



# THE ROLE OF HBA1C POINT-OF-CARE TESTING IN THE PRIMARY CARE SETTING

## Advisory Board Summary Report

On the 18<sup>th</sup> of July 2023, eight clinicians with a special interest in diabetes came together to discuss the role of HbA1c point-of-care testing (POCT) in primary care settings. Cogora met with each of the delegates prior to the advisory board to conduct individual interviews and ascertain the key areas for discussion. The delegates discussed the benefits and concerns surrounding HbA1c POCT and how they might mitigate these concerns. The clinicians concluded the advisory board by discussing the purchasing pathways surrounding the implementation of the device.

## DELEGATES



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## EXECUTIVE SUMMARY

HbA1c point-of-care testing (POCT) enables clinicians to make an informed decision on their patients' treatments at the time of consultation. Avoiding the need for a venous blood collection and testing by a laboratory means that patients only have to attend one consultation rather than up to three. This is a particularly useful reduction in rural or deprived areas with hard-to-reach patients; instead of taking long journeys to hospitals for a blood test followed by another GP appointment, everything can be done in the initial consultation. This not only reduces the required appointments, but also reduces the number of missed or wasted appointments.

Nevertheless, the faculty also presented barriers to HbA1c POCT implementation. The top three barriers identified were lack of backing from organisations, assumed inaccuracy, and general resistance to change. A lack of backing from regulatory organisations, such as the National Institute of Health and Care Excellence (NICE), was also suggested to be a cause of general resistance in the system. It was thought that convincing

NICE to endorse HbA1c POCT would be highly persuasive to commissioners.

The most important factor to ensure adoption of HbA1c POCT is how the cost-effectiveness case is presented. Despite the long-term cost savings of early diabetes detection and improved management being clear, the short-term cost savings through reduced appointments will be the convincing argument for commissioners. Cost effectiveness is likely to be seen most in diabetes hubs, where the machine will be used consistently on a daily basis; this will draw diabetes care away from GPs and thus increase the number of available appointments here. Yearly diabetes consultations require taking a venous sample for measuring lipid levels and kidney function; at such appointments HbA1c may also be measured using the same sample. However, HbA1c should be tested 2 to 4 times per year depending on treatment stability<sup>1</sup> and HbA1c POCT testing could be beneficial in these instances. The advisors considered that HbA1c POCT may be most cost effective as a screening tool.

## HbA1c POCT ENABLES CLINICIANS TO MAKE A CLINICAL DECISION DURING CONSULTATION

There were considerable differences amongst the faculty in their views and experience of HbA1c POCT. This experience ranged from routinely using it for type 1 and type 2 diabetes management, to having very little experience of its use at all. Those with experience of using HbA1c POCT reported a huge impact on their clinic; clinicians obtain the HbA1c result immediately and make an informed decision based on this. As a result, there is no need for subsequent appointments to inform the patient of their test results.

Many of the faculty also recognised the role of HbA1c in tackling health inequalities and socioeconomic deprivation. For these hard-to-reach patients who often don't attend health checks or blood test appointments, (1) the result can be obtained immediately and (2) if they attend the clinic for another reason, they can check their HbA1c serendipitously. Some clinicians found they could access these patients by running a diabetes screening hub for the day and by positioning testing units in supermarkets or shopping centres in areas of high risk. In this way, many of the undiagnosed diabetic and pre-diabetic population can be identified.

The delegates felt that the POCT was a useful tool to engage patients in their own care, as it can quickly and easily demonstrate to the patient the status and direction of the diabetes management.



1. NICE. Type 2 diabetes in adults: management (NG28). National Institute of Health and Care Excellence. 2022.

# HOW CAN CLINICIANS' CONCERNS AROUND HbA1c POCT BE OVERCOME?

The faculty expressed a clear understanding of the benefits that POCT can offer in primary care; however, building a case to mitigate the concerns of commissioners and clinicians is key to its implementation. In this session, the attendees were first asked to individually rank the challenges that they viewed as the most important. The top three concerns were a lack of backing from organisations, assumed accuracy, and general resistance to change.

## ASSUMED INACCURACY

Withdrawal of some POCT devices by the NHS in 2019 and literature suggesting variation in HbA1c results<sup>2</sup> may be influencing clinician thinking around HbA1c POCT, leading to assumed inaccuracy; however, other evidence highlights positive qualities of some POCT devices, specifically the Afinion and DCA devices, while acknowledging their limitations.<sup>3</sup>

To overcome this stigma, the faculty thought the best people to convince clinicians are other clinicians. They suggested publishing successful case studies to show the real-world benefits of HbA1c POCT as a primary care tool; concerns regarding accuracy must be met with robust evidence to the contrary to increase clinicians' confidence. Pilot studies to obtain robust data on the accuracy of HbA1c POCT compared to laboratory testing is necessary. One clinician also suggested that if there are already studies that have been completed then effective communication to the NHS, commissioners, and clinicians is key.

This assumed inaccuracy is also a barrier to using HbA1c as a diagnostic tool, as many of the faculty felt that it should be backed up with a laboratory test. Despite most of the faculty believing that it will be used for diagnosis within the next five years, they also pressed on the huge impact of a diabetes diagnosis and the importance of getting it right. To overcome concerns of accuracy, some faculty stated that their devices can be validated and quality assured by also sending a few samples to the laboratory each month and comparing the results with the POCT results. External quality assessment (EQA) is recommended by POCT device manufacturers as best practice to ensure consistency and best quality of results. However, EQA is not mandatory and uptake varies widely; a national POCT strategy would ensure standardised approaches to POCT and best practice.

## LACK OF BACKING FROM ORGANISATIONS

The faculty believed that the best way to convince a large cohort of clinicians is for HbA1c POCT to be accepted and endorsed by national bodies. NICE is viewed as the gold standard and influences more countries than just the UK; however, robust evidence is required for it to be accepted by NICE. The attendees also suggested other reputable organisations, such as the Primary Care Diabetes Society (PCDS) and Diabetes UK, whose acceptance would result in a strong influence. The faculty also noted it would also be useful if HbA1c POCT was discussed

at a British Medical Association (BMA) conference. The client could also attend events run by Diabetes UK and the Royal College of General Practitioners (RCGP) to educate professionals on HbA1c POCT.

## GENERAL RESISTANCE TO CHANGE

Throughout the advisory board, resistance to change in the NHS was noted as a considerable barrier to POCT adoption. The faculty had an idea to incentivise clinicians to incorporate HbA1c POCT in their clinics; this could include presenting data on how HbA1c POCT can help GPs to meet the requirements outlined in their contract. It was also suggested that industry could offer free servicing and control measurements of the machines either initially or permanently, so that it doesn't add to the primary care workload. This could also increase staff confidence in the machines' accuracy, as an expert would be responsible for quality assurance.

## TIME AND WORKFORCE

The faculty identified additional time required, together with short consultation times, as a potential barrier to POCT adoption. In everyday clinics, the time required to turn on the device, make sure the cartridges are warm enough to use and performing the test could become a time-consuming task to carry out the testing for one individual. However, the faculty also agreed that in diabetes hubs, this issue was less likely to prove a true barrier as the machine would be in regular use.

The faculty suggested that it would be useful if the clinicians' computers were connected to the device so that the results could be automatically input into patient's files; this would reduce time spent and reduce the margin for human error. The faculty highlighted the underutilisation of certain facilities in the UK such as pharmacies. From this point, it was suggested local community pharmacies could be better utilised to carry out HbA1c testing. This also fits in to targeting deprived communities, as the pharmacies are often better placed and have employees who speak the languages of the local populations.

## A MORE COMPREHENSIVE POCT FOR DIABETES COULD ADD MORE VALUE

The faculty discussed use of POCT if the only time it would be required was during an intensification appointment, in which case POCT may not be cost or time effective as a venous sample for lipid levels and urinary albumin to creatinine ratio (ACR) must be taken as well. However, per NICE guidance, HbA1c should be tested 2 to 4 times per year,<sup>1</sup> adapted to the patient's stability status. A HbA1c POCT could be beneficial in these instances, but further research would be needed to weigh the clinical benefits to the patient, with the cost in this setting.

2. Baron et al., Experience of point-of-care HbA1c testing in the English National Health Service Diabetes Prevention Programme: an observational study. *BMJ Open Diabetes Res Care.* 2020;8(2):e001703. doi: 10.1136/bmjdr-2020-001703

3. Zhelev et al., Accuracy and validity of HbA1c Point of Care Testing: A review of the scientific evidence and guidelines. 2020; Public Health England.

# FUNDING AND IMPLEMENTATION OF HBA1C POCT

## HOW CAN WE SHAPE A COST-EFFECTIVENESS ARGUMENT FOR HBA1C POCT ADOPTION?

There was some concern about the cost-effectiveness of HbA1c POCT in the primary care setting. This was particularly true for practices with pathology laboratory block contracts, when they can send unlimited tests and won't be charged extra.

Therefore HbA1c POCT needs to demonstrate a reduction in unnecessary clinic time through a reduction in follow ups to prove its cost-effectiveness over conventional pathology laboratory testing. They suggested that the most advantageous method to prove cost effectiveness could be to model HbA1c POCT in a screening hub. The location of the screening hub is important to maximise the identification of undiagnosed diabetic and pre-diabetic patients. The faculty suggested placing the hub in an area with a high diabetes prevalence, this includes areas with a large South Asian population and high obesity rates. Early identification and treatment of diabetic patients will fit with the GP contract goals and the NHS Long Term Plan. The use of a hub model should also mitigate the cost associated with expired cartridges as they will be in constant use.

## IMPLEMENTATION OF HBA1C POCT

The faculty agreed that it is Integrated Care Board (ICB) commissioners and Medical Management Teams who would need to be convinced to obtain funding for implementation. ICB commissioners make decisions incorporating recommendations from NICE and influence from patient organisations such as Diabetes UK. One clinician also underscored the importance of engaging with those patients who have benefited from HbA1c POCT to make a successful business case.

Throughout the discussion, the faculty highlighted the importance of pilot studies in obtaining influential data. It is critical to select the correct target cohort and to justify the methodology behind this selection; in this case, the faculty recommended targeting areas with high diabetes prevalence or risk. The funding for implementation can be sourced from the Clinical Research Network (CRN) who would then contact ICB to create the evidence at the primary care network (PCN) scale which could generate evidence in 12 to 18 months.

The 'Flash UK study' was highlighted as a good example of a successful pilot study, particularly due to the inclusion of analyses of the health economics and psychology aspects of the device.

The faculty concluded the advisory board by discussing what would make POCT a more exciting prospect. The most popular answer was the implementation of POCT machines in everyday locations such as supermarkets and fast-food outlets; they compared the COVID-19 drive-through test sites to something that could work for diabetes. The faculty thought it would be an exciting prospect for all POCT to be carried out in one site. Whereby you could get your lipid levels, ACR and HbA1c tests checked in one visit, owing to a comprehensive POCT drive-through. This could be expanded to a multitude of other therapy areas as well. Some other suggestions included a reward scheme for patients who improve their health and at-home test kits which would be reported back to clinicians.



## RECOMMENDATIONS

### 1 MORE IMPACTFUL COMMUNICATION OF THE ACCURACY DATA FOR HbA1c POCT

It is imperative that commissioners and clinicians are exposed to and educated on the accuracy of HbA1c POCT to reduce the stigma around its inferiority to a laboratory test. Clinicians who used HbA1c POCT in their practice should be championed to change the narrative and build clinicians' confidence. Moreover, industry presence at conferences and educational events can push the message out and allows open discussions to mitigate concerns.

### 2 CONDUCTING PILOT STUDIES TO OBTAIN ROBUST EVIDENCE

In order to convince regulatory bodies or commissioners, data on both the clinical benefits of HbA1c and the associated cost savings are key. This should focus on the number of appointments saved when an HbA1c POCT is available and the cost saving of this. Other clinical benefits will include the patient experience and how they are able to engage with their treatment; advocacy from patient organisations would be highly impactful in this case.

### 3 THE NHS SHOULD CONSIDER DEVELOPMENT OF DIABETES SCREENING HUBS

Despite HbA1c POCT currently playing a predominant role in diabetes management, it may be more cost effective as a screening tool for early identification of diabetes. With community diabetes hubs already in place for management of the condition, community screening hubs with HbA1c POCT machines could be an extension of this to increase availability of GP appointments and improve patient care in the community.



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