Diagnosing diabetes – which test should be used?

Diagnosis of diabetes – WHO criteria summary table[1,2]

Confirmation of the diagnosis requires a **LABORATORY** plasma glucose measurement/HbA1c. **Fingerprick** samples should not be used to diagnose diabetes.[1,3]

Test	Diabetes	High Risk 'Impaired' or 'Pre Diabetes'	Normal
HbA1C	≥ 48 mmol/mol (6.5%)	42-47 mmol/mol (6.0-6.4%)	≤ 41 mmol/mol (5.9%)
Fasting Plasma Glucose	≥ 7.0 mmol/L	6.1- 6.9 mmol/L **Impaired Fasting Glycaemia (IFG)**	≤ 6.0 mmol/L
Random Plasma Glucose	≥ 11.1 mmol/L		
OGTT	≥ 11.1 mmol/L	7.8-11.0 mmol/L **IGT- Impaired Glucose Tolerance**	≤ 7.7 mmol/L

A repeat confirmatory test is necessary in all **asymptomatic patients**[3] If the second test results are normal, regular review of the patient should be arranged. In a **symptomatic patient**, diabetes can be diagnosed with more confidence on the basis of a single abnormal test result (although a second test may be prudent).

The WHO and Diabetes UK recommend **HbA1c** as a valid option for diagnosing diabetes.[1,3] The Barnsley Local Diabetes Advisory Group suggest that **HbA1c** should be the preferred option for diagnosing diabetes – except in certain groups listed in this document *.

HbA1c testing to diagnose diabetes

- An HbA1c of 48mmol/mol (6.5%) is recommended as the cut off point for diagnosing diabetes. A value of less than 48mmol/mol (6.5%) does not exclude diabetes diagnosed using venous glucose tests.[3] The use of blood glucose tests is not recommended routinely in patients whose HbA1c is under 48mmol/mol (6.5%).[3] However if the patient has symptoms of diabetes or is at very high risk of diabetes, glucose testing should be used.[3]

- The HbA1c should be repeated in **asymptomatic patients** within 2 weeks (to guard against mislabelling or lab error).[1,4] Both results should be ≥48 mmol/mol or 6.5% to diagnose diabetes. If the results are discordant, the lower value should be used.[1] If the second sample is <48mmol/mol (6.5%) the person should be treated as at high risk of diabetes and the test should be repeated in 6 months or sooner if symptoms develop.[3]

Advantages of HbA1c:[1]

- No need for patient to fast
- More reproducible than fasting glucose, random glucose or an OGTT
- Reflects recent prevailing blood sugars (i.e. No-one with raised blood glucose will be 'missed' and people at high risk of diabetes should receive life-style advice whatever their HbA1c)
- Continuity – once diagnosis made, focus switches from glucose to HbA1c

List of patients/conditions when HbA1C may be unreliable [1]

*HbA1C may be inappropriate for patients listed below (one should use fasting glucose or random glucose as appropriate instead):

- **Rapid onset** of diabetes (HbA1c may take some weeks to rise)
- Suspected **type 1 diabetes** – rapid onset of symptoms, weight loss, ketosis
- **Children** – because most will have type 1 diabetes
- Concomitant **medication**s such as corticosteroids. Antipsychotics and immunosuppressants can also raise blood glucose, but rarely very significantly
- After **pancreatitis** or **pancreatic surgery**
- **Pregnancy** - Multiple factors lower the HbA1c in pregnancy. The diagnosis of gestational diabetes should be made by measurement of the fasting glucose or an OGTT in line with NICE guidance.[3] (See section on gestational diabetes below).
- Conditions in which **red cell survival is decreased** such as:
    - Haemoglobinopathy will normally be picked up by the lab, but suspect in racial groups where there is a high prevalence of sickle cell trait/disease or thalassaemia.
    - Haemolytic anaemia
    - Severe blood loss
    - Splenomegaly/hypersplenism
    - Antiretroviral drugs
- **Renal dialysis** may cause marked reduction in HbA1c, especially if the patient is being treated with erythropoietin
- **End- stage chronic kidney disease**
- **HIV Infection**
- **Increased red cell survival** (e.g. Post-splenectomy) may increase HbA1c
- **Iron and vitamin B12 deficiency** and their treatment may raise or lower HbA1c, but the effect is small

What if someone lowers their HbA1c below 48 mmol/mol through lifestyle change?

If a patient is diagnosed with diabetes and then drops their HbA1c below 48 mmol/mol without drugs, they should probably be managed as someone with excellently controlled diabetes on diet alone and continue to receive care appropriate for someone with this type of diabetes.

Blood Glucose tests to diagnose diabetes[3]

This can be fasting glucose (preferably), random glucose or an oral glucose tolerance test (OGTT). [1]

Symptomatic patients:

- a random venous plasma glucose concentration ≥ 11.1 mmol/l or
- a fasting plasma glucose concentration ≥ 7.0 mmol/l (whole blood ≥ 6.1 mmol/l) or
- two hour plasma glucose concentration ≥ 11.1 mmol/l two hours after 75g anhydrous glucose in an oral glucose tolerance test (OGTT).

Asymptomatic patients:

- In asymptomatic patients at least one additional glucose test result on another day with a value in the diabetic range is essential, either fasting, from a random sample or an OGTT. If the fasting random values are not diagnostic the OGTT should be used.

Impaired Glucose Tolerance (IGT)

In patients with impaired glucose tolerance, blood glucose is raised beyond normal levels, but not high enough to warrant a diabetes diagnosis.

Impaired glucose tolerance is a state of abnormal glucose homeostasis and raises the absolute risk of developing type 2 diabetes. It is characterised by insulin resistance in the muscle and to a lesser extent in the liver.

Patients with IGT should be followed up annually to reassess glucose regulation and all other cardiovascular risk factors. They are to be actively managed with life style advice.

Impaired Fasting Glycaemia (IFG)

Impaired fasting glycaemia (pre-diabetes) occurs when blood glucose levels in the body are elevated during periods of fasting, but not enough to prompt a diagnosis of diabetes.

Impaired fasting glycaemia is a state of abnormal glucose homeostasis and raises the absolute risk of developing type 2 diabetes. It is characterised by insulin resistance in the liver and normal insulin sensitivity in the muscles.

Patients with IFG should be followed up annually to reassess glucose regulation and all other cardiovascular risk factors. They are to be actively managed with life style advice.

Impaired Fasting Glycaemia (IFG) and Impaired Glucose Tolerance (IGT)

- IGT and IFG are not clinical entities but should be considered as continuum risk categories for cardiovascular disease and/or future diabetes. Assess the patient's cardiovascular disease risk.

- Patients with IGT/IFG should be recorded and receive:
  - Follow-up and regular testing (reviewed at least annually).
  - Education and advice on risk of diabetes/diet/lifestyle modification etc. (e.g. weight loss of 5kg and 30 minutes of moderate exercise 5 times weekly reduces progression to type 2 diabetes by almost 60%)
  - Patients with HbA1c of 42-48 mmol/mol are at risk of premature cardiovascular disease and should receive demonstrably effective prevention strategies.

Gestational diabetes

Testing and Diagnosis [3,5]

The criteria for diagnosing gestational diabetes is different. Gestational diabetes should be diagnosed in line with NICE guidance if the woman has either:

- a fasting plasma glucose level of 5.6mmol/l or above or
- a 2-hour plasma glucose level (OGTT) of 7.8mmol/l or above.

High risk groups in pregnancy will have an OGTT done at 24 -28 weeks. However patients with previous history of gestational diabetes will have the OGTT done as soon as possible after booking and at 24-28 weeks unless they opt for self-monitoring of blood glucose when they access the antenatal clinic at 12 weeks.

Oral Glucose Tolerance Test (OGTT) [2,6,7]

In the past an OGTT was performed using Lucozade®, however, due to changes in the glucose content in Lucozade®, BHNFT now use Rapilose® OGTT solution 75mg/300ml as a replacement.

Please note: *Patients who have had bariatric surgery cannot tolerate the volume of Rapilose® in OGTT, therefore in these patients HbA1c testing or fasting glucose levels should be used instead as appropriate.*

Adults:

- Before the test the patient should fast for a minimum of 9 hours.
- Before the test, a fasting blood sample is taken.
- 75g of glucose is then administered to the patient as Rapilose® OGTT solution 300ml (Green traffic light status on the Barnsley Joint Formulary). The solution should be consumed over a period of 5-10 minutes.
- A further blood sample should be taken after 2 hours.

What should the OGTT results be?

People without diabetes
Fasting value (before test): under 6.0 mmol/L
At 2 hours: under 7.8 mmol/L

People with impaired glucose tolerance (IGT)
Fasting value (before test): 6.0 to 7.0 mmol/L
At 2 hours: 7.9 to 11.0 mmol/L

Diabetic levels
Fasting value (before test): over 7.0 mmol/L
At 2 hours: over 11.0 mmol/L

Gestational Diabetes postnatal follow up in primary care [5]

See Appendix A

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Development Process

This guidance has been subject to consultation and endorsement by specialists in diabetes and endocrinology in Barnsley and was ratified by the Area Prescribing Committee on 11th March 2020 (Minor amendment ratified by the APC on 14th April 2021).

Appendix A

Primary care follow up of women with Gestational Diabetes Mellitus in postnatal period

Women who have had gestational diabetes have a 1 in 3 chance of developing type 2 diabetes in the following 5 years

- Offer **fasting plasma glucose** at 6 weeks postnatal check (ideally this should be done before 13 weeks)
- Or after 13 weeks - offer **HbA1c** or **fasting plasma glucose**
- (do not routinely carry out OGTT)

Interpretation of fasting plasma glucose / HbA1c results

Fasting Plasma Glucose <6.0 mmol/L
or
HbA1c<39 mmol/mol (<5.7%)

- Low risk of having type 2 diabetes at present
- Moderate risk of developing type 2 diabetes in the future

Fasting Plasma Glucose 6.0-6.9 mmol/L
or
HbA1c 39-47 mmol/mol (5.7 – 6.4%)

- High risk of developing type 2 diabetes
- Advice in line with preventing type 2 diabetes (consider referral to the NHS Diabetes Prevention Programme: https://www.england.nhs.uk/diabetes/diabetes-prevention/)

Fasting Plasma Glucose ≥7.0 mmol/L
or
HbA1c ≥48 mmol/mol (≥6.5%)

- Likely to have type 2 diabetes
- Need diagnostic test to confirm type 2 diabetes - see guidelines earlier regarding diagnostic tests and further management

Annual HbA1c

Discuss symptoms of hyperglycaemia

Lifestyle advice (weight control /diet / exercise)

Counsel on contraceptive advice and future pregnancies

- Advice that healthy BMI before next pregnancy will reduce risk of developing Gestational Diabetes again
- Patient to start taking high dose Folic acid (5mg) daily before stopping contraception and will need a prescription for this. [8]
- Patient to contact health professional as soon as they find out they are pregnant for antenatal care