



North West London Type 2 Diabetes Guidelines

Helping healthcare practitioners manage adults with diabetes

We would like to acknowledge and thank all healthcare partners and people with diabetes across North West London who contributed their expertise in producing and updating these guidelines

These guidelines were ratified by the North West London Diabetes Clinical Reference Group in December 2022

Next Review date July 2023

For queries, please email: nwlccc.diabetes@nhs.net

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WHOM TO TEST

Early diagnosis of Diabetes is important : 50% of newly presenting people with Type 2 Diabetes will already have ≥ 1 complications ¹

Diabetes is often missed in the elderly

At least half of people with Type 2 Diabetes are asymptomatic²

Finger prick capillary results can not be used to diagnose Diabetes³

Glycosuria on its own does not confirm Diabetes

People PRESENTING WITH THE FOLLOWING SYMPTOMS:

- Excess thirst
- Polyuria (especially if nocturia)
- Weight loss
- Urinary incontinence
- Tiredness
- Pruritus Vulvae / recurrent candidiasis
- Recurrent infections / abscesses
- Balanitis
- Blurred Vision / changes in visual acuity
- Erectile Dysfunction
- Pain / Numbness / foot ulcers
- Non specific or unexplained symptoms

People AT INCREASED RISK OF DIABETES:

- People with BMI > 30
- People aged over 40 with BMI 25-30 (overweight)
- People aged 25–39 of South Asian, Chinese descent (especially those with BMI > 23)
- People with a family history of diabetes
- Women with polycystic ovary syndrome.
- Coronary disease, Cerebrovascular disease, peripheral vascular disease or hypertension/hyperlipidaemia.
- people on prolonged steroid therapy.
- people on atypical anti-psychotic drugs.

People AT HIGH RISK OF DIABETES:

- Women who have had Gestational Diabetes (screen at 6 weeks and one year post-partum, and then yearly)
- Those known to have impaired glucose tolerance, HbA1c 42-47mmol/mol or oral glucose tolerance test 2-hour value between 7.8 mmol/l and 11.1 mmol/l (Impaired Glucose Tolerance IGT) or fasting glucose 5.5 - 6.9mmol/l (Non Diabetic Hyperglycaemia NDH).

1. UKPDS Group. UK Prospective Diabetes Study 6. Complications in newly diagnosed Type 2 diabetic people and their association with different clinical and biochemical risk factors. **Diabetes Research. 1990;13:1-11**
2. World Health Organisation. **Report of a WHO Consultation 1999**
3. The Expert Committee on the diagnosis and Classification of Diabetes Mellitus. **Diabetes Care. 1997;20 (7); 1183-1203**

ROUTINE DIAGNOSIS OF DIABETES

DIAGNOSTIC CRITERIA FOR DIABETES

Diabetes may be diagnosed on any of the following criteria ([WHO 2006](#), [John 2012](#)).

	Diabetes	High risk of Diabetes	Normal
HbA1c	≥ 48 mmol/mol	42-47 mmol/mol	< 42 mmol/mol
Fasting glucose	≥ 7 mmol/L	5.5 -6.9 mmol/L	≤ 5.4mmol/L
2 hr glucose in OGTT	≥ 11.1 mmol/L	7.8-11.0 mmol/L	≤ 7.7 mmol/L
Random glucose	≥ 11.1 mmol/L		

Consider an urgent direct access CT scan (to be performed within 2 weeks), or an urgent ultrasound scan if CT is not available, to assess for pancreatic cancer in people aged 60 and over with weight loss **and the new onset of diabetes**. <https://www.nice.org.uk/guidance/ng12>

When diabetes and pancreatic adenocarcinoma coexist a diagnosis of diabetes usually precedes the diagnosis of pancreatic cancer by 24 months in 74–88% of people

WHICH TEST IS BEST?

National and international expert groups do not know. Relevant groups (WHO, ADA, NICE) simply advise that HbA1c is now an option for diagnosing Diabetes.

NWL guidance recommend HbA1c – except in those groups where HbA1c may be unreliable and glucose should be used.

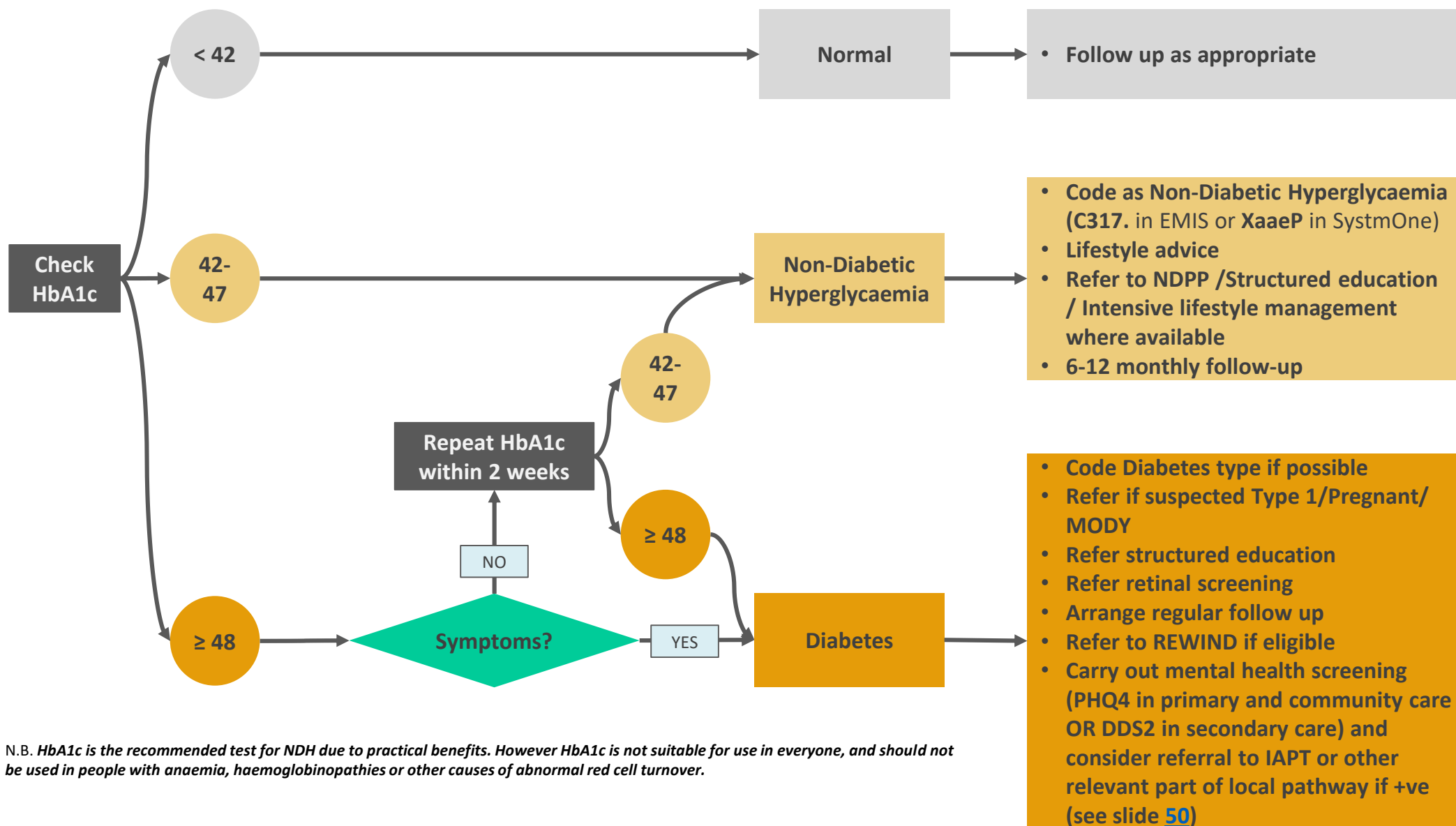
SHOULD A POSITIVE TEST BE REPEATED?

For glucose – yes, in most cases, a repeat glucose test is advised, unless there are classical osmotic symptoms of diabetes. Glucose measurements have greater biological variability compared to HbA1c.

For HbA1c – yes, in asymptomatic people. National guidance now advises a repeat HbA1c **within two weeks** in asymptomatic cases, as mislabelled samples or lab error are possible. Both results must be ≥48 mmol/mol to diagnose Diabetes; if the results are discordant, the lower is used.

The repeat sample must be sent with clinical detail (e.g. “repeat HbA1c to confirm diagnosis of Diabetes”), as repeats within 30 days may be rejected by the lab.

Do not delay urgent care while awaiting second test. For young, very symptomatic, or ill people, check ketones and seek specialist advice if necessary.



N.B. *HbA1c is the recommended test for NDH due to practical benefits. However HbA1c is not suitable for use in everyone, and should not be used in people with anaemia, haemoglobinopathies or other causes of abnormal red cell turnover.*

ROUTINE DIAGNOSIS OF DIABETES

WHEN NOT TO USE HBA1C TO DIAGNOSE DIABETES

These are the most common situations where HbA1c is not suitable.

Except in pregnancy, diagnose by fasting glucose ≥ 7.0 mmol/L twice, or once with symptoms or a random blood glucose ≥ 11.0 mmol/L with symptoms.

In pregnancy, follow NICE guidelines.

1. Rapid onset of Diabetes – an increase in HbA1c may not be detected until a few weeks later.
 - a. Suspected Type 1 Diabetes – rapid onset of symptoms, weight loss, ketosis.
 - b. Children – because most will have Type 1 Diabetes.
 - c. Steroids, antipsychotics & immunosuppressants can raise blood glucose, rarely precipitously.
 - d. After pancreatitis or pancreatic surgery.
2. Pregnancy. Multiple factors make HbA1c lower in pregnancy. The diagnosis of gestational Diabetes should be made by using glucose measurements in line with NICE guidance.
3. Conditions with reduced red blood cell survival may lower HbA1c markedly.
 - a. Haemoglobinopathy which will normally be detected by the lab, but should be suspected in racial groups where there is a high prevalence of sickle trait, sickle disease or thalassaemia.
 - b. Haemolytic anaemia
 - c. Severe blood loss
 - d. Splenomegaly
 - e. Antiretroviral drugs

Fasting glucose or OGTT is recommended for diagnosis and fructosamine should be used in these people for monitoring.
4. Increased red cell survival may increase HbA1c e.g. splenectomy.
5. Renal dialysis people have a markedly reduced HbA1c especially if treated with erythropoietin.
6. Iron and B12 deficiency and their treatment. May raise or lower HbA1c, but the effect is small.

WHAT IF YOU HAVE GLUCOSE VALUES AND AN HBA1C ON A SINGLE PATIENT?

If one only is abnormal then a further abnormal test result, using the same method, is required to confirm the diagnosis.

References

WHO 2006 – http://whqlibdoc.who.int/publications/2006/9241594934_eng.pdf

John 2012 - <http://onlinelibrary.wiley.com/doi/10.1111/j.1464-5491.2012.03762.x/pdf>

For people with Type 2 diabetes and their healthcare team the possibility of achieving remission can provide motivation and hope – something to aim for. It can help to improve how people engage in their diabetes management, not only because of the need to reduce risk of complications, but also because there is a possibility of minimising the day-to-day impact of their condition.

For the local health economy there are benefits in reduction of the cost of medications and diabetes complications.

INTENSIVE LIFESTYLE INTERVENTIONS

Intensive lifestyle interventions that result in weight loss have been reported to lead to about 10-15% remission rates at one-year follow-up. Evidence for long-term remission following lifestyle interventions is limited though increasing.

Various dietary interventions such as **low fat diets**, **low carbohydrate diets**, **Mediterranean diets**, **very low-calorie diets**, and **meal replacements** have been used to achieve weight loss in people with Type 2 diabetes. An individualised approach is recommended.

The Counterbalance study tested the theory that normal blood glucose levels could be achieved through a very low-calorie diet and showed that those people with shorter duration Type 2 diabetes who achieved normal glucose control maintained this for at least six months.

The Look Ahead study, which aimed at weight loss through intensive lifestyle intervention, reported a remission rate of 7% at four-year follow-up. The Predimed study which involved an intervention with Mediterranean diets also reported remission rate of 5% at six-year follow-up.

Remission through lifestyle interventions appears more likely in **people newly diagnosed** with Type 2 diabetes and those with **lower baseline HbA1c**

Results from the larger long-term **DiRECT** study demonstrated a 46% remission rate in routine Primary Care using a low-calorie diet and supportive follow up at 1 year, with 36% remaining in remission at 2 years.

BARIATRIC (METABOLIC) SURGERY

Different remission rates have been reported depending on the procedure used, criteria for defining remission among other factors. An international consensus statement endorsed by 45 international diabetes associations including Diabetes UK and the ADA reported that Type 2 diabetes remission occurs in about 30–60% of people following surgery. To date, there is no reliable data to view surgery as a permanent cure, although remission of up to 15 years has been reported. Generally, the **median diabetes-free years** for people with Type 2 diabetes undergoing surgery is about **eight years**, depending on the procedure and available data suggest an erosion of remission over time.

Some studies have reported relapse rates of approximately 20% at three years and 25–35% at five years.

Whilst most of the long-term benefits of bariatric surgery can be attributed to weight loss, it has been suggested that some improvements in glucose control may occur independent of weight loss, via changes in gut hormones, microbiota, bile acid metabolism, intestinal glucose metabolism and nutrient sensing

86% of obese people who manage to lose 15kg of weight within 6 years of diagnosis achieved remission from Type 2 diabetes

COMPLETE REMISSION OF T2DM

Type 2 Diabetes Remission can be confirmed if a person has achieved all of the following criteria:

- i) Weight loss
- ii) Fasting plasma glucose or HbA1c below the WHO diagnostic threshold (<7mmol/l or <48mmol/mol) on two occasions separated by at least 6 months
- iii) The attainment of these glycaemic parameters following complete cessation of glucose-lowering therapies

Ref: <https://abcd.care/sites/abcd.care/files/resources/ABCD-and-PCDS-final-statement-3March2019.pdf>)

However, remission is a fluid state and relapse can occur in various circumstances, especially if weight is regained. Patients need to continue to have regular monitoring at least annually and will need to remain on Diabetes QOF registers. The codes used below allow patients to remain on the register.

The following codes should be used for complete Type 2 remission: **C10P1** (EMIS) or **Xaagf** (SystmOne)

PARTIAL REMISSION OF T2DM

There are various definitions of partial remission including those included in this article: <https://www.bmj.com/content/358/bmj.j4030/rr-0>
The key point is that there is significant patient benefit even if complete remission isn't achieved.

WHAT IS THE IMPACT OF REMISSION ON DIABETES COMPLICATIONS?

Little is known about the actual effect of diabetes remission on new onset diabetes complications or progression of existing complications. A long-term follow-up observational study has concluded that bariatric surgery was associated with higher remission rates and fewer microvascular and macrovascular diabetes complications.

Systematic reviews have suggested that bariatric surgery may:

Protect against new cases of diabetic retinopathy, and its progression in people with Type 2 diabetes

Prevent the incidence and progression of albuminuria and stop the decline of renal function

It is recommended however that people diagnosed with diabetes continue with annual retinal and renal screening for life, even if they are in remission. The same targets for risk factors such as blood pressure and lipids should apply

Remission from Type 2 diabetes is most likely through significant weight loss (this is normally 10-15kg of weight or 10-15% of body weight).

Achieving significant weight loss is possible through a number of approaches including those below:

A Very Low Calorie Diet or VLCD (800 calories/day). The best research evidence on how to achieve remission is based on the [DiRECT study](#) which was published in 2017. In that study, 46% the people who went on an 800 calorie Very Low Calorie Diet achieved remission at one year and 36% remained in remission at 2 years. Importantly, **78%** were successful in stopping their **diabetes medication**. Nearly **86%** of people who lost more than 15kg were in **remission at one year**.

The VLCD course normally lasts for 24 weeks: 12 weeks replacing all meals with soups, shakes and snacks from a specially formulated diet plan, and then 12 weeks gradually reintroducing food. This approach is challenging, but offers the highest chance of achieving sufficient weight loss over a short period.

REWIND PROGRAM. Based on leading research by Diabetes UK, REWIND is an NHS commissioned programme for people with type 2 diabetes, which has shown an average weight loss of 12KG and 18mmol/mol HbA1c reduction after 30 weeks. This one year, three step program supports individuals to REWIND thier diabetes. On day one with the exception of Metformin, all diabetic medications are stopped. Step 1 -complete a 12 week low calorie diet plan, followed by Step2 - reintroduction of healthy eating over 12 weeks. Step 3 ongoing support with diet and exercise over 6 months.

Low Carbohydrate and **Mediterranean style** diets are very effective in helping people achieve improvements in blood glucose and body weight whilst reducing need for medication, although there have been no formal remission trials like with VLCD. The key is to reduce the amount of starchy carbohydrates and sugary food eaten.

The **Prospective Urban Rural Epidemiology (PURE)** epidemiological cohort [study](#) demonstrated potential benefits of a low carb diet across a population. Dietary intake of 135,335 individuals was recorded using validated food frequency questionnaires.

High carbohydrate intake was associated with higher risk of total mortality, whereas total fat and individual types of fat were related to lower total mortality. Total fat and types of fat were not associated with cardiovascular disease, myocardial infarction, or cardiovascular disease mortality, whereas saturated fat had an inverse association with stroke. The authors recommended that Global dietary guidelines should be reconsidered in light of these findings.

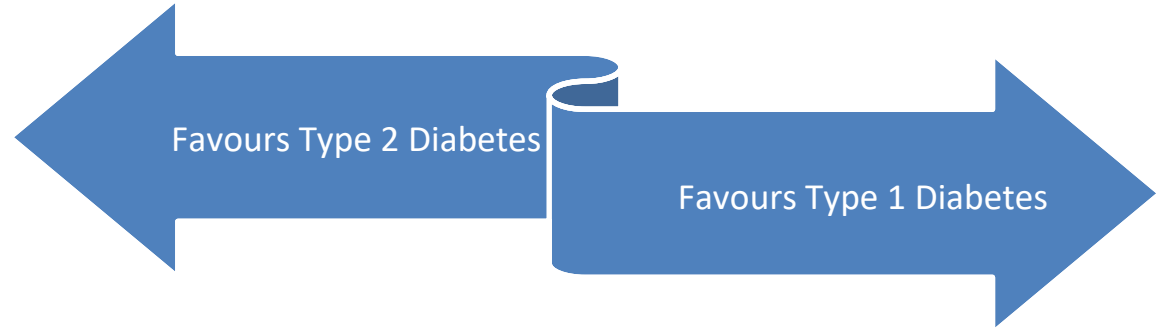
Many people with Type 2 diabetes consume large quantities of carbohydrates. The Carbs and Cals [World Foods](#) book is a useful resource to aid conversations with people and demonstrate the impact of starchy carbs on glycaemic control.

Intermittent fasting is the other approach that has been demonstrated to be effective in supporting weight, blood glucose and medication reduction. This includes:

- **5:2 diet** (eating normally for 5 days a week then eating only 500-600 calories on the other two days) and
- **Time Restricted Eating** where the patient has a long period in the day when they don't eat. With time restricted eating, most people choose a 16:8 cycle, which involves not eating for 16 hours in the day. Sometimes this is also referred to as an 8-hour eating 'window'. All meals are eaten within an 8-hour time period and the patient fasts for the remaining 16 hours. Generally, this is done daily or almost daily. There is some evidence that suggests that the best period for eating is earlier in the day

WHEN AND HOW TO TEST FOR TYPE 1 DIABETES?

4% of people diagnosed with Type 2 over the age of 40 in fact have Type 1



Less likely to be Type 1 DM

- Family history of Type 2
- No family history of Type 1 Diabetes
- BMI > 28 kg/m²
- Age > 45 yrs.
- Non-white ethnic group
- Dyslipidaemia, HDL < 1.0

Consider testing for Type 1 DM using GAD* antibodies and paired C-Peptide*Glucose, or refer to secondary care

- No family history of Type 2
- 1st or 2nd degree relative with Type 1 Diabetes
- BMI < 28 kg/m²
- Age < 45 yrs.
- White European
- Any autoimmune disease
- HDL > 1.5 mmol/l

GAD antibodies* are autoantibodies against the enzyme glutamic acid decarboxylase found in pancreatic islet cells. GAD antibodies are detectable in the serum ≈80% of people with Type 1 diabetic at the onset of Diabetes

C- peptide* can be considered in situations of diagnostic uncertainty, but must be paired with a glucose level to have any significance.

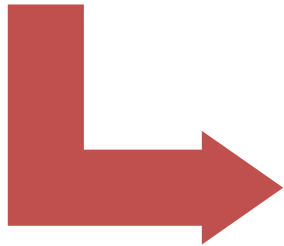
Discuss with a specialist colleague first to avoid inappropriate expensive testing.

DIAGNOSING MODY

Could the diagnosis be maturity-onset Diabetes of the young (MODY)?
See <http://www.Diabetesgenes.org>

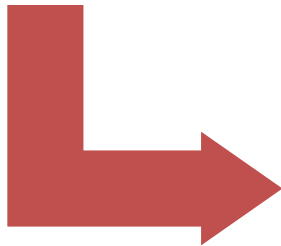
Unusual Diabetes

- Very strong maternal or paternal family history of Diabetes often in three generations with early onset, before 30yrs. With some family members diagnosed with Type 1 others with Type 2 Diabetes



Unusual response to treatment

- Highly sensitive to sulfonylurea. Or having excellent control on small amounts of insulin without having hypoglycaemia or becoming ketotic if stopping insulin



Frequent microvascular complications - MODY 1+3

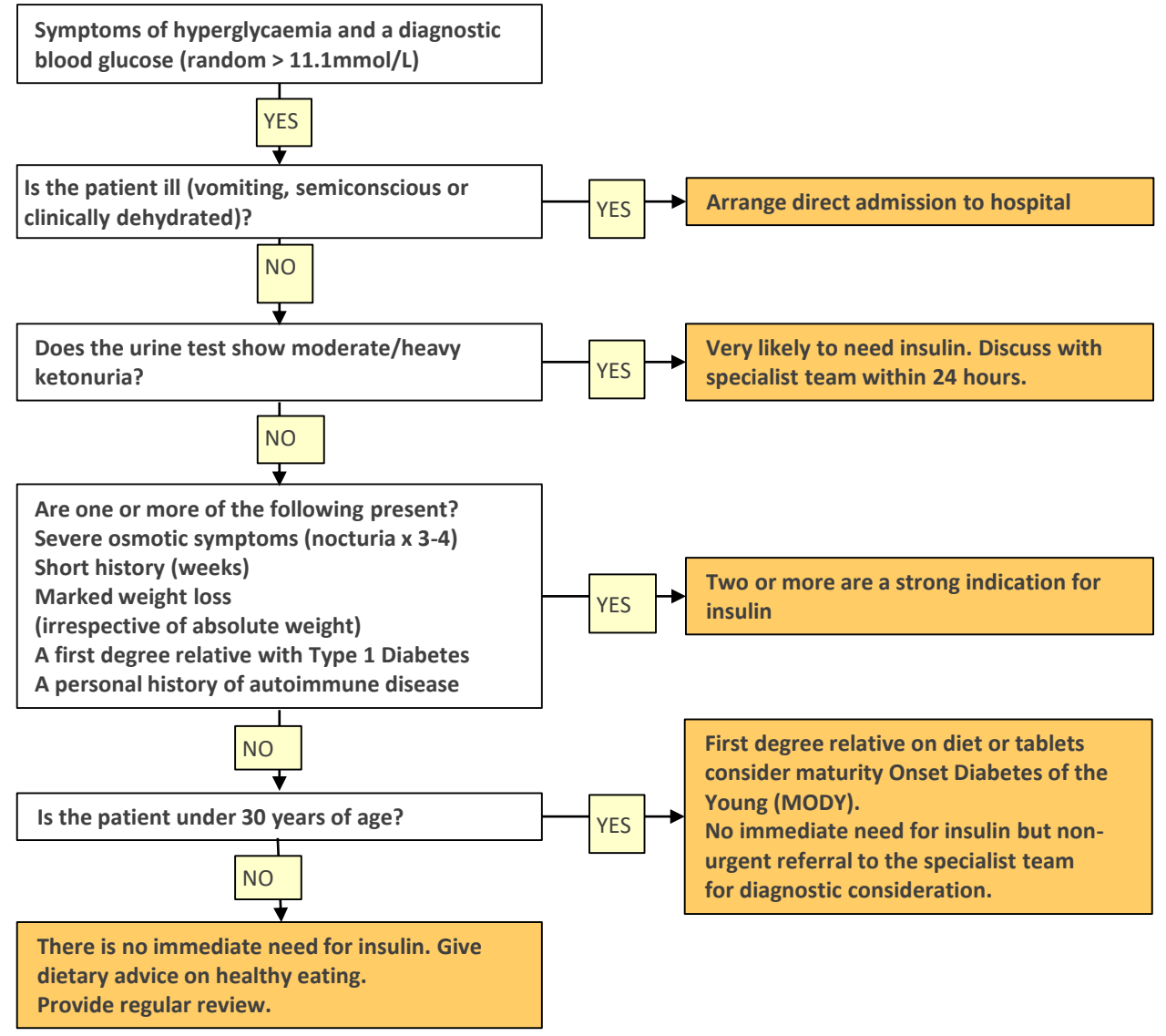
No / few microvascular complications - MODY 2

Refer to Secondary care where screening tests can be undertaken to make the diagnosis

TREATMENT DECISION TREE FOR EARLY INSULIN INITIATION

PRINCIPLES OF TREATMENT

- Offer structured education advice to all newly diagnosed people according to local availability (i.e. X-PERT, DESMOND or conversation maps). Usually wait 6-12 weeks before glucose lowering agents are introduced unless patient is symptomatic.
- Carry out mental health screening (PHQ4 in primary and community care OR DDS2 in secondary care) and refer to IAPT or other relevant part of local pathway if +ve (See slide [50](#) for details of tools)
- Metformin is recommended for all people with Type 2 Diabetes at/soon after diagnosis in view of its cardioprotective effects (UKPDS legacy effect). However:
Introduce oral hypoglycaemic agents early if fasting plasma glucose >15mmol/l and symptomatic.
- Ensure people are shown how to monitor their own diabetes if appropriate, and know what to do if results do not fall in the target range.
- Regular monitoring will identify the need to actively titrate treatment.
- Measure HbA1c every 2-6 months.
- Target HbA1c 48mmol/mol/6.5% in newly diagnosed Type 2 Diabetes and those on up to 2 oral hypoglycaemic agents unless individual target more appropriate. Involve the person in discussions about individual HbA1c target.
- In South Asian people BMI underestimates adiposity. Weight measurements need to be considered. Range for healthy weight is BMI 18.5-22.9 in South Asian people.
- Consider end of life care needs



NICE recommends that well-designed and well-implemented structured education programmes are likely to be cost-effective for people with diabetes and should be offered to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review.

Structured education programmes for people with Type 2 diabetes are an essential component of effective diabetes management. Most people will spend only 1.5 hours with a health care professional per year, the rest of the time they are required to make daily lifestyle decisions that may have a significant impact on their health and overall quality of life

The aim of structured education is for people with diabetes to improve their knowledge, skills and confidence, enabling them to take increasing control of their own condition and integrate effective self-management into their daily lives. High-quality structured education can have a profound effect on health outcomes and can significantly improve quality of life.

The referrer will play a huge role in successfully engaging the person with diabetes and increasing uptake of an education course.

Diabetes UK patient focus groups have shown that the attitude of health care professionals and information given at time of diagnosis can have a profound impact on people’s ability to self-manage their condition effectively.

If the person is not keen to engage, screen for psychological difficulties (PHQ4 in primary and community care OR DDS2 in secondary care) and refer to IAPT or other relevant part of local pathway if +ve, as well as assessment using Patient Activation Measure (PAM). See slide [50](#) for details of tools

STRUCTURED EDUCATION COURSES

DESMOND	Group education delivered by trained educators: Two half day sessions or one full day
X-PERT	Group education delivered by trained educators: 2.5 hr sessions over 6 weeks with annual follow-up sessions Offered as two options online (digital) and face to face group sessions
X-PERT Insulin	Group education delivered by trained educators: 2.5 hr sessions over 6 weeks with annual follow-up sessions Offered as two options online (digital) and face to face group sessions
DIGITAL STRUCTURED EDUCATION	NHS England accredited options include: <ul style="list-style-type: none"> • Changing Health • OurPath • Oviva <p>These will be available through the Know Diabetes information and support service and provide combinations of app, coaching (by dietitian or health coach), self measurement of weight / activity and in the case of OurPath, 3G-connected scales. Length of course varies from 6 weeks to 6 months, but can be fitted around working hours or other activities.</p>



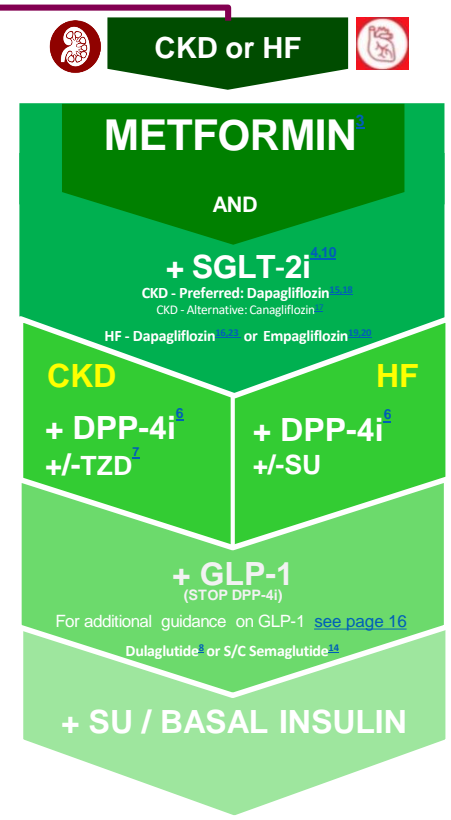
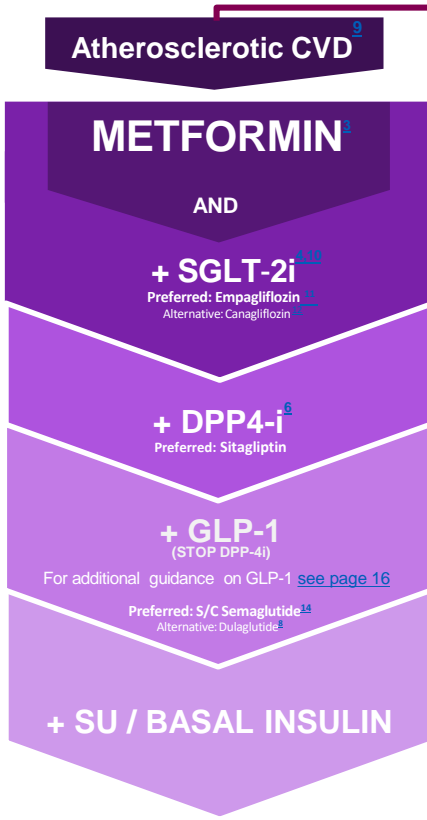
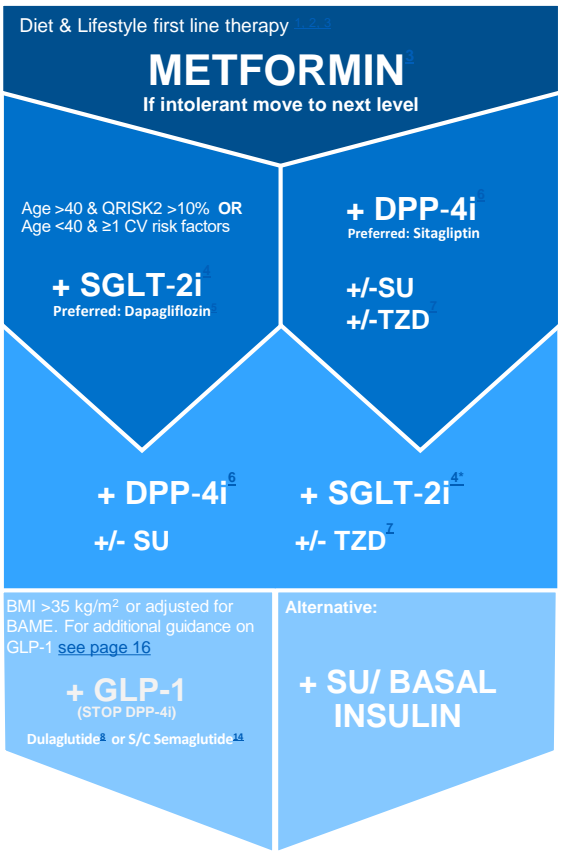
Diet & Lifestyle first line therapy ^{1,2}
Sick Day Guidance – [see page 17](#)

Does the patient have a **CARDIO-RENAL COMORBIDITY?**

NO

YES

Intensive diet & lifestyle management for all patients¹
Diabetes remission is a practical target for primary care²
Consider enrolment into REWIND Programme for either low calorie total diet replacement or low carb pathway¹



Initial therapy

Intensification if HbA_{1c}>58 or cardio-renal comorbidity

Target HbA_{1c}

Rescue therapy: Insulin or SU	Rescue based therapy if symptomatic or high HbA _{1c} Review once symptoms resolved +/- target HbA _{1c} achieved ¹
When initiating a SGLT2i	Consider a 25% dose reduction in any concomitant SU or Basal insulin & monitor for evidence of hypoglycemia
GLP-1	Only continue in those with a beneficial metabolic response after 6 months (see Additional Guidance - see page 16)

TYPE 2 DIABETES – DOSE ADJUSTMENT IN RENAL /HEPATIC IMPAIRMENT

Drug	CKD stage 1 eGFR >90 mL/min	CKD stage 2 eGFR 60-90 mL/min	CKD stage 3a eGFR 45-59 mL/min	CKD stage 3b eGFR 30-44 mL/min	CKD stage 4 eGFR 15-29 mL/min	CKD stage 5 eGFR <15 mL/min	Mild to moderate hepatic impairment	Severe hepatic impairment
Metformin	✓	✓	✓	✓ Max 500mg BD	✗	✗	Specialist initiation only	✗
Gliclazide	✓	✓	✓	✓	Use lowest effective dose		✓	✗
Linagliptin	✓	✓	✓	✓	✓	✓	✓	✓
Sitagliptin	100 mg	100 mg	100mg	50mg	25mg	25mg	✓	✗
Alogliptin	25mg	25mg	25mg	12.5mg	6.25mg	6.25mg	✓	✗
Pioglitazone (TZD)	✓	✓	✓	✓	✓	✓	✗	✗
Dapagliflozin	✓ Start 10mg	✓ Start 10mg	✓ Start 10mg	✓ Start 10mg	✓ Start 10mg	✓ Continue 10mg	✓	✓ 5mg
Canagliflozin	✓ Start 100-300mg	✓ Start 100-300mg	✓ Start 100mg	✓ Start 100mg	✓ Continue 100mg if uACR >30mg/mmol	✓ Continue 100mg if uACR >30mg/mmol	✓	✗
Empagliflozin	✓ Start 10-25mg	✓ Start 10-25mg	T2DM with eCVD ✓ Start 10mg	T2DM with eCVD ✓ Start 10mg	T2DM ✗ T2DM + HF eGFR < 20 ✗	✗	✓	✗
Ertugliflozin	✓ Start 5-15mg	✓ Start 5-15mg	✓ Start 5mg	✓ Continue 5 mg	✗	✗	✓	✗
Liraglutide	✓	✓	✓	✓	✓	✗	✓	✗
Semaglutide	✓	✓	✓	✓	✓	✗	✓	Caution: limited information
Dulaglutide	✓	✓	✓	✓	✓	✗	✓	✓
Insulin	✓	✓	✓	✓	✓	✓	✓	✓

Be Aware: Diminished glycaemic effect of SGLT-2i with eGFR < 45 mL/min, however sustained cardio-renal protection

Key ✓ Initiate ✓ No new initiation; continue at stated dose ✗ Discontinue

Treatment priority

Weight loss as a secondary benefit of glucose lowering therapy

Semaglutide subcutaneous

(once weekly)

28 days supply = 1 box of 1 pen, each pen contains four doses.

Semaglutide oral (once daily)¹³

- Use S/C Semaglutide wherever possible as greater efficacy and proven CV benefit. Oral Semaglutide should only be considered for patients who are unable to receive GLP-1 in an injectable form.
- Confirm person can adhere to the fasting administration requirement (no tea, coffee, milk, food, other medicines for 30 minutes after dosing) and an increase in total daily dosing frequency

Alternative subcutaneous preparation

Liraglutide

(once daily dose - maximum 1.2 mg)

One pre-filled pen contains 18 mg.

Primary CV risk reduction (if high risk of CVD)

Dulaglutide

(once weekly)

28 days supply = 1 box of 4 pens, each pen contains one dose.

Secondary CV risk reduction (if established CVD)

Semaglutide subcutaneous

(once weekly)

28 days supply = 1 box of 1 pen, each pen contains four doses.

Dulaglutide

(once weekly)

28 days supply = 1 box of 4 pens, each pen contains one dose.

Definitions

Established CVD:

- Evidence of prior cardiovascular event (e.g. MI/Stroke/UA),
- Prior coronary, carotid or peripheral arterial revascularisation or peripheral vascular disease
- Proven myocardial ischaemia

High risk of CVD:

- Absence of established CVD, **and**
- CVD risk factors including but not limited to:
 - coronary, carotid or lower extremity artery stenosis
 - eGFR persistently <60 mL/min/1.73 m²
 - hypertension with left ventricular hypertrophy; or persistent albuminuria

NICE Recommendation for GLP-1 agonist therapy ²¹ Starting & Dose Titration:

If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, consider triple therapy by switching one drug for a GLP-1 mimetic for adults with type 2 diabetes who:

- Have a BMI ≥35 (adjust according to ethnicity) & specific psychological or other medical problems associated with obesity
- Have a BMI <35 and for whom insulin would have significant occupational implications
- Have a BMI <35 for who weight loss would benefit other significant obesity-related comorbidities
- BMI Adjustment for Obesity: White European ≥30 & Asian ≥27.5 ²²
- Dulaglutide 1.5 mg OW; if required maybe titrated by 1.5 mg every 4 weeks as tolerated to a maximum dose 4.5 mg OW
- S/C Semaglutide 0.25mg OW, up titrate by 0.25mg every 4 weeks to maximum dose 1 mg OW
- PO Semaglutide 3mg OD, up titrate to 7mg after 1 month, maximum dose 14 mg OD if required
- Liraglutide 0.6 mg OD, up titrate to 1.2mg after one week to maximum dose 1.2mg daily (as per NWL guidelines)

Sick Day Guidance – to be reiterated to patients at every opportunity

When unwell (acute illness):

Fever, sweats, shaking

Vomiting / diarrhoea

Unable to eat or drink

Miss out / Omit / Pause:

S – SGLT-2i
A – ACEi
D – Diuretics
M – Metformin
A – ARBs
N - NSAIDs

After 2-3 days:

Feeling better = Restart paused medicines

Not better = seek medical attention

Increase blood glucose monitoring during acute illness and check for ketones. If you are using daily insulin or an SUs, you may need to increase (or decrease) the amount taken to maintain appropriate glucose control. Ensure fluid intake to minimise dehydration.

Adapted from Imperial College Healthcare NHS Trust Renal Sick Day Rules

Lifestyle Counselling – to be reiterated to patients at every opportunity

Dietary Guidance

Seek dietitian input. Individualised approach: low fat, low carbohydrate / low Glycaemic Index diet. Alternatives include low calorie total diet replacement programmes (NWL REWIND).

Physical Activity

Realistic targets should be set. The benefits of regular exercise should be explained and people should be advised to perform regular aerobic activity. Clinical studies show that walking for 30 minutes every day has cardiovascular benefits.

Weight Management

Weight loss can help the patient achieve Type 2 diabetes remission. Realistic initial weight loss target of 5% to 10% of starting weight. Consider drug therapy, e.g SGLT-2i or GLP-1. Consider surgical intervention.

Smoking Cessation & Alcohol consumption

Assess patients for smoking status and refer to Smoking Cessation Teams for support. Alcohol may influence blood glucose control (Hyper/Hypo glycaemia respectively).

Medication review

Reassess the person's needs and circumstances at each review (3-6 months) and think about whether to stop any medicines that are not effective. Adjustments for Renal & Hepatic Impairment – see [page 15](#).

GLP-1

Only continue in those with a beneficial metabolic response after **6 months** (reduction of ≥ 11 mmol/mol [1.0%] in HbA1c and weight loss of $\geq 3\%$ of initial body weight).

SGLT-2i

Stop & reassess if complicated by active foot ulcer or DKA (could be euglycemic).

DPP-4i

Not to be used in conjunction with GLP-1.

TZD

Stop in the event of HF, DKA or bladder cancer.

SU

In the event of significant hypos, stop & reassess.

Caution should be exercised when using semaglutide in patients with diabetic retinopathy treated with insulin. In patients with diabetic retinopathy treated with insulin and semaglutide, an increased risk of developing diabetic retinopathy complications has been observed. These patients should be monitored closely and treated according to clinical guidelines.

Diabetes Remission Programme



Diabetes remission is a practical target for primary care¹. Consider enrolment into NWL REWIND Programme for either low calorie total diet replacement or low carb pathway².

[For more details, click here](#)

[For full pathways, click here](#)

MHRA update June 2022: Checking Vitamin B12 serum levels in patients treated with metformin³

Test levels in patients with symptoms suggestive of, or risk factors associated with, B12 deficiency. The risk increasing with higher doses of metformin and treatment duration.

Given the recent wealth of publications regarding cardiovascular & renal outcome trials in type 2 diabetes, this Type 2 Diabetes Management Algorithm is meant as a quick reference guide as we move away from glucose-centric prescribing, based on current evidence as of August 2020. For more in-depth guidance please refer to full [North West London Diabetes Guidelines](#), the [EASD-ADA Consensus Document](#), or other [inter]national guidelines. [Also see CaReMe multi-association position statement](#).

Lifestyle management should be part of the ongoing discussion with individuals with T2DM at each visit. Increasing physical activity and reducing body weight improves glycaemic control and should be encouraged in all people with T2DM¹. Glycaemic treatment targets should be individualised based on patient preferences and patient characteristics, including frailty and comorbid conditions¹. All drugs can cause side effects, consult BNF or summary of product characteristics for full side effect profile of individual drugs. Always offer advice on sick day guidance for patients on Metformin and/or SGLT-2i¹. Stop SGLT-2is peri-operatively or if restricted food intake or dehydration¹. Patients on insulin treatment should always be advised never to stop or significantly reduce their insulin as part of the sick day response¹. SU & TZD both have low acquisition cost, this should be taken into consideration alongside increased risk of weight gain and hypoglycaemia risk (SU).

Abbreviations:

T2DM; type 2 diabetes mellitus; NWL REWIND; North West London Reducing Weight with Intensive Dietary support, eGFR, estimated glomerular filtration rate; SGLT-2i, sodium-glucose cotransporter-2 inhibitor; DPP-4i, dipeptidyl peptidase 4 inhibitor (gliptin); SU, sulfonylurea; TZD, thiazolidinedione; BMI, body mass index; GLP-1, glucagon-like peptide-1 receptor agonist; +ive, positive; CVD, cardiovascular disease; eCVD, established cardiovascular disease; MI, myocardial infarction; HF, heart failure; CKD, chronic kidney disease with eGFR < 60; HbA_{1c}, hemoglobin A1C; BD, twice daily; ACEi, Angiotensin-converting enzyme inhibitors; ARB, Angiotensin II receptor blocker; NSAID, Non-steroidal anti-inflammatory drug; DKA, diabetic ketoacidosis; uACR, urine albumin creatinine ratio; HFrEF, Heart Failure with reduced Ejection Fraction; HFpEF, Heart Failure with preserved Ejection Fraction.

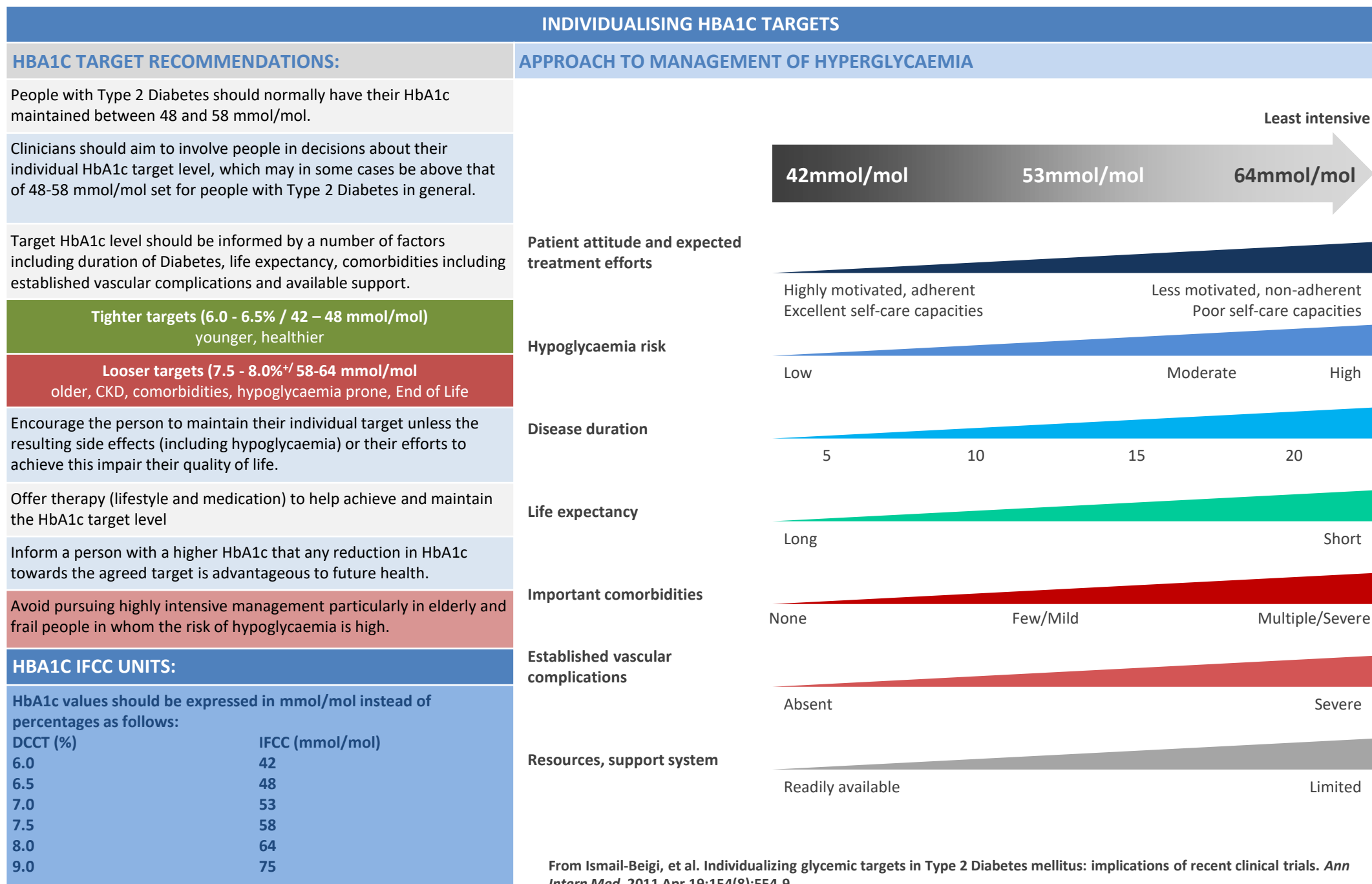
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2. NWL REWIND Programme (**R**educing **W**eight with **I**ntensive **D**ietary support) [For more details, click here](#). [For full pathways, click here](#).
3. MHRA volume 15, issue 11: June 2022: [Drug Safety Update on metformin + Vitamin B12 monitoring](#)
4. When prescribing an SGLT-2i, consider risk of volume depletion, euglycemia DKA in insulin deficient cohorts and lower limb amputation (class warning, but only observed in Cana and Eurtu). Caution in frail patients and always follow sick day rules. For more information, refer to full [North West London Diabetes Guidelines](#)
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6. FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin <https://bit.ly/2ZZCNni>
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8. REWIND (Dulaglutide CVOT); Lancet 2019; 394: 121–30; DOI: [https://doi.org/10.1016/S0140-6736\(19\)31149-3](https://doi.org/10.1016/S0140-6736(19)31149-3)
9. Patients with established atherosclerotic cardiovascular disease having had an ischemic event (e.g myocardial infarction or stroke)
10. Consider initiating Met + SGLT-2i rather than stepwise. This is in line with Position Statement by Primary Care Diabetes Europe; S. Seidu, et al., A disease state approach to the pharmacological management of Type 2 diabetes in primary care: A position statement by Primary Care Diabetes Europe, Prim. Care Diab. (2020), <https://doi.org/10.1016/j.pcd.2020.05.004>. Alternatively, the European Society of Cardiology (ESC) diabetes guideline states that SGLT-2i could be considered as first line ahead of metformin in patients with eCVD, HF or CKD - European Heart Journal (2019) 00, 169; doi: <https://doi.org/10.1093/eurheartj/ehz486>
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22. [BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups | Guidance | NICE](#)
23. DELIVER; N Engl J Med 2022; 387:1089-1098; DOI: <https://doi.org/10.1056/NEJMoa2206286>

TYPE 2 DIABETES – SUMMARY OF ANTI-DIABETIC AGENTS

Please see individual drug monographs on pages [34-37](#) and [59-60](#) for more details.

	Hypoglycaemia	Weight	GI side effects	Cardiovascular risks/benefit	Renal dosing	Liver impairment	
Metformin	No	Loss	Common	Benefits	eGFR 30-44: Max 1g daily dose Contraindicated if eGFR<30	Withdraw if risk of tissue hypoxia, predisposes to lactic acidosis	
				Caution in chronic stable heart failure			
Sulfonylureas	Associated risk	Gain	Common	Neutral	See page 15 for individual drug breakdown		
					Higher risk of hypoglycemia; increase patient monitoring	If severe, reduce dose (risk of hypoglycemia)	
DPP-4i (-gliptins)	Only when combined with SU/Insulin	Neutral	No known risks	Neutral	See page 15 for individual drug breakdown		
			Alogliptin - Common		Caution with Alogliptin and Saxagliptin in moderate-severe heart failure	Dose reduction may be required	Vildagliptin has a risk of liver toxicity
			Saxagliptin - Possible				
Thiazolidinediones (Pioglitazone)	Only when combined with SU/Insulin	Gain	No known risks	Risk Contraindicated in people with heart failure or a history of heart failure	None	Avoid, risk of liver toxicity	
SGLT-2i (-flozins)	Only when combined with SU/Insulin	Loss	No known risks	Established benefits	See page 15 for individual drug breakdown		
				Caution in significant PVD due to increased risk of digital amputation	Dose reduction may be required	Excluding dapagliflozin, avoid if severe	
GLP-1 Agonist (-tides)	No	Loss	Common	Semaglutide, Liraglutide, Dulaglutide have CV benefit	See page 15 for individual drug breakdown		
					Except Lixisenatide and Exenatide	Avoid if Liraglutide	
Repaglinide	Associated risk	Gain	Common	CVD as a rare side effect	Use with caution	Avoid if severe	
Acarbose (AGI)	If prescribed in addition to other blood glucose lowering drugs	Neutral	Common	Neutral	Avoid if eGFR<25	Avoid if severe	
Insulin	Associated risk	Gain	No known risks	Neutral	Dose reduction required, higher risk of hypoglycemia	Reduced dose required	
				Cardiac failure risk when used concurrently with Pioglitazone			



Age	<65		65-70		>70		Severe frailty or Residential care	End of Life Care
Duration > 10 years Latest HbA1c > 64-75 Complications: CVD, CKD, retinal, foot Hx of Hypoglycaemia On SU / Insulin	N	Y	N	Y	N	Y	Y	Refer to: Diabetes UK End of Life Diabetes Care Clinical Recommendations for advice on targets and potential deprescribing
Target HbA1c	<48	48-53	<48	53-58	53-58	58-64	58-69	

Adapted from Khunti and Davies 2010

KEY PRINCIPLES OF PRACTICE

- 95% of the care people with Diabetes receive is self-care and all people should have access to high quality structured education programmes e.g. X-PERT, DESMOND, conversation maps
- The ability to monitor their own glucose level gives people with Diabetes the feedback they need in order to learn how to manage their condition optimally.
- The ability to self-monitor may be affected by their mental health: use PHQ4 (in primary and community care) to screen for anxiety and depression OR DDS2 (in secondary care) to screen for diabetes distress. Use 6 item COG for cognitive impairment (more prevalent in Diabetes after age 50). See slide [31](#) for tools
- Monitoring should be based on the individual's clinical needs and in the context of Diabetes education and self-management.
- People should receive appropriate training in the technique and the actioning of the results.
- The frequency of testing will be different for different people and will change with their circumstances. Any guidelines can only be used as a framework and then adapted to meet individual needs.
- People may move between different methods of monitoring dependent on their needs at that time.
- Monitoring equipment used should be based on choice & agreed with patient.

TYPE 2 DIABETES

- Routine self-monitoring of blood glucose is not usually required if people are achieving targets on therapy without the potential to cause hypoglycaemia (see the table on the next page).
- HbA1c is important in assessing the adequacy of blood glucose control and should be tested every 3-6 months.
- Structured education is essential for people with newly diagnosed and existing Diabetes.
- Checking for wellbeing is essential as 40% of people with diabetes have poor mental health (see slide [50](#)) and this affects their ability to self-care
- People with Type 2 Diabetes usually have more stable glycaemic control. In practice, the level of monitoring will vary according to the treatment regimen used and the target level of glycaemic control set for/with the patient.
- DVLA requirements for testing when driving apply to people with Type 2 Diabetes treated with insulin, gliclazide, glimepiride, glibenclamide or another sulfonylurea, nateglinide or repaglinide.

DIABETES AND DRIVING

People with Diabetes must inform the DVLA.

- Those on insulin or oral hypoglycaemic agents which carry a risk of hypoglycaemia, such as sulfonylureas should monitor their glucose before driving. <https://www.gov.uk/government/publications/information-for-drivers-with-diabetes>
- Group 2 drivers (bus and lorry), on insulin or oral medicines which carry a risk of hypoglycaemia, are still required to check their blood glucose using finger prick testing for the purposes of driving.
- Must have awareness of hypoglycaemia. If there is a total loss of 'hypo' warning signs their license will be withdrawn.
- Must not have had >1 episode of severe hypoglycaemia requiring third party assistance while awake within the preceding 12 months. If they have had more than one episode they must inform the DVLA and their licence will be withdrawn for one year following the first episode.
- [Trend Driving Leaflet](#); [DVLA: A guide to insulin treated diabetes and driving](#)
- All results should be recorded with the time and date to provide a cumulative record as a basis for day-to-day changes in therapy. Most meters will store this information and some will allow download to a computer or smart phone
- **People with blood glucose levels <5.0mmol/L should not drive until they have eaten; If <4.0mmol/L they should not drive.**

GROUP 2 ENTITLEMENT

People with Diabetes on insulin can apply for any Group 2 licence providing the patient has:

- Had no episodes of hypoglycaemia requiring third party assistance within the previous 12 months.
 - Full awareness of hypoglycaemia and can demonstrate understanding of its risks.
 - Meter recorded evidence of regular monitoring (twice a day and at times relevant to driving).
 - Been reviewed annually by an independent consultant diabetologist and provide at least 3 continuous months of readings.
- Visit www.dft.gov.uk/dvla/medical

	ADULTS WITH TYPE 2 DIABETES			
Treatment	Diet and exercise Metformin Pioglitazone DPP-4 inhibitors SGLT-2 inhibitors GLP-1 analogues*	sulfonylureas/meglitinides alone or in combination with other suitable hypoglycaemic agents except insulin	Insulin - Basal, twice daily fixed regimens or mixed insulins	Treatment
Usual Monitoring	Not usually necessary (* except when initiating GLP-1 analogues in people taking a sulfonylurea – see next column) Do not offer a meter unless a clear action based on test results has been agreed and for short term use only, e.g. to allow patient to adjust lifestyle when newly diagnosed	4 tests per week, usually testing once week before each of the three daily meals and before bedtime See advice on Diabetes and driving on previous page.	Basal insulin: 1-2 tests per day Premixed insulin: 2-4 tests per day	Usual Monitoring
Intensive Monitoring		Before meals and 2 hours after evening meal *Intensive monitoring is essential during initiation of GLP-1 analogues for people already on sulfonylureas until stabilised	People who rely on others for administration of mixed insulins may require more frequent testing, which is recommended prior to administration. See advice on driving Before meals and 2 hours after main meal Tests before breakfast are essential to achieve the target fasting glucose Additional tests pre-meal or 2 hours after food are helpful if fasting glucose is at target but HbA1c remains high	Intensive Monitoring
Prescribing	Prescribe the minimum appropriate number of strips on acute	Prescribe on repeat Additional supplies may be necessary for driving and intensive monitoring	Prescribe on repeat Additional supplies may be necessary for driving and intensive monitoring	Prescribing

Intensive monitoring may be required in any of these situations

During intercurrent illness
Intermittent steroid therapy
Osmotic symptoms
Postprandial hyperglycaemia
Terminal care/end of life
People on the Diabetes Prevention Programme (diabetes remission programme i.e. REWIND)

To prevent development of acute complications
Pre-conception and pregnancy
Increased or regular intensive exercise
When HbA1c testing is unavailable
Impaired awareness of hypoglycaemia

PRINCIPLES

People and health care professionals should be clear about what they hope to achieve by self-monitoring blood glucose because monitoring in itself does not improve control. It is the interpretation of the result and the action taken that makes the difference.

Assessment of monitoring at least once a year is desirable and should include:

- Self-monitoring skills including the cognitive ability of the person using 6 item cognitive impairment test (especially if there are microvascular changes in other organs apart from the brain)
- The quality and frequency of testing
- The use made of the results obtained
- The continued benefit
- The impact on quality of life
- The equipment used

If the patient does not benefit from monitoring or if it is adversely affecting their quality of life, then it should be stopped.

Self-monitoring of blood glucose does not replace HbA1c testing, which should be carried out at suitable intervals as part of regular care.

Remember other health education (healthy diet, regular physical activity, maintaining a healthy psychological state, maintaining a normal body weight and avoiding tobacco) to help people reduce their risk of Diabetes-related complications.

Provide Diabetes lifestyle leaflets and actively promote structured education and referral to IAPT if necessary.

CHOOSING A BLOOD GLUCOSE METER

For people with type 2 diabetes, prescribed blood glucose test strips should cost less than £10 for a pack of 50 strips. A wide variety of blood glucose meters are available where the cost of test strips are less than £6 per pack of 50. When offering a new blood glucose meter or a change of meter, clinicians should consider a meter which uses test strips costing less than £6 per pack of 50.

A decision to change meters should be used as an opportunity to review the purpose of testing and the interpretation of results as well as provide basic lifestyle advice and leaflets. If usage is low enough that one pot of strips lasts longer than its expiry date, review of the need for blood glucose monitoring is recommended.

The choice of meter and its functionalities and features should reflect the needs of the user. Some of the key functionalities to consider are shown in the table below.

Function/Feature	Comments
Memory	Memory of at least 500 and cannot be deleted by the user
Display screen	Size and readability of the information displayed on the screen
Voice function	For users who are blind or have visual impairment
Replacement batteries	Does the manufacturer replace batteries free of charge?
Customer support	Does the manufacturer provide a freephone number to a customer support service?
External data output	Can data be transferred from the meter? Is data transfer wireless or via a cable?
Compatibility with Remote diabetes management software	Is the meter compatible with remote diabetes management software (e.g. Diasend or Tidepool)?

BLOOD GLUCOSE TEST STRIP REQUIREMENTS			LANCET REQUIREMENTS			INSULIN PEN NEEDLE REQUIREMENTS		
<p>Test strips usually come in packs of 50 which cannot be split. This table indicates quantities for usual testing. Additional supplies may be necessary for intensive testing e.g. to meet DVLA requirements for driving. If people are required to test regularly please prescribe on repeat prescriptions. People should be encouraged not to over order or stockpile supplies. Additional supplies to meet a short term need should be prescribed on acute prescriptions.</p>			<p>Prescribe a low cost brand of lancets (\leq £5 per pack of 200)</p> <p>Lancers (the finger pricking devices) are not available on prescription and replacement lancing devices are available from companies (usually free of charge). Lancets are for single use only and should be prescribed in quantities which correspond to the expected frequency of testing.</p>			<p>Prescribe a low cost brand of insulin pen needles (\leq£4 per pack of 100 pen needles). Most brands of pen needles are compatible with all devices. Pen needles come in packs of 100.</p> <p>Shorter needle lengths reduce the risk of intramuscular injection of insulin. The Forum for Injection Technique (FIT) UK considers the 4mm needle to be the safest pen needle for adults and children regardless of age, gender and body mass index (BMI).</p> <p>For those currently using longer pen needle lengths (8mm or longer), it is advisable to change to a shorter needle length (6mm or less) but only after discussion with a healthcare professional, to ensure they receive advice on the correct injection technique.</p>		
Tests per day	Tests/28 days	Packs/frequency	Tests per day	Tests/28 days	Packs/frequency	Injections per day	28 days	Packs/frequency
1	28	8 /year	1	28	2 x 200 packs / year	1	28	4 x 100 packs /year
2	56	1 pack /month; 14 packs/year	2	56	4 x 200 packs / year	2	56	8 x 100 packs /year
4	112	2-3 packs/month; 29 packs/year	4	112	8 x 200 packs / year	3	84	11 x 100 packs /year
6	168	3-4 packs/month; 44 packs/year	6	168	11 x 200 packs / year	4	112	15 x 100 packs /year
8	224	4-5 packs/month; 58 packs/year	8	224	15 x 200 packs / year			

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

BIGUANIDES (METFORMIN)

- Decreases gluconeogenesis and increases peripheral utilisation of glucose. Improves insulin sensitivity.

Preparation	Dose	Dose adjustments		
		Moderate renal impairment (eGFR= 30-44 mL/min/1.73 m ²)	Severe renal impairment (eGFR<30 mL/min/1.73 m ²)	Hepatic Impairment:
Metformin	500mg – 2g daily in divided doses, With or after a meal	Max daily dose, 1g	Contraindicated	Withdraw if tissue hypoxia likely.
Metformin modified-release	500mg - 2g once daily with evening meal If glycaemic control is not achieved, 1g twice daily should be considered.			

Contraindications:

- eGFR <30ml/min/1.73 m²,
- any acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis),
- acute or chronic conditions that may alter renal function, hepatic insufficiency
- cardiac and/or respiratory failure which may likely cause tissue hypoxia

Pregnancy and breast-feeding:

Can be used in pregnancy and breastfeeding

Cautions:

- Chronic stable heart failure (monitor cardiac and renal function)
- May cause Vitamin B12 malabsorption.
- Risk factors for lactic acidosis

Class side effects:

- GI side effects (e.g. diarrhoea, abdominal pain, nausea, taste disturbance and vomiting.)

Monitoring requirements:

- Monitor eGFR when initiating and if starting antihypertensive, diuretics and NSAIDs or other conditions that can acutely worsen renal function
- Withhold short term if dehydrated (including diarrhoea and vomiting), severe infection or shock (i.e. post-MI) and re-start once fully hydrated

Additional information:

- All people, irrespective of eGFR, should be educated on good sick day guidance (see page 16).
- Metformin MR is an option for people poorly tolerant on standard-release
- Based on clinical experience of increased side-effects, maximum dose for metformin immediate-release medicines in BNF Publications differs from product licence.
- Reduces cardiovascular disease in overweight or obese people

SULFONYLUREAS (GLICLAZIDE, GLIMEPIRIDE)

- Stimulates insulin release from the pancreas.

Preparation	Dose	Dose adjustments		
		Mild-moderate renal impairment	Severe renal impairment	Hepatic Impairment:
Gliclazide	Initially 40-80mg once daily, titrated until glycaemic control achieved before meals. Maximum daily dose: 160mg twice daily	Use with care in mild to moderate renal impairment.	Avoid	Avoid in severe hepatic insufficiency; use of insulin is recommended
Glimepiride	1mg once daily, titrated in steps of 1mg every 1-2 weeks to 4mg once daily if need be. Maximum 6mg once daily. Similar time daily, shortly before or with first main meal			

Contraindications:

- Presence of ketoacidosis
- Severe renal or hepatic insufficiency
- Gliclazide – Acute porphyrias, interaction with systemic and oromucosal miconazole

Pregnancy and breast-feeding:

Avoid

Cautions:

- Elderly due to a possible age-related increased risk of hypoglycaemia
- People with G6PD deficiency
- Concomitant use of sulfonylureas and insulin should be avoided in people with severe renal impairment (<45mL/min/1.73m²)

Class side effects:

- GI side effects (e.g. abdominal pain, nausea/vomiting, diarrhoea and constipation)
- Weight gain
- Please see individual drug monograph in the BNF for a complete side-effect profile

Monitoring requirements: Blood glucose (See page 23)

Additional information:

- Risk of hypoglycaemia when used with SGLT2i, DPP4i, pioglitazone and acarbose- consider reducing dose of sulfonylurea.
- ALL people should be told about recognition and management of hypoglycaemia when prescribed a sulfonylurea.

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

THIAZOLIDINEDIONES (PIOGLITAZONE)

- Reduces peripheral insulin resistance, leading to a reduction of blood-glucose concentration.

Preparation	Dose	Dose adjustments	
		Renal Impairment	Hepatic Impairment:
Pioglitazone	Initially 15–30 mg once daily, adjusted according to response up to 45 mg once daily with or without food. Elderly - initiate with lowest possible dose and increase gradually.	No dose adjustment is necessary	Should not be used in people with hepatic impairment (Therapy with pioglitazone should not be initiated if the ALT is > 2.5 times the upper limit of normal or with any other evidence of liver disease.)

Contraindications: <ul style="list-style-type: none"> Cardiac failure / Hx of cardiac failure (NYHA stages I to IV) hepatic impairment diabetic ketoacidosis current bladder cancer or a history of bladder cancer uninvestigated macroscopic haematuria 	Pregnancy and breast-feeding: Avoid	Cautions: Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65)	Side effects: <ul style="list-style-type: none"> Bone fracture (particularly in women); Increased risk of infection; numbness; visual impairment; weight increased
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Monitoring requirements: Review treatment after 3–6 months and regularly thereafter <ul style="list-style-type: none"> Liver function tests prior to commencing therapy, and periodically thereafter Whilst on pioglitazone, if ALT levels are increased to 3 times upper limit of normal, liver enzyme levels should be reassessed as soon as possible. If ALT levels remain > 3 X the upper limit of normal, therapy should be discontinued Weight
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Additional information: <ul style="list-style-type: none"> Important safety information – Please see hyperlinks for more detailed advice MHRA/CHM advice: Pioglitazone cardiovascular safety (December 2007 and January 2011) <ul style="list-style-type: none"> People should be informed on the signs and symptoms of DKA, discontinue treatment with the SGLT2 inhibitor immediately if DKA is suspected or diagnosed Pioglitazone: risk of bladder cancer (July 2011) <ul style="list-style-type: none"> Pioglitazone should not be used in people with active bladder cancer or a past history of bladder cancer, or in those who have uninvestigated macroscopic haematuria. Weight gain which may be due to fat accumulation, and in some cases associated with fluid retention. In some cases weight increase may be a symptom of cardiac failure, therefore weight should be closely monitored.

DPP-4 INHIBITORS: DIPEPTIDYLPEPTIDASE-4 INHIBITORS (SITAGLIPTIN, SAXAGLIPTIN, LINAGLIPTIN, VILDAGLIPTIN, ALOGLIPTIN)

- Inhibits dipeptidylpeptidase-4 to increase insulin secretion and lower glucagon secretion.

Preparation	Dose	Dose adjustments		
		Moderate renal impairment (eGFR= mL/min/1.73 m ²)	Severe renal impairment (eGFR= mL/min/1.73 m ²)	Hepatic Impairment:
Alogliptin*	25 mg once daily	eGFR 30–50: 12.5 mg once daily	eGFR <30: 6.25 mg once daily; Use with caution	No dose adjustment necessary if mild/moderate impairment. Use with caution
Linagliptin	5 mg once daily	N/A		
Sitagliptin	100 mg once daily	eGFR 30–45: 50 mg once daily	eGFR <30: 25 mg once daily	Therapeutic experience in severe hepatic impairment is limited and therefore use is not recommended by manufacturer.
Saxagliptin	5 mg once daily	eGFR <45: 2.5mg once daily		
Vildagliptin	50 mg twice daily 50 mg once daily in the morning when used in combination with a sulfonylurea	eGFR <50: 50 mg once daily		

Contraindications: <ul style="list-style-type: none"> Ketoacidosis 	Pregnancy and breast-feeding: Avoid	Cautions: <ul style="list-style-type: none"> Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65) People with a history of pancreatitis. 	Class side effects: <ul style="list-style-type: none"> Headache/dizziness Please see individual drug monograph in the BNF for a complete side-effect profile
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Monitoring requirements: <ul style="list-style-type: none"> Discontinue if symptoms of acute pancreatitis (persistent, severe abdominal pain) Vildagliptin associated with liver toxicity; seek medical attention if nausea, vomiting, abdominal pain, fatigue, and dark urine develops. Monitor liver enzymes 3 month interval for first year, periodically after.
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Additional information:
*Alogliptin not licensed for monotherapy

SGLT-2 INHIBITORS: SODIUM GLUCOSE CO-TRANSPORTER 2 AGENTS (CANAGLIFLOZIN, DAPAGLIFLOZIN, EMPAGLIFLOZIN, ERTUGLIFLOZIN)

- Inhibit sodium-glucose co-transporter 2 (SGLT-2) in the proximal renal tubule to reduce glucose reabsorption and increase urinary glucose excretion.

Preparation	Dose	Dose adjustments			
		Initiating in eGFR <60 mL/min/1.73 m ² :	If taking as current treatment- eGFR <60 mL/min/1.73 m ² :	Moderate-severe Renal Impairment (eGFR <45 mL/min/1.73 m ²):	Hepatic Impairment:
Canagliflozin	100 mg once daily Increased if tolerated to 300 mg once daily if required With or without food	100mg once daily	Reduce dose to 100 mg once daily	Loss of glycemic lowering benefit Start in CKD if urine ACR > 30 Do not initiate if eGFR<30	No dose adjustment necessary if mild/moderate impairment. Therapeutic experience in severe hepatic impairment is limited and therefore use is not recommended by manufacturer.
Empagliflozin	10 mg once daily, Increased up to 25 mg once daily With or without food	Start 10mg if eCVD	Reduce dose to 10 mg once daily	Loss of glycemic lowering benefit Start 10mg in HFrEF; Discontinue / Avoid if ≤ 20	
Ertugliflozin	5 mg once daily Increased to 15 mg once daily if necessary With or without food	5mg once daily	Reduce dose to 5 mg once daily	Loss of glycemic lowering benefit Do not initiate & discontinue if eGFR <30	
Dapagliflozin	10 mg once daily With or without food	10 mg once daily	10 mg once daily	Loss of glycemic lowering benefit Start 10mg in CKD / HFrEF for continued cardio-renal benefit Do not initiate if eGFR <15	

Contraindications: <ul style="list-style-type: none"> Diabetic ketoacidosis 	Pregnancy and breast-feeding: Avoid—toxicity in animal studies	Cautions: <ul style="list-style-type: none"> People at risk of hypotension/hypovolaemia) (e.g. Elderly, dehydration) Please see specific drug monograph in the BNF for complete cautions Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65) 	Class side effects: <ul style="list-style-type: none"> Increased risk of UTI Polydipsia urinary disorders Please see individual drug monograph in the BNF for a complete side-effect profile
Monitoring requirements: <ul style="list-style-type: none"> Renal function - before treatment and at least annually thereafter, and before initiation of drugs that may reduce renal function and periodically thereafter. Volume status and electrolytes 			

Additional information:

- [MHRA/CHM advice \(updated April 2016\): SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis \(DKA\)](#) People should be informed on the signs and symptoms of DKA, discontinue treatment with the SGLT2 inhibitor immediately if DKA is suspected or diagnosed
- [MHRA/CHM advice \(MHRA/CHM advice March 2017\): SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation \(mainly toes\)](#) SGLT2i's may increase the risk of lower-limb amputation (mainly toes) . All people taking an SGLT2i should be counselled on good preventive foot care. Review if lower limb complications develop (e.g. skin ulcer, osteomyelitis, or gangrene). Monitor people with risk factors for amputation, signs and symptoms of water or salt loss.
- [MHRA/CHM advice: SGLT2 inhibitors: reports of Fournier's gangrene \(necrotising fasciitis of the genitalia or perineum\) \(February 2019\)](#)
- if Fournier's gangrene is suspected, stop the SGLT2 inhibitor and urgently start treatment (including antibiotics and surgical debridement as required)
- [MHRA/CHM advice: SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness \(March 2020\)](#)
- SGLT2 inhibitor treatment should be interrupted in people who are hospitalised for major surgical procedures or acute serious medical illnesses and ketone levels measured, preferably in blood rather than urine. Treatment may be restarted when the ketone values are normal and the person's condition has stabilised.

SGLT2 inhibitors: safe prescribing guidance

INTRODUCTION

- In a number of drug trials various members of the SGLT-2i class have been shown to have cardio renal protective effects over and above their glycaemic effectiveness. Data on these cardio renal effects is emerging rapidly and this may be reflected in changes to the licensing arrangements for individual members of this class
- This guidance is only designed to be used for the prescription of SGLT-2i inhibitors within each individual drug's current licence (see slide 36)
- The prime purpose of this guideline is to ensure that, where an SGLT-2i is prescribed in a patient with type II diabetes for cardiorenal protection, it is undertaken safely. This can be achieved by ensuring that these agents are only prescribed for the appropriate patients and that the appropriate information is given to patients to ensure safety.

CAUTIONS

- Frail elderly
- Potential for pregnancy
- SGLT-2i should NOT be prescribed to people with type 1 diabetes *unless* under the direction of a diabetologist
- SGLT-2i should not be prescribed to people with type 2 diabetes at increased risk of *euglycaemic diabetic ketosis* – *see below***
- Always offer advice on *sick day guidance* when introducing these agents and reiterate at every opportunity i.e. stop perioperatively or if restricted food intake or dehydration.
- Reiterate that if on an SGLT-2i, very low carbohydrate diets (or ketogenic diets) carry an increased risk of ketosis.
- In people with reasonable glycaemic control and risk of hypoglycaemia, consider reducing other hypoglycaemic agents when introducing SGLT-2i.
- In people on diuretics, consider reducing the dose.
- Give advice to seek medical attention (via GP, urgent care centre or pharmacy) should they develop symptoms of a genital infection.
- Caution is advised if the person has active peripheral vascular disease including active arterial ulceration or claudication.

** TYPE 2 DIABETIC PEOPLE AT INCREASED RISK OF EUGLYCAEMIC DIABETIC KETOSIS

- Those who rapidly progressed to requiring insulin (within 1 year of diagnosis)
- Past history of diabetic ketoacidosis (DKA)
- History of pancreatic disease – including alcoholic pancreatitis as a cause of their pancreatitis
- BMI<27
- The possibility of Latent Autoimmune Diabetes in Adults

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

ALPHA GLUCOSIDASE INHIBITORS (ACARBOSE)

- *Acarbose, an inhibitor of intestinal alpha glucosidases, delays the digestion and absorption of starch and sucrose; it has a small but significant effect in lowering blood glucose.*

Preparation	Dose	Dose adjustments	
		Renal Impairment	Hepatic Impairment:
Acarbose	Initially 50 mg daily, Titrated up to maximum of 200 mg 3 times a day, if required. Before food	As Acarbose has not been studied in people with severe renal impairment, it should not be used in people with a creatinine clearance <25 ml/min/1.73m ²	Contraindicated in people with hepatic impairment

Contraindications:

- Hepatic impairment
- Hernia;
- inflammatory bowel disease;
- predisposition to partial intestinal obstruction;
- previous abdominal surgery

Pregnancy and breast-feeding:

Avoid

Cautionary use in:

- Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page [32/65](#)), hypoglycaemic episodes may be treated with oral glucose, but not with sucrose.

Side effects:

- Abdominal pain
- Diarrhoea
- Flatulence

Monitoring requirements:

- It is recommended that liver enzyme monitoring is considered during the first 6 to 12 months of treatment. If elevated transaminases are observed, withdrawal of therapy may be warranted, particularly if the elevations persists. In such circumstances, people should be monitored at weekly intervals until normal values are established.

Additional information:

- For use in people inadequately controlled by diet alone, or by diet with oral anti-diabetic drugs.
- Poorer anti-hyperglycaemic effect than many other antidiabetic drugs.
- Low incidence of hypoglycaemia.

MEGLITINIDES (REPAGLINIDE)

- *Stimulates insulin secretion.*

Preparation	Dose	Dose adjustments	
		Renal Impairment	Hepatic Impairment:
Repaglinide	Initially 500 micrograms (max. per dose 4 mg), adjusted according to response at intervals of 1–2 weeks. Maximum daily dose: 16 mg per day in divided doses. <i>Initiation not recommended in adults ≥75 years</i> To be taken within 30 minutes before main meals	Use with caution in renal impairment	Avoid in severe liver disease

Contraindications:

- Ketoacidosis
- Concomitant use of gemfibrozil

Pregnancy and breast-feeding:

Avoid

Cautionary use in:

- Debilitated people;
- Malnourished people

Side effects:

- Abdominal pain;
- diarrhoea;
- hypoglycaemia

Monitoring requirements:

- It is recommended that liver enzyme monitoring is considered during the first 6 to 12 months of treatment

Additional information:

- Licensed as monotherapy, or in combination with metformin, when metformin alone inadequate.
- Rapid onset of action and short duration of action.
- Substitute insulin during intercurrent illness (such as myocardial infarction, coma, infection, and trauma) and during surgery.



For the safe administration and use of insulin and GLP-1 receptor agonists you should be able to:

1. UNREGISTERED PRACTITIONER

Describe the effect of insulin on blood glucose levels.
Be aware of local sharps disposal policy.
Show an understanding of the ongoing nature of the therapy.
Administer insulin competently where supported by local policy.
Report identified problems appropriately.

2. COMPETENT NURSE AS 1, AND:

Actively seek and participate in peer review of one's own practice.
Demonstrate a basic knowledge of insulin and GLP-1 receptor agonists (e.g. drug type, action, side-effects) and administration devices used locally.
Demonstrate a high level of competency in the safe administration of insulin or GLP-1 receptor agonists.
Demonstrate and be able to teach the correct method of insulin or GLP-1 receptor agonist self-administration, including:

- Correct choice of needle type and length for the individual.
- Appropriate use of lifted skin fold, where necessary.
- Site rotation.
- Storage of insulin.
- Single use of needles.

Examine injection sites at least annually for detection of lipohypertrophy.
Identify correct reporting system for injectable therapy errors.
Complete the "Safe use of insulin" e-learning module . <https://www.e-lfh.org.uk/programmes/safe-use-of-insulin>
Describe circumstances in which insulin use might be initiated or altered and make appropriate referral.
Report concerns related to blood glucose or HbA1c results in a timely and appropriate fashion.

3. EXPERIENCED OR PROFICIENT NURSE

As 2, and:
Demonstrate a broad knowledge of different insulin types (i.e. action, use in regimens).
Demonstrate a broad knowledge of GLP-1 receptor agonists (e.g. drug type, action, side-effects).
Assess individual people' self-management and educational needs and meet these needs or make appropriate referral.
Support and encourage self-management wherever appropriate.
Initiate insulin or GLP-1 receptor agonist therapy where clinically appropriate.
Recognise when injection therapy needs to be adjusted.
Recognise the potential psychological impact of insulin or GLP-1 receptor agonist therapies and offer support to the person with diabetes or their carer.
Recognise signs of needle fear/needle phobia and offer strategies to help manage this.

WHAT ARE GLP-1s AND HOW DO THEY WORK?

- GLP-1s are injected to increase insulin secretion, suppress glucagon secretion, and slow gastric emptying.
- The incretin effect is described by the fact that an oral load of glucose induces a greater insulin response than when glucose is administered by IV. This is due to the effect on gut hormones, particularly glucagon-like peptide-1 (GLP-1s).
- Their effect includes stimulating glucose dependent insulin secretions, increasing satiety and slowing gastric emptying. These actions can lead to reduction in HbA1c with a low risk of hypoglycaemia (unless used with sulfonylureas). This action is often accompanied by weight loss.
- GLP-1 injections can be used to improve glucose control in adults with Type 2 Diabetes by reducing fasting and post prandial glucose levels. They can be used with metformin, a sulfonylurea or in combination with other antidiabetic drugs.
- Administered by subcutaneous injection.

INDICATIONS FOR CONTINUED USE

NICE recommends that treatment with GLP-1s is continued only if HbA1c has reduced by 1% AND a weight loss of 3% is achieved within 6 months of commencing treatment.

WHO SHOULD USE GLP-1s?

Treatment with GLP-1s is associated with the prevention of weight gain and possible promotion of weight loss

- GLP-1s should be considered as part of intensification in people with a BMI of 35 kg/m² or higher (adjusted to 30 kg/m² for people from black, Asian and other minority ethnic groups) and specific psychological or other medical problems associated with obesity or
- have a BMI lower than 35 kg/m² and:
 - for whom insulin therapy would have significant occupational implications or
 - weight loss would benefit other significant obesity-related comorbidities
- See [NW London's algorithm](#) for recommendations as to where GLP-1s fit with other glycaemic treatments.

CONTRAINDICATIONS & CAUTIONS

- GLP-1s are not substitutes for insulin in insulin-dependent people and are not licensed for use in Type 1 Diabetes.
- **Persistent and severe abdominal pain with or without vomiting may be a sign of acute pancreatitis. If this is suspected, the GLP-1 should be stopped, and if confirmed, not be resumed.**
- See individual monographs for dose adjustments in renal impairments and/or hepatic impairment, and missed dose information.
- Not recommended for use in people with severe gastrointestinal disease
- People receiving a GLP-1 in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by a reduction in the dose of sulfonylurea or insulin.
- Not recommended during pregnancy or where pregnancy is planned, or for nursing mothers.
- GLP-1 agonists require some oral medications to be taken at least 1 hours before, or 4 hours after. See individual monographs.

ADVICE TO PRESCRIBERS

Drug	Dosing interval	Supply length of a single pen at maintenance dose
Ozempic (Semaglutide)	Once weekly	28 days
Rybelsus (Semaglutide)	Once daily	28 days
Victoza (Liraglutide)	Once daily	15 days (1.2mg OD) 10 days (1.8mg OD)
Trulicity (Dulaglutide)	Once weekly	7 days
Bydureon (Exenatide)	Once weekly	7 days
Lyxumia (Lixisenatide)	Once daily	15 days

ADVICE TO PEOPLE

- Provide them with patient information leaflet. **people will need to understand the following:**
- Discuss the risk of hypoglycaemia and symptoms, treatment and prevention.
- Drivers holding a Group 1 (cars and motorcycles) license may drive and need not notify the DVLA, provided the requirements set out are met and is under regular medical review ([See DVLA guidance for requirements](#)) when being treated with a GLP-1. Normal precautions to avoid low blood glucose when driving apply. Drivers holding Group 2 (Bus and lorry) licences need to inform the DVLA if they are being treated with a GLP-1.
- Discuss common side effects such as nausea, vomiting diarrhoea, dizziness, headache and dyspepsia.
- GLP-1s may reduce appetite.
- Injection techniques- Subcutaneous injection upper arm, thigh, abdomen.
- Pen needles use/supply - a variety of pen needles are available, HCP should discuss which needle is best for them. A new one should be used for each injection.
- If they experience severe and persistent symptoms they must contact their health care provider as a matter of urgency.
- Please note, some GLP1 agonists are supplied with a pen needle.

STORAGE OF GLP-1 PEN DEVICES

- Unopened GLP-1 pre-filled pens should be stored in the refrigerator 2-8°C (36-46°F). Do not freeze.
- The GLP-1 pen in use can be kept at room temperature but away from direct light.
- See individual monograph for shelf-life/expiry. Once in use refer to individual drug information overleaf.

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

LIXISENATIDE (LYXUMIA)

Indicated in combination with oral glucose-lowering medicinal products and/or basal insulin when these together do not provide adequate glycaemic control.

Dose	Dose Adjustments	Time to be taken	Storage and Shelf-life
Do not initiate new prescriptions however may continue 20 mg maintenance once daily	Use with caution for people with an eGFR 30–50 mL/min/1.73 m ² Not recommended for people with eGFR <30 mL/min/1.73 m ² Dose of concomitant sulfonylurea or insulin may need to be reduced.	Within 1 hour before the first meal of the day or the evening meal	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Shelf-life: 14 days

- **Missed dose:** Should be injected within the hour prior to the next meal. Do not administer after a meal.
- Some orally administered drugs should be taken at least 1 hour before, or 4 hours after, lixisenatide injection.
- people receiving Lyxumia with a sulfonylurea or with a basal insulin may have an increased risk of hypoglycaemia. Reduction of the dose of the sulfonylurea or the basal insulin may be considered to reduce the risk of hypoglycaemia. Lixisenatide should not be given in combination with basal insulin **and** a sulfonylurea due to increased risk of hypoglycaemia.
- Its use does not require specific blood glucose monitoring. However, when used in combination with a sulfonylurea or a basal insulin, blood glucose monitoring or blood glucose self-monitoring may become necessary to adjust the doses of the sulfonylurea or the basal insulin.

LIRAGLUTIDE (VICTOZA)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.

Dose	Dose Adjustment	Storage and Shelf-life
Initially 0.6 mg once daily for at least 1 week, then increased to 1.2 mg once daily . Max daily dose: 1.8mg	eGFR <15mL/min/1.73 m ² : No therapeutic experience in people with end-stage renal disease, and Victoza is therefore not recommended for use in these people . Not recommended for use in people with severe hepatic impairment.	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Shelf-life: 1 month

- **Missed dose:** if a dose is more than 12 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.
- Pen adjusted to give either 0.6mg, 1.2mg or 1.8mg. Comes in a pre-filled pen - 6mg per ml.
- Victoza can be added to existing sulfonylurea or to a combination of metformin and sulfonylurea therapy or insulin.
- Self-monitoring of blood glucose is not needed in order to adjust the dose of liraglutide. However, when initiating treatment with liraglutide in combination with a sulfonylurea or insulin, blood glucose self-monitoring may become necessary to adjust the dose of the sulfonylurea/insulin.

SEMAGLUTIDE (OZEMPIC)

Dose	Dose Adjustment	Storage and Shelf-life
Initially 0.25 mg once weekly for 4 weeks, then increased to 0.5 mg once weekly for at least 4 weeks, then increased if necessary to 1 mg once weekly	No dose adjustment is required for renal impairment. Experience in people with severe renal impairment is limited. Not recommended for use in people with end-stage renal disease Dose of concomitant sulfonylurea or insulin may need to be reduced.	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Shelf-life: 6 weeks

- **Missed dose:** it should be administered as soon as possible and within 5 days after. If more than 5 days have passed, the missed dose should be skipped, and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.
- Comes in 1.34 mg per ml in 1.5 and 3ml pre-filled pens.
- When adding to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia.
- Self-monitoring of blood glucose is not needed when adjusting the dose. When initiating treatment in combination with a sulfonylurea or an insulin, blood glucose self-monitoring may become necessary to reduce the risk of hypoglycaemia.
- Caution should be exercised when using semaglutide in patients with diabetic retinopathy treated with insulin.

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

SEMAGLUTIDE (RYBELSUS)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.

Preparation	Licensed to be used in combination with:	Dose	Dose Adjustment	Time to be taken	Storage and Shelf-life
Oral Semaglutide	<ul style="list-style-type: none"> Metformin Sulfonylurea (+/-Metformin) Pioglitazone(+/-Metformin) Basal Insulin (+/-Metformin/Pioglitazone) 	Initially 3 mg once daily (if necessary) Increase 7mg once daily (if necessary) Increase 14 mg once daily	eGFR 30-50 mL/min/1.73 m ² : Use with caution eGFR <30 mL/min/1.73 m ² : Avoid	To be taken on an empty stomach and refrain from eating for 30 minutes from administration	Store in the original blister package in order to protect from light and moisture. This medicinal product does not require any special temperature storage conditions. Oral semaglutide 14 mg once daily is comparable to subcutaneous semaglutide 0.5 mg once weekly

EXENITIDE BYDREON (MODIFIED-RELEASE)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.

Preparation	Licensed to be used in combination with:	Dose	Dose Adjustment	Time to be taken	Storage and Shelf-life
Modified-Release Byetta (BYDUREON)	<ul style="list-style-type: none"> Other glucose-lowering medicinal products including basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control. 	2 mg once a week on the same day each week.	Avoid if eGFR less than 50 mL/minute/1.73 m ²	N/A	Store at room temperature in a refrigerator (<25°C). Store in the original package in order to protect from light.

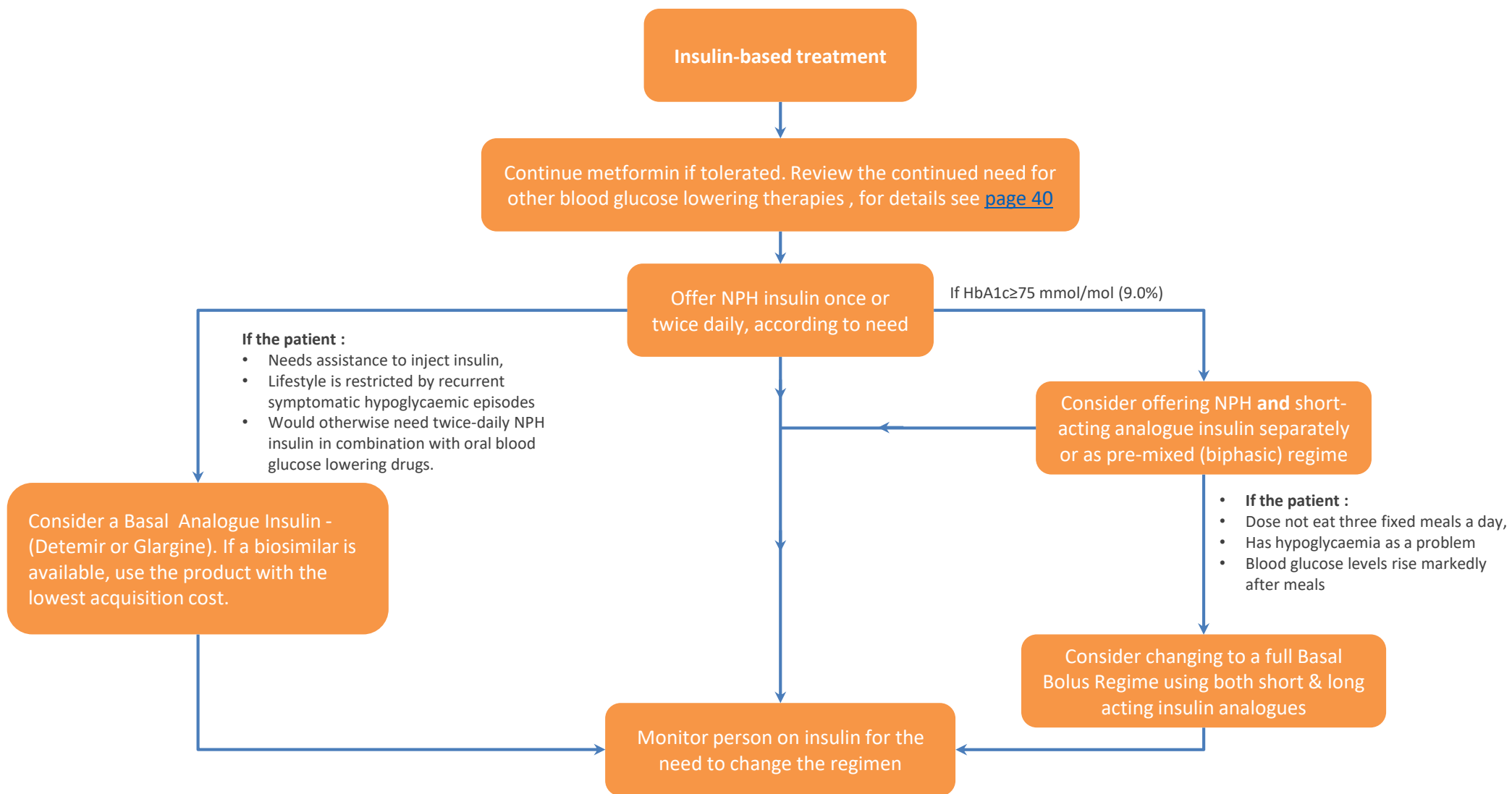
- Dose of concomitant sulfonylurea may need to be reduced to reduce the risk of hypoglycaemia.
- Blood glucose self-monitoring may be necessary to adjust the dose of sulfonylurea.
- Comes as a 2 mg powder and solvent for modified-release suspension for injection in pre-filled pen.
- People switching from standard-release (Byetta) to modified-release exenatide may experience transient elevations in blood glucose concentrations, which generally improve within the first two weeks after initiation of therapy.
- Missed dose:** it should be administered as soon as practical. For the next injection people can return to their chosen injection day. However, only one injection should be taken in a 24-hour period.

DULAGLUTIDE (TRULICITY)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.







Dose	Dose adjustments	Storage and Shelf-life
Monotherapy - 0.75 mg once weekly Add-on therapy - 1.5 mg once weekly. Uptitrate to 3.0 mg – 4.5 mg once weekly as tolerated	eGFR < 15 mL/min/1.73 m ² : Not recommended	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Do not freeze. Shelf-life: 14 days

- Dose of concomitant insulin or drugs that stimulate insulin secretion may need to be reduced.
- Missed Dose:** If a dose is missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, people can then resume their regular once weekly dosing schedule












NB: Only offer a GLP-1 mimetic in combination with insulin with specialist care advice and on-going support from a consultant-led multidisciplinary team

DIABETES – DISPOSABLE INSULIN PEN DEVICES

DEVICE	SOLOSTAR	FLEXPEN	FLEXTOUCH	INNOLET	KWIKPEN	SEMGLEE
Dosing	1 unit (1-80)	1 unit (1-60)	1 unit (1-80)	1 unit (1-50)	1 unit (1-60)	1 unit (1-80)
General features	Apidra , Lantus and Trurapi versions of this pen have different colours (dark blue for Trurapi, light blue for Apidra & grey for Lantus) and textures to help users distinguish between the types of insulin. Insuman is a white pen. Green label for basal and blue for comb.	Pen is blue, with labels of different colours for various types of insulin.		An easy-to-use doser with a large, ergonomic dial	Buff colour for human insulin, blue for analogue. Humalog Junior Kwikpen can be differentiated by an orange and white label.	A light blue pen with white label.
Special uses			Reduced manual dexterity (due to push button not having to extend)	Poor eyesight Reduced manual dexterity (usually due to different joint related conditions)		
Insulin compatibility	Sanofi Trurapi Apidra Lantus Insuman Basal Insuman Comb Insulin Lispro	Novo Nordisk NovoRapid Novomix Levemir	Novo Nordisk NovoRapid	Novo Nordisk Insulatard Levemir	Lilly Humulin Humalog Humalog Junior Abasaglar	Mylan Semglee
Device						

DIABETES – REUSABLE INSULIN PEN DEVICES

DEVICE	AUTOPEN CLASSIC	AUTOPEN 24	NOVOPEN 4	NOVOPEN 5	NOVOPEN Echo	HUMAPEN SAVVIO	HUMAPEN LUXURA HD	ALLSTAR	ALLSTAR Pro	JUNIORSTAR
Dosing	1 unit (1-21) 2 units (2-42)	1 unit (1-21) 2 units (2-42)	1 unit (1-60)	1 unit (1-60)	½ unit (0.5-30)	1 unit (1-60)	½ unit (1-30)	1 unit (1-80)	1 unit (1-80)	½ unit (1-30)
General features	Plastic		Metal Blue or chrome	Metal Blue or chrome	Metal Blue or red	Metal Audible click Multiple colours	Metal Green Audible click	Purple or Teal	Blue or Silver	Blue, red or silver
Special uses	Release button on side makes it easier for some to handle Spring loaded release button ensures that force required to push the insulin is significantly less than for other insulin pens.			Memory function on pen end indicates timing and units of last dose	Memory Function - Records dose and time since last injection for extra reassurance		Half unit doses so suitable for children or those with low insulin requirements			Allows for half-unit dose increments which helps to provide flexibility especially in young people.
Insulin compatibility	Lilly Humulin Humalog Abasaglar Wockhardt	Sanofi Insuman Lantus Apidra	Novo Nordisk Insulatard Novorapid Novomix Levemir	Novo Nordisk Insulatard Novorapid Novomix Levemir	Novo Nordisk Insulatard Novorapid Novomix Levemir	Lilly Humulin Humalog Abasaglar	Lilly Humulin Humalog	Sanofi Insuman Lantus Apidra	Sanofi Insuman Lantus Apidra	Sanofi Insuman Lantus Apidra
Device										

Introduce the likely need for insulin in the future early on as part of patient education

Emphasise that it is the pancreas that fails not the patient

Assess if greater compliance with oral agents and lifestyle changes could negate the need for insulin

ALWAYS	USUALLY	CONSIDER
Type 1 Diabetes	Type 2 Diabetes failure to reach glycaemic targets using diet and non insulin therapies	Symptomatic e.g. rapid weight loss, polyuria, nocturia
Not sure if the diagnosis is Type or Type 2 1 Diabetes	Type 2 Diabetes Pre and post surgery or following a MI	Women with Type 2 DM on oral agents hoping to conceive
Pregnant women with Type 2 DM	Chronic pancreatitis	Acute neuropathies i.e. femoral amyotrophy
Gestational Diabetes Not controlled on diet or metformin	Type 2 Diabetes requiring enteral feeding	Ketosis prone Type 2 Diabetes
Post surgical pancreatectomy		Steroid induced Diabetes

WHICH INSULIN SHOULD BE USED INITIALLY FOR T2DM DIABETES (T2DM)

Animal insulin is no longer used for insulin starts

Begin with human NPH insulin injected at bed-time or twice daily according to need such as Insuman Basal, Humulin I or Insulatard . Can be given at breakfast when required e.g.: people on steroids.

Consider, as an alternative, using a long-acting insulin analogue such as Insulin Detemir, Insulin Glargine if:

- The person needs assistance from a carer or healthcare professional to inject insulin, and use of a long-acting insulin analogue (Insulin Detemir, Insulin Glargine) would reduce the frequency of injections from twice to once daily, or
- The person's lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes, or
- The person would otherwise need twice-daily NPH insulin injections in combination with oral glucose-lowering drugs, or
- The person cannot use the device to inject NPH insulin

Consider twice daily pre - mixed (biphasic) human insulin (particularly if HbA1c \geq **75 mmol/mol or 9%**)

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 initiation of **pre - mixed insulin** if the **A1c** is high particularly above **75 mmol/mol or 9%**

This would however depend on the individual people preference and convenience.

Other factors to consider:

Lifestyle

- Meal times
- Employment

Potential risk of hypoglycaemia

- High alcohol intake
- Malnutrition
- Low BMI

Physical barriers

- Dexterity
- Vision

Emotional barriers

- Needle phobia

THERE ARE MANY TYPES OF INSULIN TO CHOOSE FROM: ALL OF TODAY'S INSULINS ARE MANUFACTURED USING RECOMBINANT DNA TECHNOLOGY

HUMAN INSULINS	ANALOGUE INSULINS
<p>e.g. Insuman Rapid, Humulin S, Insulatard</p> <ul style="list-style-type: none"> Human insulins are produced by recombinant DNA technology and have the same amino acid sequence as endogenous human insulin Time of action can be modified by the addition of protamine 	<p>e.g. Insulin Aspart (Novorapid, Trurapi) / Insulin Glargine (Lantus, Abasaglar, Semglee)</p> <ul style="list-style-type: none"> Insulin analogues are produced in the same way as human insulins, but the insulin is modified to produce a desired kinetic characteristic, such as an extended duration of action or faster absorption and onset of action. They are more expensive When starting an insulin for which a biosimilar is available, use the product with the lowest acquisition cost

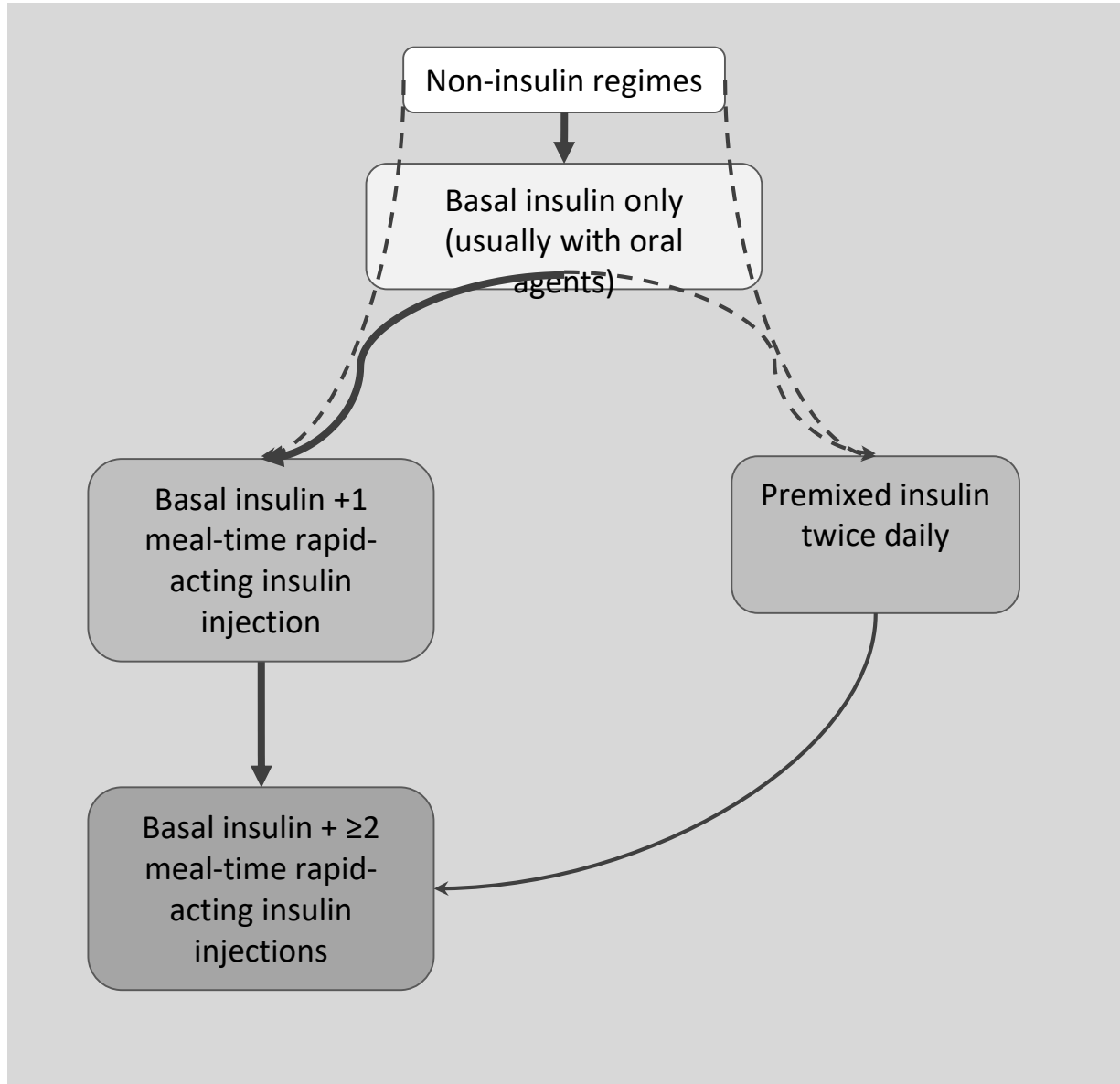
Human Insulins should be the initial choice of insulin for most people with Type 2 Diabetes as they are safe and considerably cheaper than the analogue insulins

Exceptions are:

- Those at high risk of hypoglycaemia
- Low BMI, malnourished, frail and elderly, erratic eating patterns

	RAPID ACTING	SHORT ACTING	INTERMEDIATE ACTING	LONG ACTING	MIXTURES RAPID + INTERMEDIATE ACTING	MIXTURES SHORT + INTERMEDIATE ACTING
Type	Analogue	Human	Human	Analogue	Analogue	Human
Onset of action	within 15 minutes	30 - 60 mins	1 - 2 hours	2 - 3 hours	Up to 15 mins	Up to 30 mins
Duration*	2-5 hours	up to 9 hours	11 - 24 hours	Up to 36 hours	Up to 24 hours	Up to 24 hours
Examples	Novorapid Humalog Apidra Trurapi	Humulin S Insuman Rapid	Insulatard Humulin I Insuman Basal	Levemir (Determir) Abasaglar/Lantus/ Semglee (Glargine)	NovoMix 30 Humalog Mix 25 Humalog Mix 50	Humulin M3 Insuman Comb 15, 25, 50
Peak effect	0.5 - 1.5 hours	1 - 4 hours	3 - 12 hours	varies based on the dose	1 - 4 hours	2 - 8 hours

ORAL AND NON – INSULIN THERAPY	USE WITH INSULIN
Metformin	Normal and overweight people with Type 2 Diabetes can be continued on Metformin as there is evidence that this combination is insulin sparing and has other benefits including weight management glycaemic control and cardiovascular disease (CVD)
sulfonylureas (SU) <i>Glimepiride</i> <i>Gliclazide</i>	Continue with regular dose reviews if the individual is on a daily isophane or analogue insulin. Avoid concurrent use in people with severe renal impairment (<45mL/min/1.73m ²). Risk of hypoglycaemia when used together
DPP-4 Inhibitors (DPP-4Is): <i>Alogliptin,</i> <i>Linagliptin,</i> <i>Saxagliptin,</i> <i>Sitagliptin,</i> <i>Vildagliptin</i>	May be used in combination with insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Sodium glucose co-transporter 2 Inhibitors (SGLT-2) <i>Canagliflozin,</i> <i>Dapagliflozin,</i> <i>Empagliflozin</i> <i>Ertugliflozin</i>	May be used in combination with insulin or other antidiabetic drugs (if existing treatment fails to achieve adequate glycaemic control). Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Pioglitazone	May be used in combination with insulin. If pioglitazone is used in combination with insulin people should be observed for signs and symptoms of heart failure, weight gain, and oedema. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Glucagon-like peptide-1 receptor agonists (GLP-1 Agonists) <i>Exenatide modified-release (once weekly)</i> <i>Exenatide standard-release (twice daily)</i> <i>Liraglutide (once daily)</i> <i>Lixisenatide (once daily)</i> <i>Dulaglutide (once weekly)</i> <i>Semaglatide S/C (once weekly)</i> <i>Semaglatide PO (once daily)</i>	May be used in combination with insulin. In adults with type 2 diabetes, only offer a GLP-1 mimetic in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team.
Acarbose	Not recommended in combination with insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Meglitinides: <i>Repaglinide</i>	Not recommended in combination with insulin. Risk of hypoglycaemia when used together
Please see pages 34-37 and 60-61 for individual drug monographs	



Number of injections



Regimen complexity



More flexible

Less flexible

Diabetes Care, Diabetologia. 19 April 2012 [Epub ahead of print]

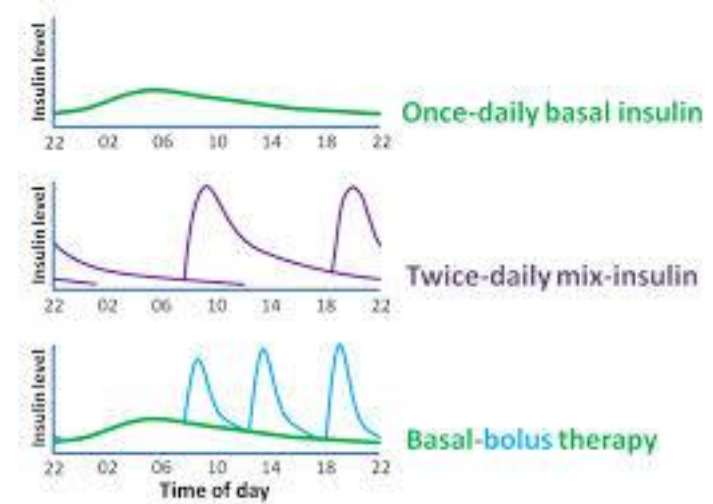
PROS

Just one injection a day

Easy for the patient to adjust the dose

Can stay on current oral agents to start with

Buys time and confidence until a twice or three or 4 times a day insulin regime is required



PROS

Provides both background and prandial cover with two injections a day

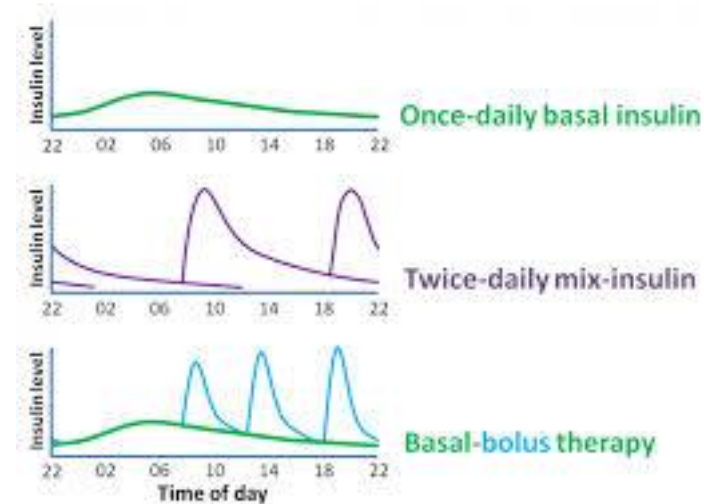
May provide sufficient background insulin to cover a light lunch

CONS

More difficult to titrate evening mixed insulin against pre-breakfast glucose due to risk of nocturnal hypoglycaemia

Requires people to have a regular meal pattern including breakfast and a main meal in the evening, rather than lunch time

Increased risk of hypoglycaemia if eat dinner very late at night or tendency to skip breakfast or lunch



Starting:

- Start with 10 units before bed of insulin if <100kg (or 20 units of insulin if >100kg)
- Tell the patient they are likely to need between 20-50 units of insulin and it is safe for them to increase the insulin
- **For elderly frail people where there is no requirement for tight control, morning NPH (human basal) insulin is safe as the peak will cover breakfast and a bit of lunch, and can be given by a morning carer who can ensure the patient has eaten. In the elderly it is quite likely that NPH will have a much longer duration of action as when the eGFR falls the half life of the insulin increases.**
- Increase by 2 units every 3rd day until before breakfast blood glucose is 8-10 mmol/l
- Reduce the sulfonylurea dose. Continue to increase by 2 units every 3rd day aiming for before breakfast blood glucoses of 6-8 mmol/l
- **STOP INCREASING** if :
 - symptoms of hypoglycaemia at night - **go back to previous dose**
 - some readings are <5mmol/l
 - when insulin dose reaches 50 units - review with Diabetes team

Reviewing:

- Is the before breakfast blood glucose 5-8 mmol/l ? **If >8 mmol/l**
- Continue to increase basal insulin by 2 units every 3rd day providing there is no nocturnal hypoglycaemia:
- If HbA1c over agreed individual target at 3-4 months? – and the before breakfast blood glucose 5-8 mmol/l; examine post prandial blood glucose readings
- **If > 10mmol/l: Switch to Twice Daily Mixed Insulin or Full Basal Bolus Regime**

Starting:

- Tell the patient the insulin needs to be given 15-30 minutes before breakfast and dinner and stress the need to eat on time. Stop all sulfonylureas & DPP4 inhibitors.
- Start with 10 units BD if <100kg (or 20 units BD of insulin if >100kg mixed insulin) 20-30 minutes before breakfast and dinner
- Start with the pre-dinner mixed insulin. Increase by 2 units every 3rd day until the 2 hour post-dinner glucose is <10 mmol/l and before breakfast blood glucose is 6-8 mmol/l
- Then increase the pre-breakfast mixed insulin by 2 units every 3rd day until the 2 hour post-breakfast glucose is <10 mmol/l and before dinner glucose is 6-8 mmol/l
- **STOP INCREASING** if:
 - symptoms of hypoglycaemia
 - pre-breakfast or dinner glucose <5mmol/l
 - when total insulin dose reaches 100 units and review with diabetic team

Reviewing:

- Is the pre-breakfast blood glucose 5-8 mmol/l and 2 hour post-meals blood glucoses if > 10mmol/l?
- Continue to increase the evening mixed insulin by 2 units every 3rd day to target post-dinner and pre-breakfast values if no nocturnal hypoglycaemia:
- Continue to increase the morning mixed insulin by 2 units every 3rd day to target post-breakfast and pre-dinner values if no day time hypoglycaemia:
- If HbA1c above agreed individual target at 3-4 months and pre-meal glucose values in target and post prandial blood glucoses > 10mmol/l:
- Review diet and consider switch to an **Full Basal Bolus Regime**

The aim of the Diabetes level 2 service is to provide a high quality service for safe initiation and optimization of injectable therapy within GP networks.

INCLUSIONS

Initiation or optimisation of injectable therapy will be provided to people with Type 2 Diabetes who satisfy the following criteria:

1. Type 2 people that are registered with a GP in the CCG over the age of 18
1. Are not achieving HbA1c targets with maximum-tolerated oral combination hypoglycaemic therapy and/or insulin/GLP-1, compliant with combination therapy without any significant improvement in HbA1c:
 - Triple therapy (three different oral agents)
 - Dual therapy (two different oral agents)
2. In people who have significantly poor glycaemic control that is unlikely to respond to triple therapy OR in people who express a desire to start injectable therapy OR need to do so for occupational reasons (e.g. GLP-1 in taxi drivers)
1. The patient or carer is deemed capable of safely managing their injectable, including being able to undertake home blood glucose monitoring, inject insulin and adjust their own dose
1. Express an intention to start injectable, having been advised of what this involves and the risks associated with the treatment

EXCLUSIONS (REFERRAL TO ACUTE SPECIALIST CLINIC REQUIRED)

1. Pregnancy
1. People aged under 18

‘An ongoing process of two-way communication, negotiation and joint decision-making in which both the person with Diabetes and the healthcare professionals make an equal contribution to the consultation.’

THE HOUSE OF CARE:

The “house of care” highlights the importance of each part of the process:

- Commissioning
- Autonomous, engaged informed people with diabetes
- Health care professionals committed to partnership working
- Organisational processes
- Without any one of these the house collapses

PERSON CENTRED:

If we want to be more helpful to people who are trying to make changes but are finding it difficult, we need to base consultations on *their* concerns, *their* goals and the practical actions *they* wish to follow. This does not mean that the HCP is passive, unresponsive or does not have a view – the consultation shares the expertise and experience of both parties in order to influence the outcome.

See [Language Matters, Language and Diabetes](#) for guidance on principles and practices for better communication with people with diabetes.

Many people may not really have considered a lifestyle or behaviour change, or may feel ambivalent about making a change. In this situation, pushing or encouraging them to plan to change may not be appropriate. Indeed, a possible goal for that person might be to decide whether they do want to make a change. Their action plan may be to work out the ‘pros and cons’ of both making the change and not making the change, along with assessing its importance to them. If they are struggling with their mood or anxiety or coping with diabetes they usually want to be asked about this as this may be the thing that is standing in their way.

Goal setting and action planning are inextricably linked but they should be seen as separate stages.

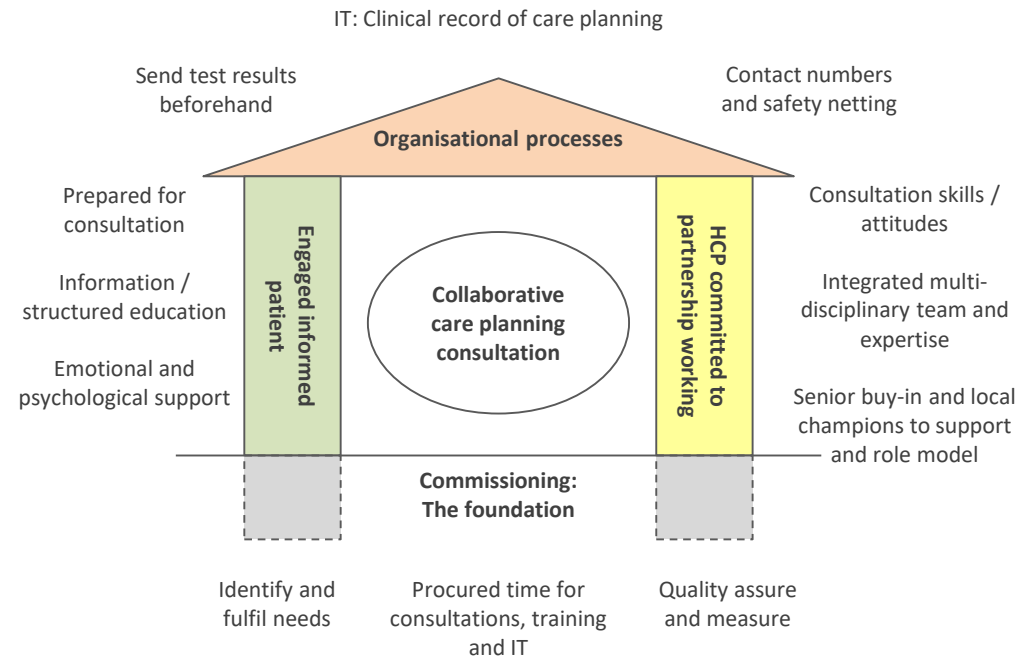
THE INFORMATION SHARING PROCESS:

Information gathering: The patient attends for an appointment with the Health Care Assistant or Nurse to have their ‘annual review’ tests (e.g. blood and urine tests, blood pressure, weight +/- foot, eye screening and mental health screening -PHQ4 (in primary and community care) OR DDS2 (in secondary care). Use 6 item Cog if over 60. See slide [31](#) for tools.

Information sharing: The annual review test results are included into a letter and posted to the patient to arrive at least one week before the Care consultation. Prompts and questions in the letter encourage the patient to consider the results and other aspects of their Diabetes before the consultation

Consultation and joint decision making: The patient attends the Care Planning consultation with the practice nurse or GP, who have received training in partnership working. This should include the elements outlined later in the guide (goal setting and action planning).

Agreed and shared care plan: The agreed care plan is produced and shared with the patient either immediately or subsequently by post or electronically



Useful tools:

- [Partners in Care: Diabetes UK guide to care planning](#)
- [Consultation Quality Index \(CQI-2\)](#): a questionnaire for understanding patient’s perception of clinician skills



GOAL SETTING:	AGREEING ACTIONS:
SUMMARISE AND PRIORITISE	FOLLOW people' PRIORITIES
<p>Goal setting involves summarising and prioritising the various issues that have been explored and discussed so far in the consultation.</p> <p>For instance the healthcare professional might say “what, of all the concerns we have talked about, rise up for you as the important things to aim for in relation to your Diabetes, over this coming year?”</p>	<p>If we want to be more helpful to people who are trying to make changes but are finding it difficult, we need to base consultations on <i>their</i> concerns, <i>their</i> goals and the practical actions <i>they</i> wish to follow.</p> <p>This does not mean that the HCP is passive, unresponsive or does not have a view – the consultation shares the expertise and experience of both parties in order to influence the outcome.</p>
ASSESS IMPORTANCE	SMART GOALS
<p>When changing something is difficult, the reason for change, the place where someone would like to be, has to be worth the effort of changing. If the goal is of low importance, but the difficulty of achieving it is high, then it is unlikely to be successfully achieved. Why would you want to put yourself through that?</p> <p>The value to someone can be assessed quite simply by asking the person to consider how important the goal or outcome is for them using a rating scale of 0 – 10 where 0 is low and 10 is high importance. For instance:</p> <p><i>“If I asked you to tell me how important this change is for you, where zero was not important at all and 10 was really, really important, where would you put yourself between zero and ten?”</i></p> <p>If they score e.g. 6, you could ask why it isn't 7 and ask what would need to happen to make it 7. You could also ask why it isn't 5 as this will help you and them explore why it IS important. This process illuminates their ambivalence and facilitates a motivational conversation.</p>	<p>Key ingredients of successful action planning:</p> <ul style="list-style-type: none"> • Plans need to be SMART • Success is addictive • Barriers to success need to be considered • Rating scales to assess confidence and readiness • Success really is addictive • Take the time to do it <p>‘SMART’ is a well known acronym, the letters of which stand for the following: S = Specific M = Measurable A = Action R = Realistic T = Time-scaled</p> <p>If an action plan can ‘tick the boxes’ of the above features, it is more likely to be successfully achieved</p>
REASSESS IMPORTANCE	ASSESS CONFIDENCE
<p>If the score is lower than 7 then the reason for picking that goal needs to be explored.</p>	<p>Rating confidence: Self efficacy theory holds that a key determinant of a person's ability to take action is the confidence they have in their ability to successfully undertake that action. So, a further way of assessing how realistic a plan is to ask the person to rate their confidence that they will be able to do it. This can be done in a similar way that we rated the importance of goals:</p> <p><i>“If I asked you to rate how confident you feel you are to be able to do this, where zero was not at all and 10 was absolutely definitely, where would you put yourself between zero and ten?”</i></p> <p>If they score e.g. 6, you could ask why it isn't 7 and ask what would need to happen to make it 7. You could also ask why it isn't 5 as this will help you and them explore what skills they DO have. This process illuminates the support and skills they can draw upon including you.</p>

OVERVIEW

Approximately 40% of people with Diabetes suffer with poor psychological well-being:

- The rate of depression and anxiety is more than doubled in people with Diabetes
- Other conditions such as diabetes distress, eating disorders, alcohol and substance use and needle phobias are more prevalent in diabetes
- People with poorly controlled diabetes and **vascular changes** in feet, eyes and kidneys have a higher likelihood of such changes **in their brains leading cognitive impairment.**
- People with type 2 diabetes are more likely to have experienced childhood adversity
- People with severe mental illness such as schizophrenia and bipolar affective disorder are at higher risk of developing type 2 diabetes . Atypical antipsychotics increase this risk.

Impact of all these conditions in Diabetes if not addressed is:

- Difficulty with motivation, hope for the future, cognitive function and self-esteem leading to difficulty with self-care

Treatment for psychological conditions has been shown to lead to reduced symptoms and improved glycaemic control, as well as the costs of healthcare.

Person Centred approach

- People with diabetes want to be asked about their psychological wellbeing and how they are managing living with Diabetes .
- People with Diabetes want a menu of choices in terms of interventions, including peer support and self-help including online resources (see below)

CLINICIAN RECOMMENDATIONS

Especially when people have off target HbA1c or are not engaged with treatment, be alert to :

- **Diabetes distress, clinical or subclinical depression, anxiety.** Use the screening tools that are at bottom of this page-DDS2 (In secondary care), PHQ4 (in primary or community care) as a screen and refer to IAPT or other relevant local pathway if +ve. [See here for other considerations and options, how to introduce medication etc.](#)
 - For moderate to severe depression, consider an antidepressant in the form of an SSRI, e.g. citalopram (20mg od, titrate up to maximum 40 g od) or sertraline (50mg od, titrate up to maximum of 200mg od). Give them at least 6 weeks at maximum dose before trialling a different antidepressant. **Don't switch from one SSRI to another as they work in the same way.** [Try a different agent](#) and/ or refer to mental health trust. **Don't use dosulepin.**
 - **Don't use anxiolytics for anxiety.** This is contraindicated. CBT is the NICE treatment of choice- so refer to IAPT

Alcohol and drug use- often used as a coping strategy when people are feeling distressed, anxious, overwhelmed or depressed. Ask about this using the AUDIT tool (see below) and whether they would like referral to local drug and alcohol services

Eating disorders and insulin dose manipulation if there is poor glucose control, low BMI or over concern with body shape and weight. Early, and occasionally urgent, referral to local eating disorder services should be considered. [Eating Disorder Resources](#)

Cognitive impairment (delirium or dementia) if they have other complications-even in people as young as 50 and even if they appear to be compos mentis. Use 6 item Cog test (see below) and consider discussion with or referral to dementia services locally. Add in extra support if required e.g. administration of medication

Relapsing or new onset of psychosis may put the person with diabetes at greater risk of poor self-care for their diabetes. Aripiprazole is the recommended antipsychotic if the person has diabetes. If the person's psychosis is stable, consider titrating the antipsychotic dose down slowly and carefully with close monitoring. Discuss with team psychiatrist if in doubt .

Mental health screening tools and other resources

Screening tools

- [Alcohol screening tool "AUDIT"](#)
- [Diabetes Distress scale \(DDS2 and DDS longer version\)](#)
- [PHQ4 \(depression and anxiety brief screen\)](#)
- [PHQ9\(depression\)](#)
- [GAD 7\(anxiety\)](#)
- [6 item Cog](#)
- [Eating Disorder screening for primary care](#)

Resources

- [Award winning self-help leaflets about a number of different mental health issues \(available in easy to read, audio available\)](#)
- [MIND Charity for information and support](#)
- [Samaritans for support in a crisis](#)

Refer to the five principles of the MCA

1. Assume a person has capacity
2. Support the individual to make their own decision
3. Someone may make an unwise decision
4. Always act, or decide, for a person without capacity in their best interests
5. Choose the least restrictive option

The two-stage capacity test

Stage one. Is there an impairment of, or disturbance in the functioning of the person's mind or brain? If so,

Stage two. Does the impairment or disturbance impede the person's capacity to make the particular decision?

Can the person:

1. Understand the information relevant to the decision,
2. Retain that information, Weigh that information as a part of the process of making a decision
3. Communicate their decision (whether by talking, using sign language or any other means)?

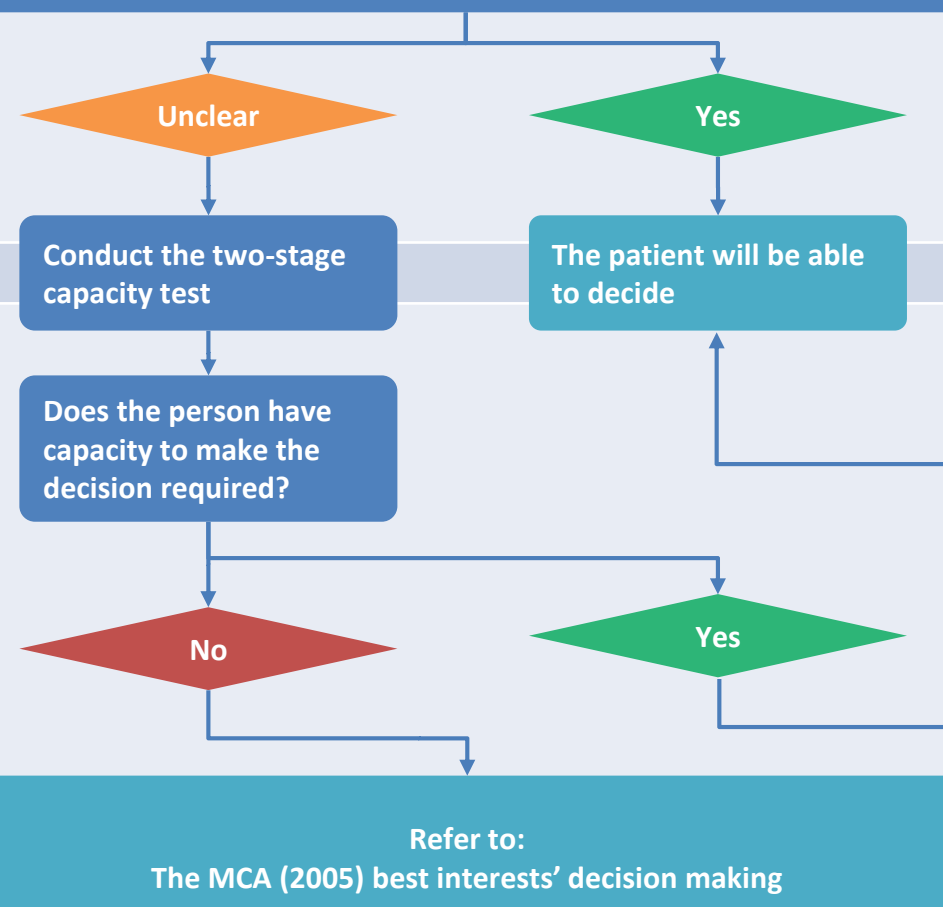
(Person must demonstrate all four functions above to be deemed as having capacity for the required decision-making)

Record this!

MCA (2005) Decision Making Flowchart

All adults should be presumed to have capacity unless an assessment of capacity has proved otherwise. If the patient is capable, consent must be obtained by the person undertaking the procedure.

Can the person make the required decision?
(Do they need additional support, more time and to be given the information in a different format or asked at a more appropriate time?)



Refer to the five principles of the MCA

- Must ensure that the proposed action/treatment is in the best interests of the person.
- The decision maker needs to check if there is an Advance Decision (AD), Lasting Power of Attorney [LPA] or Deputy covering health and welfare or if there is a friend/carer of person nominated by the person to consult.
- Advance Decision must be relevant to this decision.

The best-interest checklist

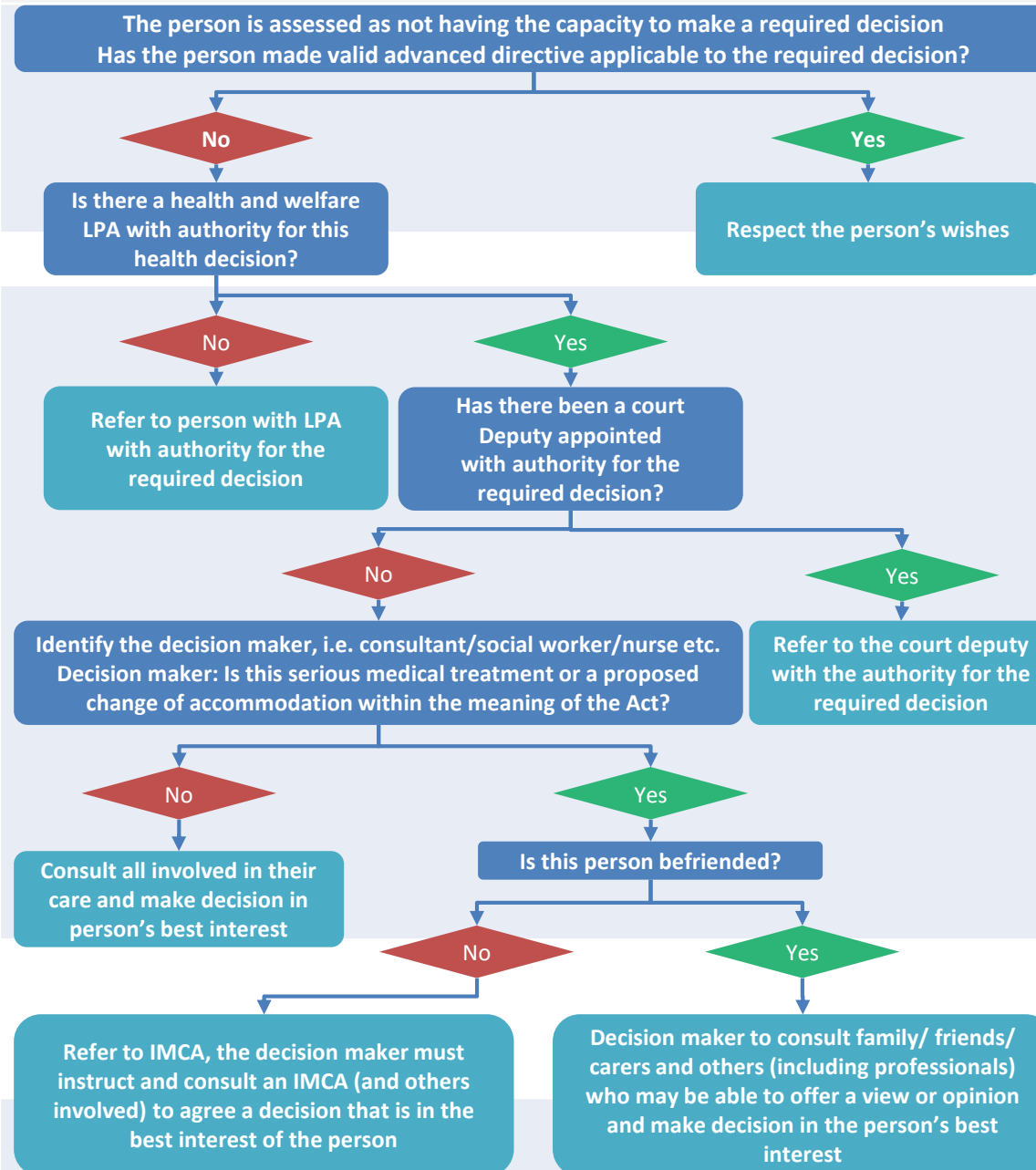
When making a decision in someone's best interests one must:

- Involve the person as much as possible
- Find out the person's wishes and feelings
- Consult people who know the person well
- Consider all relevant information in time
- Avoid making the decision if it is likely that the person might regain capacity
- Think about what would be the least restrictive option and not:
- Make assumptions based on the person's age, appearance, condition or behaviour
- Make a decision involving life-sustaining treatment that is motivated by a desire to end the person's life.
- Consult with all relevant others, i.e. the person, medic/GP, carers, Allied Health Professionals, social care staff, Advocate/IMCA, or people who know the person well, i.e. LPA or Deputy or Enduring Power of Attorneys
- Consider all the relevant circumstances relating to the decision in question
- Be able to justify and evidence their decision making
- Ensure that other least restrictive options are always explored (complete best interests decision record).

A formal best interests meeting is not always needed. It is important that consultation has taken place and the decision maker follows the guidance above with all relevant others and this is documented on the agreed paperwork.

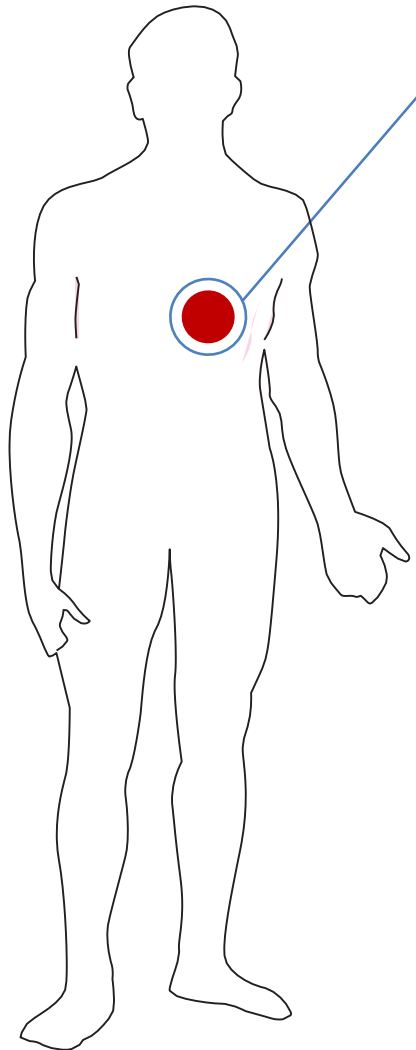
Record keeping: it is important that you accurately record and evidence any decisions made with regards to best interests.

MCA (2005) Best Interests Decision Making





WOMEN OF CHILDBEARING AGE WITH DIABETES or PREVIOUS GESTATIONAL DIABETES (GDM)	
50% of all pregnancies are unplanned	
All women with Diabetes	Offer contraceptive advice
	All forms of contraception may be used for women with Diabetes
	Pre-conception care
Stress the importance of: Folic acid Good glycaemic control Medicines review (stop ACE, ARBs and statins) Ensure retinal screen and microalbuminuria testing within the last 6 months Target HbA1c ≤ 48 mmol/mol (6.5%), if achievable without causing problematic hypoglycaemia.	
All women with Type 2 Diabetes actively seeking pregnancy	Refer to secondary or intermediate care for pre-conception counselling
	Discontinue all oral agents and injectable therapies except Metformin and insulin Optimise glycaemic control with a basal bolus regime if needed Start folic acid 5mg OD
For women with a previous history of Gestational Diabetes	Emphasise importance of annual review
	Check a HbA1c yearly to exclude Diabetes Give dietary and weight management advice Explain the high probability of recurrent GDM in future pregnancy and need for early booking
On confirmation of pregnancy	Refer immediately to the Diabetes Antenatal Clinic
	Refer to retinal screening if not within previous 3 months
	Ensure taking folic acid 5mg OD and ACE , ARBs and statins have been stopped



CARDIOVASCULAR RISK FACTOR INTERVENTION

All people with Diabetes are considered to be at high cardiovascular risk.

All require lifestyle advice and multifactorial risk factor intervention.

However note lipid guidelines now recommend QRISK2 assessment for statin initiation.

LIFESTYLE INTERVENTION

Smoking cessation should be encouraged, with use of Stop Smoking clinics as required.

Dietary intervention

- Should include weight loss for those with high waist circumferences
 - >94cm in Northern European white male**
 - >80cm in Northern European white females**
 - >90cm in South Asian males**
 - >80cm in South Asian females**and, for all should include advice about a low fat diet high in fruit and vegetables (at least 5 portions per day).
- Should include advice to decrease total dietary fat to <30% of total energy intake
- Should include advice to decrease saturated fats to <10% of total fat intake.
- Should include advice about lowering salt intake to be less than 6g of salt (=2.4 g sodium chloride) per day.
- Alcohol intake should be discussed, with the advice for males to limit to 14units per week.
- Regular intake of oily fish and other sources of omega 3 fatty acids (at least 2 portions of fish per week)

Exercise

The benefits of regular exercise should be explained and people should be advised to perform regular aerobic activity. Clinical studies show that walking for 30 minutes every day has cardiovascular benefits

BLOOD PRESSURE

All people with Diabetes should be treated to a target of 140/80 with a combination of lifestyle intervention (see above) and drug therapy. If kidney, eye or cerebrovascular damage set a target <130/80.

Up to half the people with Type 2 Diabetes will need 3 or more antihypertensive agents, and it is important for people to be made aware of this when discussion around hypertension occurs.

ACE inhibitors and ARBs are preferred first line therapy in people with any degree of nephropathy (micro- or macroalbuminuria).

In all people measure renal functions and electrolytes 1-2 weeks after initiation of ACE inhibitors and ARBs and with each increase in dose.

The British Hypertension Society's Guidelines should be followed.

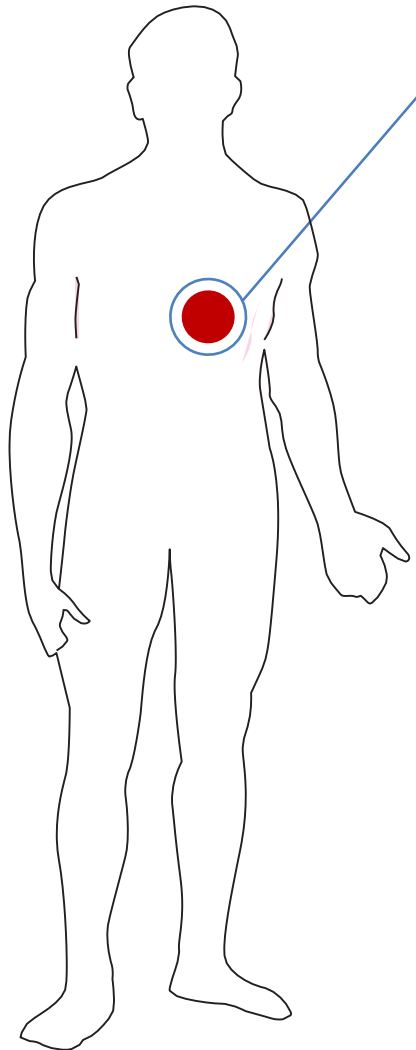
Assess blood pressure at least 3 monthly until targets are achieved, and monitor every 4-6 months once targets are achieved.

People who do not achieve target should be referred for further management. Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient's baseline.

Smoking

Please assess people for smoking status and refer to Smoking Cessation Teams for patient support.

Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.



Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.

LIPIDS

PRIMARY PREVENTION IN TYPE 2 DIABETES:

Offer atorvastatin 20 mg for the primary prevention of CVD to people with Type 2 Diabetes who have a 10% or greater 10-year risk of developing CVD.
Estimate the level of risk using the **QRISK** assessment tool

PEOPLE WITH CKD

Increase the dose if a greater than 40% reduction in non-HDL cholesterol is not achieved and eGFR is 30 ml/min/1.73 m² or more. Agree the use of higher doses with a renal specialist if eGFR is less than 30 ml/min/1.73 m²

EXCEPTION - WOMEN OF CHILD-BEARING POTENTIAL/PREGNANT

TREATMENT TARGETS

Dietary interventions alone only reduce cholesterol by <10%. To reach targets, often drug therapy will be required. The initial target is to achieve a total cholesterol of <4.0 mmol/l and an LDL of <2.0 mmol/l. Statins are first line drugs for this indication. In accordance with NICE guidelines **Atorvastatin 20mg** is first choice.

Increase from atorvastatin 20mg/day to **atorvastatin ≥40mg/day** unless total cholesterol level is below 4.0mmol/l or LDL cholesterol level is below 2.0mmol/l. Also consider intensifying to atorvastatin ≥40mg/day if there is existing or newly diagnosed CV disease, or increased albumin excretion rate.

If Atorvastatin is not tolerated consider using **Rosuvastatin**.

Monitor LFTs 6 weeks post initiation of statin. If normal check annually

In females who are planning a pregnancy or who are pregnant these drugs should be withheld until breast feeding has ceased

Ezetimibe should be prescribed as per [NICE's guidance](#).(TA 385)
If a greater than 40% reduction in non-HDL cholesterol is not achieved:

- discuss adherence and timing of dose
- optimise adherence to diet and lifestyle measures
- consider increasing the dose if started on less than atorvastatin 80 mg and the person is judged to be at higher risk because of comorbidities, risk score or using clinical judgement

It is important to note that the target triglyceride level is a fasting target, so an individual with a non-fasting result >2.3 mmol/l should be invited back to have a fasting triglyceride estimation. HDL and triglyceride interventions include lifestyle (predominantly weight loss and exercise) and drug therapies. The drug of choice is a fibrate, usually **Fenofibrate 160mg**. If using a combination lipid lowering regimen, monitoring of ALT and CK is appropriate.

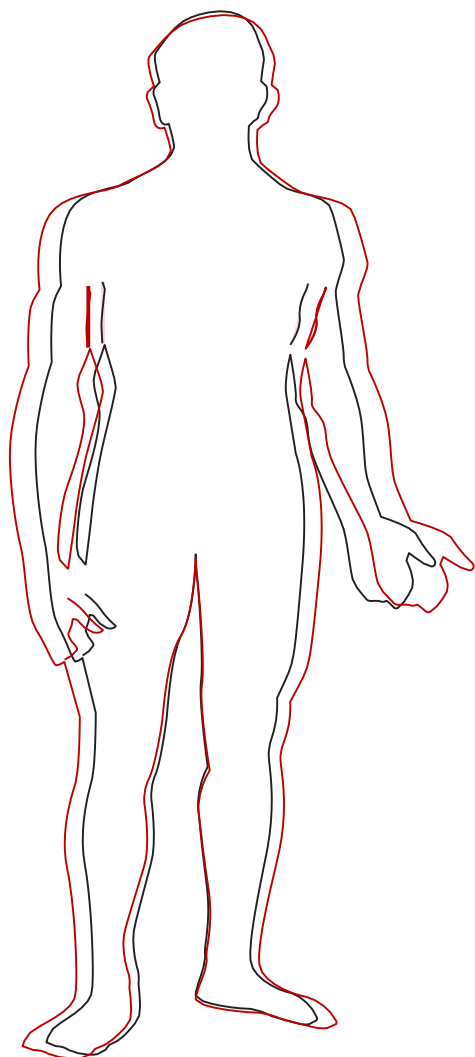
Monitor lipids 6 weekly until targets have been achieved, and annually thereafter.

Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient's baseline.

Fibrates should not be commenced if eGFR is <45. They should be discontinued with deterioration of renal function.

ANTI-PLATELET AGENTS

Where not contraindicated antiplatelet therapy (Aspirin 75 mg daily) is indicated for all people with Diabetes follow a Cardiovascular event (MI /CVA). In those who are also hypertensive the blood pressure should be controlled to ≤145/90 mmHg before commencing aspirin. If aspirin is not tolerated or is contraindicated, clopidogrel 75 mg daily should be considered; with antiplatelet therapy is not routinely offered as part of Primary Prevention.



Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity

OBESITY

BACKGROUND POINTS

Obesity is a major modifiable risk factor in the development of Type 2 Diabetes. Decrease in weight in those who are obese can improve Diabetes control enormously without the need for escalation in therapy.

Weight loss can help the patient achieve Type 2 diabetes remission

GUIDANCE

Those people with Diabetes whose adipose tissue mass is likely to contribute to the progression of their Diabetes control should be offered the opportunity to discuss their weight. The benefits to the patient of weight loss should be made clear. If the individual does not wish to consider making any changes then this should be reviewed at future consultations. Any choice of weight loss intervention should be negotiated between patient and health care professional. Consideration of what has been tried before is important.

INTERVENTIONS

Interventions include lifestyle advice, specific drug therapy such as metformin in combination with either SGLT2 or GLP1 and obesity surgery.

General points

Realistic targets for weight loss should be discussed

- Maximum weekly weight loss of 0.5-1kg
- Aim to lose 5-10% of original weight

Realistic targets for exercise will vary greatly depending on the individual. Ideally, individuals should be encouraged to take up to 45 minutes of exercise per day, 5 times per week. Encouragement to join a commercial weight loss organisation can be beneficial.

Check for mental health factors using PHQ4 in primary and community care), DDS2 (in secondary care) and refer bariatric surgery or IAPT or other relevant part of the local pathway if +ve.

Lifestyle intervention

This is the mainstay of obesity management. Any advice offered is more likely to be accepted by the patient if we as health care professionals offer the advice in an enthusiastic manner. Ideally, a combination of reduction of calorie intake and an increase in energy expenditure should be considered.

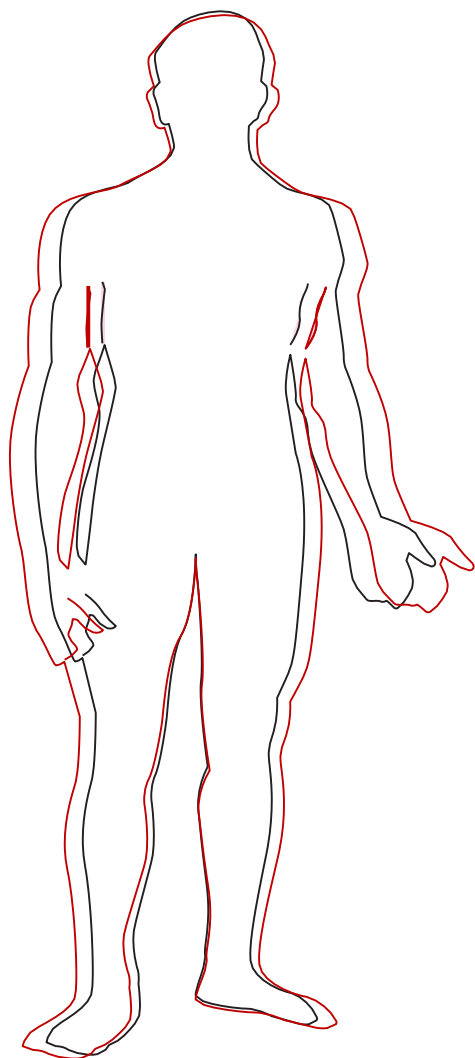
OBESITY SURGERY

Surgical intervention is considered appropriate option for adults with obesity if all of the following local criteria are fulfilled:

- they have Type 2 Diabetes and a BMI of 35 kg/m² or more
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anaesthesia and surgery
- the person commits to the need for long-term follow-up.

Bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m² in whom surgical intervention is considered appropriate.

Bariatric services provides intensive psychological interventions prior to surgical intervention-the aim is to consider and screen for binge eating disorder, depression and alcohol use disorder; to refer onward or provide self help information for these conditions as they will affect the people' ability to effectively implement any lifestyle, medication or surgical intervention offered.



Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.

OBESITY MEDICATION

BACKGROUND POINTS

Before deciding to start treatment, and choosing the drug, discuss with the patient the potential benefits and limitations, including the mode of action, adverse effects and monitoring requirements, and their potential impact on the patient's motivation.

- When prescribing, make arrangements for appropriate healthcare professionals to offer information, support and counselling on additional diet, physical activity and behavioural strategies as well as mental health interventions if appropriate

- Give information on patient support programmes.
- Follow the drug's summary of product characteristics.

DRUG THERAPY

Pharmacological agents are only to be used once lifestyle interventions have been instigated and the patient has reached a plateau in their weight loss but still wishes to lose more weight. It is important to set achievable targets for weight loss of no more than 10% of body weight.

When considering the use of pharmacological agents to aid weight loss, ensure that the patient:

1. wishes to lose weight (the benefits of weight loss should be discussed)
2. is prepared to make changes to their calorie intake following appropriate dietary advice, preferably from a dietitian with an interest in obesity
3. is prepared to increase the level of physical activity (if able), preferably up to 45 minutes of moderate exercise at least 5 times per week
4. is prepared to consider joining a commercial weight loss programme.
5. Understands that, if the drug is deemed not to be successful then it will be withdrawn.

All studies showing the greatest benefit with the weight loss drugs involved lifestyle intervention as part of the management.

SPECIFIC ADVICE ON ORLISTAT

NICE guidance available

- Use only in those with Diabetes or endocrine conditions who have a BMI >28kg/m²
- Continue beyond 3 months of therapy only if the patient has lost at least 5% of their body weight.
- Continue beyond 12 months for weight maintenance only after discussion of potential benefits and limitations with the patient.

CONTINUED PRESCRIBING AND WITHDRAWAL

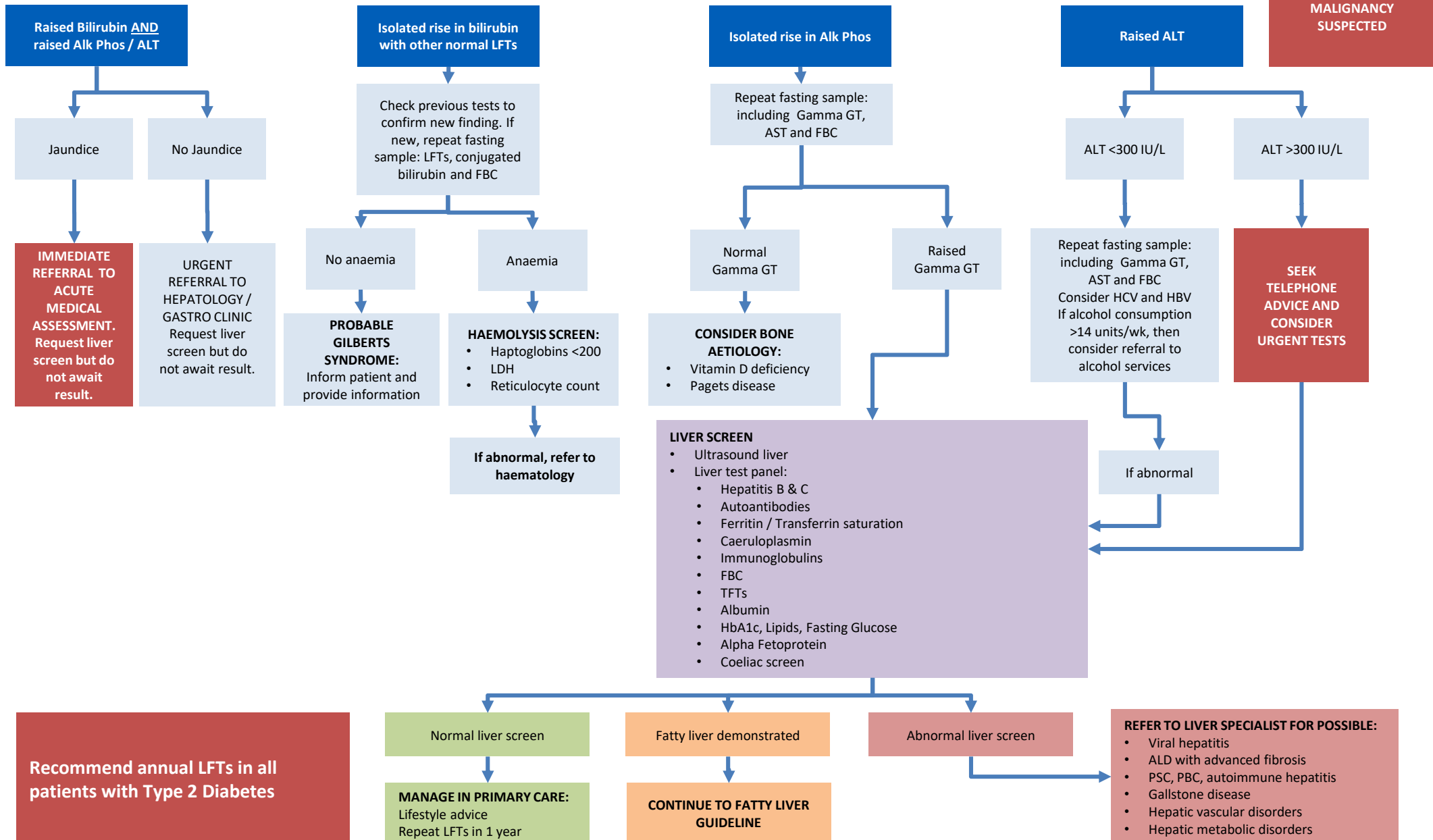
- Review regularly, to monitor the effect of drug treatment, and to reinforce lifestyle advice and need for adherence.
- Drug treatment may be used to help people to maintain weight loss, as well as to continue to lose weight.
- Consider withdrawing drug treatment if the person does not lose enough weight.

Agree goals with the person and review regularly

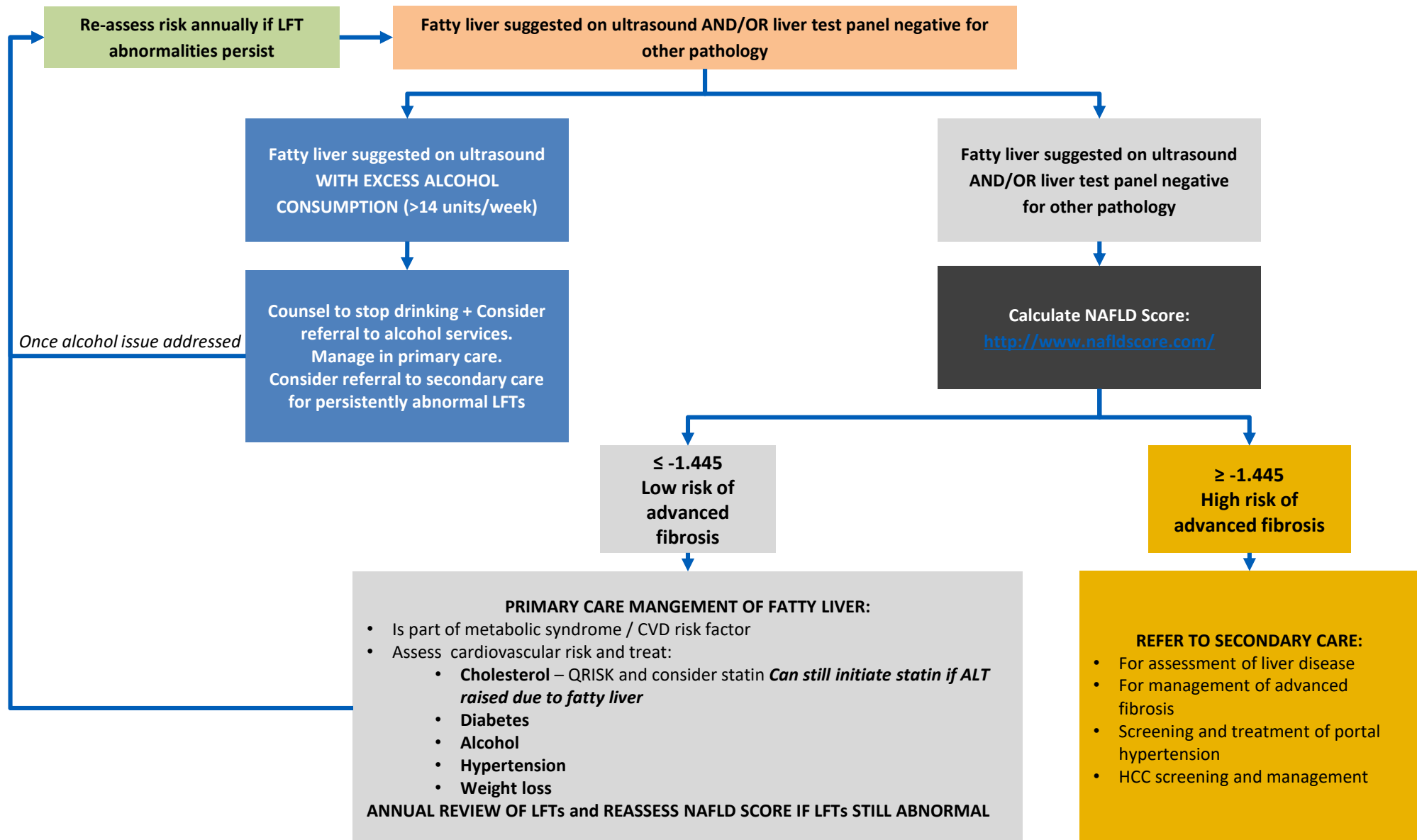
- If concerned about micronutrient intake, consider giving a supplement providing the reference nutrient intake for all vitamins and trace elements, particularly for vulnerable groups such as older people, who may be at risk of malnutrition.
- If withdrawing a person's drug treatment, offer support to help maintain weight loss because their self-confidence and belief in their ability to make changes may be low.

GP receives abnormal LFTs

- History and examination with attention to alcohol consumption, metabolic syndrome, BMI, hepatotoxic drugs and risk factors for viral hepatitis



Non Alcoholic Steatohepatitis (NASH) is a form of Non Alcoholic Fatty Liver Disease (NAFLD), now affects up to 5% of the UK population and is more common in T2DM.



Annual Foot Review
Assumed patient receiving ongoing care and education

Foot examination with shoes and socks/stockings removed

Test foot sensation
Palpate foot pulses

Ask about change in foot shape
Inspect for deformity/significant callus

Ask about any pain or numbness
Inspect footwear

Ask about previous foot ulcers
Check for signs of infection

Active Problem

Ulcer – wound below the ankle, even minor
Infection – red/hot/swollen/shiny foot
Critical Limb ischaemia – severe pain at rest or new cold red/blue/purple foot
Gangrene – Black toe/wound/foot
Could it be Charcot’s? – unexplained warmth/swelling/unusual pain in just one foot

Rapid referral to Acute Multidisciplinary Foot Team (MDFT)

Admission to secondary care if systemically unwell or vascular hub if critical limb ischaemia

High Risk

Previous ulcer or amputation or on Dialysis or with a kidney transplant or any TWO of the following:
No pulses felt in the foot
Neuropathy (numbness or unpleasant tingling/sensation/burning or painless blisters/wounds)
Significant hard skin/callus
Abnormal Foot shape/change in foot shape

Refer to local Foot Protection Team : Confirm risk status
1-3 monthly foot checks

Moderate Risk

Any ONE of the following:
No pulses felt in the foot
Neuropathy (numbness or unpleasant tingling/sensation/burning or painless blisters/wounds)
Significant hard skin/callus
Abnormal Foot shape/change in foot shape

Refer to local Foot Protection Team: Confirm risk status
3-6 monthly foot checks

Low Risk

Healthy Foot – no foot shape change, no significant callus, no skin breaks, normal skin colour
No neuropathy
Pulses felt in the foot

Footcare advice
Daily self checks
Annual foot screening in primary care

Risk Status

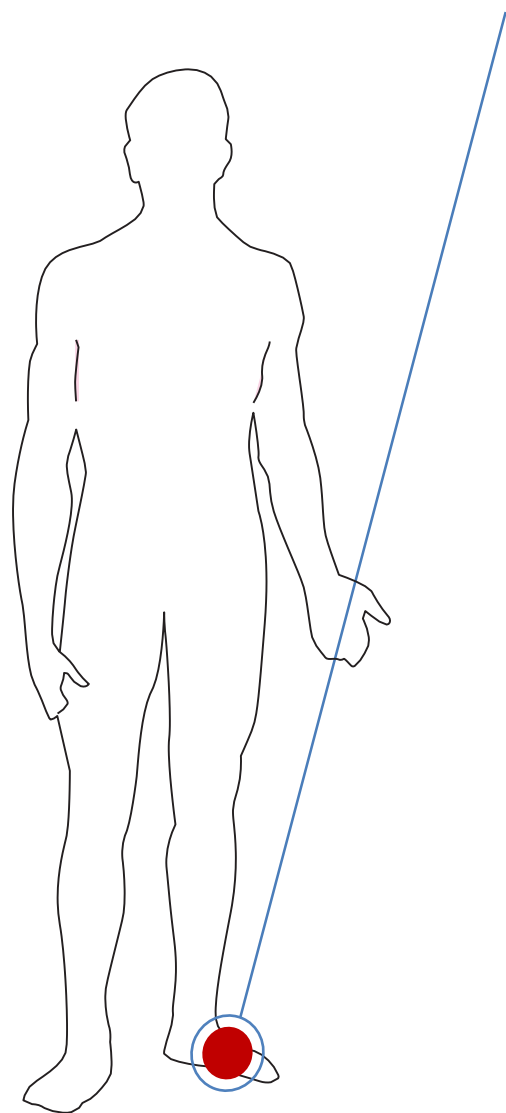
Document and explain risk status to patient and/or carer.

Provide written and verbal education and emergency contact numbers

Risk status may go up or down

Provide patient information leaflets:

- [Ulcer](#)
- [Charcot’s Foot](#)
- [High Risk](#)
- [Moderate risk](#)
- [Low risk](#)



	FINDING
History	Previous ulcer or amputation (toe/foot leg)
	Kidney Transplant or Dialysis
	Impaired vision
Inspection	Significant callus or corns
	Abnormal foot shape: High arch/bunion/flat foot
	Abnormal toes:: Claw toes/Hammer toes/overriding toes
	Change in foot shape in one foot
Neuropathy	Neuropathic pain (tingling/burning/electric shock)
	Painless blister or wound
	Score 8 or less on 10g monofilament testing
Vascular Disease	Claudication (calf or buttock pain on walking, relieved by rest)
	Any foot pulses not palpable
Active Problem	Change in foot shape in one foot with swelling and warmth
	Foot wound/ulcer
	Ingrown toenail with signs of infection
	Infection (redness/swelling/warmth/malodour/discharge)
	Gangrene (black toe foot wound)
	Foot/leg pain at rest, improved by hanging leg down
	New cold foot with new blue/red/purple colour change



High arch, prominent metatarsal heads



Bunion



Claw toes

All people with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see Cardiovascular Risk for additional requirements

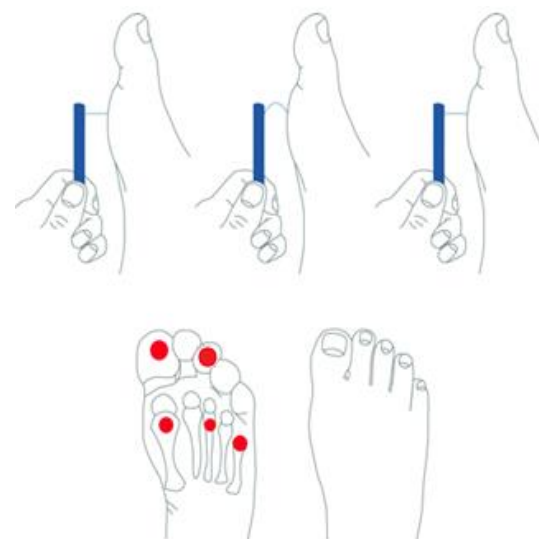
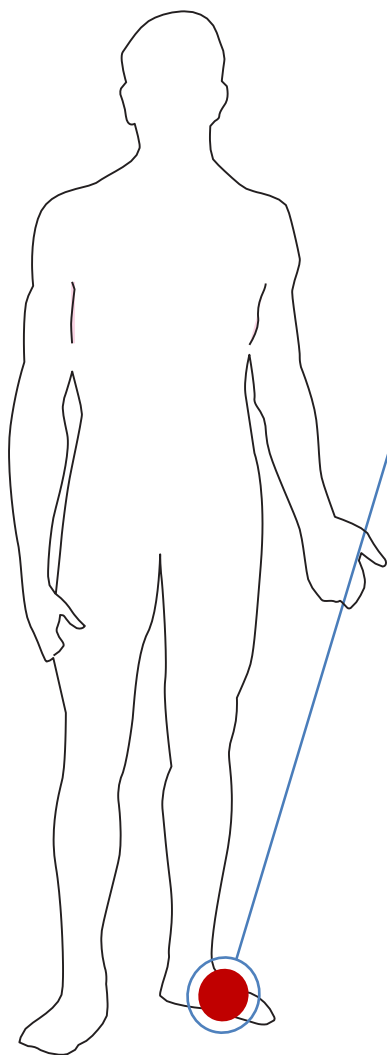
Mental health problems affect the ability to self-care. Check for: - Impaired memory - 6 item cog (see slide 31) Anxiety or depression – PHQ4 (see slide 31)

Photographs courtesy of Dermatronics 'A pictorial guide to diabetic foot examinations' 2016

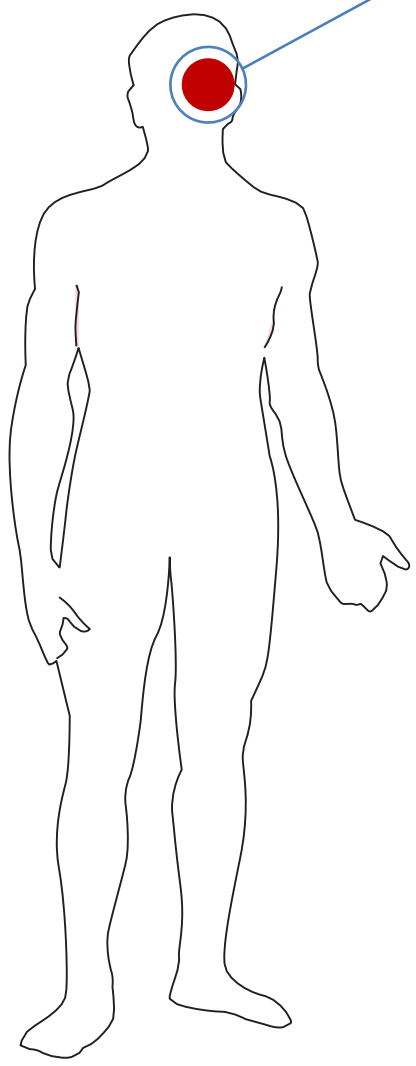
USING A MONOFILAMENT

- Apply the filament to a sensitive area of skin (e.g. the forearm) so that the patient is aware of the sensation they are supposed to feel.
 - Test 5 sites* on both feet:
 - ✓ Plantar surface of the hallux and 3rd toe
 - ✓ 1st, 3rd and 5th metatarsal heads

*If callus is present at any of the sites then test at the nearest non-calloused area.
 - Ask the patient to close their eyes and say 'yes' every time that they feel you touch the skin on the foot
 - Place the monofilament at 90° to the skin surface
 - Slowly push the monofilament until it has bent ~ 1cm (don't jab)
 - Hold the monofilament in this position for 1-2 seconds, then slowly release the pressure until the monofilament is straight
 - Remove contact from the skin
 - If the patient does not respond, repeat the test at the site twice. If there is still no response, record as a negative response
- **Maximum score 10. A score of 8 or less indicates neuropathy**
- **Replace monofilament after 500 uses (approximately 6 monthly frequent testing, yearly infrequent testing)**



	CCG	Acute Diabetes Specialist Foot Team	Foot Protection Team		Vascular Hub
Inner NW London	H & F	St Mary's Hospital T:0203 312 5437	E: clcht.spa.referral@nhs.net F:0300 008 3251		Inner NWL Vascular Hub: St Mary's Hospital Contact Vascular Surgery on-call
	Central London	F:0203 312 6875 E: imperial.idfootreferrals@nhs.net			
	West London	Chelsea & Westminster Hospital T:0203 315 3161 F:0203 315 2732 E: Diabetes.TeamCW@chelwest.nhs.uk			
	Hounslow	West Middlesex Hospital E: T: All Hounslow Diabetes foot referrals go via the Hounslow Diabetes Foot Protection Team- they will step up to the WMH Acute Diabetes Specialist Foot Team as appropriate	E: HRCH.podiatry@nhs.net T:0208 973 3470		
Outer NW London	Brent	Central Middlesex Hospital T: 020 8453 2401/2607 F: 020 8453 2415	BIDS T:020 8963 8803 / 8804 F: 020 3963 8891 E: LNWH-tr.Diabetes-BCS@nhs.net		Outer NWL Vascular Hub: Northwick Park Hospital Contact Vascular Surgery on-call M: 07976682471
	Ealing	Ealing Hospital T:020 8967 5383 F:020 8967 5507	High Risk (DICE) T:0208 383 9870 F:0208 843 1482	Moderate Risk T:0208 383 5738/ 5751 or 0208 579 5316 F:0208 383 5735 E: lnwh-tr.podealingcom@nhs.net	
	Harrow	Northwick Park Hospital: T:020 8869 2100 F: 0208 869 2961	CLCH Harrow F:0300 008 3104 E: Podiatryharrow@nhs.net		
	Hillingdon	Hillingdon Hospital T:01895 279229 E: thh.diab-endo-referrals@nhs.net	T:01895 485005 E: cnw-tr.hchcontactcentreferrals@nhs.net		



RETINOPATHY	
NSF KEY INTERVENTION	MANAGEMENT OF RETINOPATHY
Regular surveillance for diabetic retinopathy in adults with Diabetes and early laser treatment of those identified as having sight threatening retinopathy can reduce the incidence of new visual impairment and blindness in people with Diabetes.	Optimisation of BP (<130/80), lipids and glycaemic control are of paramount importance.
SCREENING	Those at highest risk of progression are those with rapid improvement in blood glucose control, presence of raised blood pressure or renal disease. There is clear evidence that long-term lipid-lowering treatment can reduce retinopathy progression in Type 2 DM.
Ensure that all people (including those blind and partially sighted) with Type 2 Diabetes (from diagnosis are referred to and followed up with retinal screening using the CCG-commissioned community retinal screening programme.	Fenofibrate The FIELD study (fenofibrate alone) and a sub analysis of the ACCORD study (fenofibrate as add-on to statin) demonstrated a reduction in need for first laser treatment by 30-40% as well as slowing progression of diabetic retinopathy
BACKGROUND POINTS	Atorvastatin A much smaller possible beneficial effect for atorvastatin was seen in the CARDS study
<ul style="list-style-type: none"> Diabetic retinopathy is the most common cause of blindness in people of working age.⁽¹⁾ Poor mental wellbeing may put people at greater risk through poor self-care -screen for depression, anxiety, diabetes distress, cognitive impairment About 26% of Type 2 diabetics have retinopathy at diagnosis.⁽²⁾ Progresses over the years: after 15 years, at least two thirds of people may have background retinopathy. 	

ALGORITHM FOR THE PRIMARY CARE MANAGEMENT OF EYE SYMPTOMS IN TYPE 2 DIABETES

Sudden loss of vision	Sudden drop in visual acuity Diffuse reddening of the iris Irregular pupil Corneal haze Painful eye	Subacute drop in visual acuity (over days-weeks)	Gradual worsening of symptoms since last examination	Minimal or background retinopathy
Possible cause				
Retinal detachment	Pre-retinal and/or vitreous haemorrhage Rubeosis iridis	Macular oedema Preproliferative or severe retinopathy	Worsening of retinopathy	
Referral/management				
Emergency referral to Ophthalmologist / Eye Casualty Same day referral	Urgent referral to Ophthalmologist Referral within 1 week	Referral Arrange referral for specialist opinion within 4 weeks	Early review Arrange recall and review every 3-6 months	Yearly review

All people with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see Cardiovascular Risk for additional requirements.

1. Audit Commission 2000. Testing Times: A Review of Diabetes Services in England and Wales.
2. Thomas RL, et al. Incidence of diabetic retinopathy in people with Type 2 Diabetes mellitus attending the Diabetic Retinopathy Screening Service for Wales: retrospective analysis. BMJ. 2012;344:e874.

DIABETIC NEPHROPATHY

Diabetic Nephropathy is characterised by the excretion of abnormal amounts of albumin in the urine, arterial hypertension or progressive decline in kidney function

ALBUMINURIA

Albuminuria is the earliest sign of kidney involvement in Type 2 Diabetes .

This is best assessed by laboratory measurement of the urinary albumin creatinine ratio (ACR).

Albuminuria is an independent risk factor for cardiovascular disease and progression to end-stage kidney disease.

All patients with albuminuria should be on maximal ACEi or ARB therapy (with appropriate reminder of good sick day guidance) and have BP controlled to target (see below)

People with type 2 diabetes and albuminuria should be preferentially treated with SGLT2 inhibitor according to the individual drug licences. [\(Please see SGLT2i safe prescribing guidance slide 15\)](#)

SEEK RENAL ADVICE IF

Unexplained sudden increases in albuminuria
Unexplained eGFR decline in absence of albuminuria

MANAGEMENT OF INDIVIDUAL WITH DIABETIC NEPHROPATHY

Patient education is an integral part of overall management

Lifestyle changes, weight loss and smoking cessation should be advised

Target HbA1c:
Type 2 Diabetes

- CKD stages 1 and 2 = 48 - 58 mmol/mol
- CKD stages 3 and 4 on non-hypo inducing agents = 52 - 58 mmol/mol
- CKD stages 3, 4 and 5 (incl on dialysis) on hypo inducing agents = 58 – 68 mmol/mol

Prescribe maximal tolerated dose of ACE Inhibitors or Angiotensin 2 receptor blockers

People with type 2 diabetes and albuminuria should be preferentially treated with SGLT2 inhibitor according to the individual drug licences. Please see SGLT-2i safe prescribing guidance

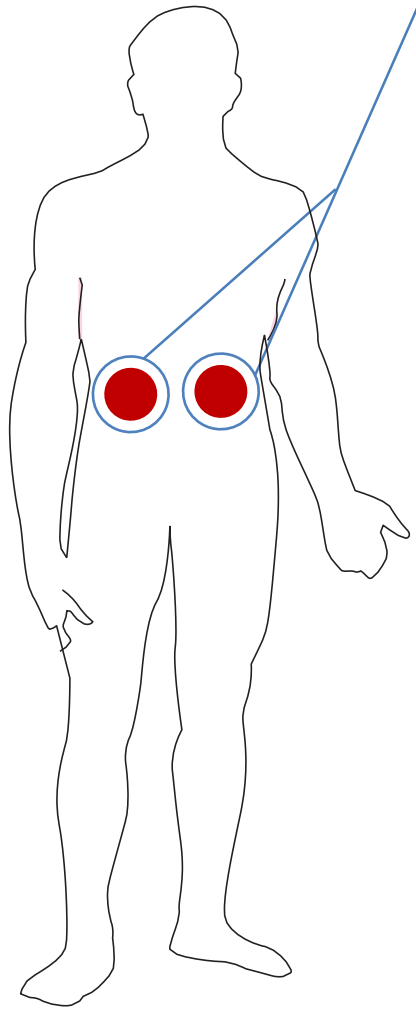
Maintain blood pressure < 140/90 (130/80 if ACR > 70)

- Calcium channel blocker drugs and I/ or thiazide diuretics are useful second line agents
- Loop diuretics are useful in the presence of volume overload (e.g. leg oedema not caused by the side effects of calcium channel blockers)
- Additional antihypertensive therapy may be required.

Treat dyslipidaemia (serum cholesterol, LDL cholesterol and serum triglycerides to targets)

Aspirin therapy if eGFR <60 and ACR>70

Ensure patient understands sick day guidance for relevant drugs eg ACE/ARBs/ Metformin/SGLT2Is



All patients with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see Cardiovascular Risk for additional requirements.

CHRONIC KIDNEY DISEASE – DIAGNOSIS

WHO SHOULD BE TESTED FOR CKD

Offer testing for CKD using eGFR, serum creatinine and urinary ACR to people with any of the following risk factors:

- diabetes
- hypertension
- acute kidney injury
- cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral vascular disease or cerebral vascular disease)
- structural renal tract disease, recurrent renal calculi or prostatic hypertrophy
- multisystem disease e.g. systemic lupus erythematosus
- family history of end-stage kidney disease (GFR category G5) or hereditary kidney disease
- Haematuria

INTERPRETING eGFR VALUES

- Interpret eGFR values of > 60 ml/min/1.73 m² with caution - estimates of GFR become less accurate as the true GFR increases
- eGFR is unreliable at extremes of body weight:
 - eGFR underestimates in people with high BMI
 - eGFR overestimated in people with low BMI
- **Confirm an eGFR result of less than 60 ml/min/1.73 m² in a person not previously tested by repeating the test within 2 weeks. Allow for biological and analytical variability of serum creatinine (±5%) when interpreting changes in eGFR**

CLASSIFICATION OF CKD USING eGFR AND ACR CATEGORIES

GFR and ACR categories and risk of adverse outcomes			ACR categories (mg/mmol) description and range			Increasing risk
			<3 Normal to mildly increased	3-30 Moderately increased	>30 Severely increased	
			A1	A2	A3	
GFR categories, description and range	≥ 90 Normal and high	G1	No CKD in the absence of markers of kidney damage*			Increasing risk
	60-89 Mild reduction related to normal range for a young adult	G2				
	45-59 Mild-moderate reduction	G3a				
	30-44 Moderate-severe reduction	G3b				
	15-29 Severe reduction	G4				
	≤15 Kidney failure	G5				

Increasing risk

HAEMATURIA

- Use dipstick reagent strips rather than urine microscopy
- Evaluate further if there is a result of 1+ or more (rpt in 2 weeks)
- Dipstick haematuria not diagnostically useful with concurrent menstrual period, infection or in catheter samples

PROTEINURIA

- Proteinuria is a useful marker of kidney damage and complication risk
- ACR is the recommended method for assessing proteinuria
- If initial ACR = 3-70 confirm with a subsequent early morning sample
- If initial ACR > 70 mg/mmol, a repeat sample need not be tested
- Confirmed ACR ≥ 3 signifies clinically important proteinuria.

CHRONIC KIDNEY DISEASE – REFERRAL CRITERIA

URGENT

- Suspected multisystem disease with evidence of renal involvement
- Suspected acute kidney injury
- Newly diagnosed eGFR < 15
- Nephrotic syndrome
- Accelerated hypertension
- Severe hyperkalaemia

NON-URGENT

- Stage 3 CKD where diagnosis uncertain
- Asymptomatic CKD G4 or G5 with or without Diabetes
- ACR > 70 mg/mmol, unless known to be caused by Diabetes and already appropriately treated
- ACR > 30 mg/mmol together with haematuria
- Sustained decrease in GFR of $\geq 25\%$, and a change in GFR category or sustained decrease in GFR of $\geq 15\text{ml/min}$ within 12 months
- Hypertension that remains poorly controlled despite the use of at least 4 antihypertensive drugs at therapeutic doses
- Known or suspected rare or genetic causes of CKD
- Suspected renal artery stenosis (serum creatinine rises by >30% or eGFR falls by >25% after starting ACEI/ARB)

INVESTIGATING THE CAUSE OF CKD

Determining the risk of adverse outcomes

Agree a plan to establish the cause of CKD during an informed discussion with the person with CKD, particularly if the cause may be treatable (for example, urinary tract obstruction, nephrotoxic drugs or glomerular disease).

Use the person's GFR and ACR categories to indicate their risk of adverse outcomes (for example, CKD progression, acute kidney injury, all cause mortality and cardiovascular events) and discuss this with them.

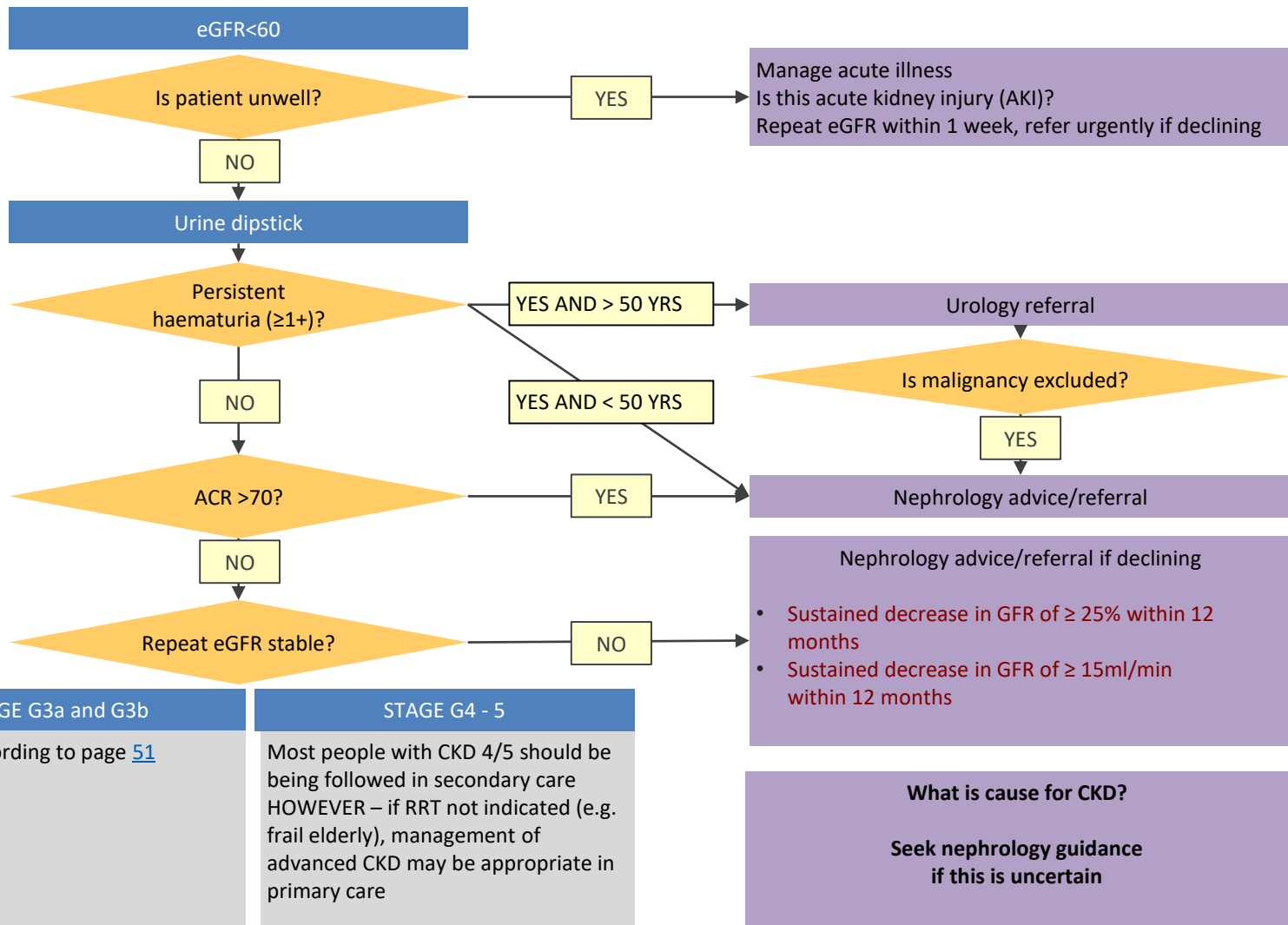
INDICATIONS FOR RENAL ULTRASOUND

- Offer a renal ultrasound scan to all people with CKD who:
- have accelerated progression of CKD
 - have visible or persistent invisible haematuria
 - have symptoms of urinary tract obstruction
 - have a family history of polycystic kidney disease and are aged over 20 years
 - have a GFR of less than 30 ml/min/1.73 m² (GFR category G4 or G5)
 - are considered by a nephrologist to require a renal biopsy.

Advise people with a family history of inherited kidney disease about the implications of an abnormal result before a renal ultrasound scan is arranged for them.

MINIMAL INFORMATION REQUIRED FOR REFERRAL OR ADVICE

- Dates and results of all previous creatinine/eGFR measurement
- Medical history
- Drug history
- Current BP
- Urine results: dipstick and a measure of urine proteinuria
- Renal Ultrasound result (unless exceptional reason delineated)
- HCO₃ Bicarbonate <20 mol/l, bicarbonate supplementation slows the rate of decline of renal function in stage 4 CKD, and is routinely used in the renal diabetic clinic
- **Refer if:**
- Sustained decrease in GFR of $\geq 25\%$, and a change in GFR category within 12 months
- Sustained decrease in GFR of $\geq 15\text{ml/min}$ within 12 months
- eGFR<20 Hb<10.5, K>6, Ca<2.1 Phosphate>1.5 (AD)



URGENT REFERRAL

- Suspected multisystem disease with evidence of renal involvement
- Acute kidney injury (without an obvious cause manageable in primary care)
- Newly diagnosed eGFR < 15
- Nephrotic syndrome
- Accelerated hypertension
- Severe hyperkalaemia (>6.5mmol/L)

Minimum information for referral

- Dates and results of previous creatinine/eGFR measurement
- Medical history
- Drug history
- Current BP
- Urine dipstick and ACR if dipstick positive

Renal Ultrasound if:

- accelerated progression of CKD
- visible or persistent invisible haematuria
- symptoms of urinary tract obstruction
- family history of polycystic kidney disease and are aged over 20 years
- eGFR of <30 ml/min/1.73 m2 (GFR category G4 or G5)

STAGE G3a and G3b	STAGE G4 - 5
Monitor according to page 51	Most people with CKD 4/5 should be being followed in secondary care HOWEVER – if RRT not indicated (e.g. frail elderly), management of advanced CKD may be appropriate in primary care

Email advice from nephrology consultants is available to North West London primary care services:

- ICHC-tr.ckd advice@nhs.net

CHRONIC KIDNEY DISEASE – ONGOING MANAGEMENT

MANAGEMENT OF STABLE CKD

Agree management plan with patient

- Lifestyle advice
- Smoking cessation advice
- Avoid NSAIDs (even topical)
- Vaccinate for influenza and pneumococcus

- BP:
- Encourage home BP monitoring
 - Target BP: < 140/90 if ACR ≤ 70
< 130/80 if ACR > 70
 - Caution of BP targets in frailty (See page 7)
 - Prioritise ACEi/ARB with associated sick day guidance

- Cardiovascular risk:
- Aspirin – if CV risk at 10yrs >20%
 - **Proton-pump inhibitors (PPIs)** – esp. if higher risk of gastric irritation with aspirin. Observational data suggest PPIs may cause insidious inflammatory kidney injury – switch to ranitidine if eGFR falling
 - Statins – all patients with CKD3b and beyond should be on unless contra-indicated

- Serum bicarbonate
- Consider sodium bicarbonate 500mg twice daily if acidotic (serum bicarbonate <22 mmol/L)

RENAL ANAEMIA

Renal anaemia can start to develop from CKD stage 3b (eGFR<45) and is common in advanced CKD5 (eGFR<15). This may require treatment with intravenous iron and erythropoietin.

Particularly in CKD stages 3b/4, renal anaemia should only be diagnosed after exclusion of other causes including iron deficiency, folate/B12 deficiency, haemolysis.

FREQUENCY OF MONITORING eGFR (NUMBER OF TIMES PER YEAR)

GFR and ACR categories and risk of adverse outcomes		ACR categories (mg/mmol) description and range			
		<3 Normal to mildly increased	3-30 Moderately increased	>30 Severely increased	
		A1	A2	A3	
GFR categories, description and range	≥ 90 Normal and high	G1	≤1	1	≥1
	60-89 Mild reduction related to normal range for a young adult	G2	≤1	1	≥1
	45-59 Mild-moderate reduction	G3a	1	1	2
	30-44 Moderate-severe reduction	G3b	≤2	2	≥2
	15-29 Severe reduction	G4	2	2	3
	≤15 Kidney failure	G5	4	≥4	≥4

Increasing risk

Increasing risk

RENIN-ANGIOTENSIN SYSTEM INHIBITORS IN CKD (ACEI and ARB)

- ACEi and ARB prevent scarring in CKD and should be used preferentially in patients with proteinuria
- Assess kidney function and electrolytes. 1-2 weeks after initiating therapy and with any subsequent dose increase, watch out for hyperkalemia
- A small rise in creatinine or a mild fall in eGFR values is expected with therapy – repeat the assessment of kidney function if the rise in creatinine is greater than 15%
- STOP therapy - If serum creatinine rises by >30% or eGFR falls by >25%: seek specialist advice (to exclude possible renovascular disease)
- If K>6.0 stop ACEi/ARB and start low potassium diet – if the patient has proteinuria or heart failure with reduced ejection fraction and would benefit from an ACEi/ARB seek Nephrological advice as introduction of potassium binders, frusemide or bicarbonate can facilitate reintroduction of these agents
- Concomitant use of ACEi/ARB with spironolactone and other potassium sparing diuretics requires close monitoring of potassium

Management of CKD in the context of frailty requires a holistic approach

Kidney Ageing

- Kidney function (GFR) declines with age:
- ~0.8 mL/min/year after 35 years old
 - up to 2mL/min/year after 70 years old
 - eGFR >30mL/min in the absence of acute illness, proteinuria or uncontrolled HTN is unlikely to progress to end-stage kidney disease

Focus of Care in Frail people

- Should be patient and outcome centred
- View CKD in the context of an individual's comorbidities and personal priorities
- Renal replacement therapy (RRT) may not improve quality of life – focus on symptom control may be more appropriate
- Advance care planning should be a priority

MANAGEMENT OF FRAIL PEOPLE WITH CKD

Identify frailty and screen for cognitive impairment

- Calculate EFI score (<https://doi.org/10.1093/ageing/afw039>)
- Screen cognition using GPCOG (<http://gpcog.com.au/>)

Medications

- Frail people are more susceptible to harm from medications
- Refer to “Drugs and CKD” page [65](#)

Blood pressure (BP) or HbA1c targets - individualise to patient:

- Be wary of falls risk – check postural BPs
- Higher BP targets are appropriate e.g.. systolic BP 130-159 mmHg / diastolic BP 70-89 mmHg

- Be wary of hypoglycaemia risk with insulin and oral hypoglycaemic agents
- Higher HbA1c targets are appropriate e.g.. 58-68 mmol/mol

Diet – avoid protein restriction / aggressive salt restriction

Monitoring of renal function

- If renal replacement therapy (RRT) is considered - refer to page [68](#)
- If RRT is unlikely to improve quality of life, tailor frequency to clinical need

In event of sudden eGFR decline exclude common causes:

- UTIs
- Dehydration
- Obstructive uropathy
- Medications (e.g.. Diuretics, anti-hypertensives, NSAIDs)

Consider nephrology advice if:

- Unexplained and sustained decline in renal function / new nephrotic range proteinuria
- Refractory and symptomatic anaemia (<100g/L) in advanced CKD (stages 3b – 5) may require intravenous iron +/- erythropoietin supplementation

Further advice

Specialty advice is available to North West London primary care services:

- ICHC-tr.ckdadvice@nhs.net (nephrology consultant advice)
- ICHC-tr.adviceelderlymedicine-imperial@nhs.net (consultant geriatrician advice)

