

Introduction

In most cases Diabetes mellitus can be diagnosed using either fasting glucose or HbA1c. Diagnosis of diabetes must be based on **either glucose or HbA1c but not a combination of the two**. Diagnostic algorithms for glucose based diagnosis of diabetes mellitus and glucose intolerance (WHO 2006) and for HbA1c based diagnosis of diabetes mellitus (WHO 2011) are shown below. Note the cut-offs used locally are different to the WHO criteria applied to the non-pregnant population and are included, along with guidance on reporting by the duty biochemist in Appendix C.

Principle

Following the oral administration of a standard dose of glucose, the plasma glucose concentration normally rises but returns towards the fasting level within 2 hours. If insulin activity is reduced the plasma glucose concentration takes longer than 2 hours to return to normal.

Preparation

1. The patient should be on a normal carbohydrate diet (at least 150g per day) for at least 3 days before the test.
2. It is desirable to postpone the test if the patient is febrile, is within 6 weeks of a myocardial infarction or major surgery or is on short-term treatment with drugs which impair glucose tolerance, such as glucocorticoids, thiazide diuretics, beta blockers, loop diuretics, progesterone and oestrogen.
3. The patient should fast from 10 p.m. on the evening before the test with the exception of drinks of water and any drugs which he/she normally takes.
4. During the test the patient should be resting and should not smoke, eat or drink, except for glasses of water.

Procedure

1. At about 9 am take 2mls venous blood into a fluoride oxalate (grey top) bottle. Note the time of the specimen on the bottle and the request form/electronic request.
2. Give the patient 75 g of glucose. This can be given in 3 different ways (see boxes below)
3. The patient needs to rest and not smoke for 2 hours until the post glucose samples are taken.
4. Take one further 2mls venous blood sample into a fluoride oxalate bottle 120 minutes after the glucose was given. Note the time of the specimen on the bottle and the request form/electronic request.
5. The test is now complete and the patient may eat. If the patient vomits during the test, stop the test.
6. Send both blood specimens with the request form (if applicable).

Preparations of 75g glucose

Polycal liquid (Nutricia Clinical).

This is available on prescription. Prepared as: 113ml Polycal liquid made up to a volume of 200ml in a beaker with water, shaken thoroughly and consumed over a 5 minute period followed by a further 100ml plain water

Rapilose.

Adults (including the elderly): 300ml to be consumed over a period of 5-10 minutes. Children: for children weighing less than 43kg the dosage should be reduced based on child's body mass; the dose is 7ml of solution per kg of body weight up to a maximum 300ml

Anhydrous Glucose.

75g dissolved in 300ml water

Automatic comment on all GTT results:

Diabetes: Fasting glucose \geq 7.0 mmol/L or 2hr glucose \geq 11.1 mmol/L (\geq 7.8 mmol/L in pregnancy)

Impaired glucose tolerance: 2 hr glucose 7.8-11.0 mmol/L

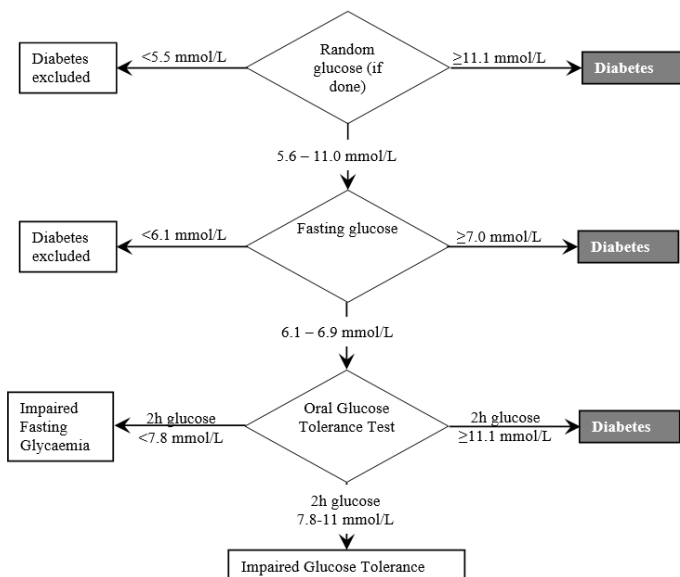
Impaired fasting glucose: 6.1-6.9 mmol/L (\geq 5.6 mmol/L in pregnancy)

In pregnancy, all abnormal results, including impaired fasting glucose, should be referred to the antenatal clinic within 72hrs (telephone No. 0117 4146929)

Please see local maternity guidelines for referral pathways.

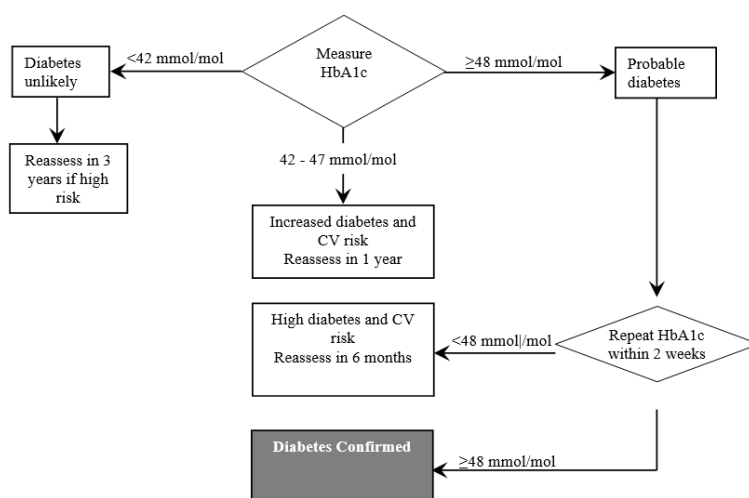
Interpretation (non-pregnancy)

Diagnostic algorithm for glucose based diagnosis of diabetes mellitus and glucose intolerance (WHO 2006)



- The above criteria apply to venous plasma. If venous whole blood or capillary blood is used, different criteria apply. Please contact laboratory.
- Fasting glucose is recommended as the initial diagnostic test where feasible.
- In the absence of classical symptoms, (thirst, polyuria and unexplained weight loss) at least two diagnostic glucose results on different days are essential.
- If discordant results are obtained, either fasting (if reliable) or 2h OGTT value may be diagnostic, but re-testing after an interval is recommended.
- Tests should not be carried out during intercurrent illness or periods of stress as this may result in false positive results.
- Impaired Glucose Tolerance and Impaired Fasting Glycaemia carry increased risk of progression to diabetes – recommended re-assess in one year.

Diagnostic algorithm for HbA1c based diagnosis of diabetes mellitus (WHO 2011)



HbA1c must **not** be used in the presence of factors affecting HbA1c formation or measurement. These include:

- Iron and vitamin B₁₂ deficiency
- Haemolytic anaemias
- Administration of iron, vitamin B₁₂ or erythropoietin
- Chronic liver disease
- Chronic renal failure (CKD 4 and 5)
- Alcoholism
- Rheumatoid arthritis
- Splenomagaly or splenectomy
- Haemoglobinopathies
- Drugs that may affect erythrocyte lifespan e.g. antiretrovirals, ribavarin, dapsone

HbA1c must **not** be used to diagnose diabetes in pregnancy

HbA1c must **not** be used if hyperglycaemia has developed rapidly, for example:

- Possible Type 1 diabetes
- Symptomatic children and young adults
- Symptoms less than three months
- Acutely ill patients
- Medication that may cause rapid rise in glucose e.g. corticosteroids, antipsychotics
- Acute pancreatic damage or pancreatic surgery

Interpretation (pregnancy)

Gestational diabetes is identified through screening based on risk factors and a GTT undertaken. Women unable to complete a GTT should be referred for blood glucose monitoring.

Note a GGT should not be undertaken after 34 weeks gestation as they cannot be interpreted.

Do not use fasting plasma glucose, random blood glucose or urinalysis as screening tools for gestational diabetes.

Women should be counselled about the risks of gestational diabetes and the implications of treatment prior to screening. Screening should be offered to the following groups:

Screening

Previous gestational diabetes:

- oral glucose tolerance test at booking or as soon as possible after booking (repeated at 26 - 28 weeks if normal)

Women with one or more risk factors listed below:

- Oral glucose tolerance test at 26-28 weeks gestation
- BMI > 30
- Previous macrosomic baby (>4.0kg) or polyhydramnios
- Previous gestational diabetes
- First degree relative with diabetes
- Origin from an area with high prevalence of diabetes (South Asia, black Caribbean, Middle Eastern)

Women with glycosuria at booking:

This is unusual so an oral glucose tolerance test should be carried out to rule out pre-existing diabetes

Women with glycosuria:

- Prior to 28 weeks – glucose tolerance test
- if 1+ glucose on 2 occasions or 2+ on 1 occasion CONSIDER referral for GTT or BG monitoring but not necessary as this is what the NICE guideline describes

Diagnosis

An oral glucose tolerance test with the following cut off values should be used for the diagnosis of gestational diabetes.

Fasting glucose ≥ 5.6 OR 2 hour glucose ≥ 7.8 mmol/l

(Note only one value needs to be abnormal to make the diagnosis)

(If the PRE GTT is higher by 1 mmol than the post result ANC would like a referral.)

Results:

Results should be checked by the community midwife within 3 working days and if abnormal (as per above) the results should be phoned to the antenatal clinic (**0117 41 46929**).

(**NB** Fasting glucose ≥ 7.0 OR 2 hour glucose ≥ 11.1 mmol/l should have already been phoned directly to ANC by the laboratory)

References

- Definition and diagnosis of Diabetes Mellitus and intermediate hyperglycaemia. Geneva WHO 2006
Use of Glycated Haemoglobin (HbA1c) in the diagnosis of Diabetes Mellitus WHO 2011