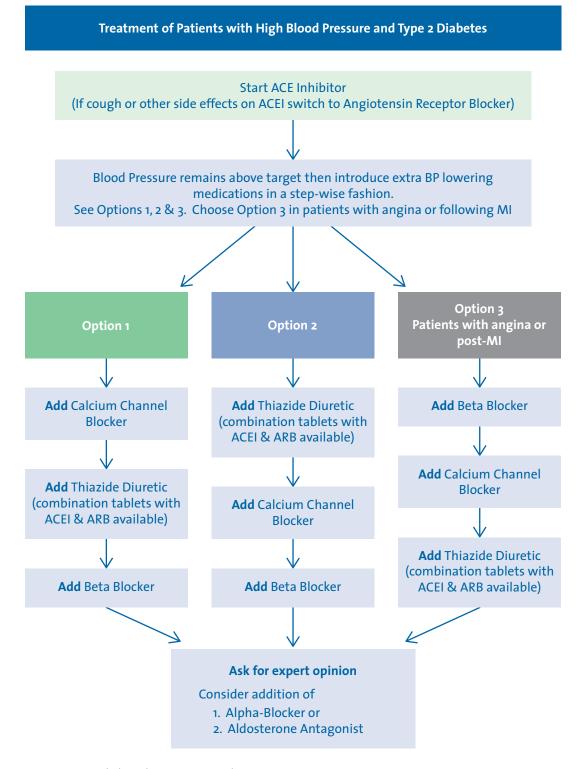
MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
Fourth Line Therapy – Aldosterone antagonist (eplerenone or spironolactone) Diuretic Block the action of aldosterone	Lowers blood pressure	Hyperkalaemia Dehydration Hyponatraemia Gynaecomastia with spironolactone only Caution: high risk of hyperkalaemia if used in combination with ACEI or ARB
Fourth Line Therapy – Alpha Blocker (doxazosin XL) Vasodilator	Lower Blood Pressure Safe to prescribe in renal failure	Dizziness Postural hypotension Increased urinary frequency

Source: National Clinical Programme Diabetes

Notes re Treatment of Hypertension:11

- The first line antihypertensive drug treatment for a person of African or Caribbean family origin should be a generic calcium-channel blocker plus either a diuretic or an ACE inhibitor
- A calcium-channel blocker should be the first line antihypertensive drug treatment for a woman for whom, after an informed discussion, it is agreed there is a possibility of her becoming pregnant.
- For a person with continuing intolerance to an ACE inhibitor (other than renal deterioration or hyperkalaemia), substitute an angiotensin II receptor antagonist/ARB for the ACE inhibitor.
- Do not combine an ACE inhibitor with an angiotensin II receptor/ARB antagonist to treat hypertension.
- If the person's blood pressure is not reduced to the individually agreed target with first line therapy, add a calcium-channel blocker or a diuretic (usually a thiazide or thiaziderelated diuretic). Add the other drug (that is, the calcium-channel blocker or diuretic) if the target is not reached with dual therapy.
- If the person's blood pressure is not reduced to the individually agreed target with triple therapy, add an alpha-blocker, a beta-blocker or a potassium-sparing diuretic (the last with caution if the person is already taking an ACE inhibitor or an ARB/angiotensin II receptor antagonist)
- Monitor the blood pressure of a person who has attained and consistently remained at
 his or her blood pressure target every 4–6 months. Check for possible adverse effects of
 antihypertensive drug treatment including the risks from unnecessarily low blood pressure
- Patients with Type 2 diabetes frequently have refractory or resistant hypertension despite the use of 3 or 4 blood pressure agents. If this is the case then seek expert advice from a consultant endocrinologist as per national model of care.

The following are treatment algorithms to help guide you in the medication management of Blood Pressure in Type 2 diabetes. All treatment should again be given in conjunction with advice on diet, reduced alcohol intake, exercise and weight loss where appropriate.



Source: National Clinical Programme Diabetes

Anti-Platelet Therapy

Recent NICE guidelines state that anti-platelet therapy (aspirin or clopidogrel) should not be offered to adults with type 2 diabetes without cardiovascular disease". Type 2 diabetes is associated with an increased risk of cardiovascular and cerebrovascular events. Anti-platelet therapy should be offered to all patients with T2DM (secondary prevention) who have a previous history of a cardiovascular or a cerebrovascular event". Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high –risk patients with previous MI or stroke (secondary prevention) but whether it should be prescribed to all patients with type 2 diabetes (primary prevention) is controversial.

Recommendations

- **1.** Aspirin (75-150mg/day) should be prescribed in patients with diabetes and a history of cardio or cerebrovascular disease (secondary prevention).
- 2. Clopidogrel (75mg/day) should be used instead of aspirin only in those with clear aspirin intolerance and aspirin allergy.
- **3.** Combination therapy with Aspirin (75mg/day) and Clopidogrel (75mg/day) can be maintained for up to 12 months after an acute coronary syndrome.

Source: National Clinical Programme Diabetes

Smoking

It has been shown that smokers have poorer glycaemic control than non-smokers or exsmokers. Smoking affects the body's metabolic control, increases insulin resistance and interferes with the action of insulin in the body. Research has shown that smokers with diabetes have a heightened risk of morbidity and premature death associated with the development of macrovascular complications. Smoking is also related to the premature development of microvascular complications.⁷

Target

All smokers, but especially those with diabetes, should be professionally encouraged to permanently stop smoking all forms of tobacco. Quitting smoking can dramatically improve diabetes control⁷

Monitoring

Patients should be asked about their smoking habits at each clinic visit.

Treatment

Non Pharmacotherapy

Some of the most effective methods of helping smokers to quit include brief intervention advice. One of the most important aspects about advising or giving support is to determine where the person is in relation to the cycle of change as outlined by Prochaska and Diclemente (1983), Cycle of Change.⁴⁵

A model using stages of change may help to understand how ready the person is to quit smoking. Smoking cessation counselling and other forms of treatment should be included in routine care.⁷

Pharmacotherapy

Nicotine Replacement Therapy (NRT) and E-cigarettes

Nicotine replacement therapy enhances cessation rates when used as an adjunct to smoking cessation counselling. Pharmacotherapy seems to limit withdrawal symptoms and increase

abstinence. To date there is no evidence of the impact of pharmacotherapy specific to diabetic smokers. However the research suggests that the extensive benefits of quitting versus the heightened risks of continuing to smoke, should guide the decision regarding use of nicotine replacement therapy and other pharmacological aides for cessation.⁷

In the case of the cardiovascular patient, current clinical evidence, suggests that undue caution may have been applied to the use of NRT. It appears sensible to advise that NRT should not be used in acute MI, unstable angina or severe cardiac arrhythmias, although the risk can be assumed to be lower than with continued smoking.⁴⁶

Nicotine replacement therapy or varenicline should be provided for smokers of more than 15 cigarettes per day who are trying to quit. Therapy in a form acceptable to the patient should be offered for appropriate length of time. (B)³⁴

Current guidelines state that there is no evidence that e-cigarettes are a healthier alternative to smoking or that e-cigarettes can facilitate smoking cessation. Rigorous studies of their short and long-term effects are needed in determining their safety and efficacy and their cardiopulmonary effects in comparison with smoking and standard approaches to smoking cessation.

Lipids

The guidance in relation to primary prevention of vascular risk factors is previously outlined. People with Type 2 diabetes have an increased prevalence of lipid abnormalities. An increased concentration of LDL cholesterol of total cholesterol is an independent risk factor for cardiovascular morbidity and mortality and lipid management is aimed at lowering LDL cholesterol, raising HDL cholesterol and lowering triglycerides. A 1.0mmol/L reduction of LDL cholesterol represents a 21% reduction in risk of CVD and a 9% reduction in risk of death from any cause among patients with diabetes.

Targets

- In patients with overt cardiovascular disease (CVD) all patients should be on a statin with the primary target of a LDL cholesterol of <1.8mmol/L
- In patients without overt CVD all patients who are over the age of 40 years and who have one or more other CV risk factor should be on a statin with the primary target of a LDL cholesterol of ≤ 2.5 mmol/L
- Targets should be set in consultation with the patient. If the target LDL cholesterol is not reached on maximally tolerated statin therapy, a reduction in LDL cholesterol of approx. 30-40% from baseline can be used as an alternative therapeutic target.
- HDL cholesterol levels of ≥ 1.0mmol/L in men and ≥1.3mmol/L in women and fasting serum triglycerides of ≤ 1.7mmol/L are desirable, but the LDL cholesterol is primary target.

Monitoring

- Lipid profile should be checked at least annually once the patient is within target LDL cholesterol.
- If patient is above the LDL cholesterol target, check lipid profile 4 monthly in response to change in lipid- lowering therapy until patient is stable and within target.

Treatment

Non-Pharmacotherapy

• Lifestyle modification focusing on the reduction of saturated fat, trans fat, and cholesterol intake; increase of omega-3 fatty acids, fibre, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes⁷.

Pharmacotherapy

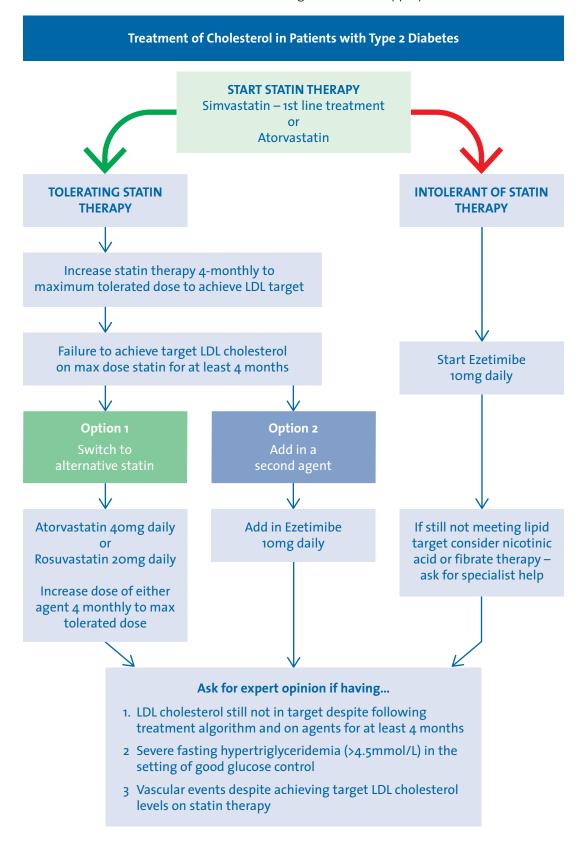
MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First line therapy - Statins	Effective lipid lowering	Insomnia
Simvastatin	agents	Leg cramps
Atorvastatin	Shown to reduce CV morbidity and mortality in	Myositis
Start at low dose and	patients with diabetes	Myalagia
increase at each 4 monthly clinic visit to achieve target		Abnormal liver function tests
LDL cholesterol		Rhabdomyolysis
Both agents are proven in		GI side effects
diabetes but Simvastatin is the first line treatment due		Hyperglycemia
to its cost effectiveness over		Headache
atorvastatin		Recommend to take at
Simvastatin at dose above		bedtime, but if compliance is an issue, switch to morning
40mg should not be prescribed due to increased		administration
risk of myopathy		
Add on therapies – may be considered to achieve lipid targets but are not currently proven to reduce CV morbidity and mortality.		
Consider add on therapy if after	4 months on maximum dose sta	tin lipid targets not achieved.
Ezetimibe	Reduce LDL cholesterol by	Myopathy, Leg cramps,
Dose of 10mg a day.	15–20%.	Fatigue, Abdominal pain, Diarrhea, Flatulence
Can be prescribed in combination with		Interactions: Ciclosporin
simvastatin		monitor levels, Warfarin –may increase INR – monitor
Fibrates	Paduca I DI shalastaral by	-
Fenofibrate	Reduce LDL cholesterol by approximately 5%	Nausea, Myositis Abnormal LFT
Gemfibrozil	More effective at reducing	Rhabdomyolysis (particularly
GEITHIDIOZII	serum triglycerides	in combination with statins)
		Monitor LFT and CK if patient
		is on combination of fibrate
		and statin

Source: National Clinical Programme Diabetes

Notes on Use of Statins

- If a patient develops symptoms on statin therapy, stop statin and then re-challenge with alternative statin at low dose and titrate slowly as tolerated by patient.
- If patient cannot tolerate any statin therapy, consider alternative lipid lowering agent ask for expert advice.
- Intensive lipid lowering therapy with Atorvastatin 8omg should be considered in patients with diabetes and acute coronary syndrome or following coronary revascularisation procedures.
- Statin therapy is contraindicated in pregnancy.
- Patients with well controlled T2DM and fasting hypertriglyceridemia >4.5mmol/L should be considered for fibrate therapy in addition to statin treatment.

The following are treatment algorithms to help guide you in the medication management of cholesterol in Type 2 diabetes. All treatment should again be given in conjunction with advice on diet, reduced alcohol intake, exercise and weight loss where appropriate.



Source: National Clinical Programme Diabetes

Diabetic Foot

The Diabetic foot is defined as a group of syndromes in which neuropathy, ischaemia, and infection lead to tissue breakdown, which results in morbidity and ultimately possible amputation.⁴⁷The annual risk of foot ulceration is between 2.2% to 7.0% in patients with diabetes. Patients with diabetes have a 10 to 20-fold increased risk of lower limb amputation compared to non-diabetic patients. Neuropathy and peripheral disease are the main pathologies underlying diabetic foot disorders:

- Peripheral vascular disease leads to poor circulation and ischaemia
- Peripheral neuropathy of the feet leads to loss of sensation
- These pathologies can lead to ulceration, infection, gangrene, and amputation

Diabetic foot ulcers are prone to infection, often with polymicrobial invasion. Foot infections are a major cause of hospital admissions among people with Type 2 diabetes and an important cause of lower limb amputation.⁴³

Monitoring

The absence of reliable symptoms and the high prevalence of asymptomatic disease make foot screening essential. All patients with diabetes should have their foot examined at each clinic visit as per the national model of foot care to look for the presence of neuropathy, ischaemia or deformity. (D) ¹⁸

Referral of Patients

Patients with diabetes should have their feet assessed and categorised according to risk:

Active foot disease (foot ulcer or Charcot foot) should be referred to the hospital diabetes multidisciplinary foot protection team/ specialist foot service and be seen within 24-48 hours. Referral pathways exist between indicative model 3 and model 4 hospitals at a regional model (refer to national foot model).

High risk foot patients should be referred to the hospital diabetes multidisciplinary foot protection team/specialist foot service and be seen within 4 weeks.

Moderate risk patients should be referred to the podiatrist either in the community or in the hospital diabetes foot protection team/specialist foot service and be seen within 4 weeks ideally.

Low risk patients should have their feet examined annually by the practice nurse and/or GP.

Algorithm for the assessment of diabetic foot is available in Appendix 5

Foot Care Patient Education

Education plays a primary role in the prevention of ulcer recurrence. This should encompass foot hygiene, the need for daily foot inspection, suitable foot wear, prompt treatment of new lesions, and the importance of regular podiatric visits. (B) 18,48

Integrated patient education should be made available to all patients with T2DM at the time of initial diagnosis and then as needed on an ongoing basis, based on formal, regular assessment of the need. Foot Care education improves the knowledge and behaviour towards foot care in the short term in people with diabetes. Education may reduce foot ulceration and complications. $(C)^{48}$

Education leaflets are available for patients on the care of the diabetic foot.

Footwear

Callus formation can precede the development of a neuropathic ulcer. The provision of orthoses or therapeutic shoes or both can reduce abnormal foot pressure, callus formation and therefore ulcer development. (B) 18

See Appendix 5 for further information on diabetic footcare and assessment.

Health professionals taking care of people with diabetes are advised to get further information from the HSE Model of Care for the Diabetic Foot.

Eye Disease

Diabetic Retinopathy

Diabetic retinopathy is one of the most common causes of blindness in the working age population in Ireland. Up to 10 per cent of people with diabetes are at risk of sight threatening retinopathy. Diabetic retinopathy may not have any symptoms or may not affect sight in its early stages. When the condition is caught early, treatment is effective at reducing or preventing damage to sight.

Diabetic RetinaScreen

Diabetic RetinaScreen is a Government-funded, quality assured programme that offers free annual diabetic retinopathy screening to people with Type 1 or Type 2 diabetes aged 12 and over. Specialised digital photography is used to look for changes that could affect eyesight.

All those on the register at the start of the calendar year will receive an invitation for diabetic retinopathy screening in the same year. A screening register was compiled for Diabetic RetinaScreen. As the eligible population is continually changing, the programme provides options for health professionals to register and verify newly diagnosed patients with diabetes*:

- 1. By contacting Diabetic RetinaScreen on Freephone 1800 45 45 55.
- 2. Through the Health Professionals section of www.diabeticretinascreen.ie with an MCRN.
- **3.** Patients can self-register online at www.diabeticretinascreen.ie. A registration form can be completed online, printed, verified with GP practice stamp and sent by Freepost to Diabetic RetinaScreen.

Once on the register, a person will automatically be invited for annual retinopathy screening.

* A patient must provide their consent in advance of sharing their details with the programme.

Anyone who takes part in the programme will receive an appointment letter for a local screening centre

Results and follow-on treatment and investigation

Results will be sent to the participant, their nominated GP and endocrinologist, who will also receive the associated management recommendation. Most will have a normal result; they will have no retinopathy or early changes to the retina and will be re-invited by Diabetic RetinaScreen the following year for annual diabetic retinopathy eye screening. If the images taken show that further investigation and possible treatment is required, the participant will be referred to a Diabetic RetinaScreen eye clinic. In the event that further treatment is required, defined pathways have been developed in conjunction with the Irish College of Ophthalmology. The participant's GP and nominated endocrinologist will receive a copy of their screening results and details of the eye clinic they have been referred to. It is not necessary for a GP to make the referral.

At the eye clinic, the patient will be assessed, treated and followed-up as necessary. Their nominated GP will be sent a copy of all correspondence relating to their attendance, diagnosis, treatment and discharge. Any further assessments of diabetic retinopathy recommended as part of the programme are free of charge.

Freephone 1800 45 45 55 or visit the Health Professionals section of www.diabeticretinascreen. ie for further information.

Renal Disease

The earliest indicator of renal disease (nephropathy) attributable to diabetes is microalbuminuria which relates to a range of albumin values in the urine that, while low, are above normal levels. A review of longitudinal studies has shown microalbuminuria to be predictive of total mortality and of cardiovascular mortality morbidity. 49

Measurement of the urine albumin: creatinine ratio (ACR) provides the most consistent and reliable measurement of urine albumin excretion.

Renal impairment is reflected by an increase in the serum creatinine above normal. Because the serum creatinine is affected by factors such as age and muscle mass, a more standardised and accurate way of describing renal function is now provided by estimating the creatinine clearance by formulae. This is referred to as the 'eGFR' or estimated glomerular filtration rate. The eGFR result is approximately equal to the degree of renal function expressed as a percentage. For instance an eGFR of 40 suggests renal function of around 40% of normal. Calculation of the eGFR which is now provided automatically by laboratories in conjunction with the reporting of the serum creatinine allows the degree of renal function to be graded in terms of severity.

Microalbuminuria

Microalbuminuria is defined by having an ACR ≥ 3.5mg/mmol in females or ACR ≥ 2.5mg/mmol in males. This corresponds to a 24 hour urinary protein excretion of 30-300mg/24hours It may reflect subclinical vascular damage in the kidneys and other vascular beds and is a marker of endothelial dysfunction that predisposes to future cardiovascular events.

Macroalbuminuria

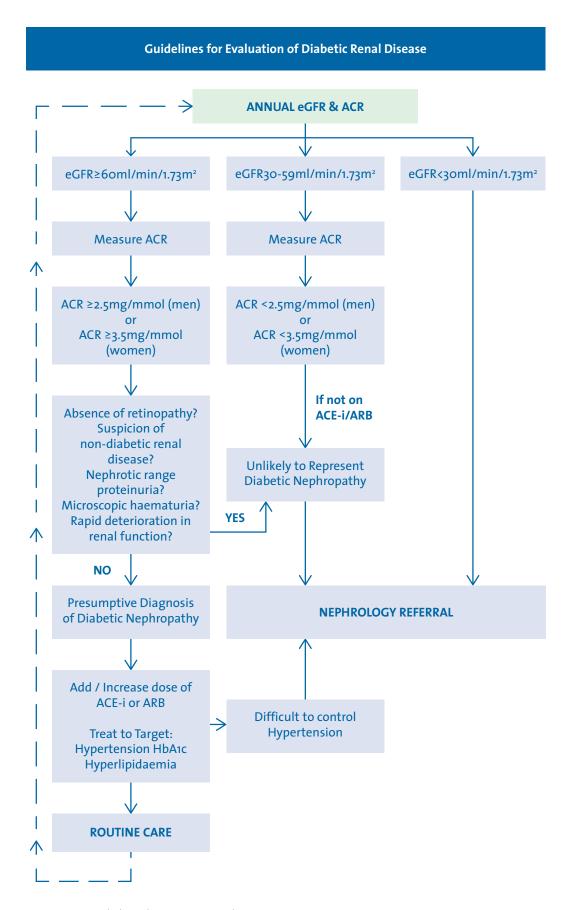
Macroalbuminuria is defined by having an ACR \geq 35mg/mmol in females or ACR \geq 25mg/mmol in males. This corresponds to a 24 hour urinary protein excretion >30omg/24hours.

It is predictive of end-stage renal disease, cardiovascular morbidity and mortality and it generally occurs after or in addition to a decline in eGFR in patients with diabetic nephropathy.

A significant proportion of patients with Type 2 diabetes develop proteinuria and renal impairment. Diabetes is now the most common cause of end-stage kidney disease requiring dialysis. This outcome however is rare in comparison with cardiovascular mortality and morbidity associated with diabetes. 49

Monitoring

Urine should be tested for ACR at first visit and at review visits if raised at first visit or preceding review, otherwise check annually. Serum Creatinine should be checked and eGFR calculated at first visit and again annually unless raised at first or preceding review visit.



Source: National Clinical Programme Diabetes

This guideline, courtesy of National Clinical Programme for Diabetes, was developed after reviewing the literature for guidelines for the evaluation of diabetic nephropathy.

The document is predominantly based on a *guideline* provided by the National Institute for Clinical Excellence at Health (NICE), in the UK.

Other documents incorporated into this guideline include a *guideline* provided by the Manitoba Renal Program in Canada and a *guideline* published by the Institute for Clinical Systems Improvement (ICSI), in the USA.

Painful Diabetic Peripheral Neuropathy

Diabetic peripheral neuropathy (DPN) is one of the commonest complications of Type 2 diabetes and may be present at time of diagnosis.

Diabetes can affect all nerves and so diabetic neuropathies are heterogeneous with diverse clinical manifestations. They may also be focal or diffuse, the most common diffuse neuropathy is the chronic sensory motor neuropathy ("glove and stocking") diabetic peripheral neuropathy and the most common focal neuropathy is carpal tunnel syndrome (median nerve compression).

DPN may be present at time of diagnosis in over 10% of patients and may affect up to 50% of patients with long standing diabetes. 50% of diabetic peripheral neuropathy may be asymptomatic but in 16% to 26% of patients with diabetes the neuropathy is painful.

Monitoring

Patients should be examined for DPN from time of diagnosis and their feet should be examined annually for signs of peripheral neuropathy using a 10gm monofilament and vibration perception (128 Hz tuning fork) – refer to foot section, Appendix 5.

Diagnosis

The diagnosis of DPN is a diagnosis of exclusion but complex investigations are rarely needed to exclude other conditions. Consider however other causes including alcohol excess, B12 deficiency (patients on metformin), underlying vasculitis, inherited neuropathies, neurotoxic medications and chronic inflammatory demyelinating polyneuropathy.

Treatment

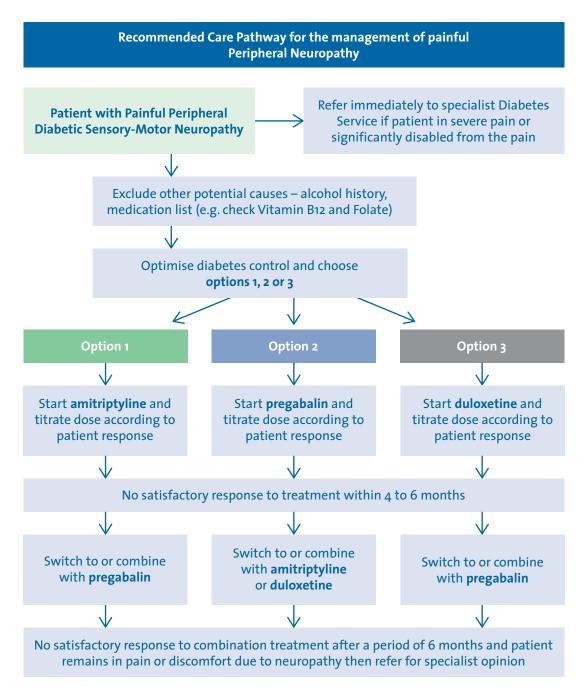
The first step is to aim for stable and optimal glucose control

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First Line Therapy - Pregabalin Start at dose of 25mg and increase by 25mg every 2 weeks to 75mg dose. Increase dose further according to patient response to 75mg bd with upward titration to an effective dose. The maximum tolerated dose is 300mg bd. AVOID ABRUPT WITHDRAWAL (taper dose over at least 1 to 2 weeks)	Symptom relief Improve well being Reduce anxiety	Drowsiness Dry mouth Fatigue Dizziness Visual disturbance Impaired memory
First Line Therapy – Amitriptyline Anti-cholinergic Start at low dose of 10mg daily, given at night, and increase daily gradually according to pain response to maximum dose of 75mg daily	Relieve pain Improve sleep pattern Improve well being	Dry mouth Urinary retention Drowsiness Hyponatraemia Fatigue Mydriasis
First Line Therapy – Duloxetine SNRI Start at 60mg dose (in the elderly start at 30mg). Increase dose according to pain response to maximum dose of 120mg daily AVOID ABRUPT WITHDRAWAL (taper dose over at least 1 to 2 weeks)	Relieve pain Improve sleep pattern Improve well being Reduce anxiety	Nausea, Vomiting Constipation Diarrhoea Weight changes Dry mouth Sweating

Second Line Therapy - combination of the above treatments - see algorithm

Third Line Therapy – ask for specialist advice, refer to consultant endocrinologist/diabetes service

Source: National Clinical Programme Diabetes



Source: National Clinical Programme Diabetes

Erectile Dysfunction

Erectile Dysfunction (ED) or impotence means not being able to have or maintain an erection long enough to have sexual intercourse. On though a benign disorder, it affects physical and psycho-social health and has a significant impact on the quality of life of patients and their partners and families.

Prevalence

Moderate to severe ED affects approximately 5 -20% of all men and is common in middle aged and older men with T2DM where it may affect up to 50% of patients ⁵¹, and it may develop in younger men with T1DM. Patients may be reluctant to discuss the problem. Usually libido

is not reduced initially and the problem is identified as not being able to sustain an erection satisfactory for intercourse. 50,51

Male patients should be asked at diagnosis and at least once per year (at their annual review) whether they have ED. Questionnaires (Erectile Dysfunction Questionnaire) are available which may help in this assessment process (e.g. Simplified International Index of Erectile Function IIEF5).

Treatments

Non Pharmacotherapy

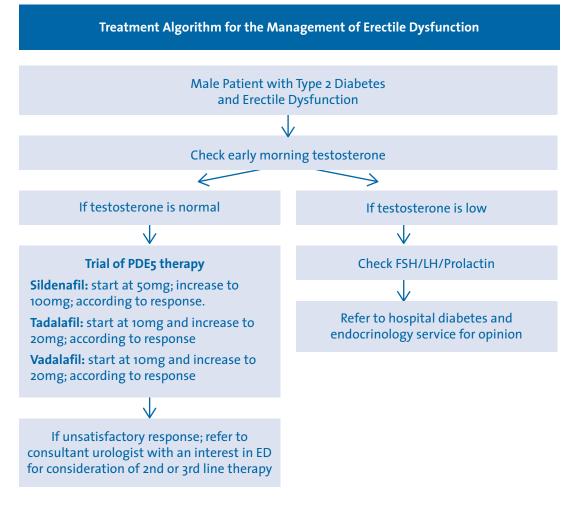
- Reducing alcohol intake, increasing exercise and weight loss are beneficial in improving erectile function
- Counselling or stress management may help erectile function
- A detailed medication history should be taken as certain drugs can affect erectile function.

Pharmacotherapy

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
First line therapy – PDE5 Inhibitors Cause smooth muscle relaxation of the blood vessels supplying the corpus cavernosum Sildenafil Tadalafil Vardenafil Start at low dose and titrate dose according to response. They are initiators of erection and require sexual stimulation for an erection to occur.	Will work in 60–75% of cases Sildenafil and Vardenafil are relatively short acting drugs with a half-life of approximately 4 hours. Tadalafil has a significantly longer half-life of 17.5 hours	Headache, flushing, dizziness, dyspepsia and nasal congestion, sudden hearing loss. Sildenafil and Vardenafil may be associated with visual disturbance in <2% of cases. Tadalafil has been associated with myalgia and mild low back pain. Small risk of non-arteritic ischaemic optic neuropathy NOT TO BE USED IN PATIENTS ON NITRATE THERAPY Caution in patients on alpha – blockers, risk of postural hypotension (check drug SPC)
Second line therapy – Vacuum Erection Device The device applies a negative pressure to the penis to draw venous blood into the penis which is then retained by application of a visible band at the base of the penis	May be more acceptable to elderly patients May be acceptable to patients on nitrate therapy	Penile pain, bruising, numbness and delayed ejaculation in up to 30% of patients. Skin necrosis may occur but is rare.

MEDICATION TYPE/ CLASSIFICATIONS	ADVANTAGES OF THIS MEDICATION	POTENTIAL SIDE EFFECTS AND/ OR NOTES OF CAUTION WHEN CHOOSING THIS MEDICATION
Second line therapy – Intracavernous Injection Therapy Used in the 25–30% of nonresponders to PDE5 therapy Alprostadil is a Prostaglandin E1 and causes vasodilation of the blood vessels. It can be given as an injection at doses of 5–40ug or as a urethral suppository at doses of 0.25–1mg.	Effective with success rates of about 70% Erection occurs typically 5–15 minutes after penile injection and frequently last 30–40 minutes.	Post injection penile pain Prolonged erections (5%) Priapism (1%) Fibrosis (2%) If erection is sustained for ≥ 4 hours – then seek medical assistance.
Third line therapy – penile prosthesis		

Source: National Clinical Programme Diabetes



Source: National Clinical Programme Diabetes

Levels of Evidence

Not all evidence is of the same quality and strength. Generally it ranges from high quality meta-analyses and systematic reviews of randomised controlled trials to expert opinion. For this reason many organisations formulating guidelines have highly developed systems for categorising evidence, that take into account a number of features of the study/information presented. While this adds to the overall credibility of the guideline produced, it can present problems for those formulating derived guidelines using a number of sources as there is no international system for categorising levels of evidence.

Scottish Intercollegiate Guideline Network (SIGN)

1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion

Grades of Recommendations

Scottish Intercollegiate Guideline Network (SIGN)

Α	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
В	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
С	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+

Good practice points

Recommended best practice based on the clinical experience of the guideline development group

References:

- **1.** Harbour, R, Miller, J. A new system for grading recommendations in evidence based guidelines BMJ 2001; 323: 334-336
- 2. Scottish Intercollegiate Guidelines Network SIGN 50 A Guideline Developers Handbook 2002 Edinburgh: Scottish Intercollegiate Guidelines Network

Audit

Monitoring the quality of care:

Quality assurance is an integral feature of modern structured diabetes care. A protocol for monitoring the quality of care includes the following:

Aggregate the data gathered at regular and annual reviews onto a database

Choose indicators (see below) to reflect outcome as well as process of care

Analyse data in line with published recommendations

Compare performance with pre-determined standards or other providers of diabetes care **Review** performance at regular meetings with peers performance of education programmes

Act to design and implement action plans for improvement

This describes an internal audit cycle, which may be conducted within a practice or shared locally in a shared care scheme, CME or other peer group, or nationally through the ICGP or another professional forum. Published audits in Ireland are uncommon, but increasingly will provide material for comparison with positive consequences for standards of diabetes care. The table below lists some of the process and outcome indicators frequently analysed. There is some merit in evaluating process measures initially, and moving on to outcome measures later.

MEASURE:	CALCULATE:
Intermediate outcomes	
HbA1c	Per cent with HbA1c >58mmol/L (7.5%) and >48mmol/l (>6.5%)
Albumin excretion	Per cent with abnormal albumin excretion
Eye damage	Per cent with retinal damage
True outcomes	
Amputation above ankle	Incidence
Myocardial infarction	Incidence
Stroke	Incidence
Foot ulceration	Incidence
Risk factor control	
Hypertension	Per cent with blood pressure >140/80 mmHg
Smoking	Per cent people still smoking
Process of care	
Eyes screened	Per cent people examined in year
Education performed	Per cent people seeing nurse educator in year
Feet examined	Per cent people examined in year
Flu vaccination	Per cent patients offered vaccination each year

These are examples. Many other indicators are possible. For a sample see <u>ICGP Sample Audit</u>

Dietary Advice for Patients

Weight management should be the primary nutrition strategy in managing glucose control in Type 2 diabetes in people who are overweight / obese. Nutritional outcome markers (weight, BMI) should be recorded and checked at regular reviews.

General Healthy Eating includes:

Regular meals containing starchy foods such as bread, cereals, pasta, rice or potatoes. Whenever possible, choose wholegrain varieties that are high in fibre, like wholegrain bread or cereals.

Low glycaemic index carbohydrate foods are preferable, such as pulses, dairy products, and oats, pasta, basmati rice, noodles, fruit and vegetables, plantain and pitta bread. Glycaemic index measures how high blood sugars increase after eating a food. Low glycaemic index foods avoid blood sugar rises and may keep excessive body fat at bay.

Carbohydrates: all carbohydrate foods (starchy and sugary) break down and release glucose into the blood, increasing blood glucose levels. Therefore the amount of carbohydrate food and drink consumed at each meal is the most important factor in achieving good blood glucose control and therefore portion sizes are important.

Snacking between meals will depend upon the patients' lifestyle, activity levels, personal preferences and the diabetes medication prescribed.

Fruit and vegetables; at least five portions of fruit and vegetables should be taken daily. Intake of fruit should be spread evenly over the course of the day. NO more than a small glass of unsweetened juice should be taken at any one time as it can raise blood sugars easily.

Reduce sugar. Sugary foods can be eaten occasionally in small amounts after a meal. Sugar-free, low sugar or diet squashes and fizzy drinks can be used. Non-nutritive sweeteners (e.g. containing aspartame) are safe.

Reduce fat, particularly saturated (animal) fats, as this type of fat is linked to heart disease. Choose monounsaturated fats, e.g. olive oil and rapeseed oil. Eating less fat and fatty foods will also help to lose weight. Use less butter, margarine, cheese and fatty meats. Choose low fat dairy foods. Avoid frying. Include oily fish twice a week, as its omega-3 fats lower the risk of heart disease and helps reduce triglyceride levels. Fish oil supplements are not generally recommended.

Use less salt, because a high intake of salt can raise blood pressure. Try flavouring food with herbs and spices instead.

Alcohol in moderation Moderate use of alcohol is recommended.

Up to 11 standard drinks a week for women and up to 17 standard drinks per week for men. (1 standard drink = approx 10g pure alcohol). Limit alcohol if overweight, hypertensive or hypertriglyceridaemic

Alcohol is high in calories and does not provide any nourishment with one standard drink containing between 100-150 calories. It is also recommended not to exceed the upper limits, spread the alcohol out over the week and not to take more than 5 standard drinks in one sitting, while also having 3 alcohol free days during the week. *Ref: The Department of Heath 2012 guidelines*

No Diabetic products. They are expensive and unnecessary. They contain a sweetener that can cause stomach upset.

For more dietry advice visit the Irish Nutrition & Dietetic Institute website.

For more specific individual dietary advice, refer to a dietician.

Source: Midland Diabetes Structured Care Programme

Physical Activity

What is the Recommended Level of Physical Activity?

It is recommended that all individuals should aim to accumulate at least 30 minutes of moderate intensity physical activity on most days of the week.

Remember:

This has been adopted as the minimum requirement for health benefits. However, 30 minutes spread over the entire day is equally beneficial as one 30 minute walk. Also 'activities of daily living' such as housework and using stairs are valuable in increasing physical activity.

What activities should be recommended

The most important consideration is;

- What activity the individual would enjoy doing the most
- What activity the individual is most likely to sustain long-term
- To maximise adherence, exercise programmes should be home-based and should be accompanied by ongoing support which includes education in cognitive behaviour skills and advice tailored to the individual's stage of change.

Safety Issues to consider when giving advice on Physical Activity:

Being active at moderate intensity should mean that:

- The person is always able to talk while being active & should not be out of breath
- Physical activity levels should only be increased gradually on a weekly basis
- It is a good idea to recommend regular physical activity of short duration initially
- The length of each session can then be increased gradually every week
- Regular breathing while exercising should be encouraged. e.g. holding of breath while lifting or pushing can increase blood pressure – a risk with diabetic retinopathy.

Pre- activity warm up

It is important to warm up by doing the activity at a slower pace for the first 5-10 minutes

Post- activity cool down

Equally, it's important to cool down afterwards by doing the activity at a slower pace for 5-10 minutes

Foot Care: Feet should be checked after every activity session

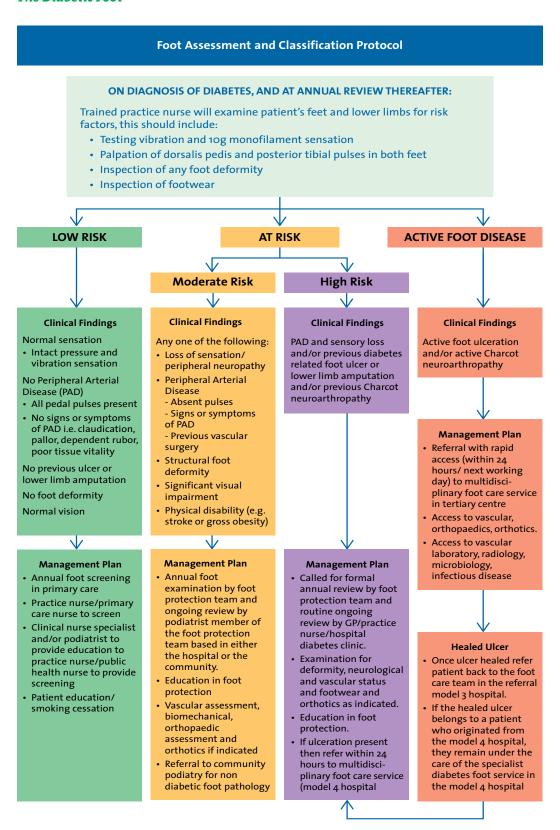
Insulin: If the person is on insulin, injection sites should be away from the muscles used while exercising

Snacks: Fast-acting carbohydrate snacks should be at hand while being active

Source: Midland Diabetes Structured Care Programme

See also www.getirelandactive.ie for national guidelines on physical activity in Ireland

The Diabetic Foot



Source: HSE Model of Care for the Diabetic Foot

Assessment of the Diabetic Foot 52,53,54

Assessment should include

» Skin/soft tissue examination:

Inspection of legs; dorsal, plantar, and posterior surfaces of the foot; and between the

» Neurological examination

Tingling or pain, loss of sensation, loss of perception of pressure and vibration, reflexes.

» Vascular evaluation

Palpation of the pulses of the lower limbs, inspection of the feet and legs for evidence of ischemic changes.

» Musculoskeletal evaluation

Evaluation of the foot and ankle range of movement, inspection for bone abnormalities, analysis of gait and stance.

» Consider infection

Whenever local (e.g. foot pain, swelling, ulceration) or systemic (e.g. poor glycaemic control, fever, malaise) problems develop. The usual signs of infection may be absent due to immunosuppression.

» Footwear examination

Inspection of the type and fit of shoe, pattern of wear of shoes and lining, presence of foreign bodies, use of insoles or orthoses.

» Measurement of sensation

Using a 10g monofilament predicts people at increased risk of ulceration due to neuropathy. The 10 g monofilament is convenient and easy to use in primary care. For further information on the use of the 10 g monofilament see below.

Foot Ulcer Classification 55,56

Clinical features that distinguish neuropathic and ischaemic foot ulcers:

SIGN/SYMPTOM	NEUROPATHIC ULCER	ISCHAEMIC ULCER
Pain	Painless	Pain may be relieved by hanging legs down
Location	Commonly seen on plantar surface of foot	Commonly located at edges of foot
Skin temperature	Warm foot	Cool foot
Foot pulses	Bounding	Absent or weak
Callus formation	Often present especially on plantar surfaces	Absent

Patients whose feet have a high risk of ulceration or gangrene need support and education about foot care. These measures can reduce amputation rates by 30-50% and early referral of patients with ulcers, along with those who have a history of ulcers, to a podiatrist is essential.⁵⁷

Further information including <u>referral form, information for foot protection team, diabetes</u> <u>peripheral vascular assessment form, diabetes foot ulcer assessment, referral form and patient education foot care leaflets is available.</u>

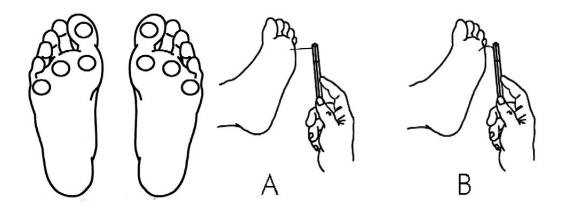
Diabetes Foot Screening Instructions

Source: HSE Model of Care for the Diabetic Foot

Sensory Assessment:

Cutaneous Pressure Assessment (10g monofilament- 5.07): delivers a 10-gram force when properly applied. Research has shown that a person who can feel the 10-gram filament in the selected sites is at reduced risk for developing ulcers.

- The sensory exam should be done in a quiet and relaxed setting. The patient must not watch while the examiner applies the filament.
- Test the monofilament on the patient's lower arm or sternum so he/she knows what to anticipate.
- The four sites to be tested are indicated on the screening form.
- Apply the monofilament perpendicular to the skin's surface (see figure A below).
- Apply sufficient force to cause the filament to bend or buckle (see figure B below).



- The total duration of the approach, skin contact, and departure of the filament should be approximately 1-1.5 seconds.
- Apply the filament along the perimeter and NOT ON an ulcer site, callus, scar or necrotic tissue. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
- Press the filament to the skin such that it buckles at one of two times as you say "time one" or "time two." Have patients identify at which time they were touched. Repeat as necessary and randomise the sequence of applying the filament throughout the examination.

Vibration Perception (128 Hz tuning folk) – Activate the tuning fork. Test on the wrist first to ensure that the patient is responding to the correct stimulus. Place the stem of the fork over the tip of the big toe (figure C) and ask the patient to tell you if they feel vibration. Record the result as absent, reduced or present depending on the patient's response.

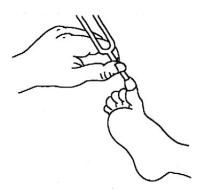


Figure C: Vibration Testing

Vascular Assessment:

This involves the manual palpation of the dorsalis pedis and posterior tibia pulses in both feet. Location of these pulses are shown on figure D.

- If a person has claudication or rest pain (especially the latter), there is sufficiently severe peripheral vascular disease to predispose to vascular ulceration.
- If a person has no claudication or rest pain, then one relies on physical examination and, if necessary, investigations to determine the risk.
- Looking at the feet to see if they are dusky red or purplish in colour and feeling them to see if they are cold give important clue that the circulation may be impaired.

Figure D: Pedal Pulse Palpation





Posterior Tibial

Dorsalis Pedis

Structural Foot Deformity

Record on the diabetes foot screening tool whether these is the presence of:

- toe deformity (figure E),
- bunion deformity (figure F),
- high arch foot (figure G),
- Charcot foot (figure H).

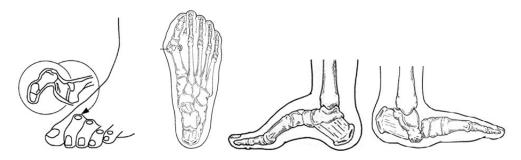


Figure E: Toe Deformity Foot

Figure F: Bunion Deformity Figure G: High Arch Foot

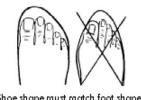
Figure H: Charcot

Footwear Assessment:

Improper or poorly fitting shoes are major contributors to diabetes foot ulcerations. Educate patients about appropriate footwear. All patients with diabetes need to pay special attention to the fit and style of their shoes and should avoid pointed-toe shoes or high heels. Properly fitted athletic or walking shoes with soft upper leathers and no or minimal seams are recommended for daily wear. If off-the-shelf shoes are used, make sure that there is room to accommodate any deformities.







Shoe shape must match foot shape.

Source: HSE Model of Care for the Diabetic Foot

DIABETES FOOT SCREENING TOOL							
Patient Name: Patient Address:		Date of latest HbA1c IFCC mmol/L Medication:					
		History of: retinopathy nephropathy MI CVA Smoker: Yes No					
		•••••		Anticoagulant	Therapy:	J Yes ☐ No	
Phone No:	••••••		••••••	GP Name:			
☐ Medical card ☐ Long term illness card ☐ neither Diabetes: ☐ Type 1 ☐ Type 2		GP Address					
Lower Limb Va	ascular Assess	<u>ment</u>					
Right Foot				Left Foot			
PT pulse: ☐ Present	☐ Absent	DP pulse: ☐ Present	☐ Absent	PT pulse: • Present	☐ Absent	DP pulse: ☐ Present	☐ Absent
Int. Claudicati		Rest Pain:		Int. Claudicati		Rest Pain:	
☐ Yes	□ No	☐ Yes	□ No	☐ Yes	□ No	☐ Yes	□ No
Oedema: ☐ Yes	□ No			Oedema: ☐ Yes	□ No		
Diabetes Related Amputation	ted	☐Yes: ☐ BKA ☐TMA	□ No □ AKA □ Digital	Diabetes Related Amputation	ted	☐Yes if Yes: ☐BKA ☐TMA	□ No □ AKA □ Digital
Peripheral Sensory Assessment							
Right Foot				Left Foot			
Vibration Sens	sation (tuning ☐ Absent	fork 128HZ):		Vibration Sens	sation (tuning	fork 128HZ):	

DIABETES FOOT SCREENING TOOL						
10g Monofilament: tick circle site if present, cross if not						
	000				0,5	923
Foot Wounds: Right Foot			Left Foot:			
Foot Ulcer	☐ Yes	□No	Foot Ulcer		☐ Yes	□ No
Previous Foot Ulcer	☐ Yes	□ No	Previous Fo	ot Ulcer	☐ Yes	□ No
Foot Deformity: Right Foot			Left Foot:			
Bunion	☐ Yes	□ No	Bunion		☐ Yes	□ No
Claw Toes	☐ Yes	□ No	Claw Toes		☐ Yes	□ No
Skin and Nail Condition: Right Foot			Left Foot:			
Skin dry	☐ Yes	□ No	Skin dry		☐ Yes	□ No
Plantar Callous	☐ Yes	□ No	Plantar Call	ous	☐ Yes	□ No
Ingrowing Nail(s)	☐ Yes	□ No	Ingrowing	Nail(s)	☐ Yes	□ No
Thickened Nail(s)	☐ Yes	□ No	Thickened I	Nail(s)	☐ Yes	□ No
Footwear Assessment:			1			
Foot Wear: Good Fit (Not too loose/too tight)		☐ Yes	□ No			
Foot Wear: Good Shape (Square box toe – not pointed)		☐ Yes	□ No			
Foot Wear: Lace/Velcro (Slip on not appropriate)		☐ Yes	□ No			
Risk Level: ☐ Low Risk Arrange Annual Review Refer to Podiatry		☐ High Risk Refer to Podiatry Refer to Multidiscipling Foot Care Service		tidisciplinary		
Signature:		Job Position:				
Printed Name:			Date:			

Source: <u>HSE Model of Care for the Diabetic Foot</u>

Education

Overview of the Practice Nurse Education Session for first consultation with newly diagnosed patient with Type 2 diabetes

The PN should cover the following topics in the education section of the consultation with the person newly diagnosed with Type 2 diabetes:

Understanding Diabetes

- The understanding of Type 2 diabetes aetiology
- The effect poorly controlled diabetes can have on the development of diabetes related complications: such as vulnerability to arterial disease, retinopathy, cardiovascular disease, nephropathy and neuropathy.
- Information session supported with relevant educational material

Self-management of Diabetes

Blood glucose monitoring **where appropriate** (see Appendix 7): PN promotes self-management skills by provision of information on the following:

- Blood glucose self-monitoring skills (see section on glycaemic control): Targets, technique, hand hygiene, meter calibration & storage, sharps disposal. Frequency: as per guidelines (see Appendix 7)
- Interpretation of results: Hypoglycaemia: symptoms, causes & treatment.
- Hyperglycaemia: symptoms, causes & treatment. Sick day rules and management of illness.

Lifestyle Issues

- Lifestyle review: Support and encouragement of appropriate behaviours known to improve outcomes; footwear, physical activity as per abilities, smoking cessation, membership of diabetic associations and support groups.
- Travel and insurance advice. ID bracelet as necessary
- Advice re driving
- Smoking cessation advice and referral to smoking cessation where necessary. Benefits associated with smoking cessation advised.
- Current activity/exercise patterns: Recommendations for exercise on an individual basis.
- C2H5OH
- Dietary intake: Knowledge of appropriate food choices
- Pre-conceptual advice as per guidelines
- Erectile dysfunction: causes and current treatments.
- Foot Education and Care advice as per National Foot Care Programme:

Medication

 Medication Management: Purpose, benefit, mode of action, timing & potential side effects of medications.

PN nurse providing diabetes care within general practice will, where necessary, integrate patient education into regular clinical care during the clinical consultation. All educational sessions should be supported with educational material.

Overview of the Practice Nurse Education Session for review consultations with patients with Type 2 diabetes

The PN should cover the following topics in the education section of the consultation with the person with Type 2 diabetes:

Review the person's understanding of diabetes, including:

- The understanding of Type 2 diabetes aetiology
- The effect poorly controlled diabetes can have on the development of diabetes related complications: such as vulnerability to arterial disease, retinopathy, cardiovascular disease, nephropathy and neuropathy
- Information session supported with relevant educational material.

Reassess the person's knowledge around self-management of diabetes, including:

Blood glucose monitoring **where appropriate** (see Appendix 7): PN promotes self-management skills by provision of information on the following:

- Blood glucose self-monitoring skills (see section on glycaemic control): Targets, technique, hand hygiene, meter calibration & storage, sharps disposal. Frequency: as per guidelines (see Appendix 7)
- Interpretation of results: Hypoglycaemia: symptoms, causes & treatment
- Hyperglycaemia: symptoms, causes & treatment. Sick day rules and management of illness.

Review Lifestyle Issues

- Lifestyle review: Support and encouragement of appropriate behaviours known to improve outcomes; footwear, physical activity as per abilities, smoking cessation, membership of diabetic associations and support groups
- Travel and insurance advice. ID bracelet as necessary
- · Advice re driving
- Smoking cessation advice and referral to smoking cessation where necessary. Benefits associated with smoking cessation advised
- Current activity/exercise patterns: Recommendations for exercise on an individual basis
- C2H5OH
- Dietary intake: Knowledge of appropriate food choices
- Pre-conceptual advice as per HSE Guidelines for the Management of Pre Gestational and Gestational Diabetes Mellitus
- Foot Education and Care advice as per guidelines.

Review of Medication Management:

• Medication Management: Purpose, benefit, mode of action, timing & potential side effects of medications.

PN providing diabetes care within general practice will, where necessary, integrate patient education into regular clinical care during the clinical consultation. All educational sessions should be supported with educational material.

Patient Guide to Blood Glucose (Sugar) Testing

The purpose of this guide:

If you have been diagnosed with diabetes, you may be advised to self-test your blood glucose levels. Your doctor, nurse or dietitian will agree blood glucose targets with you. This guide sets out how often you should self-test and what to look for when testing. It also tells you about structured diabetic education programmes which can help you manage your diabetes and where you can find further information on your condition.

How often should I test my blood glucose levels?

This depends on your treatment. Learning when to self-test your blood glucose is an important part of your diabetes education. Your doctor, nurse, dietitian or pharmacist will advise you about when to test your blood. They will also talk to you about attending a diabetes education programme.

The following guidelines are the recommended practice for blood glucose testing for people with Type 2 Diabetes. Some people may not need to self-test.

DIABETES TREATMENT	GUIDELINES FOR TESTING YOUR BLOOD GLUCOSE TESTING
People with stable Type 2 diabetes on diet alone	• Do not need to self-test.
People with Type 2 diabetes taking: • Metformin alone or • Metformin with any of the following diabetes medications: - a DPP-IV inhibitor, or - a GLP-1 analog, or - a TZD, or - SGLT2 Inhibitor	Test up to three times a week
People with Type 2 diabetes taking a Sulphonylurea or glinides such as Gliclazide on its own or taking it with any of the following diabetes medications: - a DPP-IV inhibitor, or - a GLP-1 analog, or - a TZD, or - a SGLT2 Inhibitor - metformin.	 Test 1–2 times a day Test more often if you are: driving (see driving guidelines), doing extra physical activities such as gardening or sports, experiencing hypoglycaemia 'hypo', feeling ill or stressed, consuming alcohol

DIABETES TREATMENT	GUIDELINES FOR TESTING YOUR BLOOD GLUCOSE TESTING
People with Type 2 diabetes on insulin alone or insulin with other diabetes medications.	 Test up to four times a day. Test more often if you are: driving (see driving guidelines), doing physical activities such as gardening, sports and so on, experiencing hypoglycaemia 'hypo', during illness, feeling stressed, consuming alcohol.
People with Type 2 diabetes planning a pregnancy or who are pregnant.	 Test up to seven times a day Test more often if your doctor, nurse or dietitian advises you to

'Testing for a reason'

Remember that when you are self-testing your blood glucose, you may need to do something as a result. There is no point testing if you do not fully understand what the reading is telling you. If you are unsure of what the test result means, please ask your healthcare professional (doctor, nurse, dietitian or pharmacist) for help.

The results of blood glucose testing can help you to:

- understand how food and exercise affect your blood glucose levels;
- see how well your diabetes treatments are working for you;
- identify if your blood glucose level is too low (below 4mmol/L hypoglycaemia);
- monitor (check) your blood glucose levels when you are ill or stressed;
- make sure that your blood glucose is at a safe level to drive or do other activities such as gardening or sports;
- identify changes you need to make to your diet, activity levels or drug treatments.

I don't know if I am at risk of hypoglycaemia or 'hypo'. What should I do?

It is **very important** that you ask your pharmacist, doctor, nurse or dietitian if your diabetes medications put you at risk of hypoglycaemia "hypo". This is where your blood glucose level is too low (below 4 mmol/L).

What are the signs of low blood glucose levels?

You may have some of the following symptoms if your blood glucose falls below 4 mmol/L.

Feel weak or shaky	Be nervous or cranky
Headache	Hunger
Cold sweats	Unclear thinking
Pounding heartbeat	Upset stomach

Your doctor, nurse or dietitian will advise you on how to manage hypoglycaemia.

Does driving affect how often I should test my blood?

No, unless you are on medication that puts you at risk of hypoglycaemia. If you drive and you have Type 2 diabetes and you are taking insulin, sulphonylureas or glinides, please test your blood glucose as advised by the Road Safety Authority of Ireland (RSA) and as follows:

- Test your blood glucose before driving and stop to test every two hours while driving.
- If your blood glucose is less than 5mmol/L or you are worried that you may experience a hypoglycaemic event during the drive, take a snack before driving.
- If your blood glucose is less than 4mmol/L or your feel hypoglycaemic, treat and do not drive until your blood glucose reading is corrected (above 5mmol/L) for at least 45 minutes.
- If you have a hypoglycaemia event while you are driving, stop the vehicle as soon as is safely possible, switch off the engine, remove the keys from the ignition and move from the driver's seat. Treat the 'hypo'.
- Do not start driving until 45 minutes after the blood glucose has returned to normal.
- Always carry a blood testing meter and testing strips in your vehicle.
- Always keep an emergency supply of fast acting carbohydrate (for example, Lucozade or Dextro-Energy Tablets, Lucozade Original, fruit juice, Coke, 7-Up (non-diet) in your vehicle.
- Take regular meals, snacks and rest periods on long journeys.
- · Always avoid alcohol if driving.
- Always carry personal identification to show that you have diabetes.

Structured Diabetes Education – what is it?

Structured Diabetes Education is a group programme that provides you with the knowledge, skill and ability to manage your diabetes. It will help you to live healthily, maintain and improve the quality of your life and take an active role in managing your diabetes. If you have Type 2 diabetes, it is recommended that you should attend a structured diabetes education programme. Please discuss this with your healthcare professional (doctor, nurse, dietitian or pharmacist) as they will be aware of courses available to you.

It will also help you understand your blood glucose readings and any action you may need to take. Ask your doctor, nurse or dietitian for information on structured education available to you.

Where can I get further information?

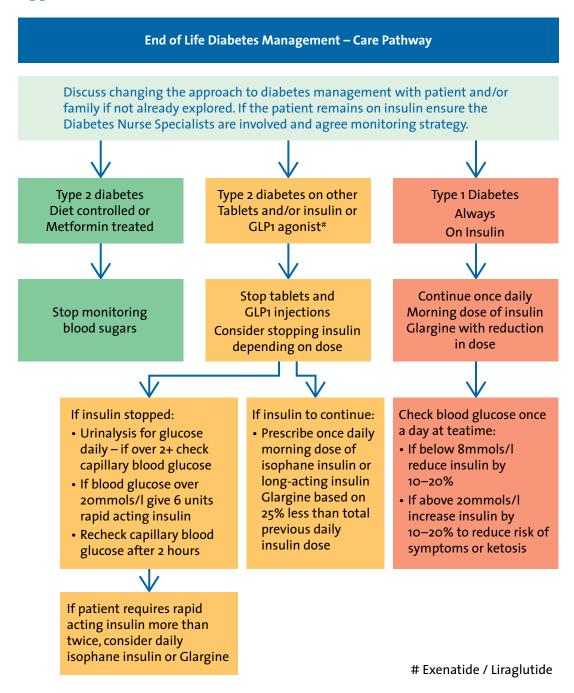
You can find more information on your condition on: <u>www.hse.ie/diabetes</u>, <u>www.diabetes.ie</u> and <u>www.rsa.ie</u>.

Did you know that you might be able to get assistance for your diabetes under the Long Term Illness Scheme? For more information please visit www.hse.ie or contact your HSE Local Health Office.

Source: National Clinical Programme for Diabetes www.hse.ie/diabetes

Glucometers

It is important that the quality control of the monitor should be checked four times a year at a minimum. Monitors should be changed / upgraded every two years. Patients should be advised to record home glucose readings in their patient record book, and to bring their book to each of their diabetic reviews.



- Keep tests to a minimum. It may be necessary to perform some tests to ensure unpleasant symptoms do not occur due to low or high blood glucose.
- It is difficult to identify symptoms due to "hypo" or hyperglycaemia in a dying patient.
- If symptoms are observed it could be due to abnormal blood glucose levels.
- Test urine or blood for glucose if the patient is symptomatic.
- Observe for symptoms in previously insulin treated patient where insulin has been discontinued.

Contact the Diabetes Nurse Specialists or Palliative Care Team if advice required.

Diabetes UK has produced three documents which deal with end of life diabetes care. It is highly recommended that these are seen for further information.

End of life Diabetes Care - Full Guidance (PDF 1MB)

End of Life Diabetes Care - Clinical Care Recommendations (PDF 907KB)

End of Life Diabetes Care Supplementary Document (PDF 523KB)

It should be noted that there are some differences between Irish and UK approaches to palliative care provision, in Ireland we favour a more integrated approach, with palliation concurrent with an appropriate level of intervention. It is hoped that we will move towards developing our own guidance in Ireland in the future.

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