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Issued 23/01/18

# *Type 2 Diabetes Guidelines for the DECENT Network*

*(Diabetes Education Care & Evaluation  
North of Tees)*

**Hartlepool and Stockton-on-Tees  
CCG**

**North of England Commissioning  
Support**

Version issue date:	23/01/18
Date of MO Q&G approval:	23/01/18
Date of review:	January 2020

Document Summary	
Directorate:	Medicines Optimisation
Document Purpose:	To support primary care clinicians in the management of Type 2 Diabetes
Document Name:	Type 2 Diabetes Guidelines for the DECENT Network
Document Ref No.	MODIAB-002
Author:	Multi-disciplinary team from primary and secondary care in Hartlepool and Stockton-On-Tees;
Target Audience:	Clinicians managing patients with Type 2 Diabetes
Description	Clinical guidance and referral pathways
Cross Reference:	
Superseded Document:	<i>Decent FIVE Guidance 2016-10</i>
Action Required:	To note for compliance with the procedure
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Document Status	
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# **Title of Report: Type 2 Diabetes Guidelines for the DECENT Network**

## **1. Introduction/Purpose of the report**

### **1.1. Background**

This purpose of this document is to support clinicians in Stockton on Tees, Hartlepool and Easington to effectively manage patients with Type 2 Diabetes in line with national guidance and standards.

### **1.2. Objectives and scope of the report**

The objective/scope of this document are to highlight the standards and guidelines available as well as providing practical guidance to clinicians

### **1.3. Key points**

- Emphasis on individual approach to care
- Limited role for self-monitoring of blood glucose
- Simple three stage approach to management of blood glucose, Metformin still to the fore
- Newer drugs – still no mortality or morbidity data

### **1.4. Target Audience**

The target audience for this document is clinicians managing patients with Type 2 Diabetes in Stockton on Tees, Hartlepool and Easington.

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## 2. Diabetes Guidelines

### 2.1. Data and Reference Sources

Where available, guidance has been collated from NICE, SIGN, Joint British Societies including Diabetes UK, The Association of British Clinical Diabetologists and the International Diabetes Federation, with additional evidence taken from peer reviewed sources where that best evidence succeeds published guidance.

#### 2.1.1. Skills for Health

Skills for Health [www.skillsforhealth.org.uk](http://www.skillsforhealth.org.uk) is the Sector Skills Council (SSC) for the UK health sector. Their purpose is to help the whole sector develop solutions that deliver a skilled and flexible UK workforce in order to improve health and healthcare.

The competencies within this document can be identified from the Skills for Health website, <http://www.skillsforhealth.org.uk/tools/advsearch.php>, using the appropriate code, for example DiabGA4 Inform individuals of a diagnosis of Type 2 diabetes or impaired glucose tolerance. To demonstrate achievement of a clinical skill completion of the Skills for Health competency document is required. The Skills for Health diabetes competence framework document (Skills for Health, 2004) is designed to support the delivery of the Diabetes NSF by highlighting the performance criteria to be met by members of the multi- professional diabetes care team.

[See Appendix Six for the list of competencies.](#)

#### 2.1.2. TREND-UK

TREND-UK (Training, Research and Education for Nurses on Diabetes) is a Working Group of diabetes nurses with different skills and backgrounds, set up to provide a facilitative forum for relevant nursing organisations to come together to create a unified voice to forge appropriate change within diabetes nursing in the UK, whether relating to clinical, educational or management issues. See their resources at the following link:

<http://www.trend-uk.org/resources.php>

#### 2.1.3. An Integrated Career and Competency Framework for Diabetes Nursing

This Framework supports the commissioning of appropriate levels of nurses to deliver diabetes services and provides a clear definition of the nursing roles – and their expected competencies – within diabetes nursing.

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### 3. Screening at Risk Patients

#### NSF Standard 1: Prevention of Type 2 Diabetes

The NHS will develop, implement and monitor strategies to reduce the risk of developing Type 2 diabetes in the population and to reduce the inequalities in the risk of developing Type 2 diabetes

Current evidence supports active, systematic case finding and screening of selected groups within the general population. Factors indicating a higher risk of developing diabetes include age, ethnicity, family history and obesity, particularly if centrally distributed giving a high waist–hip ratio. It is recommended that individuals at increased risk of developing diabetes should be advised on how they can reduce their risk, and should be supported to lose weight and increase physical activity.

#### 3.1. Criteria for screening for diabetes within targeted asymptomatic populations

Diabetes UK recommends recurring screening for diabetes in the following groups or conditions:

- a. White people aged over 40 years and people from Black, Asian and minority ethnic groups aged over 25 with one or more of the risk factors below:
  - first degree family history of diabetes
  - overweight/obese/morbidly obese with a  $\geq$  BMI of 25-30 kg/m<sup>2</sup> with a sedentary lifestyle (BMI may be overestimated in very muscular people or underestimated in those with lost muscle mass)
  - waist measurement of over > 94cm (> 37 inches) for White and Black men and > 80cm (> 31.5 inches) for White, Black and Asian women, and > 90cm (> 35 inches) for Asian men
- b. Existing ischaemic heart disease, cerebral or peripheral vascular disease or treated hypertension
- c. Previous gestational diabetes with normoglycaemia following delivery
- c. Polycystic ovarian syndrome with BMI > 30 kg/m<sup>2</sup>
- d. Known impaired glucose tolerance or impaired fasting glycaemia
- e. Severe mental health problems
- f. Hypertriglyceridemia not due to alcohol excess or renal disease

Patients with 2 or more risk factors should be offered screening every year with HbA1c. See [algorithm](#) for further clarification and risk stratification. Fasting venous plasma glucose maybe required if HbA1c not appropriate ([see Appendix One](#)) or diagnostic uncertainty.

In pregnancy the possibility of pre-existing undiagnosed diabetes or of developing gestational diabetes should be considered in patients at risk and referral made to the Specialist Team.

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### 3.1.1. Diabetes and CHD

Screening for diabetes is related to screening for cardiovascular risk. Diabetes itself confers a significantly increased risk of cardiovascular disease: secondary prevention measures for CHD are appropriate for patients with Type 2 diabetes. Consideration should be given to joint chronic disease management, given the relationship between diabetes and CHD.

CHD is associated with increased prevalence of impaired fasting glucose and impaired glucose tolerance. These states herald the onset of overt diabetes: patients are candidates for lifestyle interventions to delay the onset of diabetes as well as management of cardiovascular risk factors.

### 3.1.2. Patients with the following symptoms should be tested promptly for diabetes

- weight loss, thirst, polyuria or other urinary symptoms, e.g. incontinence, recurrent cystitis
- recurrent infections, particularly of the skin, recurrent thrush, balanitis, boils and leg ulcers
- peripheral neuropathic symptoms such as pain, numbness and paraesthesia in hands and feet
- visual changes, visual symptoms, dry eyes, cataracts
- vague or unexplained symptoms, tiredness, pruritis

[Please see Referral to Specialist Services.](#)

#### Quality Outcomes Framework

DM001 The contractor establishes and maintains a register of all patients aged 17 or over with diabetes mellitus, which specifies the type of diabetes where a diagnosis has been confirmed (points 6)

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## 4. Diagnosis of Diabetes

### NSF Standard 2: Identification of people with diabetes

The NHS will develop, implement and monitor strategies to identify people who do not know they have diabetes.

The purpose of an accurate diagnosis of type 2 diabetes is to:

- establish whether a patient presenting with symptoms of polyuria, thirst, unexplained weight loss has diabetes
- identify patients at risk of developing complications of diabetes, macro- or micro-vascular
- assess whether the patient with diabetes is likely to have Type 1 disease (ketosis prone with insulin deficiency requiring insulin replacement therapy) or Type 2 disease (insulin resistance with relative insulin deficiency)
- assess whether referral to a specialist diabetes team is necessary. A diagnosis of diabetes has important medical and legal implications therefore it is essential to be secure in the diagnosis. It is necessary to consider the effect of other medication (e.g. steroids) or concurrent illness (e.g. acute MI) on glucose levels.

#### 4.1. Using Haemoglobin A1c (HbA1c) for diagnosis (WHO 2011)

##### 4.1.1. The test

HbA1c should be measured on a laboratory venous blood sample. Point-of-care HbA1c should not be used for diagnosis. HbA1c reflects glycaemia over the preceding 2 – 3 months so may not be raised if blood glucose levels have risen rapidly. Standardisation of laboratory reporting allows for results to be compared from distant laboratories within the UK.

##### 4.1.2. Situations where HbA1c must not be used as the sole test to diagnose diabetes

- ALL symptomatic children and young people
- Pregnancy
- Symptoms suggesting Type 1 diabetes (at any age of presentation)
- Short duration of typical diabetes symptoms
- Patients at high risk of diabetes who are acutely ill
- Taking medication that may cause rapid glucose rise e.g. corticosteroids, antipsychotics
- Acute pancreatic damage/pancreatic surgery

#### 4.2. Using HbA1C for diagnosis

##### 4.2.1. With symptoms (polyuria, thirst, unexplained weight loss)

In adults with relatively slow onset of symptoms a single result HbA1C  $\geq 48$ mmol/mol will suffice

##### 4.2.2. With symptoms in situations where HbA1C cannot be used

- Do an immediate quality-assured finger-prick capillary glucose test

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- Check blood/urine ketones if available
- If glucose is >11.0 mmol/l seek same-day specialist diabetes advice
- For children and teenagers phone the specialist paediatric diabetes team same day
- Send same day laboratory venous glucose, adding HbA1C to exclude stress hyperglycaemia and / or for baseline
- Do not delay seeking advice whilst awaiting the results

#### **4.2.3. With no symptoms**

In patients without diabetes symptoms and HbA1C  $\geq 48$  mmol/mol repeat venous HbA1c in the same lab within 2 weeks for confirmation.

If the second sample is <48 mmol/mol treat as high risk of diabetes. Consider glucose testing instead if concern remains otherwise repeat the test in 6 months or sooner if diabetes symptoms develop.

#### **4.2.4. High risk of diabetes HbA1c 42-47 mmol/mol**

- Provide intensive lifestyle advice
- Warn patients to report symptoms of diabetes
- Monitor HbA1c annually
- Use clinical judgement on whether (and when) to offer standard release metformin (unlicensed indication – informed consent should be obtained and documented) to support lifestyle change for people whose HbA1c or fasting plasma glucose blood test results have deteriorated despite participation in an intensive lifestyle change programme or they are unable to participate in an intensive lifestyle change programme
- Explain that long-term lifestyle change can be more effective than drugs in preventing or delaying type 2 diabetes
- Check renal function before starting treatment, and then twice yearly (more often if they are older or if deterioration is suspected)
- Prescribe metformin for 6-12 months initially
- Monitor HbA1c levels at 3 month intervals and stop the drug if no effect is seen.

#### **4.2.5. HbA1c <42 mmol/mol**

Some of these patients may still be at risk of diabetes. If clinically at high risk manage as above.

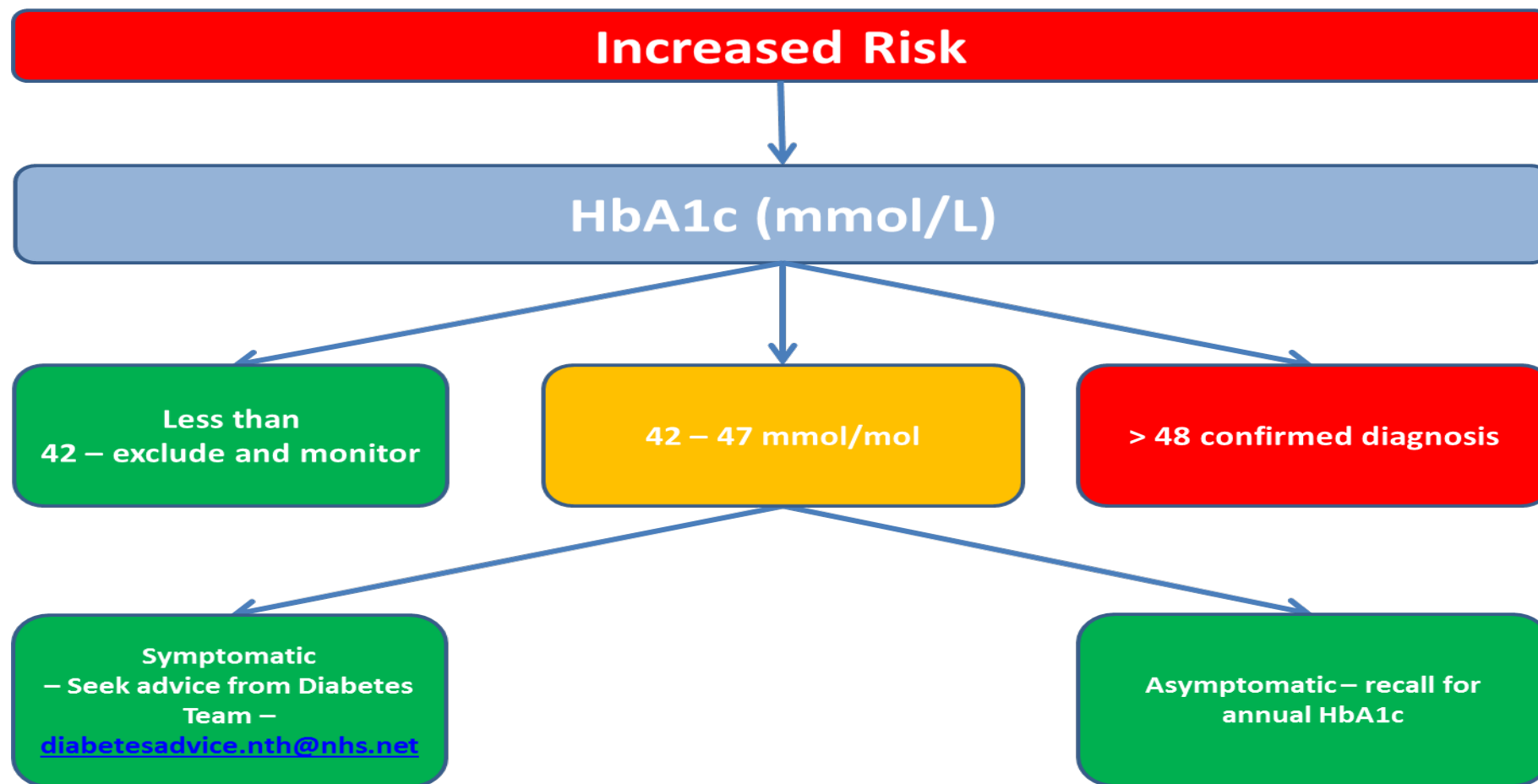
If the person has no symptoms, information, advice and support should be provided to help them change behaviour as appropriate and reduce risk factors, where possible. They may not have diabetes currently or raised blood glucose levels, but they will still be at risk of developing diabetes and cardiovascular disease in the future, so must be informed of any plans for recurring screening.

This guidance is supported by the Association of British Clinical Diabetologists (ABCD), Community Diabetes Consultants (CDC), Diabetes UK, NHS Diabetes, Primary Care Diabetes Society (PCDS), Training, Research, and Education for Nurses in Diabetes UK (TREND UK).

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#### 4.3. Flowchart for screening and diagnosis using WHO 2006 & 2011 Criteria and ABCD statement 2010

##### Flowchart for screening and diagnosis using WHO 2006 & 2011 criteria and ABCD statement 2010



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## 5. Patient Centred Education & Empowerment

### NSF Standard 3: Empowering people with diabetes

All children, young people and adults with diabetes will receive a service which encourages partnership in decision-making, supports them in managing their diabetes and helps them to adopt and maintain a healthy lifestyle. This will be reflected in an agreed and shared care plan in an appropriate format and language. Where appropriate, parents and carers should be fully engaged in this process

The active involvement of people with diabetes in the provision of their own care is the cornerstone of good diabetes care. This requires the provision of effective, ongoing education and support, which is matched to the individual's ability and capacity to learn and recognize the importance of the individual's lifestyle, culture and religion.

The impact of the diagnosis of a chronic incurable condition on a person's life should not be underestimated. It takes time for people to adjust. Patience and understanding are required from all members of the healthcare team. Education must be tailored to the individual's needs and take account of previous health beliefs and cultural differences.

Lifestyle changes to promote a healthy balanced diet, weight control, stopping smoking and regular exercise are crucial to the attainment of good diabetes control and reduction of associated risks. Lifestyle changes as detailed above should be agreed with each individual, followed by ongoing support and review from healthcare professionals to help maintain improvements. The healthcare team should work with the person with diabetes, their family and carers to achieve the goals of self- management and living healthily with diabetes.

Knowledge, behavioural skills and self-responsibility can help the patient to self-manage their diabetes and make more informed choices. In order to support and encourage self-care and self- management, DUK (2005) recommend all healthcare staff should:

- Treat individuals with respect and dignity
- Ensure that people with diabetes know how to contact members of the team providing their diabetes care and ideally have a named person who is their main contact
- Provide high quality care and regularly review their clinical and psychological needs
- Answer any questions about the quality of services received
- Provide interpreting services if English is not the person's first language and seek appropriate services for those with sensory impairment or learning disability
- Provide information and structured education about diabetes management and local health related services. Diabetes UK has produced a leaflet for

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people with diabetes entitled 'What Care to Expect' which is useful for patients and carers

- Remain up to date about diabetes and its care and treatment, in order to keep people with diabetes up to date about their condition
- Facilitate access to a second opinion if desired (subject to agreement of the GP or consultant)
- Give information about Diabetes UK or other reputable sources for information and support Northern & Yorkshire Diabetes UK 01325 488606 or email [north&yorks@diabetes.org.uk](mailto:north&yorks@diabetes.org.uk)  
[https://www.diabetes.org.uk/In\\_Your\\_Area/Northern\\_Yorkshire/](https://www.diabetes.org.uk/In_Your_Area/Northern_Yorkshire/)
- Diabetes UK Careline 0845 120 2960 or email [careline@diabetes.org.uk](mailto:careline@diabetes.org.uk)
- NHS Choices – Diabetes:  
<http://www.nhs.uk/Conditions/Diabetes/Pages/Diabetes.aspx>
- American Diabetes Association [www.diabetes.org](http://www.diabetes.org)

### 5.1. Access to DESMOND Education Programme for the newly diagnosed

DESMOND programmes are available for patients in the Stockton, Hartlepool and Easington areas led by members of the multi-professional team. Referral of newly diagnosed patients with Type 2 diabetes for less than 6 months can be made via the Retinal Screening Office (see Referral Form Appendix 2). Practice teams should register patients for the programme as a matter of course in the processing of newly diagnosed patients.

Referred patients are encouraged to bring a partner or carer to the sessions which are interactive group meetings covering aspects of diagnosis, treatment, monitoring and self-care. The sessions are designed to build an understanding of diabetes leading to the development of shared targets for care.

The programme is subject to centralised assessment and audit with continuing training of course leaders. This fulfils NICE requirements for quality control of Education Programmes in diabetes. Further modules are becoming available for continuing education for previously diagnosed patients or for ethnic groups.

DM014. The percentage of patients newly diagnosed with diabetes, on the register, in the preceding 1 April to 31 March who have a record of being referred to a structured education programme within 9 months after entry on to the diabetes register (11 points)

### 5.2. Local Diabetes Group

- Diabetes UK Northern and Yorkshire. Sterling House 22 St Cuthbert's Way, Darlington DL1 1GB, Telephone 01325 488606, Fax 01325 488816
- Hartlepool Diabetes Voluntary Support Group – meets 1st and 3rd Fridays in the Central, Library at York Road, Contact Denice O'Rourke on 01429 863425
- Middlesbrough (Diabetes UK South Cleveland Voluntary Group) Tel: Secretary Mrs Irene Angel, 01287 678150

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### 5.3. DVLA Regulations relating to diabetes

Drivers of cars or motorcycles with diabetes treated by tablets, diet or both should be made aware of the DVLA regulations relating to diabetes and how any changes in their treatment or development of complications affects their legal entitlement to drive. DVLA should be informed if they meet any of the following conditions:

- subject to hypoglycaemia on oral agents
- treatment with insulin, even if temporary e.g. pregnancy or post MI
- laser treatment to both eyes or in the remaining eye if sight in one eye only
- problems with vision in both eyes, or in the remaining eye if sight in one eye only
- any problems with the circulation or sensation in your legs or feet which make it necessary to drive certain types of vehicles only, for example automatic vehicles or vehicle a hand operated accelerator or brake. This must be noted on driving licence
- more than one episode of disabling hypoglycaemia (low blood glucose) within 12 months, or if you or your carer feel you are at high risk of developing disabling hypoglycaemia
- impaired awareness of hypoglycaemia or disabling hypoglycaemia at the wheel
- an existing medical condition worsens or any other condition that may affect safe driving develops.

To report diabetes patients fill in a DIAB1 medical questionnaire about Diabetes. Download this from [www.direct.gov.uk/motoringdriverhealth](http://www.direct.gov.uk/motoringdriverhealth) Telephone: 0870 600 0301

Drivers Medical Group, DVLA Swansea SA99 1TU E-mail: [eftd@dvla.gsi.gov.uk](mailto:eftd@dvla.gsi.gov.uk)

New regulations came into effect Nov 15 2011 allowing drivers with diabetes to apply for consideration to drive lorries and buses. More information can be found at [www.direct.gov.uk/motoring](http://www.direct.gov.uk/motoring) where you can also order the 02 application form. An information leaflet on how to complete the application can be found at [www.direct.gov.uk/motoring](http://www.direct.gov.uk/motoring) leaflets.

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## 6. Management of People with Type 2 Diabetes

### NSF Standard 4: Clinical care of adults with diabetes

All adults with diabetes will receive high-quality care throughout their life time, including support to optimise their control of their blood glucose, blood pressure and other risk factors for developing the complications of diabetes

### NSF Standards 5 & 6: Clinical care of children & young people with diabetes

All children and young people with diabetes will receive consistently high-quality care and they, with families and others involved in their day-to-day care, will be supported to optimise the control of their blood glucose and their physical, psychological, intellectual, educational and social development.

All young people with diabetes will experience a smooth transition of care from paediatric diabetes services to adult services, whether hospital or community-based, directly or via a young people's clinic. The transition will be organised in partnership with each individual and at an age appropriate to and agreed with them.

## 6.1. Lifestyle Changes

### 6.1.1. Dietary Management

Dietary management is not just about reduction of glucose levels but includes modification of all risk factors. Dietary management, weight loss (if necessary), physical activity and drug therapies are partners in achieving and maintaining low risk blood glucose, blood lipid and blood pressure levels.

All newly diagnosed patients with Type 2 diabetes should be given appropriate initial advice by a trained professional and referred to DESMOND. The general principles of dietary advice include:

- Eat regular meals planned around starchy foods, such as bread, potatoes, rice, pasta and cereals
- Reduce fried and fatty foods and change to skimmed or semi-skimmed milk
- Eat high fibre starchy carbohydrate foods
- Eat at least five portions of fruit, vegetables or pulses each day
- Reduce sugar-containing foods
- Aim to achieve and maintain a healthy weight, BMI <25kg/m<sup>2</sup> is desirable
- Reduce dietary salt intake
- Drink alcohol only in moderation – men and women are advised not to regularly drink more than 14 units a week; Fourteen units is equivalent to six pints of average strength beer or 10 small glasses of low strength wine
- Avoid binge drinking – spread your drinking over three days or more if you drink as much as 14 units a week
- Alcohol can cause hypoglycaemia and hypoglycaemia can be mistaken for alcohol intoxication
- Avoid special diabetic foods – they can be expensive and are often high in fat and calories

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All dietary advice is based around healthy eating principles and life style changes. Slow steady weight loss is more effective in maintaining weight loss.

Please see the following appendices which offer referral guidelines and support:

- [Appendix Four for the Guidelines for Referral to the Department of Nutrition and Dietetics](#)
- [Appendix Five Healthy Eating for Type 2 Diabetes Patient \(Advice Leaflet\)](#)

## 6.2. Obesity Management

- For people who are overweight or obese, weight loss and physical exercise should be encouraged
- Consideration should be given to patterns of over-eating and related psychological issues when agreeing targets and weight loss strategies. Depressive features are not uncommon in the obese population; psychological support may be required
- Anti-obesity medication may also be considered as part of a weight loss strategy when patients have made strenuous efforts to lose weight by diet and exercise. Weight loss has such an impact on cardiovascular risk that successful use of anti-obesity drugs is cost-effective in long term management of patients with diabetes who are obese
- Anti-obesity medication must not be used as a single measure in the management of obesity
- Patients may need encouragement to continue with associated exercise programmes once medication is used
- Anti-obesity drugs should be reviewed and discontinued if there is no evidence of weight loss
- Public Health Departments have work in progress around obesity prevention and management in the areas of Stockton, Hartlepool and Easington

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### 6.2.1. Anti-obesity drugs

Orlistat	BMI > 30kg/m <sup>2</sup> or  BMI > 28kg/m <sup>2</sup> with other risk factors	Consider for patients who have not reached their target weight loss or have reached a plateau on dietary, activity and behavioural changes alone  Age 18-75 years  <b><u>Stop after 3 months unless 5% of body weight lost</u></b>  Restriction of duration of treatment to 2 years has been removed from SPC but continue beyond 12 months, usually for weight maintenance, only after discussing potential benefits and limitations with the patient.
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#### Quality Outcomes Framework (GMS2)

DM013. The percentage of patients with diabetes, on the register, who have a record of a dietary review by a suitably competent professional in the preceding 12 months (3 points)

OB001. The contractor establishes and maintains a register of patients aged 16 or over with a BMI ≥30 in the preceding 12 months (8 points)

The NICE Obesity pathways can be found here:

<http://pathways.nice.org.uk/pathways/obesity#path=view%3A/pathways/obesity/surgery-for-obese-adults.xml&content=view-node%3Anodes-when-to-offer-surgery>

### 6.2.2. People with recent-onset type 2 diabetes:

- Offer an expedited assessment for bariatric surgery to people with a BMI of 35 and over who have [recent-onset](#) type 2 diabetes as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent)
- Consider an assessment for bariatric surgery for people with a BMI of 30–34.9 who have recent-onset type 2 diabetes as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent).
- Consider an assessment for bariatric surgery for people of Asian family origin who have recent-onset type 2 diabetes at a lower BMI than other populations (see [adults](#) in the path on identifying people who are overweight or obese) as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent).

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## 6.3. [Obesity Overview](#)

### 6.3.1. When to refer for specialist weight management advice

Referrals will be accepted for patients who are permanently registered with a General Practitioner in Hartlepool, Stockton on Tees, Middlesbrough & Redcar & Cleveland. Appropriate referrals will be accepted by the service from GPs, medical consultants and other suitably qualified professionals

#### Accessing the service

The access criteria for the service will be:

- Those with a BMI  $\geq 40$

OR

- with a BMI  $\geq 35$  with significant co-morbidities such as:
  - diabetes
  - hypertension
  - heart disease
  - severe respiratory disease including COPD/ severe asthma – under Specialist Consultant or Secondary Respiratory Care @ Hospital
  - sleep apnoea
  - severe hyperlipidaemia
  - Polycystic Ovarian Syndrome (PCOS)

AND

- who are aged 16+ and who can take charge of their meals, eating, cooking etc.
- who are assessed as “ready to change” using an evidence based assessment tool
- who have had previous attempts at weight loss either in primary care; community weight management programmes; exercise programmes or anti-obesity medication for a minimum of 6 months
- whose GP has completed a metabolic and endocrine assessment recently and can show the patient’s underlying endocrine diagnosis is stable and any secondary causes of obesity can be excluded (including thyroid stimulating hormone within 6 months, blood glucose and/or HbA1c, full blood count, renal and liver function)
- Patients returning to the service post discharge from Bariatric Surgery.

#### How to refer:

Referral can be made by completion of the [referral form](#) sent via [secure email](#) to the single point of referral based at Specialist Weight Management Service, Langbaugh House, Bow Street, GUISBOROUGH, TS14 7AA Tel 01287 284479 or Email [rc-pct.SWMS@nhs.net](mailto:rc-pct.SWMS@nhs.net)

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### 6.3.2. Interventional procedures

NICE has published guidance on the following procedures:

- [implantation of a duodenal–jejunal bypass sleeve for managing obesity](#), which should only be used in the **context of research**
- [laparoscopic gastric plication for the treatment of severe obesity](#) with **special arrangements** for clinical governance, consent and audit or research

### 6.3.3. Sources

The NICE guidance that was used to create this part of the pathway.

- [Obesity: identification, assessment and management of overweight and obesity in children, young people and adults](#) (2014) NICE guideline CG189
- [Implantation of a duodenal–jejunal bypass sleeve for managing obesity](#) (2013) NICE interventional procedure guidance 471
- [Laparoscopic gastric plication for the treatment of severe obesity](#) (2012) NICE interventional procedure guidance 432

## 6.4. Physical Exercise

Physical exercise should be taken every day to every 2 days for optimum effect. The physical activity should be distributed over at least 5 days. Diabetes UK recommend:

- ‘Adults and older people: 150 minutes (two and half hours) each week of moderate- to vigorous-intensity physical activity. Muscle-strengthening activity should also be included twice a week

Activity can be spread out through the day into bite-size chunks. One way to do your recommended 150 minutes of weekly physical activity is to do 30 minutes on five days a week with no more than 2 consecutive days without physical activity.

- Examples: brisk walking for 30 minutes per day, active swimming for one hour three times a week; activity at work, getting to and from work; activity during domestic activities and hobbies all contribute to a physical exercise programme
- Unless contraindicated, people with type 2 diabetes should be encouraged to perform resistance exercise 3 times per week, targeting all major muscle groups. This should progress to 3 sets of 8 to 10 repetitions at a weight that cannot be lifted more than 8 to 10 times
- Patients should be advised that:
  - Exercise may increase the risk of acute and delayed hypoglycaemia
  - Alcohol may exacerbate the risk of hypoglycaemia after exercise
  - People with diabetes may need advice on extra blood testing in the context of exercise
  - Exercise may cause foot damage (patients should receive appropriate advice on foot care & exercise)
  - In those with ischaemic heart disease medical advice should be sought

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Each Local Authority offers physical activity support – information can be found on the local authority websites or by contacting:

- <https://www.stockton.gov.uk/health-and-wellbeing/> Tel: 01642 393939
- <https://smarttools.change4life.co.uk/>
- [http://www.hartlepool.gov.uk/info/100009/leisure\\_and\\_culture/1570/health\\_and\\_wellbeing](http://www.hartlepool.gov.uk/info/100009/leisure_and_culture/1570/health_and_wellbeing)
- Tel: 01429 266522 (general enquiries) 01429 284363 (Exercise For Life Programme)

## 6.5. Recommended lifestyle measures for prevention of type 2 diabetes

- People with impaired glucose tolerance should begin and continue a program of weight control through healthy eating, including at least 150 minutes per week of moderate to vigorous physical activity
- For long-term maintenance of major weight loss ( $\geq 13.6$  kg or 30 lb), larger volumes of exercise (7 hours per week of moderate or vigorous aerobic physical activity) may be helpful

*American Diabetes Association (ADA) consensus statement regarding exercise for patients with type 2 diabetes. Diabetes Care. 2006;29:1433-1438*

## 6.6. Stopping Smoking

Patients need to be aware that smoking increases the risk of cardiovascular disease and the risk of all of the microvascular complications of diabetes. Smoking cessation advice should be offered. NICE recommend that either of the following nicotine replacement therapy, Bupropion (NICE TAG 39) or Varenicline (NICE TAG 123) should be offered to smokers who have expressed a desire to quit smoking and commits to a target stop date. Therapy is chosen according to the smoker's likely concordance, availability of counselling and support, previous experience of smoking cessation aids, contraindications or adverse effects and the smoker's preference.

NICE public health guidance 10 states that healthcare professionals who prescribe nicotine replacement therapy (NRT), varenicline or bupropion should offer advice, encouragement and support including referral to an evidence-based smoking cessation service. Pharmacotherapy should normally be prescribed as part of an abstinence contingent treatment, in which the smoker makes a commitment to stop smoking on or before a particular date. NICE technology appraisal guidance 123 states that varenicline should normally be prescribed only as part of a programme of behavioural support.

NICE public health guidance 10 states that neither varenicline nor bupropion should be offered to young people under 18. Professional judgement should be used to decide whether or not to offer NRT to young people over 12 years who show clear evidence of nicotine dependence. If NRT is prescribed, offer it as part of a

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supervised regime. Varenicline or bupropion may be offered to people with unstable cardiovascular disorders who smoke, subject to clinical judgement.

NICE public health guidance 26 states that there should be a discussion about the risks and benefits of NRT with pregnant women who smoke. Nicotine replacement therapy should be offered if smoking cessation without NRT fails, or practitioner judgement should be used if women express a clear preference for NRT. Neither varenicline nor bupropion should be offered to pregnant or breastfeeding women.

It is important that people who smoke who receive pharmacotherapy receive a full course, which will vary depending on the individual smoker. A full course for NRT is at least 8 weeks, for varenicline it is at least 12 weeks and for bupropion it is at least 8 weeks. NICE public health guidance 10 outlines that the prescription of NRT, varenicline or bupropion should be sufficient to last only until 2 weeks after the target stop date with subsequent prescriptions given only to people who have demonstrated, on re assessment, that their quit attempt is continuing.

Drugs with a metabolism that is affected by smoking (or stopping smoking) should be monitored, and the dosage adjusted if appropriate.

Quality Outcomes Framework
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SMOK002. The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the preceding 12 months (25 points)
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SMOK005. The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses who are recorded as current smokers who have a record of an offer of support and treatment within the preceding 12 months (25 points)
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# Specialist Stop Smoking Service Prescribing Grid For All Clients Including Pregnant Women And Adolescents 12-18yrs January 2015

## PLEASE NOTE:

- When two products are used in combination a reduced dose of the second product should be prescribed.
- Adolescents 12-18yrs should only receive treatment for 12 weeks. If longer treatment is required medical advice should be sought.
- Pregnant women wishing to use nicotine replacement therapy (NRT) should use NRT patches for 16hrs only. The earlier smoking abstinence is achieved the better.
- Varenicline (Champix) not to be used for clients under 18yrs old or pregnant, or women trying for a baby.

## BLUE/GREEN SHADING PRODUCTS BELOW – DENOTES COST EFFECTIVE TREATMENTS

BRAND	SUPPLIED IN	SUGGESTED REGIME	1 WEEK SUPPLY (as a single product)	RECOMMENDED MAXIMUM (MAX) DOSE <b>Please reduce by half if using as a second product.</b>
NiQuitin 24hr transdermal patch Use as 16hr patch only in pregnancy. Clear or beige coloured.	7 x 21mg 7 x 14mg 7 x 7mg	21mg for 6 weeks 14mg for 2 weeks 7mg for 2 weeks	7 7 7	1 daily 1 daily 1 daily
Nicorette 16hr Invisipatch Opaque coloured.	7 x 25mg 7 x 15mg 7 x 10mg	25mg for 8 weeks 15mg for 2 weeks 10mg for 2 weeks	7 7 7	1 daily 1 daily 1 daily
Nicotinell 24hr patch / round / beige Use as 16hr patch only in pregnancy. Non spirit adhesive. Contains coconut oil.	7 x 21mg 7 x 14mg 7 x 7mg	21mg for 6 weeks 14mg for 2 weeks 7mg for 2 weeks	7 7 7	1 daily 1 daily 1 daily
NiQuitin 2mg or 4mg lozenge Contains 15mg of sodium per lozenge.	36, 72 packs Original or Mint	1 lozenge 1-2hrs for wks 1 - 6 1 lozenge 2-4hrs for wks 7 - 9 1 lozenge 4-8hrs for wks 10 - 12	1 x 72 pack	9–15 max daily dose
NiQuitin minis 1.5mg or 4mg lozenge Contains 3.14mg of sodium. <b>NOT CURRENTLY AVAILABLE</b>	20, 60 pack 1.5mg or 4mg Mint 1.5mg Orange only	1 lozenge 1-2 hourly for wks 1-6 Gradually reduce and stop when using 1-2 daily	2 x 60 pack	8-12 daily max 15/day
Nicotinell 1mg, 2mg or 4mg lozenge Not to be used for children under 18yrs. After the 6 <sup>th</sup> month of pregnancy use only under medical supervision.	12, 96 pack 1mg 36, 96 pack 2mg 96 pack 4mg	1 lozenge 1–2 hourly for up to 3 months (gradually reduce)		8–12 max daily 15 dose (2mg) 8–12 max daily 30 dose (1mg)
Nicorette Cools 2mg or 4mg lozenge	20 pack 2mg 80 pack 4mg (4 x 20)	1 lozenge 1–2 hourly for up to 3 months (gradually reduce)	80 lozenges	8-12 daily max 15
Nicotinell 2mg or 4mg gum Avoid liquorice flavour in pregnancy (glycyrrhizin).	24, 96 pack 2mg or 4mg Fruit, Liquorice, Mint 24, 72 pack 2mg Ice Mint 72 pack 4mg Ice Mint	8-12 pieces/day Reduce at 3 months	1 x 96 pack	2mg – max daily dose = 25/day 4mg – max daily dose = 15/day Max 60mg/day
Nicorette 2mg or 4mg gum	25 pack 2mg or 4mg Fresh Mint, Icy White 105 pack 2mg Original 105 pack 2mg or 4mg Fresh Mint, Icy White, Fresh Fruit	8-12 pieces/day Continue for up to 3 months For clients using 4mg, 2mg may be helpful during withdrawal	1 x 105 pack	2mg & 4mg max daily dose 15/day
NiQuitin 2mg or 4mg gum	12, 24 & 96 packs Mint	8-12 pieces/day Continue for up to 3 months then gradually reduce gum	1 x 96 pack	2mg & 4mg max daily dose 15/day
Nicorette Microtab (refill pack) 2mg tablet	Pack Sizes: (10 per strip) Box of 100	Decrease over 3 months Stop when usage 1-2 per day	Based on 12 per day Low dependence 1 x 100 High dependence 2 x 100	1-2 tablets hourly 8-24 daily Max 40 (80mg)/day
Varenicline (Champix) Suggest taken with food/water to reduce nausea and early evening to reduce insomnia.	Starter Pack (25) Maintenance Pack (28) x 1mg	Days 1-3 – 0.5mg once daily Days 4-7 – 0.5mg twice daily Days 8-14 – 1mg twice daily Days 15 to end – 1mg twice daily	2 weeks treatment Starter pack x 1 or Maintenance pack x 1	Clients who cannot tolerate adverse effects of Champix may have the dose lowered to 0.5mg – B.D. Clients may be weaned off Champix using the starter pack in reverse – weeks 10-12.



CONSIDER BLUE/GREEN SHADED PRODUCTS BEFORE RED SHADED PRODUCTS BECAUSE OF COST IMPLICATIONS				
BRAND	SUPPLIED IN	SUGGESTED REGIME	1 WK SUPPLY (as a single product)	RECOMMENDED DOSAGE <b>Please reduce by half if using as a second product.</b>
Nicorette Inhalator 15mg Cartridge	Refill pack 4, 20, 36 cartridges	Up to 6 cartridges/day weeks 1–8 Reduce by half for weeks 8-10 Stopped by end of week 12	Low dependency 1x 20 High dependency 1x 36	6 max daily
Nicorette Quick Mist (Suitable for use in pregnancy)	1mg mouth spray (150 sprays) (Duo pack available)	Reduce slowly over 12 week period	1 x duo pack	Max 4 sprays/hr Max 64 sprays/day
Nicorette Nasal Spray 10mg/ml Each spray 50ul = 0.5mg nicotine	200 metered sprays/100 doses per unit.	1 spray to each nostril, 2 an hour for 1-8 weeks when required Reduce by half week 8-10 stop by end of week 12	Maximum 2 bottles of nasal spray	Daily limit = 64 sprays

### SPECIAL WARNINGS AND PRECAUTIONS FOR USE

CONDITION	BRAND	MONITORING (Please refer to British National Formulary (BNF) for Individual Manufacturers' Specifications)
Lactation	All products Nicotinell lozenge/gum	NRT is not contraindicated in lactation. Nicotine from smoking and NRT is found in breast milk, but in smaller amounts than through smoking & 2 <sup>nd</sup> hand smoke. Intermittent NRT may minimize the amount in breast milk between administration and feeds – best used just after a breast feed. Use lozenge only on advice from a physician. Nicotinell liquorice gum not to be used.
Stable Cardiovascular Disease	All products  NiQuitin patch, gum & lozenge	In smokers who are hospitalised as a result of myocardial infarction, severe dysrhythmia or CVA and who are considered haemodynamically unstable, treatment should be initiated under medical supervision. SPCs – state once patients are discharged from hospital they can use NRT as normal.
Diabetes Mellitus	All products	Patients should be advised to monitor their blood sugar levels more closely when NRT is initiated as catecholamines released by nicotine can affect carbohydrate metabolism.
Gastro Intestinal Disease	All oral and nasal products	Swallowed nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastritis or peptic ulcers. Oral preparations should be used in these conditions with caution.
Renal/Hepatic Disease	All products NiQuitin lozenge Champix	Clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects. NiQuitin CQ Lozenge contains 15mg of sodium – people on a low sodium diet should take this into account. Moderate to severe renal impairment – champix dose can be reduced. End stage renal failure – champix is not recommended. No champix dosage adjustment required in hepatic impairment.
Phaeochromocytoma and Uncontrolled Hyperthyroidism	All products	Nicotine causes release of catecholamines and should be used with caution in patients with hyperthyroidism and phaeochromocytoma.
Mental Health Problems	All NRT products and Champix	Patients on antidepressants such as fluvoxamine and amitriptyline and antipsychotics e.g. clozapine should be advised that a reduction in dose may be required during smoking cessation. Champix should be discontinued if agitation, depressed mood or behaviour change is observed.

#### COMBINATION THERAPY STOPPING SMOKING

In trials a combination of two different NRTs was more effective than a single product (NICE No. 39). Advise reduced dose of second product. Larger doses of CYP1A2 substrates can be required while smoking to ensure efficacy as tobacco is a CYP1A2 inducer. Doses of commonly used medicines which are substrates for CYP1A2 may require reduction on stopping smoking inc. theophylline, caffeine and many antidepressants and antipsychotics.

#### DANGERS OF NRT OVERDOSE

The minimum lethal dose in a non-tolerant adult is estimated to be 40-60mg. Symptoms include nausea, abdominal pain, sweating, headache and dizziness or in extreme cases hypotension alteration in pulse rate and breathing difficulties. Oxygen treatment may be required. Severe toxicity can occur in children especially on consumption of oral products. Patches should be removed, folded in half adhesive side inwards and disposed of safely.

#### ADDITIONAL HELPFUL INFORMATION:

Nicotinell gum is the only NRT product unsuitable for vegetarians as it contains gelatine. All oral NRT products are sugar free. It is not advisable to drink coffee or sodas 15 minutes prior to using NRT lozenges and gum as this may reduce absorption. It is advisable to take champix medication with food as this can reduce queasiness.

**Note (1) – Please reduce by half if using as a second product. Note (2) –**Please note that the above information is a guide only, developed by **North Tees & Hartlepool NHS Foundation Trust Stop Smoking Service** and is based on Summaries of Product Characteristics (SPCs) at [www.medicines.org.uk](http://www.medicines.org.uk) and British National Formulary (65) December 2014 [www.bnf.org](http://www.bnf.org)

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<b>NRT products</b>	Duration of nicotine replacement therapy (NRT) in people maintaining abstinence from cigarettes is usually 8-12 weeks (depending on which form and dose of NRT is used), followed by a gradual reduction in dose. Use should be restricted to the licensed duration of the form of NRT used [NICE]. More dependent smokers tend to use NRT for longer; if treatment is stopped too soon these people might relapse (McRobbie and McEwen, 2005). NICE states that In trials a combination of two different NRT products was in general more effective than a single NRT for high dependency patients (NICE TAG 39). NRT should be discontinued if the attempt to quit is abandoned [NICE]. All formulations are available on NHS prescription. NRT patches, gum, lozenges, S/L tablets inhalators and nasal and oral sprays are also available for general OTC sale from pharmacies. Patches and gum are suitable first line options.
<b>Transdermal</b>	16-hour and 24-hour preparations, both releasing approximately 1 mg nicotine per hour. Steady-state nicotine levels are achieved 8-10 hours after application.
<b>Oral products</b>	Nicotine absorption via the buccal mucosa, with peak plasma concentration occurring after 20-30 minutes. Oral formulations include gum, inhalator, sublingual tablets, lozenges and Oral spray. Inhalators and oral spray are expensive and therefore not first line choice.
<b>Nasal spray</b>	The most rapidly acting form of NRT available. It is available on NHS prescription and OTC from pharmacies. Due to cost it should not be first line choice, should be reserved for heavier more dependent smokers
<b>Bupropion</b>	Licensed in the UK for use as an aid to smoking cessation in conjunction with behavioural support. It is a relatively weak but selective inhibitor of the neuronal re-uptake of dopamine and noradrenaline. Exact mechanism of action in smoking cessation is unclear; presumed to affect brain pathways of addiction and withdrawal.
<b>Treatment</b>	Recommended treatment dose is 150 mg once a day for 6 days, increasing to 150 mg twice a day (doses at least 8 hours apart). Continue the lower dose of 150 mg once a day if: > 65 years of age, existing hepatic impairment (mild to moderate) or existing renal impairment. Record a baseline BP & monitor periodically during treatment. Advise the person to stop smoking 7-14 days after starting bupropion. Consult latest SPC or BNF for contra-indications and interactions.
<b>Duration</b>	Recommended course 7-9 weeks, if abstinence not achieved at 7 weeks discontinue
<b>Varenicline</b>	Licensed in the UK for use as an aid to smoking cessation for smokers who have expressed a desire to quit smoking. Varenicline should normally be provided in conjunction with counselling and support, but if such support is refused or is not available, it should not preclude treatment (NICE TAG123) Consult latest BNF for contra-indications and cautions in use.
<b>Treatment</b>	Dosing to start 1 to 2 weeks before planned cessation date. 0.5mg once daily for 3 days then 0.5mg twice daily for next 4 days followed by 1mg twice daily for 11 weeks.
<b>Duration</b>	Patients should be treated with varenicline for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment at 1 mg twice daily may be considered (Due to cost our current PCT guidance recommends an interval of at least 3 months.

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## 6.7. Glycaemic Control

### 6.7.1. IDF Global Guideline Clinical Monitoring Recommendations for Standard care

- Site-of-care plasma glucose monitoring at random times of day is not recommended
- Monitor blood glucose control by HbA<sub>1c</sub> every 2 to 6 months depending on level and stability of blood glucose control, and change in therapy
- Provide measurement of HbA<sub>1c</sub>, before clinical consultation
- Communicate the HbA<sub>1c</sub> result to the person with diabetes consider use of Diabetes UK information prescriptions:

<http://medicines.necsu.nhs.uk/download/diabetes-uk-information-prescriptions/>

### 6.7.2. Targets for Glycaemic Control

#### NICE/NSF/DUK/ADA/IDF

- Any improvement in glycaemic control is likely to reduce the risk of diabetic complications: the lower the glycaemia the lower the risk of complications
- In the observational part of the UKPDS an 11mmol/mol lower HbA<sub>1c</sub> was associated with a 21% reduced risk of diabetes related death and 37% reduced risk of microvascular complications

Involve adults with type 2 diabetes in decisions about their individual HbA<sub>1c</sub> target. Encourage them to achieve the target and maintain it unless any resulting adverse effects (including hypoglycaemia), or their efforts to achieve their target, impair their quality of life.

Standard targets may not be relevant to the individual patient; their circumstances, capabilities and willingness to improve control should be taken into account. Children, pregnant women and the elderly require specific consideration.

Adopt an individualised approach to diabetes care that is tailored to the person's needs and circumstances, taking into account their personal preferences, comorbidities, risks of polypharmacy, and their ability to benefit from long-term interventions due to reduced life expectancy. Such an approach is especially important in the context of multi-morbidity.

### 6.7.3. Initial target setting

Set a target HbA<sub>1c</sub> level of **48 mmol/mol (6.5%)** for most adults with type 2 diabetes that is managed either by lifestyle and diet, or by lifestyle and diet in combination with a single drug that is not associated with hypoglycaemia.

If adults with type 2 diabetes achieve an HbA<sub>1c</sub> level that is lower than their target and they are neither on therapy likely to cause hypoglycaemia nor experiencing symptoms of hypoglycaemia, encourage them to maintain it. **[NICE 2015]**

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Highly intensive management to achieve HbA1C levels below 48 mmol/mol is to be avoided out with pregnancy.

Achieving HbA<sub>1c</sub> below diagnostic range should not be described as “no longer having diabetes” since that causes confusion and risks patients disengaging from appropriate long-term monitoring and interventions.

#### 6.7.4. Progressive target setting

Reassess the person's needs and circumstances at each review and consider whether to stop any medicines that are not effective. **[NICE 2015]**

If HbA1c levels rise **to or above 59 mmol/mol** intensify drug treatment, set a new target HbA1c level of **53 mmol/mol**, and reinforce advice about diet, lifestyle and adherence to drug treatment.

Consider relaxing the target HbA1c level on a case-by-case basis for adults with type 2 diabetes: these factors will need particular consideration for people who are older and frail. [new 2015]

Relaxed targets should take into account the potential impact of intensified treatment versus the risks posed by poorer control (thirst, nocturia, dehydration, infections).

Candidates for a relaxed HbA<sub>1c</sub> target of 59 – 75 mmol/mol:

- Those who are unlikely to achieve longer-term risk-reduction benefits (for example, people with a reduced life expectancy where guidelines for managing diabetes towards the End of Life may be useful)
- Those for whom tight glycaemic control poses risks of hypoglycaemia, especially if un-recognised or who would need third party intervention to manage hypoglycaemia
- Those with 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 as part of their job)
- Those for whom intensive management would not be appropriate (for example, people taking multiple drugs for various conditions and people with significant or complex comorbidities)

#### Quality Outcomes Framework

SMOK002. The percentage of patients with any or any combination of the following conditions: CHD, PAD, stroke or TIA, hypertension, diabetes, COPD, CKD, asthma, schizophrenia, bipolar affective disorder or other psychoses whose notes record smoking status in the preceding 12 months (25 points)

DM007. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months (17 points)

DM008. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months (8 points)

DM009. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months (10 points)

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### 6.7.5. Available Hypoglycaemic Therapies: oral and injectable

See prescribing information & BNF for individual products & side effect profiles as they do differ among agents and note updated DVLA guidance as relevant to any driving licence held. [Local preferred choices are found here.](#)

### 6.7.6. Metformin

Metformin is the usual first choice for monotherapy. In UKPDS, metformin in overweight patients with Type 2 diabetes was associated with 32% lower relative risk for any diabetes-related endpoint, 42% for diabetes-related death and 36% for all-cause mortality, in comparison with conventional treatment. There is a reduction in the incidence of obesity related cancer in those patients taking metformin. Therapy should be introduced gradually to minimise GI side effects.

Prolonged release metformin is available in the form of Glucophage SR. Whilst some patients may find this a more acceptable preparation, it is more expensive. Consider a trial when GI tolerability prevents continuation of standard metformin.

- A liquid formulation of metformin is available if needed.
- Caution should be exercised in renal impairment and liver disease.
- Review dose if serum creatinine >130 micromol/l or eGFR < 45 ml/min/1.73 m<sup>2</sup>.
- Stop metformin if serum creatinine >150 micromol/l or eGFR < 30 ml/min/1.73 m<sup>2</sup>. Prescribe with caution for those at risk of sudden deterioration in kidney function.

### 6.7.7. Sulfonylurea

A sulfonylurea is considered first line in the non-obese, if metformin is not tolerated or is contraindicated or if rapid symptom control is needed (NICE). Add as second line if blood glucose control remains or becomes inadequate with metformin unless there are significant concerns regarding metabolic syndrome or risk of hypoglycaemia.

The common sulfonylureas used locally are Gliclazide and Glipizide. Glibenclamide should **not** be used due to increased risk of hypoglycaemia. A once daily long acting sulfonylurea can be used if concordance is a problem.

Caution is needed with all sulfonylureas when used in mild to moderate hepatic and renal failure. Tolbutamide may be used in renal impairment (as may gliclazide) but careful monitoring of blood glucose concentration is essential. Care is required to choose the lowest possible dose that produces adequate control of blood glucose. Any of the drugs in this class can cause hypoglycaemia, particularly if used in combination with 'gliptins or insulin. Patients who are malnourished for any reason or use alcohol in excess are particularly at risk.

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### 6.7.8. Rapid-acting secretagogue

Repaglinide is a short acting agent, with similar pharmacological structure to sulfonylureas, licensed for monotherapy or in combination with metformin but has a limited indication for patients with erratic lifestyles where glycaemic control has proven difficult with other oral drugs.

### 6.7.9. Glitazone

This class of drug enhances peripheral glucose uptake, particularly into fat cells, with additive effects to SUs, metformin and insulin. Pioglitazone can be used as monotherapy when metformin is contraindicated or not tolerated. This may be particularly appropriate in the obese, especially South Asian patients (*Association of British Clinical Diabetologists Position Statement on Glitazones, September 2004*).

Glitazones can take up to 12 weeks to reach full effect so are not useful in rapid symptom control. Main side effects are fluid retention leading in some patients to cardiac failure and macular oedema; anaemia; weight gain; and peripheral fractures. They should not therefore be used in patients with cardiac failure, known maculopathy or osteoporosis. There is a small increased risk of bladder cancer associated with pioglitazone use. Pioglitazone should not be used in patients with active or previous bladder cancer, or in those with un-investigated macroscopic haematuria. Pioglitazone should be used with caution in elderly patients as the risk of bladder cancer increases with age. However, in patients who respond adequately to treatment, the benefits of pioglitazone continue to outweigh the risks.

Consider adding Pioglitazone to metformin as alternative to sulfonylurea where risk of hypoglycaemia is particularly relevant; adding to sulfonylurea if metformin not tolerated; and to combined metformin plus sulfonylurea where insulin is likely to be unacceptable or ineffective due to hypoglycaemic risk, employment considerations, needle anxiety or obesity/metabolic syndrome. Pioglitazone should only be continued if HbA<sub>1c</sub> is reduced by > 5 mmols/mol in six months.

Triple therapy (metformin, glitazone, sulfonylurea) is clinically effective. Triple therapy may be useful temporarily if a sulfonylurea has been introduced because of hyperglycaemic symptoms. Consider gradual sulfonylurea withdrawal in these patients after full effect of glitazone has been achieved (>12 weeks) to minimise weight gain.

Multiple drug therapy can result in reduced concordance. Combination preparations may therefore be useful once doses of individual drugs have been titrated if their use reduces number of tablets or dose frequency. Pioglitazone/Metformin (Competact) combination is available.

Pioglitazone is also licensed for combination with insulin in type 2 diabetes mellitus patients with insufficient glycaemic control on insulin, but the risk of oedema and heart failure is increased.

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### 6.7.10. Acarbose

Acarbose is licensed for monotherapy, but has limited glycaemic efficacy and is not well tolerated due to GI upset. Some centres do use it in combination with insulin.

### 6.7.11. Incretin mimetics and enhancers

**Incretin (GLP-1) mimetics and enhancers** (gliptins, DPP-4 inhibitors) have the potential to improve glucose control with minimal risk of hypoglycaemia. They promote glucose-dependent peptide-mediated insulin secretion and lower glucagon secretion. Either class may be used in combination with some other oral hypoglycaemic agents. **Do NOT combine incretin mimetics with enhancers as there is no pharmacological justification.**

**Incretin mimetics** are licensed for use in combination with oral agents and with insulin. Consider adding to metformin and a sulfonylurea if HbA<sub>1c</sub> remains at or above 59 mmol/mol AND BMI > 35 kg/m<sup>2</sup> for Europids (lower BMI can be used for other ethnic groups) with problems associated with high weight OR BMI < 35 kg/m<sup>2</sup> for Europids (lower BMI can be used for other ethnic groups) where insulin is unacceptable because of occupational implications or weight loss would benefit other co-morbidities. Incretin mimetics should only be continued if reduction in HbA<sub>1c</sub> is ≥ 11mmols/mol and weight loss is ≥ 3% of initial body weight after six months of treatment.

Incretin mimetics should not be used if there is a history of acute pancreatitis and should be withdrawn if the patient develops symptoms or signs of acute abdomen or pancreatitis: persistent, severe abdominal pain. Patients should be informed of the characteristic symptom of acute pancreatitis. Risk factors for pancreatitis such as hypertriglyceridaemia or alcohol excess should be considered in the initial assessment. If pancreatitis is suspected, therapy should be discontinued and glucose control managed through other means.

Incretin mimetics should be used with caution in cardiac failure. Patients with inflammatory bowel disease and diabetic gastroparesis may have difficulty with transient gastrointestinal adverse reactions, including nausea, vomiting and diarrhoea. Thyroid adverse events, including increased blood calcitonin, goitre and thyroid neoplasm have been reported in liraglutide clinical trials in particular in patients with pre-existing thyroid disease so it should therefore be used with caution.

Combining incretin mimetics therapy with insulin should be supervised by a specialist and ideally be used in combination with once or twice daily basal insulin (NPH, Levemir or Lantus) rather than mixed insulins. Patients on mixed insulins or basal bolus regimens should change to basal insulin before the initiation of incretin mimetic.

Lixisenatide, liraglutide, exenatide and dulaglutide are injectable GLP-1 preparations and their differing half-lives mean they are suited to differing patient characteristics in

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terms of hyperglycaemia pattern so they are classified Green HI – hospital specialist initiation.

**Lixisenatide** is a once daily preparation licensed for use in combination with metformin, sulfonylurea or pioglitazone or basal insulin, or both, when adequate glycaemic control has not been achieved with these drugs; it should not be used in combination with both basal insulin and a sulfonylurea because of an increased risk of hypoglycaemia.

**Liraglutide** is a once daily preparation licensed for use in combination with sulfonylurea or metformin monotherapy, when control is not achieved with maximal doses of the primary hypoglycaemic agent, or as a third line agent in combination with metformin plus sulfonylurea or metformin plus thiazolidinedione. It can also be used with basal insulin therapy.

**Exenatide** can be used with basal insulin, with or without metformin and/or pioglitazone.

**These are only to be used in combination with insulin with specialist care and advice and on-going support from a consultant-led multi-disciplinary team.**

#### **6.7.12. Weekly Incretin (GLP-1) mimetic options**

Weekly preparations can be used when concordance issues have been identified or to fit with a varied lifestyle when the impact of a daily preparation has been demonstrated. **They should not be used first line.**

- **Exenatide** once weekly preparation can be used with basal insulin, with or without metformin and/or pioglitazone.
- **Dulaglutide** is a once weekly preparation licensed for use in combination with metformin, sulfonylurea or pioglitazone, or basal insulin, when adequate glycaemic control has not been achieved with these drugs; it should not be used in combination with both basal insulin and a sulfonylurea because of an increased risk of hypoglycaemia.

**Exenatide and Liraglutide are the only two GLP-1s currently approved for local use.**

#### **6.7.13. Incretin enhancers: gliptins, DPP-4 inhibitors**

If a gliptin is to be used, NICE guidance advises selection based on the appropriate licensed indications, with the lowest acquisition cost. Consider gliptin if: BMI > 30 kg/m<sup>2</sup> for Europids (lower BMI relevant for other ethnic groups); problems arising from body weight; HbA<sub>1c</sub> ≥ 59mmol/mol despite metformin; or if glitazone or insulin would otherwise be started. Gliptins should only be continued if HbA<sub>1c</sub> is reduced by > 5mmol/mol in six months. There are differences between the drugs in terms of use in renal dysfunction.

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The DPP-4 inhibitors **alogliptin, sitagliptin, vildagliptin, saxagliptin and linagliptin** are oral agents. **Local first line choice is alogliptin.**

All are licensed for use as monotherapy (if metformin inappropriate).

**Alogliptin, sitagliptin, vildagliptin and saxagliptin** are licensed for use in combination with metformin or a sulfonylurea (if metformin inappropriate) or pioglitazone, when treatment with either metformin or a sulfonylurea or pioglitazone fails to achieve adequate glycaemic control.

**Linagliptin** is licensed for use in combination with both metformin and a sulfonylurea, when dual therapy with these drugs fails to achieve adequate glycaemic control but not for use with pioglitazone.

The combination of gliptin and insulin (with or without metformin) is also licensed for use when stable dose of insulin has not provided adequate glycaemic control.

#### **6.7.14. Sodium–glucose co-transporter-2 inhibitors**

SGLT2 is a low-affinity, high-capacity sodium coupled glucose transporter located on the luminal side of the renal proximal tubule and accounts for most glucose reabsorption in the kidneys. By selectively and reversibly inhibiting SGLT2, this class of agent lowers blood glucose in people with type 2 diabetes by: blocking the reabsorption of glucose in the kidneys and promoting excretion of excess glucose in the urine, creating a diuretic effect. Efficacy therefore is dependent on kidney function. Caloric loss in urine is associated with modest weight loss and reduced abdominal obesity.

Taking SGLT2 inhibitors is associated with an increased risk of mild to moderate urogenital tract infections, which must be explained in detail before commencing therapy, particularly in patients who are sexually active. There are no long-term data on the effects of SGLT2 inhibitors on macrovascular disease, diabetes-related complications and mortality but therapy may be associated with raised cholesterol.

The FDA Adverse Event Reporting System (FAERS) has identified an increased risk of diabetic ketoacidosis (DKA), ketoacidosis, or ketosis requiring hospital intervention in patients treated with SGLT2 inhibitors. Key features were:

- Metabolic acidosis accompanied by elevation in urine or serum ketones but not associated with high glucose levels typical of diabetic ketoacidosis
- Potential diabetic ketoacidosis (DKA) triggering factors identified in some cases included acute illness (e.g., urinary tract infection, urosepsis, gastroenteritis, influenza, or trauma), reduced caloric or fluid intake, and reduced insulin dose
- Potential factors contributing to the high anion gap metabolic acidosis identified in some cases included hypovolemia, acute renal failure, hypoxemia, reduced oral intake, and a history of alcohol use

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- Approximately half of the cases did not identify a typical DKA triggering factor or alternative explanation for the metabolic acidosis
- One third of cases related to off-label use in Type 1 DM

SGLT2 inhibitors are licensed for use as monotherapy or as dual therapy in combination with metformin or a sulfonylurea in patients who are not able to be adequately controlled with metformin and a sulfonylurea. **Use in dual therapy with Metformin only if an SU is contraindicated or not tolerated or the person is at significant risk of hypoglycaemia or its consequences.** SGLT2 inhibitors as monotherapy have a low risk of hypoglycaemic events. There is a risk of hypoglycaemia when combined with sulfonylurea:

- Use in Type 1 diabetes is absolutely contra-indicated
- Care in elderly
- Cautious if poor eater or low weight
- Cautious if alcohol excess
- Cautious if renal function deteriorating
- Cautious if cardiac disease especially if on loop diuretics
- Cautious if antihypertensive therapy includes ACE inhibitor, ARB or thiazide diuretic
- Cautious if adding to sulfonylurea or insulin

The available SGLT2 inhibitors **Canagliflozin**, **Dapagliflozin** and **Empagliflozin** have differing licensing considerations based on age and renal function, described below. **Local first line choice is Empagliflozin.**

Drug and age restriction	Dose	Renal cut off
Canagliflozin: No upper age restriction	100mg increasing to 300mg depending on effect	No initiation below 60ml/min/1.73m <sup>2</sup> If eGFR drops below 60ml/min/1.73m <sup>2</sup> dose to reduce to 100mg Discontinue if eGFR drops below 45ml/min/1.73m <sup>2</sup>
Empagliflozin:  Not for use if over 85 years old	10mg increasing to 25mg depending on effect  Consider reduction if used in combination with sulfonylurea	No initiation below 60 ml/min/1.73m <sup>2</sup> If eGFR drops below 60ml/min/1.73m <sup>2</sup> dose to reduce to 10mg Discontinue if eGFR drops below 45 ml/min/1.73m <sup>2</sup>
Dapagliflozin:  Not for use if over 75 years old	10mg  5mg if used in combination or in hepatic impairment	Not below 60ml/min/1.73m <sup>2</sup>

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## 6.8. DVLA Guidance regarding hypoglycaemic therapies



Individuals can be fined up to £1,000 if the DVLA is not informed about a medical condition that affects driving and face prosecution if an accident occurs as a result. The DVLA retains the right to suspend or remove any licence if there are significant health concerns such as hypoglycaemia requiring third party intervention.

### 6.8.1. Diabetes treated by tablets or non-insulin injections

Car or motorcycle licence holders are required to notify DVLA if tablets or non-insulin injections risk hypoglycaemia so sulfonylurea therapy is the group of most concern. The use of exenatide, liraglutide or gliptins currently carries no specific driving restrictions for Group 1 (car or motorcycle) licences.

Group 2 drivers are required to notify DVLA if they have diabetes treated with tablets. If they are then started on exenatide, liraglutide or a gliptin they are only required to notify DVLA if this is in combination with a sulfonylurea. The increased risk of hypoglycaemia from exenatide, liraglutide or gliptins when used in combination with sulfonylureas is such that these are felt to be a potentially high risk treatment for drivers holding Group 2 (LGV or PCV) licences and that individual assessment will be required.

Car or motorcycle licence must tell DVLA if tablets or non-insulin injections risk hypoglycaemia via form DIAB1.

Bus, coach or lorry licence holders must fill in: form VDIAB1SG if diabetes is treated by sulphonylurea or glinide tablets OR form VDIAB1GEN if diabetes is treated by any other tablets or non-insulin injections

### 6.8.2. Diabetes treated by insulin

Any patient commencing insulin must declare this to the DVLA. Failure to do so may invalidate insurance and is subject to legal action. Patients transfer to a 3 yearly renewable licence rather than continue with a licence to the age of 70 and each renewal requires a health declaration, either from the patient themselves or from a health professional. People using insulin cannot hold an LGV or PCV licence and must undergo a medical assessment before applying for a C1 licence.

Car or motorcycle licence must tell DVLA if diabetes is treated with insulin via form DIAB1. Bus, coach or lorry licence holders should use form VDIAB1I.

## 6.9. Considering Insulin Transfer

The use of insulin can significantly worsen obesity and thus increase cardiac risk. Concentrating solely on HbA<sub>1c</sub> may not be appropriate for the individual patient in terms of their overall management. Use of insulin may impact on employment, be socially difficult or be practically difficult. In these circumstances

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use of other therapies in combination may be the best option for the patient concerned even though target HbA<sub>1c</sub> may not be achieved.

## 6.10. Insulins

Consider pre-mixed preparations that include short-acting insulin analogues, rather than pre-mixed preparations that include short-acting human insulin preparations, if:

- a person prefers injecting insulin immediately before a meal **or**
- hypoglycaemia is a problem, **or**
- blood glucose levels rise markedly after meals

Consider switching to a long-acting insulin analogue (insulin detemir, insulin glargine) from NPH insulin in people:

- who do not reach their target HbA<sub>1c</sub> because of significant hypoglycaemia, **or**
- who experience significant hypoglycaemia on NPH insulin irrespective of the level of HbA<sub>1c</sub> reached, **or**
- who cannot use the device needed to inject NPH insulin but who could administer their own insulin safely and accurately if a switch to a long-acting insulin analogue were made, **or**
- who need help from a carer or healthcare professional to administer insulin injections and for whom switching to a long-acting insulin analogue would reduce the number of daily injections

Particular forms of employment may be affected and should be discussed before insulin transfer. Employers may not view insulin treatment favourably (e.g. off-shore workers, Armed Forces, dangerous chemical or machinery workers) and shift patterns may be relevant to the choice of regimen or dose timings.

It is not unusual to continue metformin when transferring to insulin but this requires careful consideration of individual needs and the cautions around metformin use. For some individuals it may be appropriate to combine multiple oral agents, including pioglitazone, with insulin but this requires specialist evaluation due to the clinical risks of combination therapies.

Starting insulin requires lengthy consultations and patients may need considerable support in the short term, including out of hours access to advice. When initiating insulin it is important to consider the competences of the team involved. Detailed competences are given in Skills For Health competences Diab\_HA11 & Diab\_HA12 for insulin management (2004). Training is needed in appropriate choice of insulins, choice of injection devices, choice of monitoring devices and insulin dose adjustment. As devices change on a not infrequent basis, the team has to have mechanisms for regular skills updates. Liaison with the Secondary Care team may be valuable both for individual patient referral and in developing training programmes.

[Appendix Eight: Skills for Health Diabetes competences](#)

[Appendix Nine: Choosing the right insulin regimen](#)

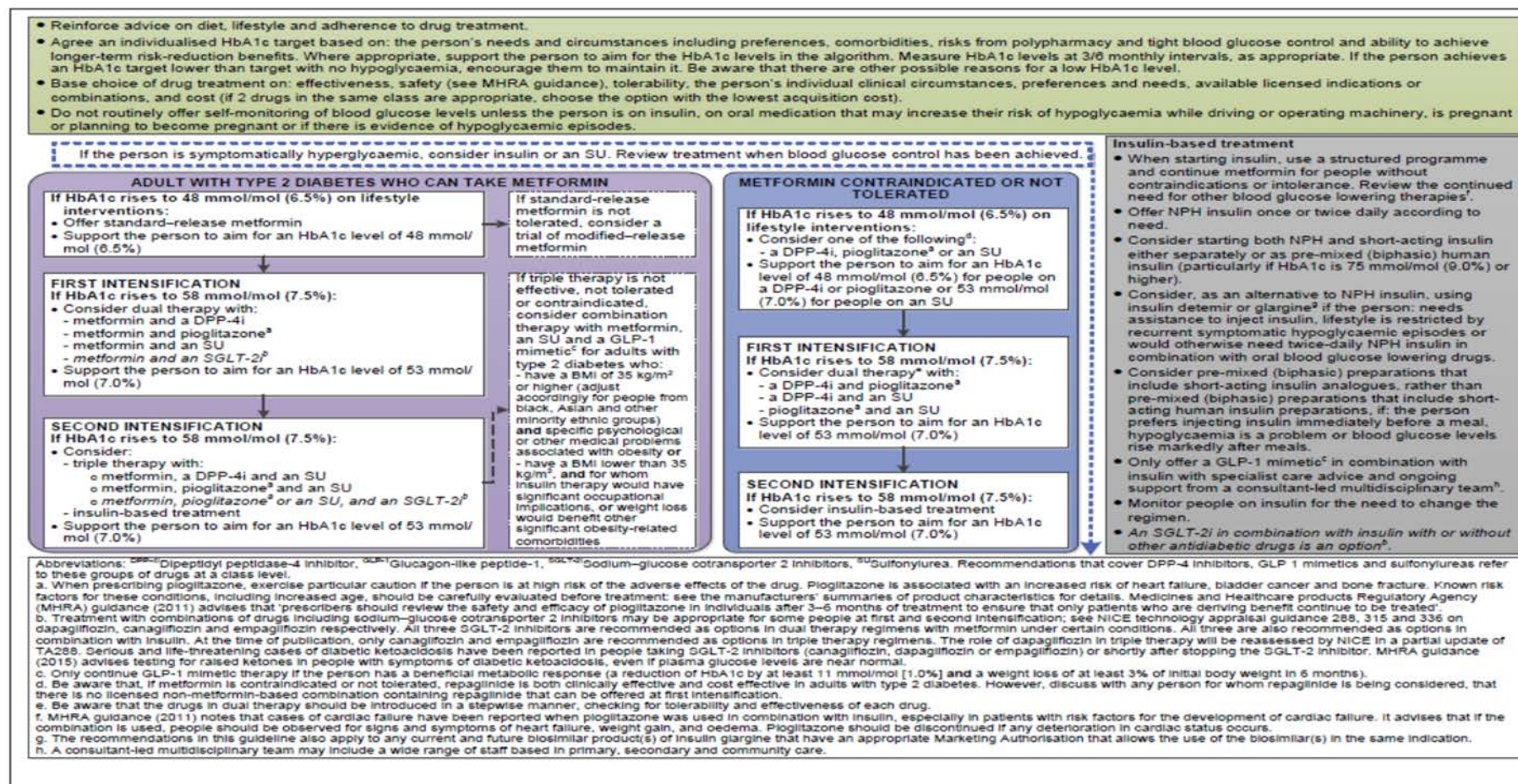
[Appendix Ten: Referral form for Diabetes Specialist Nursing Services \(Stockton on Tees\)](#)

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## 6.11. Treatment Algorithms

### Algorithm for blood glucose lowering therapy in adults with type 2 diabetes



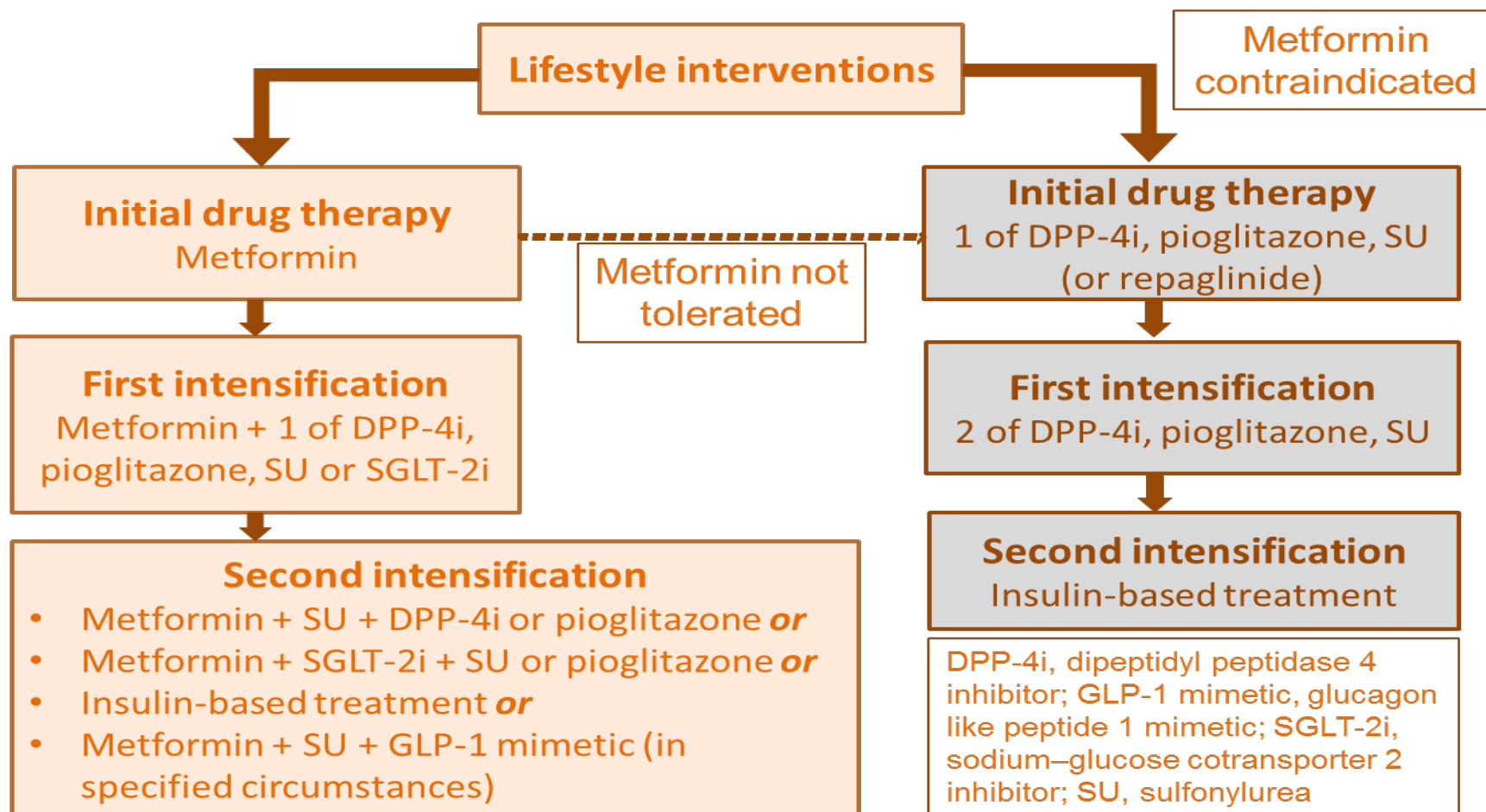
'Type 2 diabetes in adults: management', NICE guideline NG28 (December 2015)

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# Simplified blood glucose lowering pathway

See the guideline algorithm for definitive guidance



## 6.12. Med info

Notes on medicines other than insulin See local formulary for individual drug choices	
Metformin	<p>Benefits of increasing doses of metformin above 2g daily are limited and the BNF recommends a daily max of 2g. Specialist advice may support doses above this range in individual patients.</p> <p>Only oral agent associated with reduced CV risk and weight reduction.</p> <p>► Prescribe with caution for those at risk of sudden deterioration in kidney function and those at risk of eGFR falling below 45ml/min/1.73m<sup>2</sup></p> <p>► Reduce dose if eGFR below 45ml/min/1.73m<sup>2</sup></p> <p>► Stop if eGFR below 30ml/min/1.73m<sup>2</sup></p> <p>Counsel patients to stop temporarily if acutely unwell, particularly with vomiting and diarrhoea</p> <p>Metformin MR – only if intolerant (GI side effects) on standard release metformin</p>
Sulphonylurea	<p>Consider if patient not overweight, if metformin not tolerated or contra- indicated or if rapid response required because of hyperglycaemic symptoms.</p> <p>Do not prescribe gliclazide MR or tolbutamide Treat osmotic symptoms rapidly Contraindicated in pregnancy</p> <p>Risk of hypoglycaemia so patients will have to undertake home glucose monitoring. Educate about risk.</p> <p>No need to check BM routinely unless hypoglycaemia or driving.</p>
Thiazolidinedione (TZD)	<p>Pioglitazone:</p> <p>Contraindications: heart failure, active bladder cancer or history of bladder cancer, un-investigated haematuria, pregnancy</p> <p>Cautions: Increased risk of bone fractures, particularly women Carries long term risk of limb fracture.</p> <p>Caution with liver disease.</p> <p>Rare reports of liver dysfunction – monitor liver function before and periodically during treatment.</p> <p>Start at 15-30mg daily and titrate to 45 mg daily according to response. NICE criteria: Discontinue if reduction in HbA1c is less than 0.5% (5.5 mmol/mol) after 6 months of treatment.</p>
DPP4 inhibitors (Gliptins)	<p>No long term safety data</p> <p>Low risk of hypoglycaemia – useful in patients at risk of hypoglycaemia. Appears to be weight neutral – useful if further weight gain would cause significant problems.</p> <p>Do not use in pregnancy and breastfeeding. Discontinue if symptoms of acute pancreatitis</p> <p>Consider stopping if NICE criteria for continuation not met.</p> <p>NICE criteria: Discontinue if reduction in HbA1c is less than 0.5% (5.5 mmol/mol) after 6 months treatment.</p>

GLP-1 mimetics	<p>Injected therapy</p> <p>Avoid in pregnancy and breastfeeding. Discontinue if pancreatitis suspected</p> <p>Main side effects GI disturbance (especially nausea) ~ 30% of patients</p> <p>Associated with weight loss</p> <p>GLP-1 used in combination with insulin <b>ONLY</b> in specialist care setting</p> <p><b>NICE criteria: Add as part of triple therapy ONLY if BMI is <math>\geq 35\text{kg/m}^2</math> in people of European descent (adjust for ethnic groups) and there are specific psychological or medical problems associated with high body weight, or BMI<math>&lt;35\text{kg/m}^2</math> and insulin is unacceptable because of occupational implications or weight loss would benefit other co-morbidities.</b></p> <p><b>Can be considered in dual therapy with metformin or a sulfonylurea if either metformin, OR a sulfonylurea AND pioglitazone AND DPP-4 inhibitors contra-indicated or not tolerated (only liraglutide and prolonged release exenatide considered by NICE for dual therapy).</b></p> <p><b>Consider stopping if reduction in HbA1c is less than 1% (11 mmol/mol) and there is less than 3% weight loss after 6 months<sup>2</sup> (only HbA1c reduction required for dual therapy)</b></p>
SGLT-2	<p>Caution with thiazide or loop diuretic use.</p> <p><b>Volume depletion</b> – Correct hypovolaemia before starting treatment</p> <p>Consider interrupting treatment if volume depletion occurs</p> <p>Determine renal function before treatment and annually thereafter.</p> <p>Dapagliflozin – avoid if eGFR <math>&lt;60\text{ml/min/1.73m}^2</math></p> <p>Canagliflozin - monitor renal function at least twice a year in moderate impairment; avoid initiation if eGFR less than 60 mL/minute/1.73 m<sup>2</sup>; avoid in combination with metformin if eGFR less than 60 mL/minute/1.73 m<sup>2</sup>; reduce dose to 100 mg once daily if eGFR falls persistently below 60 mL/minute/1.73m<sup>2</sup> and existing canagliflozin treatment tolerated; avoid if eGFR less than 45 mL/minute/1.73m<sup>2</sup></p> <p>Empagliflozin - avoid initiation if eGFR below 60 mL/minute/1.73 m<sup>2</sup>; reduce dose to 10 mg once daily if eGFR falls persistently below 60 mL/minute/1.73 m<sup>2</sup>; avoid if eGFR is persistently below 45 mL/minute/1.73 m<sup>2</sup> NICE criteria:</p> <p>Dapagliflozin, canagliflozin or empagliflozin can be used in a dual therapy regimen in combination with metformin</p> <p>AND</p> <p>In combination with insulin with or without other antidiabetic drugs. Canagliflozin and empagliflozin can be used in a triple therapy regimen in combination with metformin and a sulphonylurea or a thiazolidinedione.</p> <p>Dapagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in adults, only in combination with metformin and a sulfonylurea.</p> <p>Discontinue if reduction in HbA1c is less than 0.5% (5.5 mmol/mol) after 6 months treatment.</p>
Repaglinide	<p>Repaglinide is a short acting agent with rapid onset of action and short duration of activity, with similar pharmacological structure to SUs, it stimulates insulin secretion and is licensed for monotherapy or in combination only with metformin but has a limited indication</p>



Introduction of Insulin for Type 2 diabetes for planned transfer via group sessions or 1:1	
Group approach structured education programme for Insulin start	
<ul style="list-style-type: none"> <li>Type 2 diabetes and insulin management</li> <li>Lifestyle change and healthy eating</li> <li>Management of Hypoglycaemia and Hyperglycaemia (Sick days)</li> <li>Ongoing care</li> <li>2 or 4 sessions according to local arrangements</li> </ul>	
Insulin regime based on individual considerations	
<b>Option 1</b>	Isophane insulin (basal) once or twice daily
<b>Option 2</b>	Pre-mixed insulin (human) twice daily. Most likely required initially if: Symptomatic Short history of diabetes BMI <25kg/m <sup>2</sup> HbA1c >75mmol/mol (9.0%) Start premixed insulin with breakfast and evening meal

**Insulin Dose:** Start with 8 -10 units per dose  
**Titrate:** Increase by 2 - 4 units per dose according to blood glucose profile every 3-7 days (provide written guide for dose titration)  
**Targets:**  
**Needs to be individualised**  
HbA1c <53mmol/mol (7%)  
Blood glucose target  
Fasting: 4 – 7mmol/l  
Pre-meals: 4 – 7mmol/l

**Oral agents**  
Stop TDZ, DPP4 and SU but continue metformin

**Long acting analogues plus oral agents**

Can be used for elderly requiring community nursing support,  
Or if problematic hypoglycaemia (use local guidelines)  
NB Could also use twice daily isophane for elderly patients (stop Sulphonylurea)

**Basal bolus regime**

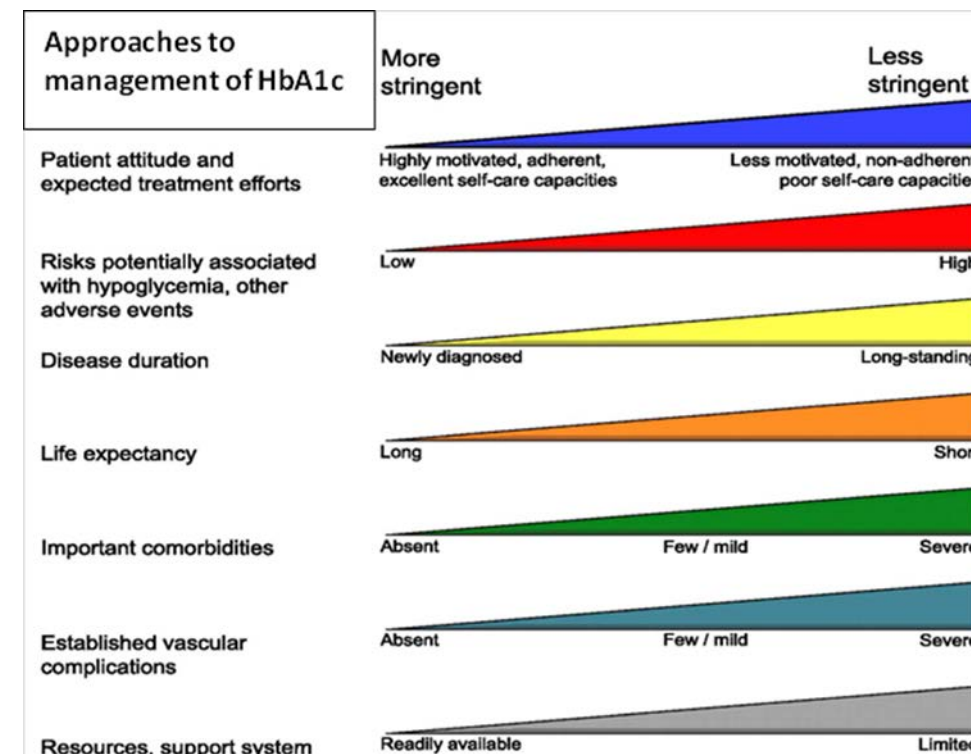
Not routinely used in the management of Type 2 diabetes – seek specialist advice

Isophane insulin	Premixed insulin	Long acting analogue
Insuman Basal Humulin I Insulatard	Insuman Comb Humulin M3	Levemir (Detemir) Lantus (Glargine)

Local preferred choices are found here:

<http://medicines.necsu.nhs.uk/guidelines/tees-guidelines/>

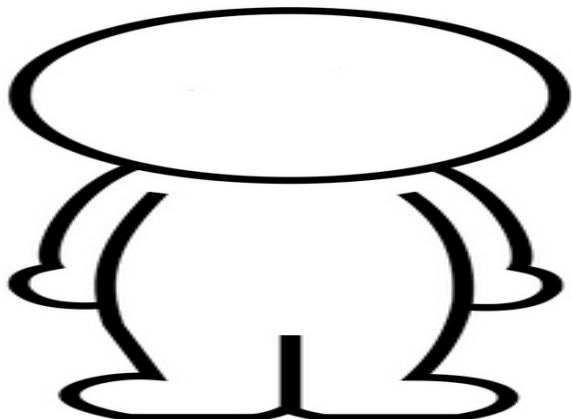
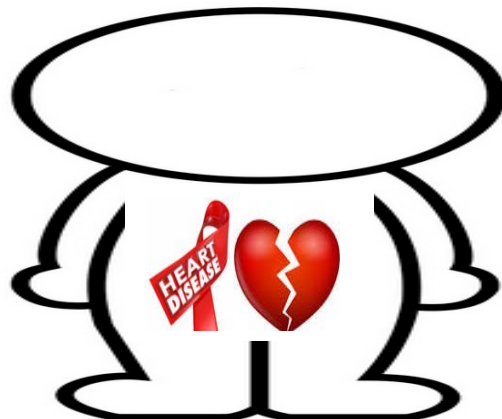
- Type 2 diabetes and insulin management
  - Lifestyle change and healthy eating
- KEY POINTS**
- HbA1c targets and glucose-lowering therapies must be individualized.
  - Diet, exercise, and education remain the foundation of any type 2 diabetes treatment program.
  - Unless there are prevalent contraindications, metformin is the optimal first-line drug.
  - After metformin, there are limited data to guide us. Combination therapy with an additional 1–2 oral or injectable agents is reasonable, aiming to minimize side effects where possible.
  - Ultimately, many patients will require insulin therapy alone or in combination with other agents to maintain glucose control.
  - All treatment decisions, where possible, should be made in conjunction with the patient, focusing on his/her preferences, needs, and values.
  - Comprehensive cardiovascular risk reduction must be a major focus of therapy.





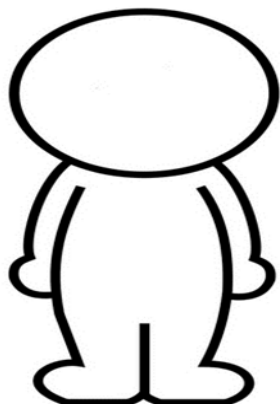
## 6.13. Case Studies

Remember – the newer drugs have been tested mainly in short term trials, looking at proxy end points and against other new drugs or placebo rather than against the established proven therapies such as Metformin or Insulins; evidence proving reduction in mortality or morbidity is awaited and none are better than conventional treatments at controlling blood sugar; **Ask yourself, would this new drug be better than an older drug?**

T2DM/Obese			T2DM Heart failure/IHD		
					
Options	Drugs	Comments	Options	Drugs	Comments
<b>Initial Drug therapy</b>	Metformin	Start slow and go slow	<b>Initial Drug therapy</b>	Metformin	
<b>First intensification</b>	Metformin & Gliptin	GLP-1 mimetics are not cost effective at 1 <sup>st</sup> intensification	<b>First intensification</b>	Gliptin	<b>Caution some evidence of increased HF admissions with saxagliptin</b>
<b>Second intensification</b>	Metformin & gliptin & flozin		<b>Consider Insulin earlier</b>		
<b>or</b>	Metformin & GLP1 (incretin mimetic)	<b>Do not combine GLP1 &amp; gliptin</b>			
Drugs to avoid		Reason	Drugs to avoid		Reason
Sulphonylurea		Weight gain	Sulphonylurea		Weight gain
Pioglitazone		Weight gain	Pioglitazone		Worsens HF

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## T2DM/BMI <30



Options	Drugs	Comments
Initial Drug therapy	Metformin	<b>Even if BMI normal &amp; not obese</b>
First intensification	Metformin & SU	<b>Consider Insulin early</b>
Second intensification	Metformin & SU & Pioglitazone	<b>Unless Contraindicated</b>
Third intensification	Metformin & SU & Pioglitazone & Gliptin	

## Caveats

<b>Metformin:</b>	<ul style="list-style-type: none"> <li>Consider even in non-obese individuals</li> <li>Continue Metformin even if eGFR is 30 but be cautious if concomitant alcohol excess which can lead to increased risk of lactic acidosis</li> <li>Consider monitoring vitamin B12 if unexplained anaemia.</li> </ul>
<b>Sulphonylureas:</b>	<ul style="list-style-type: none"> <li>Hypoglycaemia is a risk especially with drop in eGFR (urinary infection / other infections)</li> <li>Anticipate drop in blood sugar control / hypoglycaemia in patients started on Trimethoprim if control is very good and eGFR is low</li> <li>Avoid starting sulphonylurea in newly diagnosed obese patients (options are weight neutral drugs such as DPP4 inhibitors, SGLT2 inhibitors and GLP1 agonist to supplement Metformin)</li> </ul>
<b>DPP4 Inhibitors:</b>	<ul style="list-style-type: none"> <li>Consider as a weight neutral option</li> <li>Avoid if previous incidence of pancreatitis or recurrent gall stone cholangitis.</li> <li>Review results in 6 months to one year and if compliance is good and control is not improving, especially in patients with greater than 10 years of type 2 diabetes, stop DPP4 inhibitors as it is highly likely that beta cell function is very limited.</li> </ul>
<b>GLP1 Agonist:</b>	<ul style="list-style-type: none"> <li>Monitor progress at 4 months and 6 months and ensure control has improved from start of therapy (6 months, HbA1c improvement by 1% and weight loss 3% from baseline)</li> <li>Avoid in history of pancreatitis, significant alcohol excess and history of gallstone disease</li> <li>Document advice given to patient especially symptoms of pancreatitis, namely pain abdomen, vomiting which can mimic the side effects of the drug itself</li> </ul>
<b>Glitazone:</b>	<ul style="list-style-type: none"> <li>Pioglitazone only currently available drug</li> <li>Avoid if history of heart failure (NYHA 3 or more), osteoporosis and fracture and bladder malignancy including haematuria</li> <li>Increased fracture risk, particularly in elderly women</li> </ul>
<b>SGLT2 Inhibitors:</b>	<ul style="list-style-type: none"> <li>Ensure eGFR is greater than 60 ml/min/1.73</li> <li>Avoid if history of recurrent genital and urinary tract infections</li> <li>Inform patient the side effects as this will improve compliance</li> <li>Inform and document in notes the increased incidence of DKA recently linked with use of SGLT2 inhibitors.</li> <li>Inform the patient of the possibility of DKA even with blood sugar less than 20</li> </ul>

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## Case Scenario One

<b>Patient Detail:</b>	<ul style="list-style-type: none"> <li>• 59 year old travelling salesman with type 2 diabetes, frequent driving and poor diet (sporadic).</li> <li>• Other co-morbidities include COPD (current smoker) with a steroid inhaler</li> <li>• BMI 35</li> <li>• Hypertension with blood pressure 170/80</li> <li>• Ischaemic heart disease with MI 8 years ago with signs of moderate left ventricular dysfunction</li> <li>• eGFR 65 ml/min</li> </ul>
<b>Current medication:</b>	<ul style="list-style-type: none"> <li>• Metformin 1 gm b.d.</li> <li>• Sitagliptin 100 mg daily</li> <li>• Compliance could be better</li> </ul>
<b>Treatment options that are contraindicated:</b>	<ul style="list-style-type: none"> <li>• Glitazones (ischaemic heart disease and heart failure)</li> <li>• Sulphonylurea (weight gain)</li> </ul>
<b>Pharmacological options:</b>	<ul style="list-style-type: none"> <li>• An SGLT2 inhibitor</li> <li>• GLP1 agonist</li> <li>• Basal insulin</li> </ul>
<b>Treatment options include:</b>	<ul style="list-style-type: none"> <li>• Adding SGLT2 to Metformin with frequent reviews (4 monthly)</li> <li>• Lifestyle choices including smoking cessation and improved compliance</li> <li>• Referral to a structured education programme</li> <li>• Frequent reviews and low threshold to progress to insulin given significant cardiovascular risk</li> </ul>
<b>Comments:</b>	<p>This case demonstrates the need for a multi-professional approach with early involvement of secondary care (offering advice) and later on earlier start of insulin if individualised targets are not being met given the significant risk for a vascular event, if control remains poor</p> <p>The aim should be to improve control in less than one year from of start of review.</p>

## Case Scenario Two

<b>Patient Detail:</b>	<ul style="list-style-type: none"> <li>• 52 year old male plumber with frequent drives between jobs and diagnosed to have type 2 diabetes 5 years ago. Due to work pressure declined structured education programme</li> <li>• Erratic lifestyle with poor meals requiring to snack in between jobs, has a "sweet tooth"</li> <li>• Is keen to improve blood sugar control and is now coming around to considering other treatment options</li> <li>• Has a strong family history of ischaemic heart disease and stroke and continues to smoke</li> <li>• BMI 28 with blood pressure satisfactory at 130/70</li> <li>• HbA1c 75 mmol/mol (9%)</li> <li>• Renal functions satisfactory with eGFR &gt; 90</li> </ul>
<b>Current medication:</b>	<ul style="list-style-type: none"> <li>• Metformin 1 gm b.d.</li> <li>• Gliclazide 160 mg b.d</li> <li>• Compliance is good</li> </ul>
<b>Management Review:</b>	<ul style="list-style-type: none"> <li>• Lifestyle choices including healthy dietary options whilst on the move (less sweets in the car and other healthier options)</li> <li>• Smoking cessation and re-referral to a structured education programme</li> <li>• Set individual targets and consider adding a glitazone to Metformin (ensure no signs of heart failure or fracture risk)</li> <li>• Consider adding a DPP4 to Metformin</li> <li>• Another option is a combination of all three over a period of time (Metformin &amp; glitazone &amp; DPP4 inhibitor) with frequent review.</li> </ul>

### Case Scenario Three

<b>Patient Detail:</b>	<ul style="list-style-type: none"> <li>45 year old sales manager diagnosed with type 2 diabetes two years ago and has a busy job including evening school run and children's activities</li> <li>Current BMI 30</li> <li>Satisfactory blood pressure of 132/83</li> <li>HbA1c 70 (8.5%)</li> <li>His renal function is satisfactory with an eGFR &gt;90</li> <li>Good compliance</li> <li>He has been struggling to lose weight with intermittent improvements and drop in weight when joined Weight Watchers</li> <li>Diet and family meals could be healthier</li> </ul>
<b>Current medication:</b>	<ul style="list-style-type: none"> <li>Metformin 1 gm twice daily and has been so for the past 2 years as he missed his last appointment at the surgery for a diabetes review</li> <li>Patient's main concern is weight gain but is motivated to reduce his weight and improve his diabetes control</li> </ul>
<b>Management Review:</b>	<ul style="list-style-type: none"> <li>HbA1c has to be addressed and target set. Suggested target of 65 mmol/mol in 4 months (8%)</li> <li>Set targets for weight including Weight Watchers and a referral to a structured education programme</li> <li>Address lifestyles including dietetic input for healthier eating</li> </ul>
<b>Treatment options include:</b>	<ul style="list-style-type: none"> <li>Sulphonylurea – to avoid as weight gain and risk of hypoglycaemia (frequent driving) and intermittent meals</li> <li>A DPP4 inhibitor – a certain possibility</li> <li>A glitazone – to avoid as once again fluid retention/weight gain is a side effect</li> <li>SGLT2 inhibitor – certainly to be considered</li> <li>GLP1 agonist – once again a definite possibility due to weight loss</li> </ul>
<b>Comments:</b>	Given this gentleman's busy lifestyle the treatment option would be a DPP4 inhibitor with individualised treatment plans as mentioned above and 4 months review.

### Case Scenario Four

<b>Patient Detail:</b>	<ul style="list-style-type: none"> <li>60 year old female with a BMI of 26 diagnosed with type 2 diabetes a year ago and established on Gliclazide 40 mg b.d. with subsequent increase to a maximum of 160 mg b.d. over the past one year.</li> <li>Patient has been complaining of further weight loss over the last 2 months but progressive worsening of blood sugar control associated with malaise, lethargy and back pain.</li> <li>Compliance is good</li> <li>Renal function is satisfactory with an eGFR of 70</li> <li>HbA1c currently 80 mmol/mol compared to 60 four months ago</li> <li>Patient is at a loss as to understand why control has deteriorated so rapidly</li> </ul>
<b>Management Review:</b>	<ul style="list-style-type: none"> <li>This lady's lifestyle and compliance is not being questioned and even with this her control has significantly deteriorated. The red flag features of weight loss and back pain cannot be ignored either</li> <li>The possibilities are sudden deterioration of beta cell function which could be secondary to a head of pancreas lesion or merely a progression of rapid beta cell function loss</li> </ul>
<b>Management Options:</b>	<ul style="list-style-type: none"> <li>Cause of back pain and weight loss needs to be investigated urgently, possibly with CT scan of the abdomen and pelvis under the two week rule.</li> <li>Treatment options are limited and insulin will need to be considered with early referral to secondary care if insulin initiation is not being carried out in the surgery</li> </ul>

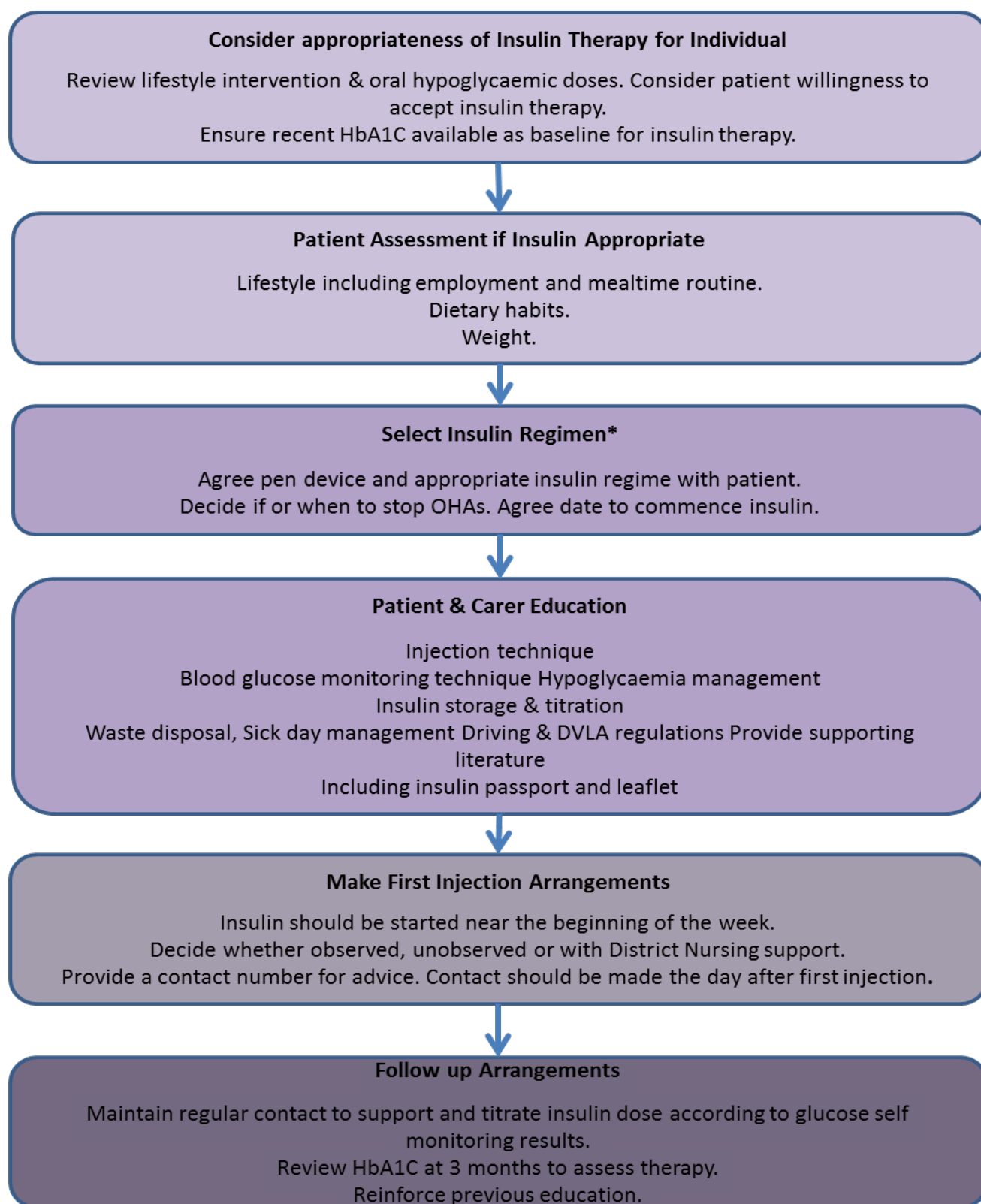
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## Case Scenario Five

<b>Patient Detail:</b>	<ul style="list-style-type: none"> <li>• 48 year old female with an office job in Human Resources diagnosed with type 2 diabetes four years ago and took part in structured education programme (DESMOND) two years ago.</li> <li>• Work pressure has significantly worsened following move into a new team</li> <li>• Lifestyle extremely erratic with frequent take-aways</li> <li>• BMI 32</li> <li>• Good blood pressure control</li> <li>• HbA1c 70 mmol/mol (8.5%)</li> <li>• Normal renal function (eGFR &gt;90)</li> </ul>
<b>Current medication:</b>	<ul style="list-style-type: none"> <li>• Metformin 1 gm b.d.</li> <li>• Maximum dose of Pioglitazone</li> <li>• Patient's main aspiration is to improve diabetes control and improve weight simultaneously addressing lifestyle issues also</li> </ul>
<b>Management Options:</b>	<ul style="list-style-type: none"> <li>• HbA1c and weight need to improve and the patient is well motivated to do this</li> </ul>
<b>Treatment options:</b>	<ul style="list-style-type: none"> <li>• A DPP4 inhibitor and a SGLT2 inhibitor and a GLP1 agonist, all 3 of which will improve weight</li> <li>• Glitazone will need to stop as this is contributing to weight gain</li> <li>• An approach would be to stop the glitazone and add a GLP1 agonist or a SGLT2 inhibitor, both of which could be started in Primary Care</li> <li>• Alternatively, a trial with a DPP4 inhibitor (gliptin) could be considered with Metformin</li> <li>• Individual targets to be set with review in four months' time</li> </ul>

## 6.14. Algorithm for Commencing Insulin in Type 2 Diabetes

### Algorithm for Commencing Insulin in Type 2 Diabetes



## 6.15. Insulin Adjustment and Problem Solving

There are some general guidelines to help you to adjust your insulin doses and resolve problems with your blood glucose levels. **These guidelines relate to 2 injections each day.**

You should only change insulin doses if there is a trend of three or more high or low blood glucose levels. It is important to only change one of the doses of insulin at a time and to wait for 2-3 days before making any further changes. If the blood glucose levels do not respond as you expected, please ring a member of the Diabetes Team for advice.

Problem			Solution
<b>High</b>	blood sugar	Pre <b>Breakfast</b>	Put <b>pm</b> insulin <b>up</b> by: 1-2 units
<b>Low</b>	blood sugar	Pre <b>Breakfast</b>	Put <b>pm</b> insulin <b>down</b> by: 1-2 units
<b>High</b>	blood sugar	Pre <b>Lunch</b>	Put <b>am</b> insulin <b>up</b> by: 1-2 units
<b>Low</b>	blood sugar	Pre <b>Lunch</b>	Put <b>am</b> insulin <b>down</b> by: 1-2 units
<b>High</b>	blood sugar	Pre <b>Tea</b>	Put <b>am</b> insulin <b>up</b> by: 1-2 units
<b>Low</b>	blood sugar	Pre <b>Tea</b>	Put <b>am</b> insulin <b>down</b> by: 1-2 units
<b>High</b>	blood sugar	Pre <b>Bed</b>	Put <b>pm</b> insulin <b>up</b> by: 1-2 units
<b>Low</b>	blood sugar	Pre <b>Bed</b>	Put <b>pm</b> insulin <b>down</b> by: 1-2 units
<b>Low</b>	blood sugar	Pre <b>Bed</b> and during night, then <b>High</b> Pre <b>Breakfast</b>	Put <b>pm</b> insulin <b>down</b> by: 1-2 units
Hypo – after or during exercise			Give extra sugary snack before exercise, extra starch afterwards and possibly reduce insulin by 1-2 units if exercise is very strenuous
Blood glucose going up and down – no pattern			Major food and insulin changes. Make earlier clinic appointment. Contact Diabetes Team.
Blood glucose high after meals then zooming down low. Hypos with no pattern or reason			Try changing the injection site and reduce the insulin. Contact the Diabetes Team

## 6.16. Insulin used in North Tees and Hartlepool

Insulin Names	Clear/Cloudy	Specific to meal times	Disposable pen device	Cartridge and Insulin pen
<b>Actrapid</b>	Clear	No – For use with IV therapy only	No 10 ml vial only	No
<b>ASPART/Novorapid®</b>	Clear	Yes, just before or just after breakfast, lunch and evening meal	Yes FlexpenFlextouch	Yes Novopen
<b>LISPRO/Humalog®</b>	Clear	Yes, just before or just after	Yes KwikPen	Yes Savvio Pen

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		breakfast, lunch and evening meal		
Novomix 30	Cloudy	Yes, just before breakfast and evening meal	Yes Flexpen	Yes Novopen
Humalog Mix 25 Humalog Mix 50	Cloudy	Yes, just before breakfast and evening meal	Yes KwikPen	Yes Savvio
Humulin M3	Cloudy	Yes <b>20-30 mins before</b> breakfast and evening meal	Yes KwikPen	Yes SavvioPen
Humulin S	Clear	Yes, 15-30 mins before breakfast, lunch and evening meal	No	Yes AutoPen Classic or SavvioPen
Humulin I	Cloudy	No	Yes KwikPen	Yes AutoPen Classic or SavvioPen
Abasaglar (glargine)	Clear	No	Yes KwikPen	Yes Autopen Classic
<b>DETEMIR</b> /Levemir ®	Clear	No	Yes Flexpen	Yes Novopen
<b>GLARGINE</b> /Lantus ®	Clear	No	Yes SoloStar	Yes Clickstar
Insulatard	Cloudy	No	Yes Innolet	Yes Novopen

High concentration insulins	<b>Not yet considered for local use</b>			
Degludec – <b>not yet considered for local use</b>	Clear	No	Yes Flextouch	No

The NICE Guideline Development Group agreed that there was strong evidence to indicate that insulin degludec was not cost-effective and therefore was confident that this option should not be recommended in T2DM.

## 6.17. Managing Cardiovascular Risk Factors

Type 2 diabetes is a cardiovascular disease associated with hyperglycaemia.

Cardiovascular disease is the major cause of death in people with diabetes. It is therefore important to manage cardiovascular risk factors as well as improving glycaemic control. Lifestyle intervention, lipid management, blood pressure management and use of low dose aspirin should be considered (NICE, UKPDS). People with diabetes over 50 or who have over 10 years' duration of known diabetes have a cardiovascular risk similar to non-diabetic patients post MI. The QRISK2 risk engine can be useful for those patients under 50 years to estimate 10-year cardiovascular event risk and the need for therapy, but for older patients the excess risk is high enough to justify intervention with statins and to consider aspirin. Diabetes can be associated with silent cardiac ischaemia so risk assessment should include an ECG.

### 6.17.1. Blood Pressure Management in Type 2 Diabetes

#### NSF/NICE/UKPDS/BHS

Hypertension is associated with an increased risk of many complications of diabetes, including cardiovascular disease.

- 40-60% of people with Type 2 diabetes (aged 45-75) have hypertension
- The majority will need combination therapy to meet BP targets
- Tight BP control reduces the risk of any diabetic complications and of diabetes related death
- Tight BP control confers more benefit than tight glucose control in reducing complication risk

### 6.17.2. Targets for BP Control

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 disease).

- With the increasing prevalence of Type 2 diabetes in younger people, it must be remembered that the NICE target of 140mmHg systolic is well above the 75<sup>th</sup> centile for men under 30 and women under 40 years of age. Even the BHS “optimal” target is above the 75<sup>th</sup> centile for 20 year old females
- Aggressive management of hypertension also increases the risk of postural hypotension, particularly in the elderly. Any reduction in blood pressure, even though target levels are not achieved, is still worthwhile in terms of reducing risk of vascular events. Standard targets may be quite unsuitable.

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## 6.18. Management of Hypertension in adults with Type 2 Diabetes

### 6.18.1. Lifestyle Management

Management of blood pressure should include lifestyle interventions which have a blood pressure lowering effect: weight management, salt intake, alcohol use, physical activity.

Smoking cessation should be discussed in terms of the increased risk of cardiovascular disease and microvascular complications of diabetes.

## 6.19. Drug Therapy

- Thiazide-related diuretics, beta-blockers, ACE inhibitors and angiotensin 2 receptor antagonists (AIIA/ARB) have all been shown to reduce cardiovascular mortality and morbidity in Type 2 diabetes
- Beta-blockers are no longer preferred as a routine initial therapy for hypertension (BHS, NICE)
- Thiazides carry theoretical risk of worsening glycaemia and hyperlipidaemia, but the benefits in terms of systolic reduction outweigh the risks
- The presence or absence of complications can guide the choice of first line agent
- Drugs may be introduced for dual effect on blood pressure and angina
- ACEI or ARBs may cause a rise in serum creatinine, treatment should be carefully monitored and reviewed if significant deterioration in renal function
- Combination therapy is no longer recommended
- An EU review recently concluded that combination use of medicines from two classes of RAS blocking agents is not recommended. The review identified evidence from large clinical trials such as ONTARGET, ALTITUDE and VA NEPHRON-D and from meta-analyses such as Makani 2013. These studies showed that combination use was associated with an increased risk of hyperkalaemia, hypotension, and impaired renal function compared with using either class of RAS blocking agent alone. No significant benefits of combination use were seen in patients who did not have heart failure.
- If combination use is considered absolutely necessary, it must be carried out under specialist supervision and with close monitoring of blood pressure, renal function, and electrolyte levels (particularly potassium). Consider monitoring patients when combination use is started and on a monthly basis thereafter, and also after changing dose and during intercurrent illness likely to be needed and may be helpful in maintaining electrolyte balance
- The balance of current evidence suggests that alpha blockers are not suitable as first line agents but can be useful in combination. There is no evidence of benefit of Doxazosin MR preparation over standard preparation though number of tablets may be an issue at high doses

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**Quality Outcomes Framework**

DM002. The percentage of patients with diabetes, on the register, in whom the last blood pressure measured in the preceding 12 months, is 150/90mmHg or less (points 8, max threshold 93%)

DM003. The percentage of patients with diabetes, on the register, in whom the last blood pressure measured in the preceding 12 months, is 140/80mmHg or less (points 10, max threshold 78%)

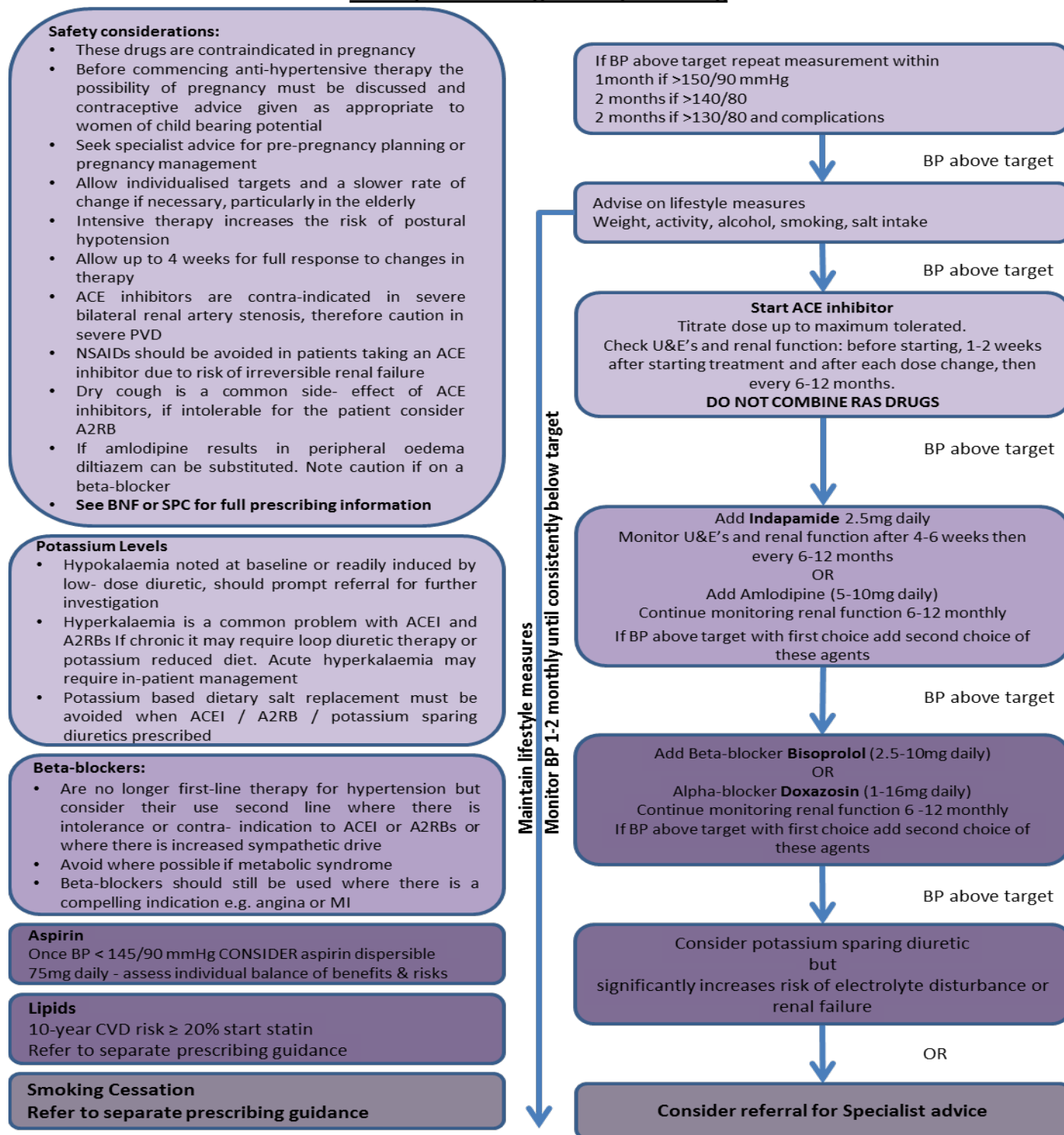
DM006. The percentage of patients with diabetes, on the register, with a diagnosis of nephropathy (clinical proteinuria) or micro-albuminuria who are currently treated with an ACE-I (or ARBs) (points 3, max threshold 97%)

## 6.20. Algorithm for Management of Hypertension in Type 2 Diabetes

### Algorithm for Management of Hypertension in Type 2 Diabetes

**Target <130/80 mmHg with retinopathy, cerebrovascular disease or microalbuminuria**

**Other patients Target <140/80 mmHg**



## 6.21. Lipid Management for Adults with Type 2 Diabetes

### 6.21.1. NSFs for Diabetes, CHD, Older Persons / NICE / HPS / CARDS

- Raised blood lipid levels are known to be a risk factor for coronary heart disease
- Management of blood lipid levels can add to reduction in cardiovascular risk in Type 2 diabetes
- All patients with Type 2 DM, irrespective of age and initial cholesterol levels should be considered for treatment with a statin unless clearly at low cardiovascular risk or statins are contraindicated
- Consideration must be given to pre-pregnancy planning in women of child bearing age and caution exercised in managing people under 18 years

### 6.21.2. Targets and Treatment

Patients with Type 2 diabetes are considered to be at high risk of cardiovascular disease, requiring secondary prevention therapies, unless *all* of the following apply:

- Not overweight
- Normotensive in the absence of anti-hypertensive therapy
- No microalbuminuria
- Non-smoker
- No family history of cardiovascular disease
- No personal history of cardiovascular disease
- No high risk lipid profile

Estimate risk annually in this group: (QRISK2) and manage as high risk if estimated risk is >10% over 10 years.

### 6.21.3. Total Cholesterol, HDL-Cholesterol and LDL-Cholesterol

The aim is to maintain total cholesterol < 4.0 mmol/l for all treated patients. If the total cholesterol remains above 4.0 mmol/l, lifestyle intervention alongside drug titration is necessary unless the patient has a high HDL-Cholesterol (>1.4 mmol/l) or low LDL-Cholesterol (<2.0 mmol/l), both of which confer a reduced risk ratio. New NICE lipid guidance 2014 recommends the use of non-HDL cholesterol rather than LDL cholesterol.

### 6.21.4. Non-HDL cholesterol = total cholesterol – HDL cholesterol

Dyslipidaemia in Type 2 diabetes is more commonly characterised by decreased HDL cholesterol levels. Low HDL-Cholesterol is an indication for review of diet and other lifestyle measures. Exercise and dietary measures have more impact on HDL-Cholesterol than drug management. Aim to maintain HDL-Cholesterol >1.0 mmol/l in men and >1.2 mmol/l in women.

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### 6.21.5. Triglycerides

Triglycerides have been shown to be independent risk factors in certain groups of people with diabetes. Initial treatment with statins will have an impact on triglycerides levels as well as cholesterol. Triglyceride treatment targets are as follows:

- Ideally triglyceride levels should be <2.3mmol (CHD & Diabetes NSFs, DUK, NICE)
- Abnormal levels indicate need for dietary and lifestyle change (especially alcohol consumption)

### 6.21.6. Lifestyle Management

Management of lipids should include lifestyle interventions which have a lipid altering effect, particularly:

- weight management
- alcohol use
- physical activity

Smoking cessation should be discussed in terms of the increased risk of cardiovascular disease and microvascular complications of diabetes.

### 6.21.7. Statin therapy

The evidence basis for the use of statins in diabetes is strongest for simvastatin and atorvastatin but statins do vary in their risk of interactions, tolerability and potency. Although the most common form of dyslipidaemia in diabetes is low HDL cholesterol and elevated triglycerides, the roles of fibrates and the nicotinic acid group are still unclear and a statin is the drug class of first choice. Dose titration may be required to achieve the targets but side effects, especially myopathy, are dose related, which must be taken into consideration when advising patients.

Hypertriglyceridaemia – a fasting lipid profile must be measured before determining need for treatment of hypertriglyceridaemia. Dietary and other lifestyle modifications are the mainstay of treatment. In isolated, severe hypertriglyceridaemia a fibrate is usually more appropriate than a statin. However, mixed hyperlipidaemia should be treated with a statin, initially. Combination therapy with a statin and a fibrate should only be considered after specialist assessment. If combination therapy with a statin is being considered, use fenofibrate 200mg daily but be aware that there may be an increased risk of myositis.

Ezetimibe is currently licensed for the management of primary hypercholesterolaemia and homozygous familial hypercholesterolaemia. Consider referral to a specialist if combination therapy is needed.

For severe cholesterolaemia ezetimibe 10mg daily can be added to an optimal statin dose. Ezetimibe can also be used in combination with a low dose of statin when

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side effects produced by high statin doses prevent optimal lipid control. Try atorvastatin 20mg with ezetimibe 10mg daily initially.

**Note: there is insufficient evidence to support the use of ezetimibe monotherapy.**

#### Quality Outcomes Framework

DM004. The percentage of patients with diabetes, on the register, whose last measured total cholesterol (measured within the preceding 12 months) is 5 mmol/l or less (points 6, max threshold 75%)

#### 6.21.8. Use of Low Dose Aspirin in Type 2 Diabetes

Do not offer antiplatelet therapy (aspirin or clopidogrel) for adults with type 2 diabetes without cardiovascular disease.

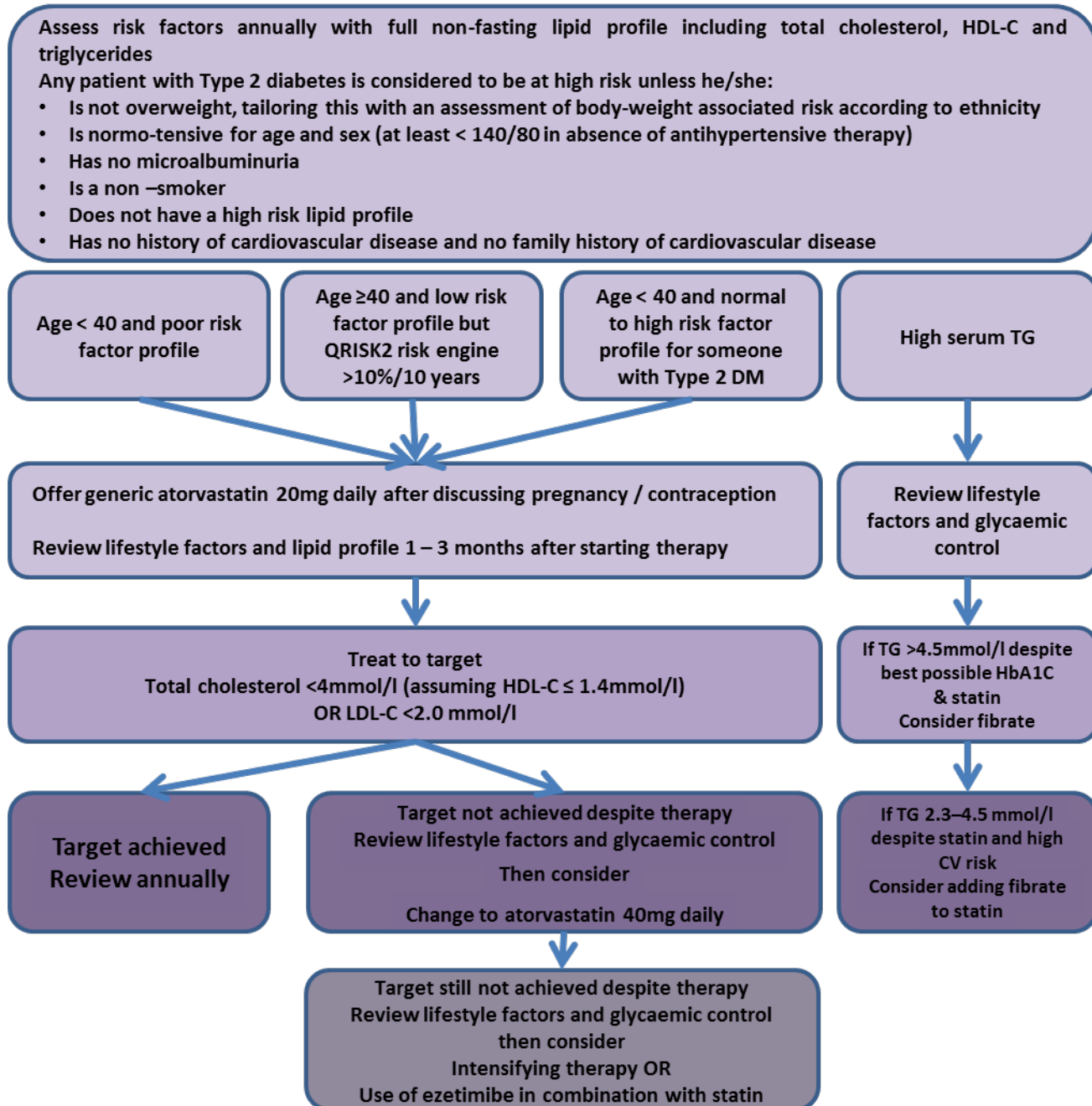
Treatment is recommended for

- Patients with known cardiovascular disease (review ECG for evidence of asymptomatic IHD) OR cerebrovascular disease OR peripheral vascular disease
- Clopidogrel should only be used *instead* of aspirin in those with clear intolerance, and concomitant use of PPI should be reviewed, but may be combined with aspirin in the context of acute cardiac events or procedures
- There is little evidence for enteric coated aspirin reducing the incidence of G-I bleeding

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## **Algorithm for Management of Blood Lipids in Type 2 Diabetes**

**Targets Total cholesterol <4.0 and LDL cholesterol < 2mmol/l, Triglyceride <2.3 mmol/l (or >40% reduction in non-HDL cholesterol) in patients at high premature cardiovascular risk for their age**



Consideration of high intensity statin should take into account co-morbidities, wishes of patient and risk/ benefit assessment. Myopathy occurs in <1% of patients but is dose related and may progress to rhabdomyolysis, a cause of renal failure and death. If myopathy is diagnosed or suspected and creatine kinase is >5 times the upper level of normal, the statin should be stopped. Asymptomatic elevations of liver enzymes occur in about 1-2% of patients. Caution is needed with heavy alcohol consumption. Drug interactions may increase the plasma levels of statins. Combination with fibrates increases myopathy risk. Liver function tests (LFTs) should be monitored prior to therapy after 3-6 months, 12 months but not again unless clinically indicated. Treatment should be stopped if serum transaminases rise to and persist at 3 times the upper limit of normal. Hypothyroidism should be adequately managed before statin therapy commenced. Evidence base for newer agents is limited compared to simvastatin or atorvastatin in diabetes. Ezetimibe is currently licensed for primary hypercholesterolemia.

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## 7. Annual Review

### NSF Standard 10: Detection and management of long-term complications

All young people and adults with diabetes will receive surveillance for long-term complications of diabetes.

- NSF / NICE
- Diabetes / Registers
- Annual Review Checklist

#### 7.1. NSF / NICE

- All patients with Type 2 diabetes should receive regular surveillance for the long-term complications of diabetes
- All patients with Type 2 diabetes who develop long-term complications of diabetes should receive timely, appropriate and effective investigation and treatment to reduce their risk of disability and premature death
- Annual review for people with diabetes is key to the detection and monitoring of complications
- Annual review should include a review of glycaemic control, review of cardiovascular risk factors, complication screening, and follow up of results through action plans agreed with the patient and / or carer
- Annual review should include preventative measures such as influenza or pneumococcal vaccination
- Annual review offers the opportunity for Pre-pregnancy counselling and review of contraception ([Appendix 12](#))

#### 7.2. Diabetes Registers

An up-to-date diabetes register is essential to facilitate call/ recall systems for all people with a clinical diagnosis of diabetes. A system for following up non-attendees should be in place to:

- Improve attendance
- Reduce the likelihood of patients with Type 2 diabetes presenting with complications at a later stage.

### Quality Outcomes Framework

DM017. The contractor establishes and maintains a register of all patients aged 17 or over with diabetes mellitus, which specifies the type of diabetes where a diagnosis has been confirmed (points 6)

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# The National Insulin Passport and Information Support Booklet

## Recommendations for issuing the patient insulin passport and booklet

### Purpose of the passport and information

- To improve patient safety by empowering patients as they take an active role in their treatment with insulin
- Target audience – adults over the age of 18 requiring insulin as a therapy for their diabetes

### Key principles

- To acknowledge the **important role** a person plays in conveying accurate information about the insulin products they use
- To **empower patients** to be the link with all people they come into contact with about their healthcare
- The **responsibility of the patient** should be acknowledged in:-
  - ensuring the passport is updated when the insulin is changed or new insulin started
  - presenting the passport to any healthcare professional who may be involved in reviewing, prescribing, administering or dispensing their insulin
- The passport and supporting information should be **issued during a face to face** consultation and should be linked to the safety aspects of insulin as a treatment
- It is the **responsibility of the healthcare professional** to ensure that the patient is appropriately informed about the purpose of the passport and information and to check their understanding of it
- Patients need to be encouraged to **carry the passport at all times**
- The person completing the passport needs to ensure that **all information is up to date and accurate**
- A **record should be made** in the patient's medical record, using read codes, when the passport and information booklet are issued

The recommended read codes are:-

Read Code	Term
8CE01	Insulin alert patient information booklet given
8IF...	Professional judgment not to engage patient with insulin alert requirements
671F0	Insulin alert patient information booklet information discussed
8CE02	Insulin passport given
8BAi	Insulin passport completed
8BAj	Informed dissent not to carry insulin passport

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For SystmOne, the read codes are:

Read Code	Term
XaYQX	Insulin alert patient information booklet given
XaYRc	Professional judgment not to engage patient with insulin alert requirements
Professional judgment not to engage patient with insulin alert requirements	Professional judgment not to engage patient with insulin alert requirements
Professional judgment not to engage patient with insulin alert requirements	Professional judgment not to engage patient with insulin alert requirements
Professional judgment not to engage patient with insulin alert requirements	Professional judgment not to engage patient with insulin alert requirements
XaYQd	Insulin alert patient information booklet information discussed
XaYQZ	Insulin passport given
XaYQh	Insulin passport completed
XaYQi	Informed dissent not to carry insulin passport

It is recommended that a record of the status of the passport is included in the diabetes template as part of the minimum data set, using the above read codes. This needs to include an option to record that the patient has made an informed decision not to accept the passport or information.

### 7.3. Annual Review Checklist

The Annual Review components may be undertaken in a variety of locations depending on local arrangements. Complication screening may be done within practice, at hospital appointments or within One Stop Screening Shop. Review of the results of complication screening, discussion of the implications and agreeing a management plan form the major part of the Annual review.

In addition to its necessity for individual monitoring, annual review data will be collated for the purpose of clinical audit and service evaluation. NICE, nGMS QOF, National diabetes audit.

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<b>Weight management</b>	BMI Agree individual target & treatment plan Consider dietetic referral and / or anti-obesity drugs or bariatric surgery
<b>Lifestyle review</b>	Smoking. If appropriate offer NRT. Diet including alcohol. Consider dietetic referral. Physical activity. Agree target. Consider Exercise on prescription, Cardiac Rehabilitation programmes. Contraception review and pre-pregnancy planning if appropriate, including review of therapies (Appendix 10) Driving –DVLA aware, hypoglycaemic awareness. Patients with recurring hypoglycaemia or reduced awareness may need to discontinue driving unless and until awareness improves or frequency of episodes is reduced. Employment issues.
<b>Glycaemic control</b>	Self – monitoring results and HbA <sub>1c</sub> . Hypoglycaemia frequency and management. Sick day rules. Agree target HbA <sub>1c</sub> . Therapy review. Issue & check understanding of insulin passport or if already has one, check accuracy of information therein.
<b>Blood Pressure control</b>	Sitting and standing. Consider ambulatory recording. Agree target BP according to risk stratification (ACR, CVD percentage risk & cholesterol).
<b>Complication screening</b>	Enquire about problems with vision. Review referral to and results from Retinal Screening programme. Optometrist. Enquire about symptoms of neuropathy including postural hypotension, numbness / tingling /pain in feet, erectile dysfunction. Enquire about claudication or rest pain. Foot inspection for callous, blisters, ulcers. Palpation of foot pulses. 10g monofilament screen. Consider Podiatry referral. Enquire about chest pains, shortness of breath, ankle swelling. ECG at least 3 yearly if over 50, otherwise as clinically indicated. Consider echocardiogram if heart failure
<b>Renal function</b>	Urea and electrolytes, creatinine. Urinalysis for protein, haematuria, nitrate. Urine for microscopy if nitrate positive. Early morning urine for microalbuminuria and ACR if no proteinuria. ACR may be raised due to pre-existing ischaemic heart disease or peripheral vascular disease: review ECG & BP target.
<b>Liver function</b>	Liver function tests
<b>Lipid profile</b>	Cholesterol, HDL cholesterol, triglycerides. Review therapy
<b>Immunisation</b>	Influenza yearly, pneumococcal (once)
<b>Depression screen</b>	Standardised questionnaire Consider referral for counselling / psychological support

## 8. Complications Screening

### 8.1. Diabetic Retinopathy

Diabetic retinopathy is the most common specific complication of diabetes and is a leading cause of blindness. Twenty years from the onset of diabetes more than 60% of those with Type 2 diabetes will have some retinopathy.

The aim of programmes for diabetic retinopathy should be to:

- Reduce the incidence of diabetic eye disease and blindness through better screening (early detection) and improved access to effective treatment
- Improve support for people with visual handicap / blindness caused by diabetes

### 8.2. North of Tees Diabetic Eye Screening Programme

All patients with T2DM need regular retinal screening and there is a National Diabetic Eye Screening Programme. The North Tees, Hartlepool and Easington joint Diabetic Eye Screening Programme for all patients with diabetes over the age of 12, has been operational since December 2005. Newly registered patients are referred by GP practices direct to the Programme Administration team, who also monitor the call/recall of patients – GPs are notified if patients do not attend appointments or fail to respond to their invite for screening and will also be notified if a patient decline the option of screening

All images are graded by fully accredited team of graders with direct referral from the programme to the Ophthalmology Departments in James Cook University Hospital or Sunderland Eye Infirmary as appropriate. Patients with cataracts or other ocular problems may have ungradeable photographs; they will be offered slit lamp examination by the Optometrist team. Patients with limited mobility who are able to co-operate with digital screening will be offered the use of patient transport services to their nearest screening centre. If patients are truly housebound and unable to attend the hospital eye services for treatment if they should require it will be removed from the screening service but only with the authorization of the Consultant Ophthalmologist and the patients GP.

Patients should continue to have regular eye appointments with their optometrist of choice whilst simultaneously attending regular Diabetic Eye screening.

### 8.3. During pregnancy

Diabetic Eye Screening should be performed every 3 months. If background diabetic retinopathy is found to be present an additional screen should be performed at 16-20 weeks, and for at least 6 months post-partum as recommended by the National Diabetic Eye Screening Programme.

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Pregnant Patients will be monitored in Digital Surveillance Clinics by the Ophthalmologist

Additional fundoscopy may be undertaken within the Combined Obstetric Diabetes Clinics depending on the presenting HbA1C.

#### **8.4. Additional Screening Services**

Hartlepool One Stop Shop offers blood pressure and foot screening with phlebotomy for annual review screening blood tests at the Retinal Screening appointment. Easington & Stockton patients are offered foot screening.

Optical Coherence Tomography (OCT) is operational in the screening programme which allows closer monitoring of the Retina and early detection of macular oedema using a 3d image.

#### **8.5. Renal Disease in Type 2 Diabetes**

Progressive renal damage is a serious, potentially fatal complication of Type 2 diabetes. Microalbuminuria is a strong independent predictor for cardiovascular disease. Diabetic nephropathy is potentially preventable with good glycaemic and blood pressure control. In diabetes 50% of glomeruli can be sclerosed and useless with a normal serum creatinine.

The aim of programmes for diabetic nephropathy should be to:

- Reduce the rate of progression from microalbuminuria to diabetic nephropathy with ACE inhibitors
- Reduce the rate of deterioration in renal function in patients with diabetic nephropathy with BP control
- Reduce the risk of cardiovascular disease in patients with diabetic nephropathy.

#### **8.6. Assessment of urine albumin**

Urine microalbumin concentration and Albumin Creatinine Ratio should be assessed in patients without proteinuria. Testing for microalbuminuria should ideally be done on an early morning urine sample. Patients should be asked to collect the first urine passed on rising after at least 6 hours bed rest. Nocturia does not interfere with the sample collection but night working, concurrent infection, menstruation and sexual intercourse will impact on the results. Samples should be collected in a plain urine container without preservative (*white top not red top*). An abnormal result should be rechecked twice on non-successive days.

2/3 abnormal results constitutes high risk for CVD, and should inform choice of targets and treatment for hypertension and lipid management as well as prompting the need for an ECG review.

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### 8.6.1. Microalbuminuria

- Albumin: Creatinine Ratio (ACR)  $\geq 2.5$ mg/mmol (men)  $\geq 3.5$ mg/mmol (women) on lab testing
- Albumin concentration  $\geq 20$ mg/l on laboratory testing or using microalbumin testing strips.

### 8.6.2. Proteinuria

- Albumin: Creatinine ratio  $\geq 30$  mg/mmol
- Albumin concentration  $\geq 200$ mg/l

## 8.7. Assessment of renal function using serum creatinine and eGFR

Serum creatinine ( $\mu$ mol/l) underestimates the decline in glomerular filtration rate (ml/min) and serum creatinine can be normal in the presence of moderate chronic kidney disease. eGFR is a more sensitive indicator of renal function.

### 8.7.1. eGFR

- Modification of Diet in Renal Disease equation (serum creatinine, age, sex, ethnic origin)
- $eGFR(\text{ml/min}) = 175 [\text{serum creatinine}(\mu\text{mol/l}) \times 0.011312]^{-1.154} \times [\text{age}]^{-0.203}$  multiplied by 0.742 if female multiplied by 1.212 if black
- Not useful in acute renal failure; in oedematous states; in amputees; in pregnancy; in muscle wasting or malnourished states, *which includes insulin deficient states* or in children.

Quality Outcomes Framework
DM006. The percentage of patients with diabetes, on the register, with a diagnosis of nephropathy (clinical proteinuria) or micro-albuminuria who are currently treated with an ACE-I (or ARBs) (points 3, max threshold 97%)

## 8.8. Foot Screening in People with Type 2 Diabetes

Ulceration, amputation and neuropathic pain are the principal lower limb complications of diabetes. They are associated with significant physical and psychological morbidity for people with diabetes, and result in a substantial cost to the NHS. The aim of programmes for diabetic foot care should be to:

- Reduce the risk of lower limb complications by provision of foot care education, early detection of complications through screening, provision of podiatry if necessary and provision of appropriate footwear.
- Reduce the rate of amputation in patients who develop foot ulceration through prompt intervention.

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## 8.9. Northern Regional Diabetes Interest Group Risk Category Guidelines

(refer to neurovascular protocols from Podiatry if further information needed)

LOW RISK	INCREASED RISK	HIGH RISK	VERY HIGH
<ul style="list-style-type: none"> <li>• 10/10 monofilament score</li> <li>• &lt; 15v neurothesiometer score</li> <li>• Tuning fork sensation present</li> <li>• All foot pulses easily palpated</li> <li>• No tissue abnormality</li> <li>• Pulses clear triphasic or biphasic on Doppler examination</li> <li>• No pathological corns / callus</li> <li>• No foot deformity</li> <li>• No previous foot ulcer /amputation</li> <li>• No previous lower limb angioplasty or bypass surgery</li> <li>• No immunosuppressant therapy or conditions</li> <li>• No sight or self-care problems</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 10 monofilament score</li> <li>• 16-24v neurothesiometer score</li> <li>• Absent tuning fork sensation</li> <li>• Pulses difficult to palpate, or one absent to palpation</li> <li>• Tissue abnormality</li> <li>• Pulses damped biphasic or monophasic on Doppler</li> <li>• Pathological corns /callus</li> <li>• Foot deformity present</li> <li>• No previous foot ulcer /amputation</li> <li>• No previous lower limb angioplasty or bypass surgery</li> <li>• No immunosuppressant therapy or conditions</li> <li>• Sight or self-care problems</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 10 monofilament score</li> <li>• &gt; 25 neurothesiometer score</li> <li>• Absent tuning fork sensation</li> <li>• One or more pulses absent to palpation</li> <li>• Pulses severely damped, or absent on Doppler</li> <li>• Rest pain</li> <li>• Severe foot deformity (including charcot)</li> <li>• History of foot ulcers /amputation</li> <li>• Previous lower limb angioplasty or bypass surgery</li> <li>• Immunosuppressant therapy conditions</li> <li>• Claudication 50 – 100</li> </ul>	<ul style="list-style-type: none"> <li>• Current foot ulcer</li> <li>• Gangrene or history of gangrene</li> <li>• Amputation</li> <li>• Severe foot deformity (including charcot)</li> <li>• Rest pain</li> <li>• Claudication under 50 yards</li> <li>• Marked neuropathy + Bounding pulses+ Prominent dorsal veins (charcot risk)</li> </ul>

### Quality Outcomes Framework

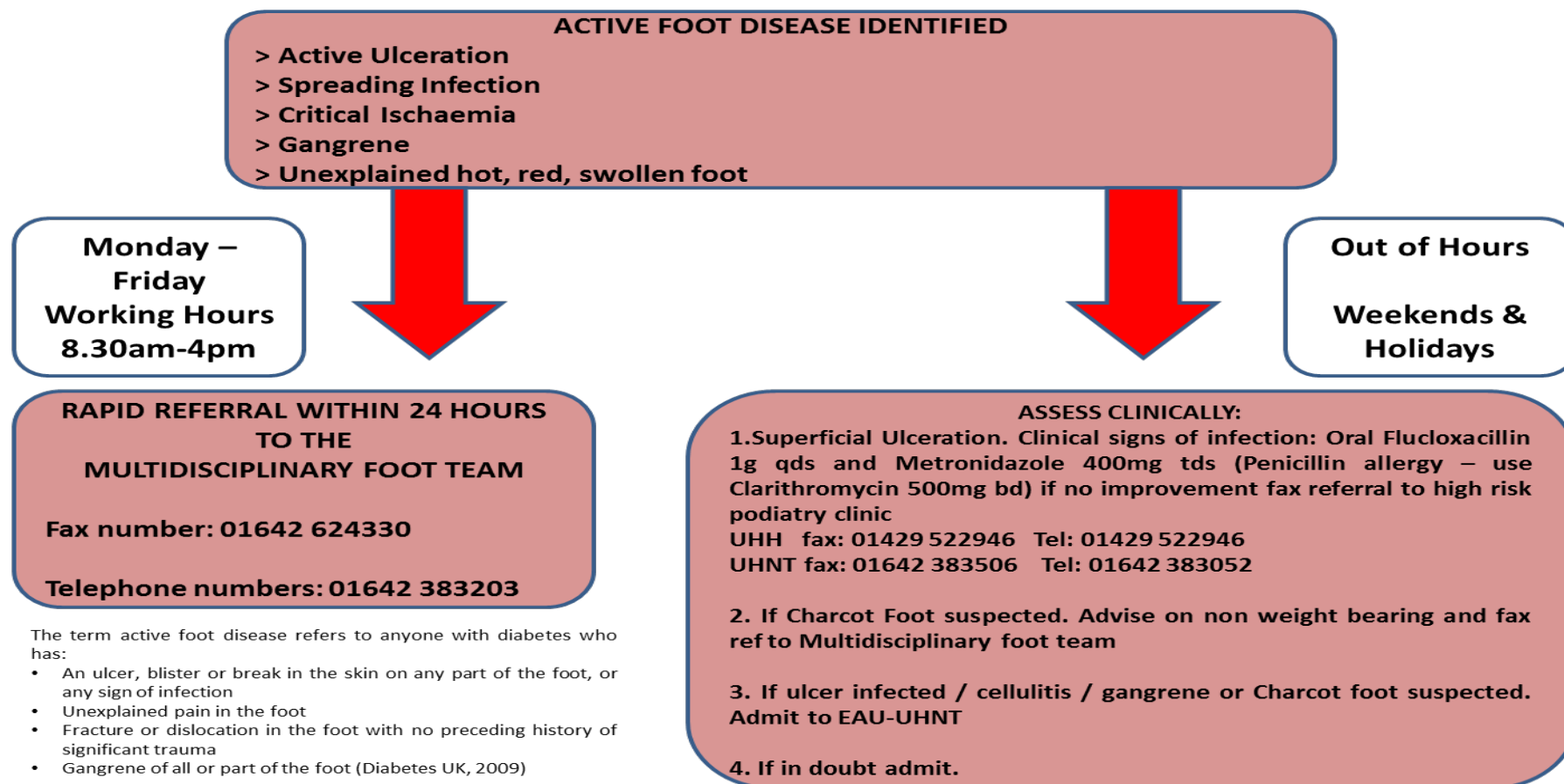
DM012. The percentage of patients with diabetes, on the register, with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer) or 4) ulcerated foot within the preceding 12 months (points 4 max threshold 90%)

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## Outpatient Diabetes Active Foot Disease Referral Pathway

### Outpatient Diabetes Active Foot Disease Referral Pathway

#### North Tees and Hartlepool NHS Foundation Trust OUTPATIENT DIABETES ACTIVE FOOT DISEASE REFERRAL PATHWAY



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# Foot assessment to be carried out on patients with diabetes who are admitted to hospital

Foot assessment consists of three components:

1. History and inspection regarding any ulcer/infection or amputation.
2. Vascular supply: to be assessed by palpating foot pulses – dorsalis pedis and posterior tibial. If unable to assess foot pulses, then check capillary refill time.



Posterior tibial pulse: Locate the medial malleolus. 2-3cm below and behind it you should find the posterior tibial pulse.



Dorsalis pedis pulse: Place your fingers half way down the dorsum of the foot on the bony area in the line between the first and second toes.

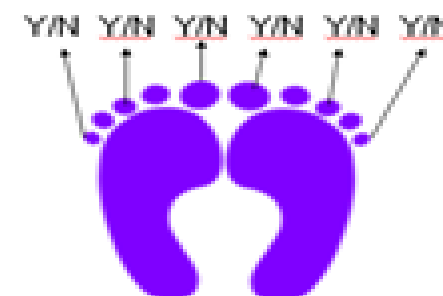
## 3. Assessment of foot sensations: to be done using Ipswich Touch Test

Preparation:

1. Remove socks and shoes
2. Explain them that you will be touching their toes and they should say left or right as soon as they feel the touch, depending on which foot was touched.
3. Ask them to close their eyes.

Performing the Test:

1. Touch the tips of their toes gently with your index finger. Touch all 6 toes as shown in the accompanying picture.
2. The touch must be very gentle, light and brief (for 1-2 seconds only). Do not press, push, tap or stroke the skin.
3. If the patient feels the touch, he/she should say right or left depending on the side touched. Record the responses by circling Y for Yes and N for No on the diagram.
4. If the person does not respond, do not repeat the touch or press harder.



2 or more negative responses means impaired sensation which indicates higher risk of foot ulcer

**Remember to complete the DIABETES INPATIENT FOOT CARE ASSESSMENT**

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## CONTINUING DIABETIC FOOT ASSESSMENT

Check that initial foot assessment done on admission. If not, please inform the Junior Doctors on the ward.

Initial Foot Assessment by Nursing Staff within 24 hours of admission and then to be assessed every alternate day.

Has patient had any previous foot ulceration?

Has patient ever been under care of Vascular Team for lower limbs?

Are there any dressings on the feet? If so, remove

Examine feet including the heels

Any breaks in skin or ulcers?

Any signs of pressure e.g. redness?

Any swelling/discolouration e.g. pale/purple

**YES TO ANY OF ABOVE**

**NO TO ALL OF ABOVE**

**ACTIVE FOOT DISEASE OR  
HIGH RISK OF FOOT DISEASE**



**Provide pressure relief**  
**Refer for foot care**  
**Inform the doctors**

**Refer to Podiatry on Extension  
3052 (UHNT) / 2946 (UHH)**

**AT RISK OF FOOT DISEASE**



**Consider pressure relief**  
**Check feet alternate day**

**Consider referral to Community  
Podiatry if not already registered**



# DIABETES INPATIENT FOOT CARE ASSESMENT

## TO BE COMPLETED ON ADMISSION FOR PATIENTS KNOWN TO HAVE DIABETES, BY THE ADMITTING DOCTOR

PASTE ADDRESSOGRAPH Patient's name: Date of Birth: Hospital Number:	Date of admission: Date of initial feet assessment:
--	--

<b>1. History/Inspection: Normal/Abnormal</b> (mark as abnormal if answer to any of a/b/c is YES)		
a. Any previous H/O foot ulcer: Yes/No		
b. Previous Amputation: Yes/No		
c. Ulceration to Feet (circle as appropriate)		
Right	Y/N	Infection Y/N
Left	Y/N	Infection Y/N
<b>2. Vascular supply: Normal/ Abnormal</b>		
	Right	Left
Dorsalis pedis	Present/absent	Present/absent
Posterior tibial	Present/absent	Present/absent
Capillary refill time	<2 seconds/>2 seconds	<2 seconds/>2 seconds
Any gangrene	Present/absent	Present/absent
<b>3. Sensations</b> (check using your finger as detailed overleaf): <b>Normal / Abnormal</b>		



**If any active ulcer/infection, contact the diabetes team at the earliest**



**If abnormality in 2 or more of the above parameters is detected, contact Podiatry team by phone within 1 working day**



**If abnormality in 1 of the above, arrange follow up with Podiatry as out-patient by faxing a referral to Podiatry**



**If all above three are normal, consider referral to Community Podiatry on discharge, if not already registered with them.**

**Podiatry contact phone numbers: 83052 (UHNT) & 22946 (UHH)**  
**Podiatry Fax number: 83506 (UHNT) & 22946 (UHH)**

**Instructions for checking sensations and pulses are overleaf**

**During hospital stay, inspect feet on ALTERNATE DAY as detailed on next sheet**

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### Assessment of foot pulses:



**Posterior tibial pulse:** Locate the medial malleolus. 2-3cm below and behind it you should find the posterior tibial pulse.



**Dorsalis pedis pulse:** Place your fingers half way down the dorsum of the foot on the bony area in the line between the first and second toes.

### Assessment of foot sensations: to be done using Ipswich Touch Test

#### Preparation:

1. Remove socks and shoes
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3. Ask them to close their eyes.

#### Performing the Test:

1. Touch the tips of their toes gently with your index finger. Touch all 6 toes as shown in the accompanying picture.
2. The touch must be very gentle, light and brief (for 1-2 seconds only). Do not press, push, tap or stroke the skin.
3. If the patient feels the touch, he/she should say right or left depending on the side touched. Record the responses by circling **Y for Yes** and **N for No** on the diagram.
4. **If the person does not respond, do not repeat the touch or press harder.**

Ask patient to close his/her eyes and touch the tips of 1<sup>st</sup>, 3<sup>rd</sup> & 5<sup>th</sup> toe of each foot lightly with your finger for 1 to 2 seconds. Record results by circling Y (yes) or N (no)

**2 or more negative = impaired sensation = high risk of ulceration**



## 9. Monitoring

### 9.1. Self-Monitoring

#### 9.1.1. Self-monitoring of blood glucose

Take the “[Driver and Vehicle Licensing Agency \(DVLA\) At a glance](#)” guide to the current medical standards of fitness to drive into account when offering self-monitoring of blood glucose levels. **[NICE 2015]**

Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless the person:

- is on insulin **or** experiences symptomatic hypoglycaemia **or**
- is on oral medication that may increase their risk of hypoglycaemia while driving **or**
- operating machinery **or**
- is pregnant, or is planning to become pregnant

For more information, see the NICE guideline on diabetes in pregnancy.

Consider short-term self-monitoring for adults with type 2 diabetes who start treatment with oral or intravenous corticosteroids. **[new 2015]**

If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include:

- the person’s self-monitoring skills
- the quality and frequency of testing
- how the results are used
- the impact on the person’s quality of life
- the continued benefit to the person
- the equipment used. **[2015]**

Self-monitoring should not be considered as a stand-alone intervention. Approaches should be individualised and agreed in consultation with the person with diabetes. Clearly if patients are not going to act upon results either by adjusting therapy or seeking further advice the usefulness of self-monitoring must be re-evaluated.

Patients with Type 2 diabetes should be educated on interpreting the results of self-monitoring and tests of long term glycaemic control.

Home capillary blood glucose monitoring may be particularly useful under certain circumstances:

- Preconception period and pregnancy
- If there has been an elevation in the HbA<sub>1c</sub> level

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- If there is an increase in the frequency or severity of episodes of hyperglycaemia or hypoglycaemia
- If there has been a change in, or adjustment of, treatment
- If the person with Type 2 diabetes experiences a change in lifestyle that affects the amount of exercise taken, or their eating habits (e.g. weight reduction programme)
- Any period of illness or infection
- Increases in frequency or duration of driving
- Increases in frequency or duration of travelling, especially long haul flights.

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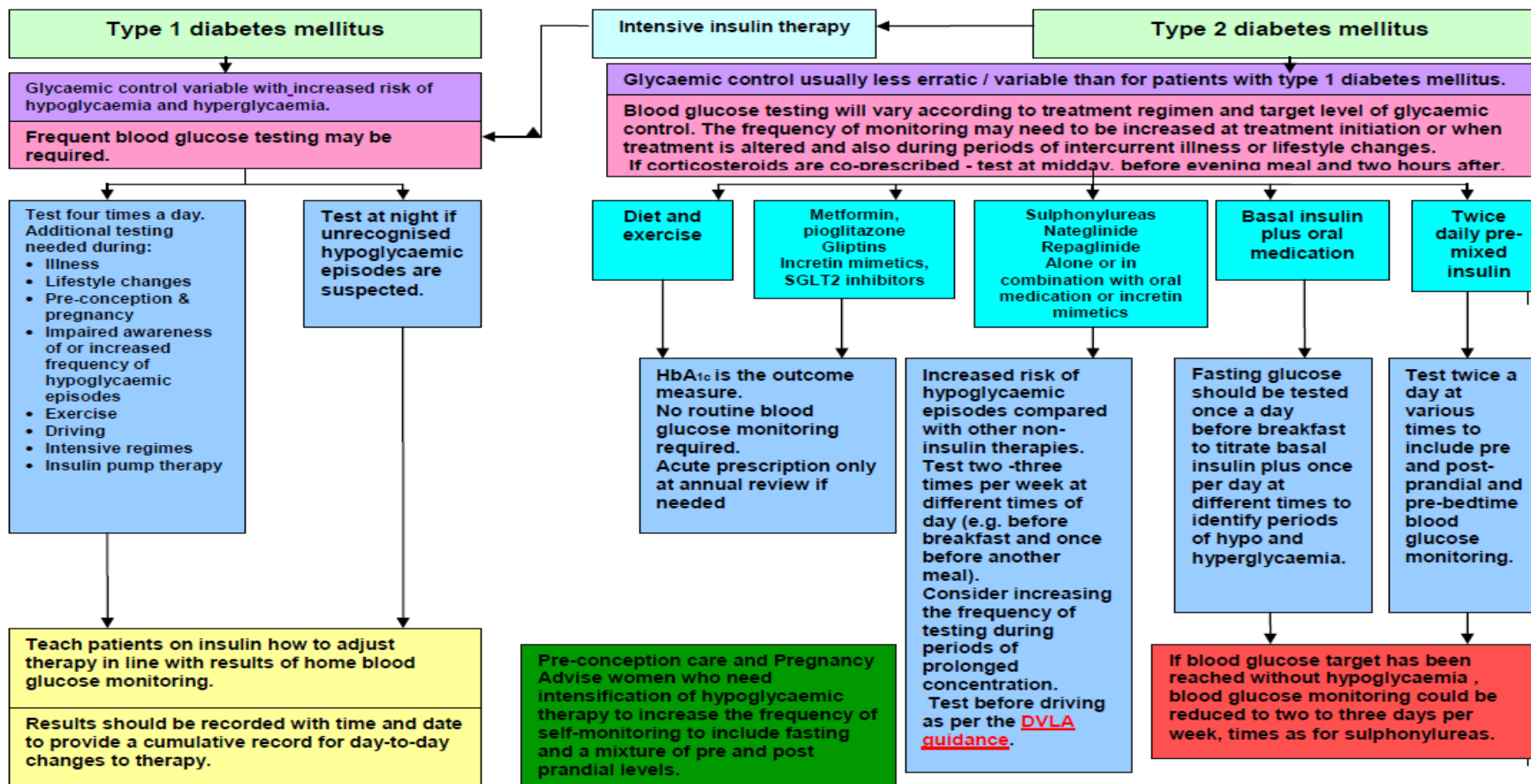
# Guidelines for Self-Monitoring Blood Glucose in Patients with Diabetes Mellitus



South Tees Clinical Commissioning Group



Hartlepool and Stockton-on-Tees Clinical Commissioning Group



## Advice for People using insulin:

Carry your glucose meter and blood glucose strips with you. Check blood glucose before driving (even on short journeys) and test regularly (every 2 hours) on long journeys.  
[DVLA guidance](#)



**NICE Guidance states:**

Self-monitoring of plasma glucose should be offered to people with Type 2 diabetes only as an integral part of self-management education. **Purpose, interpretation and action required should be agreed in advance.** It should be recognised that frequent blood testing by all patients may be wasteful and not based on evidence & can impair quality of life. Unnecessarily frequent blood testing can lead to anxiety and is a waste of limited NHS resources; whilst inappropriately infrequent testing may lead to a worsening of control. Long term management is best monitored by HbA1c results.

**HbA1c:**

May be a more meaningful determinant of long term glucose control. Patients should be involved in decisions about their HbA1c target level, which should usually be 48-58mmol/mol highly intensive management to levels of less than 48mmol/mol should be avoided. Modifying other cardiovascular risk factors (such as smoking status, blood pressure, lipids) are just as important, if not more important, than blood glucose control.<sup>3,4</sup>

**NICE Pathway recommends self-monitoring should be assessed in a structured way to at the diabetes annual review<sup>6</sup>**

- self-monitoring skills
- the quality and frequency of testing
- how the results are used
- the impact on quality of life
- the continued benefit
- the equipment used. Consider documenting within the clinical record target setting, frequency of testing and duration of monitoring agreed.

**Guidance quantities of Testing Strips, Needles and Lancets to be prescribed:**

Patients with	Quantities / Packs of			
	Testing Strips packs of 50	Lancets (packs of 100)	Needles (packs of 100)	
Type 1 diabetes	3 packs every month Additional test strips and lancets may be required in certain situations. Please see box overleaf.	1-2 packs every month	1-2 packs every month	<ul style="list-style-type: none"> <li>• These are average quantities as a guide; clinical judgement should be used in assessing individual requirements.</li> <li>• Special situations like pregnancy, hypoglycaemic awareness or pump therapy will require more frequent testing.</li> <li>• Expiry dates, should also be taken into account.</li> <li>• Consider prescribing as an acute therapy at clinic review rather than a repeat prescription.</li> <li>• Finger prick devices and lancets are generally meter specific.</li> <li>• Patients should be encouraged to help reduce waste by using up test strips before ordering more or changing meters.</li> <li>• Additional test strips and lancets will be required for drivers to comply with DVLA guidance.</li> </ul>
Type 2 diabetes using insulin	1-2 packs every month	1 pack every two months	1 every 2 months	
Type 2 diabetes using Sulphonylureas	1 pack every three-four months. Additional test strips and lancets will be required for drivers to comply with DVLA guidance. <a href="#">DVLA guidance</a>	1 pack every six to eight months	0	

Class of different Type 2 antidiabetic medication	Biguanides	Sulphonylureas	Glitazones (Thiazolidinediones)	Rapid acting insulin secretagogues (Glinides, Prandial glucose regulators)	Dipeptidyl peptidase 4 inhibitors (Gliptins)	Incretin mimetics (GLP-1 mimetics)	SGLT2 inhibitors
Examples	Metformin	Gliclazide Glipizide Glimepiride Tolbutamide	Pioglitazone	Nateglinide Repaglinide	Sitagliptin Vildagliptin Saxagliptin Linagliptin	Exenatide Liraglutide	Dapagliflozin Canagliflozin

<sup>1</sup>National Institute for Clinical Excellence. Management of Type-2 diabetes: management of blood glucose. New NICE Guideline CG66 (Updated May 2008).

<sup>2</sup>Diabetes UK statement on SMBG

<sup>3</sup>Shaughnessy AF and Slawson DC What happened to the valid POEMs? A survey of review articles on the treatment of type 2 diabetes BMJ. 2003; 327: 266

<sup>4</sup>MeReC. Type 2 diabetes

<sup>5</sup>NICE pathway-Blood glucose lowering therapy for type 2 diabetes- October 13

Reproduced with thanks to Wrexham LHB and Darlington and Durham PCT. Adopted by South Tees CCG and Hartlepool and Stockton CCG October 2014 review date September 2016



## 10. Complications Management

### NSF Standard 11 & 12: Detection and management of long-term complications

The NHS will develop, implement and monitor agreed protocols and systems of care to ensure that all people who develop long-term complications of diabetes receive timely, appropriate and effective investigation and treatment to reduce their risk of disability and premature death. All people with diabetes requiring multi-agency support will receive integrated health and social care.

- Diabetic Retinopathy
- Renal Disease in Type 2 Diabetes
- Foot Care in People with Type 2 Diabetes
- Autonomic neuropathy
- Erectile dysfunction
- Depression

### 10.1. Diabetic Retinopathy

#### 10.1.1. Eye care and screening test for all people with diabetes

- Maintain good blood pressure control and good blood glucose levels
- Refer to Retinal Screening Service for assessment and planned review
- Refer for specialist opinion if cataracts are interfering with vision or the retina is obscured
- Classify eye care as:
  - Routine care (annual review if no retinopathy)
  - Early review (every 3 to 6 months if lesions have occurred/ worsened, scattered exudates hypertension or renal disease)
  - Referral required (to specialist ophthalmologist)
- Introduce ACE inhibitor or AIIA if retinopathy confirmed and not planning pregnancy

#### 10.1.2. Referral timings to ophthalmology specialist

- **Immediately:** within a day (e.g. sudden loss of vision or evidence of retinal detachment)
- **Urgently:** within 1 week recommended (new vessel formation, preretinal and / or vitreous haemorrhage, rubeosis iridis)
- **Soon:** within 4 week recommended (drop in visual acuity, hard exudates, macular oedema, retinal findings, retinopathy present).

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## 10.2. Diabetic Renal Disease

### 10.2.1. Renal care for all people with diabetes

- Maintain good blood pressure control and good blood glucose levels
- Measure serum creatinine and eGFR at least annually or as guided by eGFR
- Measure albumin creatinine ratio or albumin concentration annually
- If microalbuminuria or proteinuria is present, repeat twice more within one month
- Classify albumin excretion annually as:
  - Lower risk (absence of microalbuminuria or proteinuria) or
  - Higher risk (2 out of 3 positive tests).

Monitoring frequency as dictated by eGFR		
<b>Normal</b>	> 90 ml/min	Annual check
<b>Mild impairment</b>	60 – 89 ml/min	Annual check
<b>Moderate impairment</b>	30 – 59 ml/min	6 monthly check
	Consider referral to specialist care if progressing or other concern e.g. BP	
<b>Severe impairment</b>	15 – 29 ml/min	3 monthly check
	Referral to specialist	
<b>Established</b>	< 15 ml/min	3 monthly check
	Referral to specialist	

### 10.2.2. Management of patients with high risk albumin excretion or eGFR <60 or serum creatinine >150

- Optimise blood pressure control
  - ACEI / AIIA greater effect on ACR and vascular protective effects
  - All anti-hypertensive agents are useful if BP lowered
- Address other risk factors
  - Weight management
  - Smoking cessation
  - Lipid management
  - Consider low dose aspirin weighing up benefit/risk balance
- Tighten blood glucose control
- Screening for cardiovascular disease
  - check ECG for silent or unrecognised ischaemia
- Referral to specialist diabetes care recommended once serum creatinine consistently >150mmol/l
- Referral to specialist diabetes care recommended if eGFR <30
- Referral to specialist diabetes care recommended for persistent proteinuria or elevated ACR in the absence of significant cardiovascular disease

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## **10.3. Diabetic Foot Care**

### **10.3.1. Assessment of foot risk factors for all people with diabetes (see grading system overleaf)**

- Examine feet as part of annual review to detect risk factors for ulceration
- Test foot sensation using a 10g monofilament
- Palpate foot pulses
- Inspect foot shape and footwear
- Arrange recall and annual review of complications and their risk factors

### **10.3.2. Management of all people with diabetes**

- Arrange recall and annual review
- Ensure tight blood glucose control
- Agree management plan including foot care education
- Advise on appropriate footwear

### **10.3.3. Management of the at risk foot**

- Inspect feet 3-6 monthly

### **10.3.4. Management of the high risk foot**

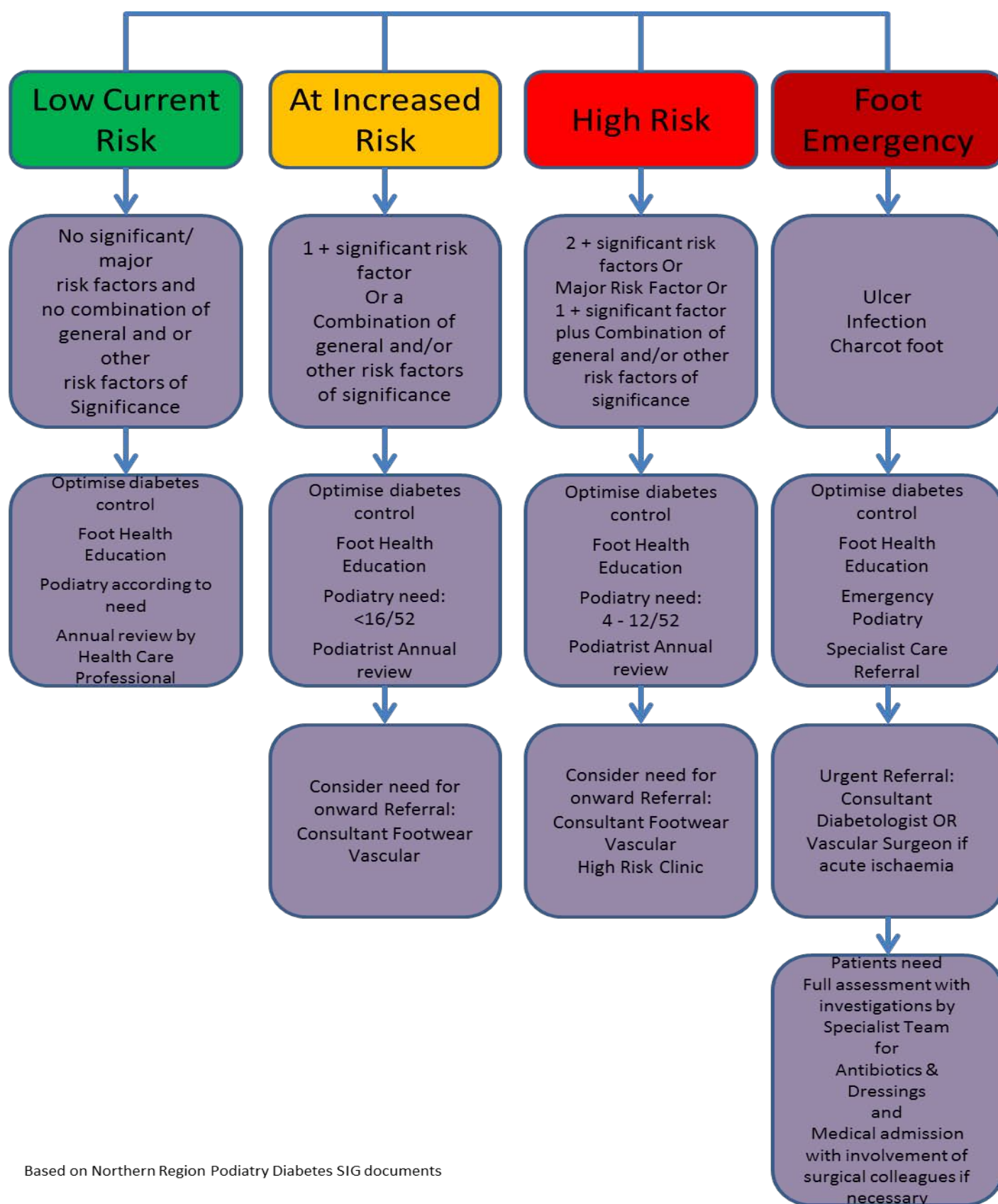
- Arrange frequent review (1-3 monthly) from specialised podiatry team
- Evaluate provision of frequent skin and nail care
- Review education / footwear / vascular status

### **10.3.5. Management of the ulcerated foot**

- Urgently arrange foot ulcer care from a specialist team
- Ensure investigation and treatment of vascular insufficiency
- Ensure local wound management, appropriate dressings and debridement as indicated
- Ensure effective means of distributing foot pressures, including specialist footwear / casts
- Ensure systemic antibiotic therapy for cellulitis or bone infection

**[Please see Appendix 12 for Antibiotic Treatment of Foot Complications](#)**

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Based on Northern Region Podiatry Diabetes SIG documents

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## 10.4. Managing neuropathic pain

Diabetic neuropathy can be difficult to manage and may not respond well to straightforward simple analgesia. It may though co-exist with osteo-arthritis and a trial of paracetamol can be helpful with those symptoms. Improving glycaemic control can help with symptom control and should be addressed. If on 'statins a myositic component should be considered. Other contributory factors should be considered such as B<sub>12</sub> deficiency especially in patients on high dose or long-term Metformin. Symptoms may be worse at night so drugs with sedative side-effects may be doubly useful. Depressive symptoms are common and may need to be addressed with psychological support and / or pharmacological management. Patients are likely to need a combination of strategies.

Consider:	<p>Offer a choice of amitriptyline, duloxetine, gabapentin or pregabalin as initial treatment for neuropathic pain (except trigeminal neuralgia)</p> <p>If the initial treatment is not effective or is not tolerated, offer one of the remaining 3 drugs, and consider switching again if the second and third drugs tried are also not effective or not tolerated.</p> <p>Consider tramadol only if acute rescue therapy is needed (see recommendation 1.1.12 about long-term use).</p> <p>Consider capsaicin cream[4] for people with localised neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments</p> <p>Combination therapy of duloxetine or amitriptyline with gabapentin can be used if monotherapy at the maximum tolerated dose does not control symptoms</p>
Complex cases	Opiates may need to be used if pain is severe and the Specialist Pain Team may be needed

### 10.4.1. Treatments that should not be used

Do not start the following to treat neuropathic pain in non-specialist settings, unless advised by a specialist to do so:

- cannabis sativa extract
- capsaicin patch
- lacosamide
- lamotrigine
- levetiracetam
- morphine
- oxcarbazepine
- topiramate
- tramadol (this is referring to long-term use)
- venlafaxine.

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## 10.5. Autonomic Neuropathy

Autonomic neuropathy can be difficult to manage and can present with hypotension, GI symptoms, sweating or loss of hypoglycaemic awareness. Management consists of relief of symptoms where possible, e.g.; use of drugs affecting gastric motility or constipation, and safety measures, particularly in terms of postural symptoms and hypoglycaemia avoidance. The presence of autonomic neuropathy is a risk factor for silent or atypical myocardial ischaemia so cardiovascular disease assessment and disease prevention strategies should be reviewed.

Think about the possibility of autonomic neuropathy affecting the gut in adults with type 2 diabetes who have unexplained diarrhoea that happens particularly at night.

When using tricyclic drugs and antihypertensive drug treatments in adults with type 2 diabetes who have autonomic neuropathy, be aware of the increased likelihood of side effects such as orthostatic hypotension.

## 10.6. Erectile dysfunction

Men with erectile dysfunction in the context of diabetes should be assessed for other neuro-vascular complications or psycho-social issues. Anti-hypertensive or cardiac medications may well contribute to the problem which should be discussed with patients. Patients with diabetes are entitled to phosphodiesterase type-5 inhibitors on prescription but may require higher doses to obtain an adequate response, use sildenafil. Caution is required in patients on co-existing vaso-dilator medication and contra-indications include co-prescribing with oral nitrates. Patients with eGFR below 30ml/min should be given low starting dosage. If patients do not respond to, or cannot have, phosphodiesterase type-5 inhibitors consider referral to Urology team for assessment and advice after discussion with patient and, preferably, their partner.

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## 11. Referral to Specialist Services

### NSF Standard 7: Management of diabetic emergencies

The NHS will develop, implement and monitor agreed protocols for rapid and effective treatment of diabetic emergencies by appropriately trained healthcare professionals. Protocols will include the management of acute complications and procedures to minimise the risk of recurrence.

### NSF Standard 8: Care of people with diabetes during admission to hospital

All children, young people and adults with diabetes admitted to hospital, for whatever reason, will receive effective care of their diabetes. Wherever possible, they will continue to be involved in decisions concerning the management of their diabetes.

### NSF Standard 9: Care of women in pregnancy

The NHS will develop, implement and monitor policies that seek to empower and support women with pre-existing diabetes and those who develop diabetes during pregnancy to optimise the outcomes of their pregnancy.

There are no fixed rules for referral to the specialist team. The following suggestions are a guide and individual practitioners may wish to refer for various reasons including patient concerns, drug reactions limiting therapeutic options or variations in the competencies /capacities of practice teams. Referral to the specialist team does not necessarily mean referral for consultant review –referrals may be directed to other members of the multi-professional team as appropriate to shorten the patient journey. Patients may be referred via Choose and Book or direct to the Specialist Teams in UHNT or UHH. NTHFT are piloting a diabetes email helpline for non-urgent advice ([diabetesadvice.nth@nhs.net](mailto:diabetesadvice.nth@nhs.net)). Advice on appropriate referral routes is included in Choose and Book criteria. [See Appendix 15 for Secondary Care Teams contact details.](#)

### 11.1. Referral to Diabetes Nurse Specialists

**Referral to a specialist diabetes team is recommended for these people with Type 2 diabetes:**

#### 11.1.1. Same day referral to Diabetes Team (telephone, fax)

- Any patient with new or pre-existing diabetes who has **ketonuria and weight loss**
- All women with pre-existing diabetes who become pregnant, as soon as conception is confirmed
- Any woman who develops gestational diabetes or gestational impaired glucose tolerance
- People who develop infected, necrotic or gangrenous foot ulceration
- People who develop a suspected Charcot foot



### 11.1.2. Priority referrals to Diabetes Team (telephone, fax, letter)

- People under 25 years old with no ketonuria but confirmed diabetes
- Women who are contemplating pregnancy
- People who develop severely at risk feet
- People who develop persistent proteinuria or elevated ACR without significant cardiovascular disease
- People who develop renal impairment should generally be referred to Diabetes not directly to Nephrology
  - Serum creatinine >150 OR eGFR < 60 and deteriorating OR eGFR < 30 ml/min/1.73m<sup>2</sup>
  - Rapid decline in renal function (eGFR or creatinine)
  - Absence of other evidence of microvascular disease e.g. no retinopathy on screening

### 11.1.3. Routine referral to Diabetes Team or request for advice (telephone, fax, letter or email [diabetesadvice.nth@nhs.net](mailto:diabetesadvice.nth@nhs.net))

- People in whom insulin transfer is being considered or is necessary
- People in whom novel therapies are being considered
- People who develop recurrent hypoglycaemia or poor glycaemic control
- Hypertension requiring multiple therapies
- Dyslipidaemia with poor response to, or intolerance of, 'statin therapy
- Painful peripheral or troublesome autonomic neuropathy, mononeuropathy or amyotrophy
- Morbid obesity with poor control or complications.

[See Appendix 9 for referral form for the North Tees DSN service.](#)

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## 11.2. Referral to Other Specialist teams

### 11.2.1. Same day referral to other specialist team (telephone, fax)

- **Ophthalmology** – People who have a sudden loss of vision, pre-retinal or vitreous haemorrhage or retinal detachment
- **Vascular Surgeons** – People who develop acute (not chronic) vascular insufficiency with cold, pale, pulseless extremity

### 11.2.2. Priority referrals to other specialist team (telephone, fax, letter)

- **Nephrology** – *Serum creatinine >150 µmol/l or eGFR < 30 ml/min with features of other renal disease e.g. haematuria without infection*
- **Ophthalmology** – People who develop sight threatening retinopathy
- **Cardiology Rapid Access Chest Pain Clinic** – People who develop new onset angina (within previous 4 weeks). People who develop significant worsening of existing angina (over the previous 12 weeks).

### 11.2.3. Routine referral to other specialist team or request for advice (telephone, fax, letter) Urology

- **Erectile dysfunction** – patients should be referred to for specialist counselling and treatment.

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## Appendix One: Methods & Criteria for Diagnosing Diabetes Mellitus (WHO definitions)

### Using glucose test for diagnosis (WHO 2006)

- **With symptoms (polyuria, thirst, unexplained weight loss) diabetes is confirmed by:**
  - A random venous plasma glucose concentration  $\geq 11.1\text{mmol/l}$  OR
  - A fasting venous plasma glucose concentration  $\geq 7.0\text{mmol/l}$  (whole blood  $\geq 6.1\text{ mmol/l}$ )
- **With symptoms but negative glucose screening**

If the screening test result is negative but the individual shows symptoms or signs suggestive of diabetes or its complications, s/he should be told that diabetes has not been excluded. Follow up with an HbA1c and if the result is indeterminate (40 – 48mmol/mol) then, and only then, do an OGTT to establish true diagnosis.

- **With no symptoms but an elevated screening glucose**

The person should be given written details of the screening procedure and the precise result of the test. They should be told that the test has indicated a possible rise in blood glucose that needs further checking and should be reassured as far as possible while ensuring their understanding of the importance of completing the tests to confirm/refute the diagnosis. The person should be asked not to make any changes in diet or drug therapy but should make a routine appointment with the GP in the two to four weeks following screening (an earlier appointment may be necessary if the person is symptomatic).

A diagnosis must not be based on a single glucose determination and requires a confirmatory venous plasma test. At least one additional glucose result taken on another day is essential. This can be either fasting or from a random sample. Diagnostic values are in the same range as that used in symptomatic patients. Therapy should not be instigated until diagnosis has been confirmed.

- **Acting on results: identified Intermediate Hyperglycaemia**
- **Impaired Fasting Glucose** fasting plasma glucose 6.1-6.9 mmol/
- **Impaired Glucose Tolerance** 2 hour post carbohydrate load plasma glucose 7.8 – 11.0 mmol/l

Intermediate hyperglycaemia is not benign. It is associated with increased risk of large vessel disease (2-5x risk of CHD) and with increased risk of progression towards overt diabetes. These patients will need to be monitored in the long term for the development of overt diabetes and should have appropriate risk management for their large vessel disease. Changes in lifestyle have been shown to reduce progress to overt diabetes in impaired glucose tolerance. (DPP 2002).

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## Factors that influence HbA1c and its measurement (*from WHO report adapted from Gallagher et al.*)

### 1. Erythropoiesis

- Increased HbA1c: iron, vitamin B12 deficiency, decreased erythropoiesis
- Decreased HbA1c: administration of erythropoietin, iron, vitamin B12, reticulocytosis, chronic liver disease

### 2. Altered Haemoglobin

- Genetic or chemical alterations in haemoglobin: haemoglobinopathies, HbF, methaemoglobin, may increase or decrease HbA1c

### 3. Glycation

- Increased HbA1c: alcoholism, chronic renal failure, decreased intra-erythrocyte pH
- Decreased HbA1c: aspirin, vitamin C and E, certain haemoglobinopathies, increased intra-erythrocyte pH
- Variable HbA1c: genetic determinants.

### 4. Erythrocyte destruction

- Increased HbA1c: increased erythrocyte lifespan: Splenectomy
- Decreased HbA1c: decreased erythrocyte lifespan: haemoglobinopathies, splenomegaly, rheumatoid arthritis or drugs such as antiretrovirals, ribavirin and dapsone

### 5. Assays

- Increased HbA1c: hyperbilirubinaemia, carbamylated haemoglobin, alcoholism, large doses of aspirin, chronic opiate use
- Variable HbA1c: haemoglobinopathies
- Decreased HbA1c: hypertriglyceridaemia

If uncertain as to the impact of any of these situations or factors, use glucose testing for diagnosis and discuss the patient with your local laboratory or specialist diabetes team.

## IDF Global Guideline Clinical Monitoring Recommendations for Secondary care

As above plus

- Use appropriate alternative measures where HbA<sub>1c</sub> methods are invalidated by haemoglobinopathy or abnormal haemoglobin turnover
- Continuous glucose monitoring is an additional option in the assessment of glucose profiles in people with consistent glucose control problems, or with problems of HbA<sub>1c</sub> estimation.

### Local Recommendations from North Tees and Hartlepool Biochemistry Department

- HbA<sub>1c</sub> should be measured at 3-6 monthly intervals, depending on level and stability of blood glucose control, and change in therapy
- Shorter intervals may be clinically appropriate for selected patients (pre-pregnancy planning, pre-operative assessment), but this should be discussed with the laboratory case by case

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## Appendix Two: Oral Glucose Tolerance Test

### Oral 75g Glucose Tolerance Test

#### Potential scenarios where OGTT can be used:

- 1) Pregnancy
- 2) Symptomatic &/or high risk patients with HbA1c 40 – 48 mmol/mol or IFG
- 3) Where HbA1c cannot be used as a diagnostic test (see Annex from WHO report on page 11)

Patients should be advised to continue their normal diet until the evening before the test. Dietary changes made beforehand can influence the result. Concurrent illness or steroid therapy will influence the result.

Patient should have nothing to eat from 10pm the evening before but can have water to drink after 10pm. The patient should not eat during the test but may have water to drink. The patient should not exercise or smoke during the test.

#### **Fasting level**

Check capillary glucose and take blood sample for laboratory plasma glucose.

If the capillary glucose is above 10mmol/l, the requesting physician should be consulted before proceeding with the test.

#### **Glucose load**

- 75g glucose is given in the form of Rapirose OGTT solution which delivers 75g of glucose in 300mls

#### **2 hour level**

Blood sample for plasma glucose is taken again 2 hours after the Rapirose is given.

#### **1999 WHO Criteria for interpretation of 75g OGTT**

<b>Normal glucose tolerance</b>	
Fasting glucose	≤ 6.0 mmol/l
OGTT 2 hour glucose	< 7.8 mmol/l
<b>Abnormal glucose tolerance</b>	
<b>Impaired fasting glucose</b>	
Fasting glucose	6.1 – 6.9 mmol/l

Or

<b>Impaired fasting glucose</b>	
OGTT 2 hour glucose	7.8 – 11.0 mmol/l

#### **Diabetes**

<b>Impaired fasting glucose</b>	
Fasting glucose	≥ 7.0 mmol/l
OGTT 2 hour value	≥ 11.1 mmol/l

Impaired fasting glucose and impaired glucose tolerance are not benign conditions. They are associated with increased risk of large vessel disease and with increased risk of progression towards overt diabetes. These patients should be monitored long term for the development of diabetes and should have appropriate management of cardiovascular risk factors. Lifestyle changes can slow the progression to diabetes.

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## Appendix Three: DESMOND Education Referral Form

### DESMOND Education Referral Form

Diabetes Education and Self-  
Management for Ongoing and  
Newly Diagnosed

Date:			
Dr's Name:		Tel No:	
Surgery Address:			

Patient Name:		DOB:	
Patient's Tel No:			
Address:			
Date of Diagnosis:			
Treatment for Diabetes:			

Bio Medical Data:			
Blood Pressure:		DOB:	
Cholesterol:			
HDL:			

Smoking status:    Non    ☐    Passive    ☐    Smoker    ☐

Please do not send incomplete forms (Including HBA1C) as they will be returned.

Send form to: DESMOND Co-ordinator, SPA Team, Mandale House, Harbour Walk, Hartlepool, TS24 0UX

## **Appendix Four: Guidelines for Referral to the Department of Nutrition & Dietetics**

### **North Tees and Hartlepool NHS Foundation Trust (including referral form and pathway)**

#### **Service Provision**

North Tees & Hartlepool and Easington area.

#### **Acute services**

UHNT – In-Patient dietetic referral for newly diagnosed type 1 diabetes and complex type 2

#### **Community services**

University Hospital Hartlepool – Hospital Diabetes Dietitian clinics

Community Clinics in G.P Surgeries (North Tees area).

University Hospital Hartlepool – Hospital Dietetic Out-Patient clinics.

Easington area / Co Durham Peterlee Community Hospital – and GP Surgery Clinics.

#### **Aims of Diet therapy**

To influence the risk factors which affect co-morbidity:

1. to promote euglycaemia
2. to provide the foundation for establishing Healthy Eating habits
3. to promote weight control based on healthy eating habits
4. to influence improved lipid profiles
5. to provide education to enable control and minimise risks associated with hypo and hyperglycaemia and thereby facilitate self-management
6. to promote physical activity/healthy lifestyle changes
7. to incorporate the dietary/nutritional guidelines recommended by NICE, National Obesity Forum, Diabetes UK etc.,
8. to provide appropriate information to support the acquisition of knowledge, behavioural skills and self-responsibility to support self-management.

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## Referral Criteria

- Newly diagnosed Type 2 diabetes if DESMOND not appropriate (see below guidelines, table 1)
- Newly diagnosed Type 1 diabetes (please mark as 'urgent')
- Existing Type 1 or Type 2 diabetes requiring support or education, for example at annual review – see table 2

- **Newly Diagnosed T1 DM**

Confirmation of diagnosis by appropriate medical practitioner in line with the diagnostic criteria established for the Trust's guidelines.

Diagnosis recorded in medical notes whether paper or computer generated.

- **Newly diagnosed T2 DM**

Most patients\* should be provided with basic dietary information on diagnosis (handheld record in North Tees and Hartlepool) and referred to the DESMOND programme where they will receive further dietary education. At the end of the programme they will have the opportunity to self- refer to the dietetic service for individual dietary support.

If a patient does not agree to be referred to DESMOND or is unable to attend the programme a referral to the Dietitian should be completed.

\* The dietary education provided by DESMOND is not appropriate for all patients. Please see table 1 below:

DESMOND may still be useful to these patients and will be offered following individual dietetic assessment where appropriate.

**Table 1 – newly diagnosed diabetes with one or more of the following should be referred to Dietetics rather than DESMOND.**

Chronic Kidney Disease – **particularly where serum potassium and/ or phosphate elevated**

Low BMI (<18.5 kg / m<sup>2</sup>)

Significant unintentional weight loss

Palliative care

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## Existing T1 or T2 Diabetes requiring support or education about diet

If one or more of the following is noted during diabetes review, please consider referral to Dietetic department

**Table 2**

### **Elevated blood lipids**

**Changes in diabetes treatment** – for example new oral anti-diabetic agent, insulin mimetic or commencing insulin

**Erratic blood glucose** (problems with hypoglycaemia /hyperglycaemia/ increase in or high HbA1c)

**Large lifestyle changes** influencing diet and diabetes management (change in work pattern, giving up smoking, bereavement, change in household e.g. living alone having lived with partner / family, retirement)

**Significant unintentional weight loss, low BMI or poor appetite**

**Coeliac Disease**

Please state reason for review / annual review on your referral

Please note that specific needs from the above list are not necessary for a dietitian referral – '**Patient requested referral**' is acceptable

### **Referral Process for Diabetes Dietitian**

Referrals are accepted in either electronic or paper format using a dietetic referral form (see P61 currently – or give this an appendix number)

### **Please provide the following referral Information for outpatient Referrals:**

- Patient identifying number, name and contact details
- Diagnosis and reason for referral
- Relevant biochemistry; HbA1c, cholesterol (HDL, LDL and total), triglyceride, Cholesterol/HDL risk ratio
- Blood Pressure status
- Current medications
- Name and contact details of referrer

Send referrals to:

Dept. of Clinical Nutrition and Dietetics, University Hospital Of North Tees, Hardwick, Stockton. TS19 8PE or

Fax: 01642 383172 [nth-tr.dieteticsdept-uhnt@nhs.net](mailto:nth-tr.dieteticsdept-uhnt@nhs.net)

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## **UHNT and UHH Acute (In-patient) diabetes Referrals.**

Request for Diet Therapy conveyed to the Dietician/Dietetic Dept. using the Dietetic Referral form (see Appendix p61 or give an appendix no') or by telephone, providing patient details, reason for referral, estimated discharge date and name of referrer

If initial contact is made verbally or by telephone the request should be supported by a completed Dietetic

Referral Information form (photocopy is acceptable).

### **First line dietary information from GP or Practice nurse**

First line dietary information is provided in the handheld record (North Tees and Hartlepool); this should be available on diagnosis with diabetes and at review where an update is required.

Evidence based dietary information can also be obtained from the Diabetes UK website [www.diabetes.org.uk](http://www.diabetes.org.uk)

Patients in Easington should be given introductory advice from their Practice Nurse.

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## Appendix Five: Healthy Eating for Type 2 Diabetes Patient (Advice Leaflet)

### Healthy Eating in Type 2 Diabetes

#### What is diabetes?

People with diabetes are less able or unable to control the amount of glucose (sugar) in their blood. As a result glucose can no longer be used as energy, leading to high levels in the blood. We get glucose from either sweet or starchy foods that we eat. Diet plays a vital role in controlling your blood glucose levels. People with diabetes need to eat a healthy diet, high in fibre and low in sugar and fat. Eating a healthy diet is recommended for everyone.

Food can be divided in five groups:

- starchy foods
- fruit and vegetables
- dairy products
- meat, fish, eggs and pulses
- foods high in fat or sugar

The number of portions you will need varies from person to person, and these are given as a guide. Your dietitian will be able to tell you how much you should eat.

#### Starchy foods

Bread, rice, potatoes and pasta contain carbohydrate, which is broken down into glucose and used by your cells as fuel. Choose carbohydrates that are more slowly absorbed (that is, lower GI) as these won't affect your blood glucose levels as much and they'll keep you feeling fuller for longer. Starchy foods are naturally low in fat and high-fibre choices (wholemeal and wholegrain options) will also help keep your bowels regular, preventing digestive disorders.

#### How much per day?

One third of your diet should be made up of these foods, so try to include them in every meal but avoid large portions.

#### What's a portion?

One portion is equal to: 2–4 tbsp. cereal; 1 slice of bread; 2–3 tbsp. rice, pasta, couscous, noodles or mashed potato; 2 new potatoes or half a baked potato; half a small chapatti; 2–3 crispbreads or crackers.

#### Fruit and vegetables

Fruits and vegetables are naturally low in fat and calories, while being packed with vitamins, minerals and fibre. They can help protect against stroke, heart disease, high blood pressure and certain cancers.

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### **How much per day?**

Aim for at least five portions. Fresh, frozen, dried and tinned fruit and vegetables all count. Aim for a mix of colours to get as wide a range of vitamins and minerals as possible.

### **What's a portion?**

Roughly what you can fit into the palm of your hand.

### **Dairy products**

Milk, cheese and yoghurt contain calcium, which helps to keep your bones and teeth strong. They are also a good source of protein, but some can be high in fat, so choose lower-fat alternatives where you can (but look out for added sugar in its place).

### **How much per day?**

Aim for three portions.

### **What's a portion?**

One portion is equal to:

- 190ml ( $\frac{1}{3}$  pint) of milk
- a small pot of yogurt
- 2 tbsp. cottage cheese
- a matchbox-sized portion of cheese (45g/1oz)

### **Meat, fish, eggs and pulses**

These foods are high in protein, which is needed for building and replacing muscle cells in the body. They also contain minerals, such as iron, which are needed for producing red blood cells. Omega-3 fish oils, found in oily fish such as mackerel, salmon and sardines, can help to protect the heart.

Good sources of protein for vegetarians include beans, pulses, lentils, soya and tofu.

### **How much per day?**

Aim for 2-3 portions.

### **What's a portion?**

One portion is equal to:

- 60–85g (2–3oz) meat, poultry or vegetarian alternative
- 120–140g (4–5oz) fish
- 2 eggs
- 2 tbsp. nuts
- 3 tbsp. beans, lentils or dahl

### **Foods high in fat and sugar**

Technically, your body doesn't need any foods in this group, but eating them in moderation can be part a healthy, balanced diet. Sugary foods and drinks will raise your blood glucose so opt for diet/light or low-calorie alternatives. It's also worth remembering that fat is high in calories, so try to reduce the amount of oil you use in your cooking and choose lower-fat alternatives wherever possible.

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## How much per day?

0-4 portions (the fewer the better).

## Salt, herbs and spices

Eating too much salt (6g/0.2oz or more per day) can raise your blood pressure, which can lead to stroke and heart disease, so limit the amount of processed foods you eat and try flavouring foods with herbs and spices instead (from diabetes.org.uk, accessed 30.10.14)

## Exercise

Exercise is important to keep you fit and feeling well. It helps control your weight and improves control of your diabetes.

## Sample menu

Examples of healthy, balanced meals:

### Breakfast

Fruit or a small glass of pure, fresh, unsweetened or no added sugar fruit juice, bowl of porridge or cereal (Weetabix, Branflakes, Shreddies, Cornflakes), 1 – 2 slices toast

### Mid-morning snack if needed

1 – 2 plain biscuits or fruit, if needed

### Light meal

- Lean meat, chicken, fish, oily fish, eggs, cheese or beans
- Salad vegetables
- 2 slices of bread, plain or toasted
- Low fat, low sugar yoghurt / fromage frais, milk pudding, fresh / frozen fruit / tinned fruit in juice

### Mid-afternoon snack if needed

1 – 2 plain biscuits or fruit, if needed

### Cooked meal

- Lean meat, chicken, fish, oily fish, eggs, cheese or beans.
- Vegetables, cooked or stir-fried or salad
- Boiled or jacket potatoes, rice, spaghetti, wholemeal pasta or noodles
- Low fat, low sugar yoghurt / fromage frais, milk pudding, fresh / frozen fruit / tinned fruit in juice

### Bedtime snack

1 – 2 plain biscuits or crackers, small sandwich, small scone, 1/2 teacake, a crumpet or small bowl of cereal and milk

## Best choices throughout the day

You should choose:

- skimmed or semi skimmed milk, up to 570ml (1 pint) each day
- tea, coffee (with sweeteners - no sugar), water, reduced sugar squash, diet soft drinks
- wholemeal and wholegrain starchy foods
- fats containing olive or rapeseed oils

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## Remember

As long as you are careful there is no reason to miss out on special occasions. Try to eat at regular times, and try to eat roughly the same amount of starch at each meal and snack.

## Contact numbers

If you would like any further information please contact your GP or practice nurse. If you are receiving care from a dietitian you can contact them at either:

### University Hospital of North Tees

Telephone: 01642 624768 Monday – Friday, 9.00am – 5.00pm

Non-urgent messages can be left on the answering machine

### University Hospital of Hartlepool

Telephone: 01429 522529 Monday – Friday, 9.00am – 5.00pm

Non-urgent messages can be left on the answering machine

## Further Information is available from:

- DESMOND courses
- Ask your Practice Nurse about the local education courses for patients with diabetes
- Diabetes UK Telephone: 0207 424 1000 [www.diabetes.org.uk](http://www.diabetes.org.uk)
- NHS choices: <http://www.nhs.uk/Conditions/Diabetes-type2/Pages/Living-with.aspx>

## References

Nutrition Subcommittee Diabetes Care Advisory Committee of Diabetes UK (2003). The implementation of nutritional advice for people with diabetes. *Diabetic Medicine*: 20; 786-807.

American Diabetes Association (2003) Evidence based nutrition principles and recommendations for treatment and prevention of diabetes and related complications. *Diabetes Care*: 26; supp Jan 2003.

NICE Guidelines for the Management of Type 2 Diabetes 2008

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## Appendix Six:

## Adult Dietetic Referral form



HCR237 - Adult  
Dietetic Referral Form

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## Appendix Seven: Skills for Health List of Diabetes Competencies & Trend UK Integrated Career and Competency Framework for diabetes nursing

### Skills for Health List of Diabetes Competencies (all areas)

- Review and monitor a patient's nutritional wellbeing
- Identify symptoms of diabetes in a child or young person and refer them for further assessment
- Assess a child/young person with symptoms of diabetes and make a diagnosis
- Inform a child or young person and their family of a diagnosis of Type 1 diabetes
- Inform a child/young person and their family of a diagnosis of Type 2 diabetes or impaired glucose tolerance Provide therapy to meet the immediate healthcare needs of the child or young person newly diagnosed with Type 1 diabetes, and their family
- Support a child/young person with Type 1 diabetes, and their family, in the early stages after diagnosis
- Provide information and support to a child or young person recently diagnosed with Type 1 diabetes, and their family, to enable them to establish safe and healthy dietary aims
- Support a child/young person with Type 1 diabetes, and their family, in the first year after diagnosis
- Enable a child or young person with Type 1 diabetes, and their family, develop their knowledge and skills about diet and diabetes
- Gather and evaluate information to establish the healthcare needs of children and young people with diabetes
- Agree individualised care plans with children and young people to manage diabetes
- Implement and monitor individualised care plans to meet the needs of children and young people with diabetes
- Ensure the safety of a child/young person with diabetes in school
- Support a child/young person and their family using insulin therapy to manage their diabetes Enable a child/young person with diabetes to begin to take oral medication to improve their health Monitor and support a child/young person with diabetes using oral medication to improve their health
- Provide care and support to meet the immediate needs of the child or young person newly diagnosed with Type 2 diabetes, and their family
- Provide advice and support to enable a child or young person recently diagnosed with Type 2 diabetes, and their family, manage their diabetes by diet and physical activity
- Provide ongoing advice and support about food and physical activity to a child or young person with Type 2 diabetes, and their family, to enable them to manage challenges to their health
- Assess the need for a child/young person with Type 2 diabetes to start insulin therapy

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- Enable a child or young person with Type 2 diabetes to start insulin therapy
- Undertake advanced examination and risk assessment of the feet of an individual with diabetes
- Implement specialist foot treatment for an individual with diabetes
- Provide wound care to treat an ulcerated foot of an individual with diabetes
- Provide advice and information to men with diabetes about erectile dysfunction
- Assess a man with diabetes for erectile dysfunction
- Provide treatment for erectile dysfunction in a man with diabetes
- Provide information and advice to enable an individual with diabetes to minimise the risks of hypoglycaemia
- Arrange appointments for individuals with diabetes
- Assess the suitability of insulin pump therapy for an individual with Type 1 diabetes
- Provide preliminary education about insulin pump therapy for an individual with Type 1 diabetes
- Provide dietary education for an individual with Type 1 diabetes who is contemplating insulin pump therapy
- Enable an individual with Type 1 diabetes to administer insulin by pump
- Provide ongoing support to an individual administering insulin by pump
- Provide ongoing dietary education for an individual with Type 1 diabetes administering insulin by pump
- Provide advice and information on planning pregnancy to all women with diabetes of childbearing age
- Agree care plans to help women with diabetes prepare for a safe and healthy pregnancy
- Support and review care plans to help women with diabetes prepare for a safe and healthy pregnancy
- Agree continuing care plans for women with diabetes who are pregnant
- Agree new care plans for women with diabetes who are pregnant
- Support and review care plans for women with diabetes who are pregnant
- Agree and support care plans to help women manage their diabetes during labour and immediately following delivery
- Agree and implement care plans for women with diabetes after they have given birth
- Identify symptoms of gestational diabetes and refer a woman for further assessment
- Assess a woman for gestational diabetes and make a diagnosis
- Inform a woman of a diagnosis of gestational diabetes
- Agree care plans with women who have gestational diabetes
- Support and advise women with gestational diabetes after they have given birth
- Assess a woman for gestational diabetes and make a diagnosis
- Inform a woman of a diagnosis of gestational diabetes
- Agree care plans with women who have gestational diabetes
- Provide psychological and emotional support to a child/young person with diabetes and their family to enable them to manage their diabetes
- Provide psychological and emotional support to help a young person with diabetes develop self-management skills
- Enable a young person with diabetes develop self-management skills
- Help a young person manage their diabetes during adolescence

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- Help a young person prepare to manage the transfer from children to adults healthcare services
- Help a young person adapt to adults' healthcare services
- Identify symptoms of diabetes and refer individuals for further assessment
- Inform individuals of a diagnosis of Type 1 diabetes
- Provide therapy to meet the immediate healthcare needs of individuals newly diagnosed with Type 1 diabetes
- Support an individual with Type 1 diabetes in the early stages after diagnosis
- Help an individual using insulin therapy to manage their diabetes understand the effects of food, drink, physical activity and medication on their health and well-being
- Assist individuals with diabetes to help and support each other
- Assess and advise individuals with suspected diabetes Assess and investigate individuals with suspected diabetes Develop a diagnosis of diabetes
- Inform individuals of a diagnosis of Type 2 diabetes or impaired glucose tolerance Assess the healthcare needs of individuals with diabetes and agree care plans Work in partnership with individuals to sustain care plans to manage their diabetes Examine the feet of an individual with diabetes and advise on care
- Assess the feet of individuals with diabetes and provide advice on maintaining healthy feet and managing foot problems
- Help an individual understand the effects of food, drink and exercise on their diabetes
- Help individuals with diabetes to change their behaviour to reduce the risk of complications and improve their quality of life
- Develop, agree and review a dietary plan for an individual with diabetes Enable individuals with diabetes to monitor their blood glucose levels Help an individual with diabetes to improve blood glucose control
- Help individuals with diabetes reduce cardiovascular risk
- Enable an individual with Type 2 diabetes to start insulin therapy Help individuals with Type 2 diabetes to continue insulin therapy Identify hypoglycaemic emergencies and help others manage them
- Assist individuals with diabetes to manage their condition when they have been admitted to a hospital ward for other health needs
- Monitor and support a care plan for an individual with diabetes admitted to a general ward
- Review and evaluate the progress of a care plan for an individual with diabetes admitted to a general ward and prepare for discharge
- Work with individuals and others to minimise the effects of specific health conditions
- <http://www.trend-uk.org/resources.php>
- An Integrated Career and Competency Framework for Diabetes Nursing

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## Appendix Eight: Choosing the Right Insulin Regimen

### CHOOSING THE RIGHT INSULIN REGIMEN Guide for Practice Nurses

#### Regimen

There is no one 'Right' choice, and one regimen is not necessarily forever. If it is unsuitable it should be changed.

#### Who Decides?

Your role is to explain the options and present all the pros and cons. The final decision must be made by the person themselves.

To carry out your role, you will need to understand:

- How insulin works
- Why insulin is needed and the principles of normal insulin production
- The types of insulin available and common insulin regimens
- The benefits and disadvantages of various delivery devices

#### Common Insulin Regimens

Traditionally, people with Type 2 diabetes transferring to insulin therapy would stop taking their oral hypoglycaemic medication. However, there are many advantages to combining insulin with oral agents and this is now much more common. The advantages include:

- Lower risk of weight gain and lower risk of hypoglycaemia
- A simpler treatment regimen
- Better glycaemic control while insulin is being introduced and the dosage adjusted

Here are some examples of combination treatments and when they can be used:

- Once-daily intermediate-acting insulin at bedtime plus sulphonylurea or Metformin can be effective for people who are resistant due to obesity. It is particularly appropriate where the person's blood glucose is high overnight and in the morning, but comes down once they start their daily activities.

Insulins:      Insulatard      Humulin I

- Twice daily pre-mixed insulin plus Metformin can be effective for people with significant hyperglycaemia after meals

Insulins:      Human Mixtard 30      )timed 20-30 mins      Novomix 30      )timed with  
                 Humulin M3                      )before meals      Humalog Mix 25      )meals

- Long acting peakless insulin (taken whenever is convenient, provided it is taken at the same time each day) plus OHAs can be used where the person has high blood glucose during the day and at night, and 'would otherwise need twice-daily basal insulin injections in combination with oral anti-diabetic drugs'. Long- acting basal insulin can be used with OHAs 'For those whose lifestyle is significantly restricted by recurrent symptomatic hypoglycaemic episodes' (NICE). Finally, it is useful for people who are reluctant to consider insulin therapy, as there is only one daily injection involved. This needs to be weighed against the flexibility to deal with increases in blood glucose levels at meal times and to adjust according to activity.

Insulins:      Glargine      Detemir

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## Appendix Nine: Referral form: Diabetes Specialist Nursing Services (North Tees)

### Referral Form for Diabetes Specialist Nursing Service

<b>Name:</b>		<b>DOB:</b>	
<b>Patient's Tel No:</b>		<b>NHS No:</b>	
<b>Address:</b>			
<b>Date of Diagnosis:</b>			
<b>Treatment for Diabetes:</b>			
<b>Dr's Name:</b>		<b>*Urgent / Non-Urgent</b>	<small>*Please circle</small>

<b>Treatment:</b>							
Diet only:		Diet & Medication:		Medication:			
Diet & Insulin:		Insulin:					
Which Insulin Regime:		Once Daily:					Units
		Twice Daily:		am		pm	Units
		Four times Daily					Units
HbA1c:		mmol/mol	BMI:				
<b>Reason for Referral</b> – PLEASE DO NOT USE THIS FORM IF THE PATIENT REQUIRES BYETTA/VICTOZA. A LETTER OF REFERRAL WOULD NEED TO BE SENT TO DIABETES CONSULTANT LED CLINIC							
<b>Any Other Illness / Medication/ Relevant History</b>							
Referred by:					Date:		

**Please fax to Diabetes Specialist Nursing Team, University Hospital of North Tees on 01642 624091**

## Appendix Ten: Steps to decrease pregnancy risk

### Information for GPs and the Primary Care Team Pregnancy in Women with Type 1 and Type 2 Diabetes

Women with diabetes have high risk pregnancies compared to the general maternity population with Type 2 diabetes carrying the same risks as Type 1 diabetes. Pre-conception care and good blood glucose control before and during pregnancy can decrease these risks.

All women with diabetes of child bearing age should receive the following information

- The risks associated with pregnancy in terms of fetal loss, growth and abnormalities
- Good blood glucose control before and during pregnancy offers the best chance of decreasing the risks
  - HbA<sub>1c</sub> should be <48mmol/mol
  - Home blood glucose tests should be between 3.5 and 5.9 mmol/l fasting and not higher than 7.8mmol/l post-prandially
- Effective and reliable contraception is important to avoid unplanned pregnancy
  - Combined OCP, IUCD, progesterone injections, implants and patches are safe to use
- Women should contact their diabetes team if they are considering pregnancy

Women who wish to become pregnant

- Check HbA<sub>1c</sub>
- Refer to Preconception Combined Clinic for advice
- Review medication
  - Discontinue ACE inhibitor
  - Substitute Methyl dopa for treatment of hypertension
  - Discontinue statin
  - Continue contraception until the woman has been seen by the Diabetes care team
- Women on oral hypoglycaemics will be switched to insulin by the Diabetes care team
- Monitor blood glucose more frequently as advised by the Diabetes care team
- Prescribe Folic acid 5mg to continue to 12 weeks' gestation
- Give smoking cessation advice
- Explain the benefits of breast-feeding

Women who are already pregnant

- Steps as above
- Urgent faxed or telephoned referral to Diabetes Specialist Team at local hospital for Combined Medical / Obstetric care

Women who have had their baby

- Commence effective contraception as soon as possible
- Review medication
- Women treated with insulin during pregnancy will continue with it while breast-feeding
- ACE inhibitors and statins should be avoided while breast-feeding but restart when weaned to re-introduce cardio-protection

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## Appendix Eleven: Antibiotic Treatment of Foot Complications

### Antibiotic treatment of foot complications in people with diabetes

The following suggestions are based on local specialist clinical experience and opinion from national experts. There is limited clinical trial evidence to inform these recommendations but they refer to national guidance where available<sup>1</sup>. They have been developed and will be reviewed with the local microbiology unit.

**Any patient with such infections should be assessed by and may need to remain under the care of the multi-professional diabetes specialist team with surgical consultation as required**

### Diagnosis of infection

- a clinical diagnosis should be made, based on the findings in the foot and the changes in these findings with time and / or therapy
- markers of inflammation, e.g. CRP, may be useful in conjunction with full blood count findings
- the use of superficial swabs to diagnose infection and / or guide treatment is discouraged as it is difficult to differentiate between colonising and pathological organisms resulting in such swabs being of no clinical value. Deep tissues swabs can be useful and should be sent after appropriate podiatric or surgical debridement of the wound

### Other considerations

- Patients with large or small vessel disease, peripheral neuropathy, poor glycaemic control or other factors contributing to poor healing, such as concomitant steroid use or poor nutrition, can deteriorate rapidly
- Patients need review of these factors included in their overall management plan for diabetic foot problems
- X-Ray evidence of osteomyelitis may take some weeks to develop
- Charcot foot may masquerade as, or co-exist with, infection

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## Suggested antibiotic regimes

History of allergy and recent antibiotic exposure should be taken into account for individual patients and patients should know how to access emergency advice if the foot worsens despite antibiotic therapy. Low doses may not be effective but renal and liver function should be considered when prescribing. Concomitant drug therapy may need adjustment.

### Mild Infections – Duration – Usual duration: 7 – 14 days

Feature	Sample	First Choice	Second choice (including penicillin hypersensitivity)	MRSA
Purulent or inflamed wound present: <ul style="list-style-type: none"> <li>Limited to skin and superficial soft tissues</li> <li>Inflammation extends &lt;2cm from wound</li> <li>Not systemically unwell</li> </ul>	Ulcer swabs <b>only if pus</b> is present or initial following treatment failure	Oral <b>flucloxacillin</b> 1g qds (500mg qds if frail, elderly or poorly tolerant)	Oral <b>clarithromycin</b> 500mg bd, <b>or</b> oral <b>doxycycline</b> 200mg stat followed by 100mg od or bd	Check the sensitivity, if sensitive  Oral <b>clarithromycin</b> 500mg bd, <b>or</b> oral <b>doxycycline</b> 200mg stat followed by 100mg od or bd  If resistant to above antibiotics: discuss with microbiologists.

**Follow up:** if the patient does not respond/partially responds to initial treatment: oral **Clindamycin** 300-450mg QDS + oral **Ciprofloxacin** 500mg BD. Please seek advice from diabetic team/ microbiologists if no improvement

### Moderate Infections – Duration – Usual duration: 2-6 weeks: ideally 10 – 14 days IV followed by 2-4 weeks of oral.

Feature	Sample	First Choice	Second choice (including penicillin hypersensitivity)	MRSA
Purulent or inflamed wound present in a patient who is systemically well and/or one of the following: <ul style="list-style-type: none"> <li>inflammation extends &gt;2cm from wound</li> <li>lymphangitis</li> <li>spread beneath superficial fascia</li> </ul>	Soft tissue samples; deep soft tissue swabs post-debridement or after cleansing the ulcer with saline.	<b>IV Piperacillin/tazobactam</b> 4.5g tds (bd if CrCl <20ml/min)  Consider adding Teicoplanin 10mg /kg (rounded to	Documented <b>anaphylaxis to penicillin:</b> <b>IV Teicoplanin</b> 10mg /kg (rounded to nearest 100mg) 12 hourly for 3 doses then ONCE daily + <b>ciprofloxacin</b> (IV 400mg BD or oral 500mg BD) + <b>metronidazole</b> (IV 500mg TDS or oral 400mg TDS)	<b>Teicoplanin</b> 10mg /kg (rounded to nearest 100mg) 12 hourly for 3 doses then ONCE daily + <b>ciprofloxacin</b> (IV 400mg BD or oral 500mg BD) + <b>metronidazole</b> (IV 500mg TDS or oral 400mg TDS)  Adjust the dose appropriately if

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<ul style="list-style-type: none"> <li>abscess formation</li> <li>necrosis or gangrene</li> <li>involvement of muscle, tendon, joint or bone</li> </ul>	MRSA screening should be carried out.	nearest 100mg) 12 hourly for 3 doses then ONCE daily, if there is a high suspicion of MRSA	<b>Non anaphylactic reaction:</b> establish the degree of reaction <b>Meropenem</b> 1g TDS (BD if CrCl <50ml/min, reduce to OD if CrCl <10ml/min), initial treatment must be supervised and in the hospital.	the patient is elderly, has impaired renal function or is obese/underweight. The dose can be discussed with the ward pharmacist.
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**Severe infections** – Duration – Usual duration: 2-6 weeks. Patient should be transferred to hospital for in-patient treatment

Feature	Sample	Parenteral First Choice	Second choice (including penicillin hypersensitivity)	MRSA
<p>Infection in a patient with evidence of systemic inflammatory response syndrome (SIRS). SIRS is manifested by ≥2 of the following:</p> <ul style="list-style-type: none"> <li>Temperature &gt;38°C or &lt;36°C</li> <li>Heart rate &gt;90 beats/min</li> <li>Respiratory rate &gt;20 breaths/min or PaCO<sub>2</sub> &lt;32 mm Hg</li> <li>White blood cell count &gt;12 000 or &lt;4000 cells/μL</li> </ul>	<p>Blood culture; bone biopsy (whenever possible); deep soft tissue biopsy; deep soft tissue swabs post-debridement or after cleansing the ulcer with saline.</p> <p>MRSA screening should be carried out</p>	<p><b>Piperacillin/tazobactam</b> 4.5g tds (bd if CrCl &lt;20ml/min)</p> <p>Consider adding Teicoplanin 10mg /kg (rounded to nearest 100mg) 12 hourly for 3 doses then ONCE daily, if there is a high suspicion of MRSA</p>	<p>Documented <b>anaphylaxis to penicillin:</b> <b>Teicoplanin</b> 10mg /kg (rounded to nearest 100mg) 12 hourly for 3 doses then ONCE daily + <b>ciprofloxacin</b> (IV 400mg BD or oral 500mg BD) + <b>metronidazole</b> (IV 500mg TDS or oral 400mg TDS)</p> <p><b>Non anaphylactic reaction:</b> establish the degree of reaction <b>Meropenem</b> 1g TDS (BD if CrCl &lt;50ml/min, reduce to OD if CrCl &lt;10ml/min), initial treatment must be supervised and in the hospital.</p>	<p>For known MRSA,</p> <p><b>Teicoplanin</b> 10mg /kg (rounded to nearest 100mg) 12 hourly for 3 doses then ONCE daily + <b>ciprofloxacin</b> (IV 400mg BD or oral 500mg BD) + <b>metronidazole</b> (IV 500mg TDS or oral 400mg TDS)</p> <p>Adjust the dose appropriately if the patient is elderly, has impaired renal function or is obese/underweight. The dose can be discussed with the ward pharmacist.</p>

**Follow up:** once patient is stabilised from infection, review the microbiology and inflammatory marker results. Further antibiotic management should be guided by culture and sensitivity results. When the patient is suitable for discharge discuss with microbiology for suitable choices.

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## Suggested home discharge:

### Intravenous therapy

- If pseudomonas not identified: **Ertapenem** 1gm OD IV, reduce the dose if GFR <30ml/min
- If pseudomonas identified: consider adding oral Ciprofloxacin 500mg BD

Patients with MRSA colonisation or anaphylactic penicillin allergy: **IV Teicoplanin 10mg/kg** (rounded to nearest 100mg) OD + oral **ciprofloxacin** 500mg BD + oral **metronidazole** 400mg TDS

### Oral therapy

After completing at least 2 weeks of IV therapy, consider stepping down to oral therapy.

- If pseudomonas not identified: Oral **Flucloxacillin** 1g QDS
- If pseudomonas identified: consider adding oral Ciprofloxacin 500mg BD

Patients with MRSA colonisation or anaphylactic penicillin allergy: Oral **Clindamycin** 300-450mg QDS + oral **Ciprofloxacin** 500mg BD

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## Appendix Twelve: DVLA Guidance

For medical practitioners – At a glance guide to the current medical standards of fitness to drive:

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/491028/aagv1.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491028/aagv1.pdf)
- <https://www.gov.uk/guidance/current-medical-guidelines-dvla-guidance-for-professionals-conditions-d-to-f>

General information:

- <https://www.gov.uk/diabetes-driving>
- [https://www.diabetes.org.uk/Guide-to-diabetes/Living\\_with\\_diabetes/Driving/](https://www.diabetes.org.uk/Guide-to-diabetes/Living_with_diabetes/Driving/)
- <http://www.diabetes.co.uk/diabetes-and-dvla-driving-licence.html>

Information for drivers with diabetes treated by non-insulin medication, diet, or both.

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/455115/INF188X2\\_080413.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/455115/INF188X2_080413.pdf)

DIAB1 online: confidential medical information

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/254415/DIAB1.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/254415/DIAB1.pdf)

A guide to filling in your DIAB1 medical form

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/401828/INF250\\_030215.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/401828/INF250_030215.pdf)

INF188/5 Lorry and/or bus drivers with diabetes treated by diet alone; When do you need to tell us?

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/208413/INF188X5.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/208413/INF188X5.pdf)

A guide for drivers with Insulin Treated Diabetes who wish to apply for Vocational Entitlement (small lorries, minibuses, large lorries and buses)

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/251492/INS186\\_091013.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251492/INS186_091013.pdf)

VDIAB1SG – Confidential medical information (form) for Bus, Coach or lorry licence on tablets

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/435812/VDIAB1SG.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/435812/VDIAB1SG.pdf)

VDIAB1GEN – Confidential medical information for Bus, Coach or lorry licence with certain tablets or non-insulin injections

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/320722/VDIAB1GEN.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/320722/VDIAB1GEN.pdf)

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DVLA requirements and advice for the monitoring of blood glucose in people with diabetes – Summary of DVLA advice – table on page 48 & 49 in ***‘For medical practitioners : At a glance guide to the current medical standards of fitness to drive’ November 2014 Edition (including August 2015 and January 2016 amendments)***:

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/491028/aagv1.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491028/aagv1.pdf)

Licence Groups:

- <https://www.gov.uk/driving-licence-categories>

A Guide to Insulin Treated Diabetes and Driving:

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/313214/DIABINF.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/313214/DIABINF.pdf)

INF188/2:

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/455115/INF188X2\\_080413.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/455115/INF188X2_080413.pdf)

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## Appendix Thirteen: Prescribing Insulin safely poster (from Regional Insulin Safety & Knowledge project)

North Tees and Hartlepool NHS Foundation Trust

# Being forthright about insulin safety

**4 Rights  
don't make a wrong**

Can you read this fax for me?  
Is that insulin dose 20 units or 70?

So I give 25 of the Humalog Mix? What's that other number for?

They gave me the wrong pen so I just used a pencil to push the plunger and stuck the needle on the cartridge.....

**Right insulin**

**Right dose**

**Right time**

**Right device**

**Write it right**

I keep going low- can't understand it. But it's since I got my new insulin. It's cloudy, not like my old one.

-I take it at dinner time.  
-So about 7 then?  
-No pet. We always have our dinner at 12 o' clock.

Once a day always means morning.....

**Generic name or type, then trade name for double check.**  
**Is it clear or cloudy for another check.**  
**Written number and figures for units so no confusion.**  
**Time the dose is taken, ie. breakfast, lunch, evening meal and bed time.**  
**Delivery device.**

Aspart, (Novorapid), clear, ten 10 units with lunch, via Flexpen  
 30/70 mix, Humulin M3, cloudy, fourteen 14 units with breakfast and evening meal, Luxura pen



**On the phone?**  
Spell it out this way and make it clear.

putting patients first
Regional Insulin Safety and Knowledge Project
Pasinate about health

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## Appendix Fourteen: Specialist Weight Management Advice Service referral form



Referral Form -  
Amended Aug 2015.doc

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## Appendix Fifteen: NICE Quality Standards of Care for Diabetes in adults 2015

- People with diabetes and/or their carers receive a structured educational programme that fulfils the nationally agreed criteria from the time of diagnosis, with annual review and access to ongoing education
- People with diabetes receive personalised advice on nutrition and physical activity from an appropriately trained healthcare professional or as part of a structured educational programme
- People with diabetes participate in annual care planning which leads to documented agreed goals and an action plan
- People with diabetes agree with their healthcare professional a documented personalised HbA1c target, and receive an ongoing review of treatment to minimise hypoglycaemia
- People with diabetes agree with their healthcare professional to start, review and stop medications to lower blood glucose, blood pressure and blood lipids in accordance with NICE guidance
- Trained healthcare professionals initiate and manage therapy with insulin within a structured programme that includes dose titration by the person with diabetes
- Women of childbearing age with diabetes are regularly informed of the benefits of preconception glycaemic control and of any risks, including medication that may harm an unborn child. Women with diabetes planning a pregnancy are offered preconception care and those not planning a pregnancy are offered advice on contraception
- People with diabetes receive an annual assessment for the risk and presence of the complications of diabetes, and these are managed appropriately
- People with diabetes are assessed for psychological problems, which are then managed appropriately
- People with diabetes with or at risk of foot ulceration receive regular review by a foot protection team in accordance with NICE guidance.
- People with diabetes with a limb-threatening or life-threatening diabetic foot problem are referred immediately to acute services, and the multidisciplinary foot care service is informed
- People with diabetes with an active foot problem that is not limb-threatening or life-threatening are referred to the multidisciplinary foot care service or foot protection service within 1 working day and triaged within 1 further working day
- People with diabetes admitted to hospital are cared for by appropriately trained staff, provided with access to a specialist diabetes team, and given the choice of self-monitoring and managing their own insulin
- People admitted to hospital with diabetic ketoacidosis receive educational and psychological support prior to discharge and are followed up by a specialist diabetes team
- People with diabetes who have experienced hypoglycaemia requiring medical attention are referred to a specialist diabetes team

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## Appendix Sixteen: Contributors and Secondary care contact details

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Dr Sue Jones	Consultant Diabetologist
Dr Sony Anthony	Consultant Diabetologist
Lisa Doughty Maggie Robinson	Diabetes Specialist Nurses
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Madeleine Henson	Podiatrist
Sue Pott	Retinal Screening Manager
Joanna Bushnell	Medicines Optimisation Pharmacist
Dr Rupert Smith	General Practitioner
Dr Rashmi Dube	Consultant Microbiologist

Secondary Care Contact Details	
Consultant Team for North Tees and Hartlepool NHS Foundation Trust	
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