

**The use of POCT HbA1c devices in the NHS  
Diabetes Prevention Programme:  
Recommendations from an expert working  
group commissioned by NHS England**

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#### Introduction

The NHS Diabetes Prevention Programme (NHS DPP) aims to target people already identified to be at high risk of developing type 2 diabetes, with lifestyle intervention [1]. Those at high risk are usually defined by a two stage process: a risk score identifies those at sufficiently high risk to require a blood test; followed by a blood test of a measure of glycaemia such as haemoglobin A1c (HbA1c). A value between 42-47 mmol/mol is used to define non-diabetic hyperglycaemia and eligibility for enrolment into the programme[2]. HbA1c will also be used to monitor outcome during and after the DPP.

HbA1c is an established marker of glycaemia that is usually tested on venous blood in the laboratory but can also be measured on point of care test (POCT) devices. The use of HbA1c to identify people at high risk of developing diabetes represents a change in use for the test, which currently is used to diagnose type 2 diabetes and to monitor people with diabetes.

To date, UK guidance has not fully supported the use of POCT HbA1c for diagnosis of diabetes or categorisation of people in high risk states, due to the combined issues of accuracy and precision of currently available devices [2,4,5]. Guidance has therefore suggested that POCT HbA1c should only be considered where performance of these devices is comparable to laboratory assays, and delivery must be implemented within an appropriate quality framework.

In this document we discuss the advantages and disadvantages of POCT HbA1c for use in the NHS DPP and specify recommendations for its use.

What is the potential role for POCT HbA1c in the DPP?

1. For identification of people with non-diabetic hyperglycaemia:

a. Identification of individuals will largely be undertaken in community settings. In most instances patients will be identified on the basis of existing blood results from the last 12 months, which may have been taken as part of routine care or as part of NHS Health checks.

b. In high risk areas, a direct to consumer approach, may be favoured with procured providers making contact with members of the public directly. In these individuals the categorisation of non-diabetic hyperglycaemia should be undertaken by the same process of risk scoring and a measure of glycaemia, outlined in national guidance [2].

c. In some people the HbA1c test is invalid as a diagnostic test due to interference [4]. A fasting venous glucose will need to be undertaken to categorise risk in these individuals [2].

2. For monitoring of people once enrolled into the NHS DPP:

Baseline measurement may, and subsequent monitoring of HbA1c will, be undertaken by procured providers of the NHS DPP. In this context a POCT device could be used as a substitute for venous blood tests in individuals who can have HbA1c testing. For those in whom HbA1c cannot be used, monitoring will need to continue with fasting venous glucose.

What advantages and disadvantages of POCT HbA1c over laboratory testing should be considered?

Advantages

- Real time reporting of results may have a greater impact on a subject who is given their result at the time of enrolment. This impact may enhance the motivation of the subject and help them change their behaviour (although this is yet to be confirmed in studies).
- Real time reporting may also enable immediate decision making, potentially reducing follow up appointments.
- It may also be more convenient for the patient and the provider to undertake a finger prick test rather than venous blood test, which will require a larger sample volume, a phlebotomist and transportation of samples to the local laboratory.
- In the long term, there may be cost savings.
- Depending on where the NHS DPP is delivered, having a POCT on site may also be of
- Value to ensure easier access, or even remote access, to patients.

## Disadvantages

- There is currently no evidence to support that rapid turnaround of HbA1c tests in this context results in better patient outcomes, optimised care delivery, or improvement in HbA1c.
- Results in the diabetic range (i.e. > 48 mmol/mol) would need a confirmatory test using a methodology validated for diagnosis (as per national guidance), which may be associated with patient anxiety in the interim.
- Further blood tests may be required (for example a lipid profile, renal function etc.) which would necessitate venous blood testing in any case.
- The need to provide laboratory glucose testing will remain for people who cannot have a reliable measure of HbA1c and POCT glucose testing cannot be used, therefore the provision to undertake venous blood tests will be necessary anyway.
- Though the number of individuals to be tested is large nationally, in any one location the number may not be sufficiently large to warrant procurement of a POCT device.
- Not all sectors implementing POCT can deliver the quality framework required to support POCT.
- Not all POCT HbA1c devices meet established analytical performance criteria.
- Without the laboratory economies of scale, POCT implementation may be more costly.

The decision to implement POCT for HbA1c in the context of the NHS DPP will therefore be based on the cost effectiveness of this approach over established laboratory testing for each individual location. This decision will be underpinned by data on the projected workload for each provider and feasibility of implementation in view of the need for a clear quality framework to support the device (see below). Whilst it may be considered beneficial to report an HbA1c result in real time to the patient to enable immediate decision making, there is currently limited evidence to support that this approach results in better patient, or process outcomes compared to HbA1c testing in the laboratory[6,7].

## Why is a POCT quality framework needed?

Pathology laboratories operate standards of practice that ensure quality and confidence in results reporting. These practices are benchmarked against standards outlined by accreditation services (derived from international standards ISO 15189[8] and ISO 22870[9]), such as the UK accreditation service standards (UKAS) [10]. The standards cover all aspects of undertaking a test from factors before a test is undertaken (pre-analytical), the analytical process itself and actions after a result is validated to being reported (postanalytical) [8,11]. These procedures are in place to ensure accuracy of results, to identify errors in analysis and detail ways in which to address them.

There are many features of POCT that make it vulnerable to poor performance. These include inadequate training and competency assessment of a large number of users from non-laboratory backgrounds, inadequate quality maintenance and underestimation of risk by the user in a busy clinical environment. This is in addition to the analytical quality of the device itself, which must be carefully assessed.

The aim of the POCT quality framework is to therefore ensure an analytical test that is removed from the laboratory environment, and undertaken by non-laboratory staff, still retains the quality aspects of the laboratory and has safeguards in place to prevent incorrect results from being reported.

What are the key components of the quality framework?

Recognising the expanding repertoire of POCT analyses, devices, provision outside of laboratories and potential pitfalls of incorrect implementation, the Medicine and Healthcare products Regulatory Agency (MHRA) produced guidance on the management of in vitro POCT devices [12]. It is clear from this guidance and the ISO standards covering POCT (22870:2006) [9] that there are a number of processes, systems and steps that need to be in place to ensure POCT is managed appropriately and a quality service is delivered. These points collectively form the quality framework and are fully explained in the MHRA document.

Themes of the quality framework:

- to have a clear management structure with responsibility for delivery of the service, taken in the form of a POCT committee and POCT manager
- to maintain quality of the testing process through adequate training of users, clear documentation of operating procedures and competency assessments
- to maintain and evaluate quality of the analytical method through appropriate internal quality control and external quality assessment schemes
- to identify and react appropriately to process failures using documented procedures

It is clear from the MHRA guidance that the significant expertise that the local laboratory can provide should be actively sought and formalised through a service level agreement.

The established laboratory service will have the expertise, experience and systems in place to advise on the need for POCT, its procurement and virtually every step in the implementation and ongoing management of the device and its users. Procurement of POCT without input from local laboratories is therefore not recommended.

What analytical performance criteria are required?

The performance criteria for HbA1c methods have been clearly defined and POCT devices are expected to meet these [13] for use in the NHS DPP. These criteria outline minimum performance criteria and traceability to international standards. Decision making about specific POCT devices should take into consideration performance from published studies [for example 13–15], external quality assessment data and is best taken with local UKAS accredited laboratory support, as non-laboratory procurers may not be suitably qualified to evaluate and select appropriate devices.

Are POCT HbA1c and laboratory HbA1c results comparable?

All methods that measure HbA1c have different accuracy and precision, such that (within acceptable limits) some assays may result in higher and others in lower values around a reference point [13]. If HbA1c is used to diagnose diabetes or categorise people at risk of developing diabetes around specific cut points the variation in bias between methods is of importance. The relationship between the POCT device result and the local laboratory assay must be established during an independent method evaluation, a process undertaken in conjunction with the local laboratory when a new method or device is implemented to compare its results to the laboratory. The bias can further be evaluated when external quality assessment is undertaken. It is therefore essential that the same method (POCT or laboratory) is used in any one individual enrolled into the NHS DPP.

This is of particular importance in general practice where it is likely that the POCT device would also be used to monitor people with established diabetes and a change in HbA1c values when switching from one method to another may become apparent.

Recommendations for using POCT HbA1c in a DPP:

Routine use of POCT HbA1c in favour of laboratory testing requires careful multidisciplinary consideration, since there is currently no evidence demonstrating better outcomes from

HbA1c POCT over laboratory testing. The following recommendations are advised as best practice for POCT HbA1c in the DPP:

- POCT HbA1c should only be considered where there is evidence for cost effective implementation. There should be an investigation into projected workload, workflow and whether changes to local practice and the established laboratory service can meet these demands to circumvent the need for POCT HbA1c.
- Procurement of HbA1c POCT devices should only be considered in collaboration with the local UKAS accredited pathology laboratory with the involvement of a local POCT committee.
- A service level agreement with the local laboratory should be made to ensure adequate support at every stage during device selection, procurement, evaluation, implementation and thereafter to help initiate, advise on and maintain the quality framework.
- A designated member of a POCT committee (POCT coordinator) should act as a liaison between the laboratory and the user.
- Advice on which device to purchase should be obtained with local laboratory support and expertise, relating to the minimum analytical performance criteria, published studies on device performance, local laboratory experience and external quality assessment data.
- All parameters of the MHRA stipulated quality framework must be in place prior to implementation of the POCT HbA1c device.
- All POCT HbA1c devices must have a clear process for internal quality control and be enrolled into an external quality assessment programme.

## Clinical considerations

### Pre analytical considerations:

Patients with any of the known conditions that preclude HbA1c testing for a diagnosis of diabetes [4] should not have a POCT HbA1c measured as part of a DPP. Such individuals will require fasting plasma glucose testing for identification and monitoring during the DPP.

### Post-analytical considerations of a POCT test:

- An asymptomatic patient with a value  $>48$  mmol/mol should have a confirmatory HbA1c test to confirm a diagnosis of diabetes, using a methodology validated for diagnosis of type 2 diabetes.
- Individuals identified on the basis of a laboratory HbA1c result should have a baseline POCT HbA1c, if POCT is to be used to monitor progress during the DPP.
- Once enrolled in the NHS DPP testing of HbA1c should be by the same modality that is if enrolled on basis of a POCT result, all subsequent testing should be via the same POCT methodology.

## Specifications for HbA1c and fasting plasma glucose testing

### Specifications for HbA1c and fasting glucose testing in the NHS DPP pre-qualifying questionnaire

Providers are required to deliver testing to measure HbA1c on patients enrolled in the NHS Diabetes Prevention Programme. HbA1c testing may be performed using venous blood samples analysed by laboratory based analysers or capillary whole blood samples measured on point of care testing (POCT) devices. Once selected, the same analyser (laboratory-based or POCT) should be used for repeated measures in the same individuals.

HbA1c testing using laboratory based analysers must be undertaken in Clinical Pathology UK Accreditation Service (UKAS) accredited laboratories, using methods that are directly traceable to the International Federation of Clinical Chemistry and Laboratory Medicine reference measurement procedure.

POCT devices must meet the analytical performance criteria of laboratory based methodologies as stipulated in expert guidance [13]. POCT devices must function within an appropriate quality framework that ensures all parameters of MHRA stipulated guidance on POCT are met [12].

There are circumstances that result in HbA1c being less reliable for diagnosis / categorisation [3], and FPG should be used on those individuals where such circumstances arise. The circumstances include (see [3] for full list):

- Abnormal haemoglobins (variant haemoglobins)
- Anaemia
- Altered lifespan of the red blood cell.

Fasting glucose testing should be performed according to local standard operating procedures compatible with best practice guidance [16,17]. Venous glucose should be measured on analysers with standardised methodologies that are directly traceable to the reference measurement procedure. These assays should be performed in UK Accreditation Service accredited laboratories demonstrating appropriate quality control and quality assurance.

At the time of writing, point of care capillary blood glucose devices (including those meeting ISO 15197[18]) do not meet the accuracy or quality assurance criteria required for diagnostic testing and are therefore not recommended for use in this capacity.

## References:

- 1 NHS Diabetes Prevention Programme.  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/456149/Non\\_diabetic\\_hyperglycaemia.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456149/Non_diabetic_hyperglycaemia.pdf);:Accessed 22/1/2016.
- 2 NICE PH 38 Prevention of type 2 diabetes.  
<https://www.nice.org.uk/guidance/ph38/resources/type-2-diabetes-prevention-inpeople-at-high-risk-1996304192197>;:Accessed 22.1.2016.
- 3 WHO Guidance on HbA1c for diagnosis of diabetes.  
[http://www.who.int/diabetes/publications/report-hba1c\\_2011.pdf](http://www.who.int/diabetes/publications/report-hba1c_2011.pdf);:Accessed 22.01.2016.
- 4 John WG. Use of HbA1c in the diagnosis of diabetes mellitus in the UK. The implementation of World Health Organization guidance 2011. Diabet Med Published Online First: 2012. doi:10.1111/j.1464-5491.2012.03762.x
- 5 NHS Health Checks Best Practice Guidelines.  
[http://www.healthcheck.nhs.uk/commissioners\\_and\\_providers/national\\_guidance1/2015](http://www.healthcheck.nhs.uk/commissioners_and_providers/national_guidance1/2015);:Accessed 22/01/2016.
- 6 Grieve R, Beech R, Vincent J, et al. Near patient testing in diabetes clinics: Appraising the costs and outcomes. Heal Technology Assess 1993;**3**:1–74.
- 7 St John A. The Evidence to Support Point-of-Care Testing. Clin Biochem Rev 2010;**31**:111–9.
- 8 ISO 15189:2012 Medical laboratories Requirements for quality and competence.  
[http://www.iso.org/iso/catalogue\\_detail?csnumber=56115](http://www.iso.org/iso/catalogue_detail?csnumber=56115);:Accessed 22/01/2016.
- 9 ISO 22870:2006 Point-of-care testing (POCT): Requirements for quality and competence.
- 10 UKAS Laboratory Accreditation Standards.  
<http://www.ukas.com/about/aboutaccreditation/the-accreditation-process/accreditation-standards/>;:Accessed 22/01/2016.
- 11 International Organization of Standards: 15189 Medical laboratories – Requirements for quality and competence. 2012.
- 12 MHRA: Management and use of IVD point-of-care test devices. 2013.  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/371800/In\\_vitro\\_diagnostic\\_point-of-care\\_test\\_devices.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf)
- 13 Weykamp C, John G, Gillery P, et al. Investigation of 2 Models to Set and Evaluate Quality Targets for Hb A1c: Biological Variation and Sigma-Metrics. Clin Chem 2015;**61**:752–9. doi:10.1373/clinchem.2014.235333

14 Lenters-Westra E, Slingerland RJ. Six of eight haemoglobin A1c point-of-care instruments do not meet the general accepted analytical performance criteria. Clin Chem 2010;**56**:44–52.

15 Lenters-Westra E, Slingerland RJ. Three of 7 haemoglobin a1c point-of-care instruments do not meet generally accepted analytical performance criteria. Clin Chem 2014;**60**:1062–72.

16 Association of Clinical Biochemistry guidance on glucose testing.  
<http://www.acb.org.uk/Nat%20Lab%20Med%20Hbk/Glucose.pdf> 2012;:Accessed 22/01/2015.

17 Sacks DB, Arnold M, Bakris GL, et al. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem. 2011;**57**:e1–47.

18 ISO 15197: 2013 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.  
[http://www.iso.org/iso/catalogue\\_detail?csnumber=54976](http://www.iso.org/iso/catalogue_detail?csnumber=54976);:Accessed 22/01/2016.