DIAGNOSING DIABETES MELLITUS IN NON-PREGNANT ADULTS

Version:	5.0
Ratified by:	Laboratory Medicine Policy Board
Date ratified:	10th December 2012
Name of originator/author:	Dr Edmund Lamb
Director responsible for implementation:	Mrs Ruth Lapworth
Date issued:	December 2019
Review date:	3 years after date issued
Target audience:	Clinical staff (medical, nursing and scientific), Trust wide and primary care

Version Control Schedule

Version	Date	Author	Status	Comment
1.0	Reviewed Dec 2004, October 2009	Dr Edmund Lamb	Archived	
2.0	18 May 2012	Dr Edmund Lamb	Archived	
3.0	10 December 2012	Dr Edmund Lamb	Archived	Amended to include diagnosis using HbA1c as an alternative to glucose-based criteria in line with national guidance.
4.0	10 December 2015	Dr Edmund Lamb	Archived	Clarified that this policy does not cover pregnancy as per NICE guidelines Diabetes in Pregnancy: Management from preconception to the post natal period (NG3 Published Feb 2015)
5.0	October 2019	Dr Sally Stock		Reviewed following change in reporting to HbA1c and fasting glucose. As requested by the South East Strategic Clinical Network (SESCN) for NHS Diabetes Prevention Programme (NHS DPP), and in order to support primary care with the identification of those patients at risk of Type 2 diabetes.

Contents

1 Policy Summary

This policy gives guidance on how plasma glucose concentration and HbA_{1c} should be used to diagnose diabetes mellitus in non-pregnant adults.

2 Introduction

Diabetes mellitus can be diagnosed using criteria based either on:
(1) blood concentrations of glycated haemoglobin (HbA_{1c}) or
(2) plasma glucose concentrations.

HbA_{1c} is endorsed for the diagnosis of type 2 diabetes only in non-urgent situations in adults over 18 years old. The two criteria should not be interchanged in individual patients i.e. in each patient the diagnosis must be established using one or other of the criteria, not a mixture.

A. DIAGNOSIS BASED ON HbA_{1c} CRITERIA

In 2011 the World Health Organisation recommended that HbA1c can be used as a diagnostic test for diabetes mellitus provided certain stringent quality assurance conditions are satisfied.[1] These conditions are satisfied by HbA_{1c} analyses undertaken within Clinical Biochemistry in East Kent Hospitals University NHS Foundation Trust: they are not necessarily satisfied by other HbA_{1c} analyses (e.g. point of care testing devices). This advice has been endorsed for use in the UK.[2]

As requested by the South East Strategic Clinical Network (SESCN) for NHS Diabetes Prevention Programme (NHS DPP), and in order to support primary care with the identification of those patients at risk of Type 2 diabetes, we provide the following comments on HbA1c reports, when HbA1c is requested for diagnostic (as opposed to monitoring) purposes:

HbA1c Diagnostic (diagnosis/screening):

Since most confounding factors tend to lower HbA1c, and those that raise it do so by a relatively small amount, a high HbA1c is a good indicator of diabetes (i.e. it has high specificity). The higher the HbA1c the more likely diabetes is present.

< 42 mmol/mol - normal

42 - 47 mmol/mol - non-diabetic hyperglycaemia (NDH). There is a high risk of progression to type 2 diabetes. Consider referral to National Diabetes Prevention Programme

≥ 48 mmol/mol - indicative of diabetes. If patient is symptomatic, diagnosis is confirmed. If asymptomatic, repeat testing within 4 weeks is required for confirmation.

HbA1c below 48 mmol/mol does not exclude diabetes, even if all of the conditions below are followed, due to the possibility of undiagnosed confounders.
Where there is any doubt about the reliability of HbA1c it should not be used and glucose testing following existing WHO criteria should be performed instead (please see BIO NO 048 oral glucose tolerance test (OGTT) protocol for adults).

When to use HbA_{1c} for diagnosis

Risk factors – any 2 present

- Overweight
- Family history
- Over age 30 if Maori/Asian (Indian subcontinent) /Pacific Island descent
- Over age 40 if European
- Diabetes in pregnancy
- Had a big baby (more than 4 kg)
- Inactive lifestyle, lack of exercise
- Previous high blood glucose/impaired glucose tolerance

Associated risk factors – supports risk factors

- Circulation/heart problems
- Smoker
- High blood pressure
- Diet high in saturated fat

Presence of possible symptoms for over 2 months – supports risk factors

- Tiredness
- Thirst
- Passing lots of urine
- Infections/boils/rashes
- Weight loss
- Blurred vision
- Slow healing
- Sensation change

When NOT to use HbA_{1c} for diagnosis

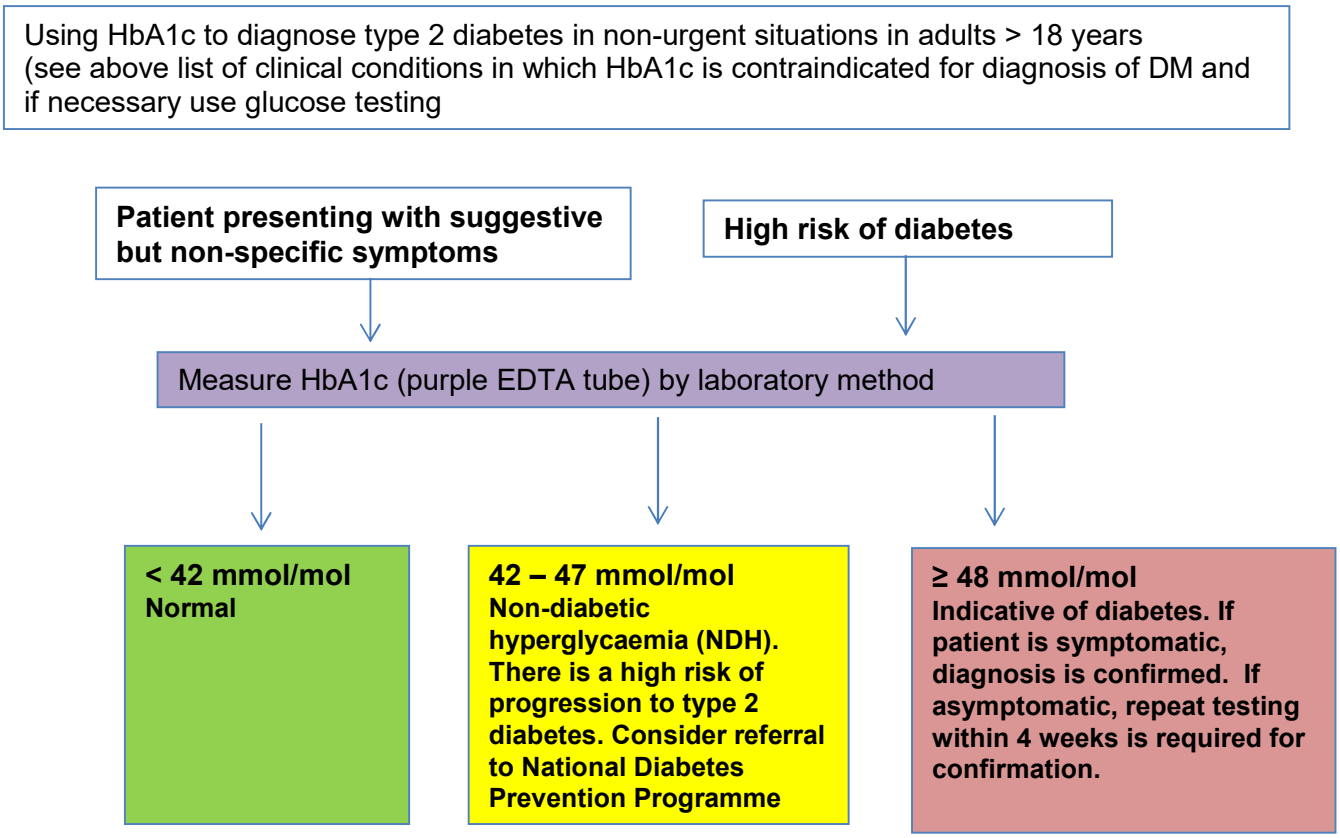
A diagnosis of diabetes using glucose measurement must be considered in patients with:

- All symptomatic children and young people
- Pregnancy - current or recent (< 2 months)
- Suspected Type 1 diabetes no matter what age
- Short duration of diabetes symptoms
- Patients at high risk of diabetes who are acutely ill (HbA1c >48 mmol/mol confirms pre-existing diabetes, but a value <48 does not exclude it and such patients must be retested once the acute episode has resolved)
- Patients taking medication that may cause rapid glucose rise e.g. corticosteroids, antipsychotics (if recently started with rapid glucose rise)
- Acute pancreatic damage or pancreatic surgery
- Haemoglobinopathies (HbS, HbC etc)
- Anaemia (Hb <105 g/L), haemolytic and iron deficiency anaemias and situations of increased red cell turnover
- Kidney failure
- HIV infection
- Recent blood transfusion

*Please note this list is not exhaustive – in cases of doubt discuss with the duty biochemist on 01233 616287 or extn. 723-6287 or contact the specialist diabetes care team.

Clinical judgement is needed for each patient to consider the possibility of conditions that might cause inappropriate exclusion or inclusion in the diabetes diagnosed category.

Diagnosis of Diabetes Mellitus using HbA1c – flow diagram



B. DIAGNOSIS BASED ON GLUCOSE CRITERIA

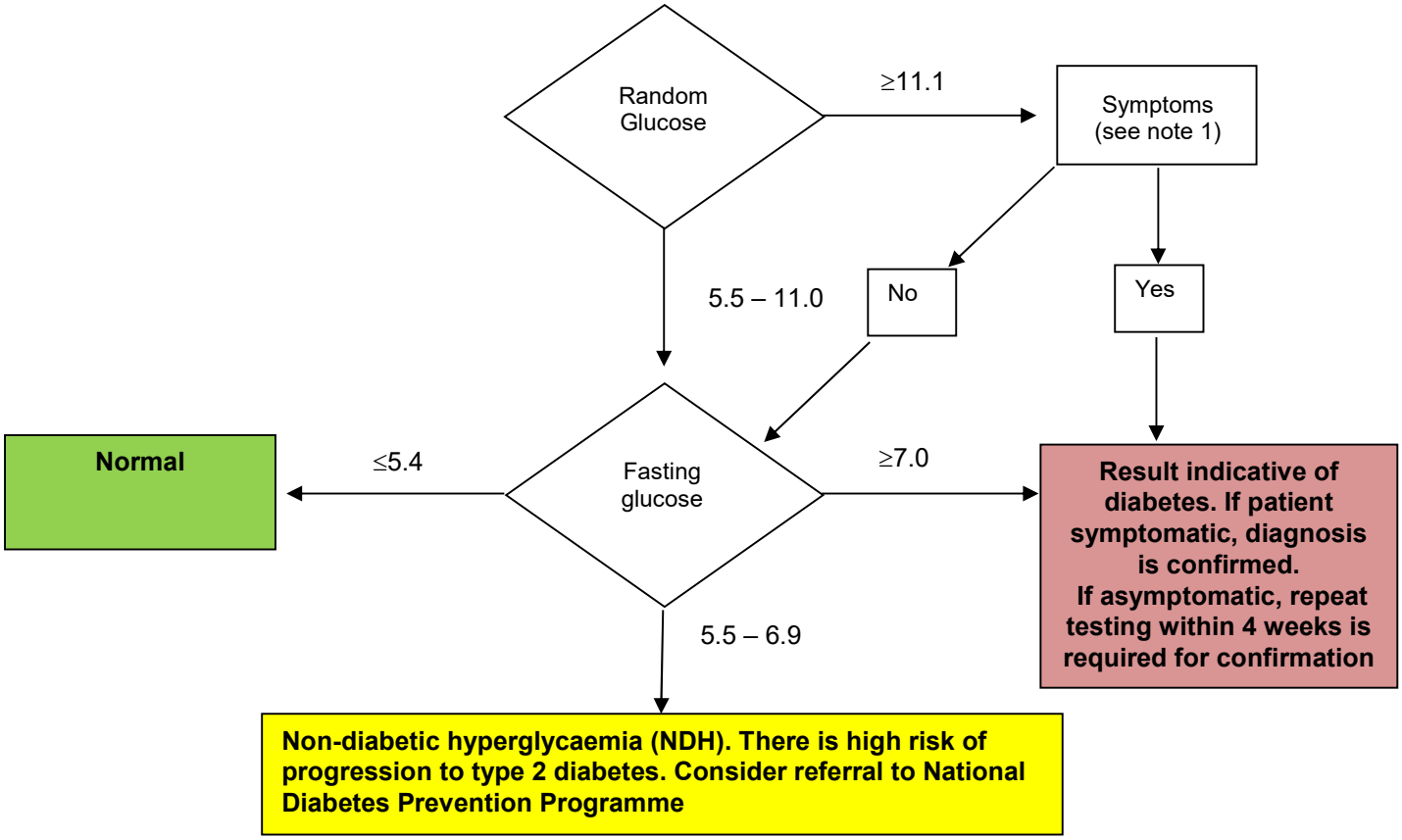
As requested by the South East Strategic Clinical Network (SESCN) for NHS Diabetes Prevention Programme (NHS DPP), and in order to support primary care with the identification of those patients at risk of Type 2 diabetes, we provide the following comments on fasting glucose reports:

3.0 – 5.4 mmol/L – assuming this is a fasting sample, normal fasting glucose

5.5 – 6.9 mmol/L - assuming this is a fasting sample, result indicates non-diabetic hyperglycaemia (NDH). There is high risk of progression to type 2 diabetes. Consider referral to National Diabetes Prevention Programme

≥7.0 mmol/L – assuming this is a fasting sample, result indicative of diabetes. If patient symptomatic, diagnosis is confirmed. If asymptomatic, repeat testing within 4 weeks is required for confirmation.

Diagnosis of Diabetes Mellitus using glucose – flow diagram



Notes: 1. Classical symptoms are thirst, polyuria or unexplained weight loss.
2. If patient is asymptomatic, and raised fasting glucose is the first documented abnormality, a further diagnostic glucose result on a different day is essential.

All glucose concentrations refer to venous plasma (mmol/L).

3 Purpose and Scope

This policy gives guidance on when and how to use biochemical tests to diagnose diabetes mellitus in non-pregnant adults.

4 Definitions

HbA_{1c}: haemoglobin that has been glycated at the N-terminal valine of the beta-chain.
Diabetes mellitus: a metabolic disorder of multiple aetiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects insulin secretion, insulin action, or both.

5 Duties

All staff involved in the diagnosis of diabetes mellitus, whether clinical or laboratory, must adhere to this policy.

6 Policy specific information

Not applicable.

7 Key Stakeholders, Consultation, Approval and Ratification Process

East Kent Hospitals University NHS Foundation Trust is the key stakeholder for this policy.

Consultation has been through e-mail and face-to-face communication between clinical biochemistry staff and Trust consultant diabetologists (Drs Chakraborti, Flynn, Joseph, McGettigan, Vella and Williams) during February to May 2012. Copies of correspondence are held by Dr Lamb.

Previous versions were discussed at the Eastern and Coastal Kent PCT long Term Conditions Board meeting on 25th October 2012 and at the Ashford CCG protected learning time in November 2012.

Changes to HbA1c and fasting plasma glucose reporting was implemented on Monday 4 February 2019, in line with recommendations from the South East Strategic Clinical Network (SESCN) for NHS Diabetes Prevention Programme (NHS DPP), and in order to support primary care with the identification of those patients at risk of Type 2 diabetes. Consultation with EKHUFT Endocrinologists (lead Dr Joseph) was undertaken. Changes were also communicated to all CCGs. Evidence of communication can be found on the shared drive and on QP (BIO CF 2020).

8 Review and Revision Arrangements

Three years from implementation date, by author.

9 Dissemination and Implementation

TrustNet, by proactive implementation through the Care Groups by appropriate clinical leads and by proactive dissemination to primary care partners.

10 Document Control including Archiving Arrangements

Archive of this document will be through Q-Pulse with a copy hosted within the clinical biochemistry pages of TrustNet http://www.ekhuft.nhs.uk/pathology/.

11 Monitoring Compliance

Within the Trust, compliance with this policy must rest with the requesting Care Groups. All breaches require reporting through Datix and non-compliance and root cause analysis reviewed through the CSS Care Group governance routes. The policy is set by the Trust and monitoring shall be through the Trust's higher governance framework.

12 References

1. World Health Organization. Use of glycated haemoglobin (HbA1c) in the diagnosis of diabetes mellitus, 2011. Available at: http://apps.who.int/iris/handle/10665/70523, accessed 1st December 2015

2. John WG. Use of haemoglobin A_{1c} (HbA_{1c}) in the diagnosis of diabetes mellitus in the UK: implementation of World Health Organisation guidance, 2011. Diabetic Medicine 2012;29:1350-7

3. World Health Organization. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus. WHO/NCD/NCS/99.2 ed. Geneva, 1999.

4. https://www.england.nhs.uk/diabetes/diabetes-prevention/

13 Associated Documentation

Not applicable

Appendix C - Equality Impact Assessment

Equality and Human Rights Impact Analysis (EHRIA)

Part One – Screening Tool

Name of the policy, strategy, function or methodology:	Diagnosing diabetes mellitus

Details of person completing the EHRIA	
Name	Dr Edmund Lamb
Job Title	Consultant Clinical Scientist
Directorate/Department	Laboratory Medicine
Telephone Number	X74736

1. Identify the policy, strategy, function or methodology aims

What are the main aims, purpose and outcomes of the policy, strategy, function or methodology?
To ensure a consistent and accurate approach to the diagnosis of diabetes mellitus in non-pregnant adults across the health service in East Kent.
Does it relate to our role as a service provider and/or an employer?
Service provider.

2. Assess the likely impact on human rights and equality

Use this table to check if the policy, strategy, function or methodology:

- could have a negative impact on human rights or on any of the equality groups, or
- could have a positive impact on human rights, contribute to promoting equality, equal opportunities or improve relations.

It is not necessary to complete each box, nor to mark whether it is positive or negative, although you can do this if you find it helpful.

	Protected Characteristic								
	Race	**Sex**	**Disability**	**Sexual Orientation**	**Religion or belief**	**Age**	**Gender reassignment**	**Marriage & Civil Partnership**	**Pregnancy & Maternity**
Could this policy, procedure, project or service affect this group differently from others? **YES/NO**									
Could this policy, procedure, project or service promote equal opportunities for this group? **YES/NO**									
Right to life *e.g. decisions about life-saving treatment, deaths through negligence in hospital*									
Right not to be tortured or treated in an inhuman or degrading way *e.g. dignity in care, abuse or neglect of older people or people with learning disabilities.*									
Right to respect for private and family life e.g. *respecting lgb relationships, confidentiality*									
Right to freedom of thought, conscience and religion *e.g. respect for cultural and religious requirements*									
Right to freedom of expression *e.g. access to appropriate communication aids*									
Right to freedom of assembly and association *e.g., right to representation, to socialise in care settings*									
Right to education *e.g. access to basic knowledge of hygiene and sanitation*									
Right to liberty e.g. informal detention of patients who do not have capacity									

3. How does it impact on people's human rights and equality?

Using the table above, explain anticipated impacts. If a full EHRIA is recommended, you can summarise the impacts - it is not necessary to set these out in detail,

Could people's human rights be impacted negatively? Could the policy, strategy, function or methodology result in inequality or discrimination?
No
Could this policy, strategy, function or methodology result in positive impacts on people's human rights or equality? Could it present opportunities to promote equality?
No

4. Recommendations

Is a full EHRIA recommended? If not, give reasons
No. The policy has equal impact.

5. Publication of EHRIA

Give details of where Screening Tool or the full EHRIA will be published and when this will take place
n/a.

Details of person completing the EHRIA	
Name	Dr Edmund Lamb

Signed Date: 10th December 2012

Approval and sign-off	Name
Head of Department/Director	Mrs Ruth Lapworth

Signed …… Date: ……

Appendix D – Author's Checklist of compliance with the Policy for the Development and Management of Organisation Wide Policies and Other Procedural Documents

POLICY:

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

	Requirement:	Compliant Yes/No/ Unsure	Comments
1.	**Style and format**	Yes	
2.	**An explanation of any terms used in documents developed**	Yes	
3.	**Consultation process**	Yes	
4.	**Ratification process**	Yes	
5.	**Review arrangements**	Yes	
6.	**Control of documents, including archiving arrangements**	Yes	
7.	**Associated documents**	n/a	
8.	**Supporting references**	Yes	
9.	**Relevant NHSLA criterion specific requirements**	n/a	
10.	**Any other requirements of external bodies**	n/a	
11.	**The process for monitoring compliance with NHSLA and any other external and/or internal requirements**	n/a	

Appendix E – Plan for Dissemination of Policies

To be completed and attached to any policy when submitted to the appropriate committee for consideration and approval.

Title of document:	Diagnosing diabetes mellitus in non-pregnant adults		
Version Number:	5.0		
Approval Date:		**Dissemination lead:**	
Previous document already being used?	Yes		
If yes, in what format (paper / electronic) and where (e.g. Directorate / Trust wide)?	Electronic , hosted on Q-Pulse and copied to pathology area of TrustNet		
Proposed instructions regarding previous document:	Destroy all previous material		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Format (i.e. paper or electronic)**	**Comments:**
Trust clinical staff	TrustNet	electronic	
Primary care	Newsletters	electronic	

Author's Dissemination Record - to be Used Once Document is Approved – to be kept with the master document

Date document forwarded to be put on the Trust's central register / in SharePoint:		**Date document put on Directorate register (if appropriate) / on Directorate webpage (if applicable)**	

Disseminated to: (either directly or via meetings, etc.)	**By Whom?**	**Format (i.e. paper or electronic)**	**Date Disseminated:**