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How can point-of-care HbA1c testing be integrated into UK primary care consultations? – A feasibility study

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ABSTRACT

Aims: Point-of-care (POC) HbA_{1c} testing gives a rapid result, allowing testing and treatment decisions to take place in a single appointment. Trials of POC testing have not been shown to improve HbA_{1c}, possibly because of how testing was implemented. This study aimed to identify key components of POC HbA_{1c} testing and determine strategies to optimise implementation in UK primary care.

Methods: This cohort feasibility study recruited thirty patients with type 2 diabetes and HbA_{1c} > 7.5% (58 mmol/mol) into three primary care clinics. Patients' clinical care included two POC HbA_{1c} tests over six months. Data were collected on appointment duration, clinical decisions, technical performance and patient behaviour.

Results: Fifty-three POC HbA_{1c} consultations took place during the study; clinical decisions were made in 30 consultations. Five POC consultations with a family doctor lasted on average 11 min and 48 consultations with nurses took on average 24 min. Five POC study visits did not take place in one clinic. POC results were uploaded to hospital records from two clinics. In total, sixty-three POC tests were performed, and there were 11 cartridge failures. No changes in HbA_{1c} or patient behaviour were observed.

Conclusions: HbA_{1c} measurement with POC devices can be effectively implemented in primary care. This work has identified when these technologies might work best, as well as potential challenges. The findings can be used to inform the design of a pragmatic trial to implement POC HbA_{1c} testing.

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1. Introduction

Diabetes is a growing health problem affecting 382 million people globally [1] and poses a major financial burden to healthcare systems [1–3]. In the United Kingdom (UK) the

National Health Service (NHS) treatment costs for diabetes amount to £13.8 billion annually [2]; in the United States the costs for diabetes care in 2013 were \$548 billion [1]. The majority of these costs result from treating diabetes-related complications. Monitoring of HbA_{1c} and management with

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glucose-lowering medications are cheap in comparison [2,4–7] and can reduce the risk of developing future complications [5,8,9] and hospitalisations.

Monitoring of people with type 2 diabetes mellitus usually takes place in primary care in the UK, but the process is currently fragmented, involving a series of steps which include multiple visits to the primary care clinic (GP practice) by the patient. The patient is first required to attend the clinic to have a venous blood sample taken, which is sent for analysis in a central laboratory. The HbA_{1c} value is available within a few days and the patient is then usually required to make a second visit to the clinic to discuss the result. In some cases, if no changes to medication are necessary, the patient may not need to attend the clinic again, and may remain unaware of their actual HbA_{1c} value.

Point-of-care (POC) tests may be undertaken on a range of instruments including hand held or bench-top devices and are designed for use in an office, treatment room or at the bedside. Typically they use a finger-prick blood sample or a urine sample to provide rapid test results, usually within a few minutes. This approach to testing can improve the currently fragmented process of monitoring patient's HbA_{1c} by allowing the test to be performed, discussion of the test result, and any necessary medication changes to take place within a single consultation [10].

POC testing allows a real-time discussion of the test result between clinicians and patients and removes the need to telephone through results or to schedule follow-on appointments [11]. This streamlined consultation process is more convenient to patients [12] and has been linked to improvements in patient satisfaction and motivation to self-manage [13,14]. Despite this, trials to date, have not been able to demonstrate that POC HbA_{1c} testing results in an improvement in HbA_{1c} [4]. It is central to POC testing that, if action is to be taken on the test result, this takes place during the consultation rather than at a later time, or the benefits of the immediacy of POC testing are lost [15]; this did not always take place in previous trials [16]. Moreover, some previous trials recruited patients with well-controlled diabetes [17] whose potential to improve their glycaemic control is limited. As a consequence, the way POC HbA_{1c} testing was implemented in previous trials may have contributed to its lack of effect on HbA_{1c}. It therefore remains unclear whether POC testing is inherently ineffective, or whether it simply hadn't been implemented optimally in previous trials.

If POC testing is acted on within the patient consultation, it reduces time to clinical decision-making, may affect communication between the patient and clinician and could change patient behaviour. Because this type of testing may impact on several aspects of the test-treatment pathway, an evaluation should be carefully designed to examine all of the steps involved [18]. These should include technical performance of the device, impact on clinical decisions, or patient and clinician behaviours. We therefore aimed to identify key components of POC HbA_{1c} testing and optimise the way it is implemented into UK primary care. To achieve this, a theoretical framework was proposed (shown in Table 1) including components important to POC testing which were based on a framework for designing and evaluating trials of diagnostic tests [18].

2. Materials and methods

2.1. Setting and recruitment

This study was cohort design in which all participants received POC HbA_{1c} testing. It was set in three primary care clinics in the Thames Valley area of the United Kingdom (UK) between May 2015 and April 2016. The study was approved by the Office for Research Ethics Committees Northern Ireland (Reference 14/NI/1127) in December 2014. Substantial amendments were approved in February and November 2015.

Thirty adults who had a diagnosis of type 2 diabetes mellitus for at least 3 months and a recent HbA_{1c} > 7.5% (58 mmol/mol) were recruited to the study by a general practitioner (GP) or practice nurse. Participants had three study visits over six months and for some, two interviews. Eligible patients were identified by clinic staff based on recent laboratory HbA_{1c} results which indicated that their glycaemic control was sub-optimal (>7.5%, 58 mmol/mol). They were invited to participate in the study via a letter of invitation and a participant information sheet. A minimum of 24 h was allowed before participation was confirmed and informed consent was taken. Each study participant was given a unique and anonymous identifying number, which was used for all study materials.

2.2. Point-of-care devices, cartridges and connectivity

The Alere Afinion AS100 point-of-care device was used in each of the clinics along with a bar-code scanner, printer and HbA_{1c} test cartridges. This instrument was selected on the basis of published evaluations and a systematic review on the quality of instrument performance [19,20] as well as being validated against the laboratory HbA_{1c} method. Training on operation of the device was provided to clinicians who were seeing study patients in each of the participating clinics. Devices in two of the GP clinics (Clinics 1 and 2) were connected via a connectivity converter and a secure NHS Ethernet connection using Conworx Poccellarator™ software directly to the John Radcliffe Hospital in Oxford. Each operator was provided with a unique bar code, which was scanned each time a sample was run. Patient identifiers were typed in manually as the patient NHS number in Clinics 1 and 2 to allow synchronisation of date and time of test and HbA_{1c} test result with the patient's electronic hospital records. The anonymous patient study ID was used as the patient identifier in Clinic 3. Each batch of cartridges was quality control checked in the John Radcliffe hospital laboratory prior to delivery to clinics, meaning clinic staff did not need to conduct any quality control procedures.

2.3. Study procedure

During the first study visit (visit 1 or baseline visit), patient eligibility was assessed, written informed consent was given, a venous blood sample was taken for laboratory HbA_{1c} measurement, patient height and weight were measured, and patients completed four questionnaires. Fifteen patients were

Table 1 – Theoretical framework – essential aspects of HbA_{1c} monitoring and behaviours which could impact on success of testing.

HbA _{1c} testing appointment	Outcome measures
<ul style="list-style-type: none"> • Patient attendance • Appropriate monitoring intervals • Test result reviewed by clinician • Appropriate medication prescribed • Patient collects prescription • Patient is adherent to medication 	<ul style="list-style-type: none"> • HbA_{1c} test result • Medication changes • Patient understanding of diabetes and HbA_{1c} • Patient believing behaviour can affect outcomes • Patient satisfaction with care/treatment • Motivation and adherence to medication/appointments
Specific for POC testing:	
<ul style="list-style-type: none"> • POC test is administered during the consultation • Feedback of result and action taken on result in POC consultation • Adequate instrument performance • Streamlined care pathway 	<ul style="list-style-type: none"> • Feedback of test result given during consultation • Advice/medication change given during consultation • Feedback from patients and clinicians in qualitative interviews • Technical failures • Location of device • Sequence of appointment • Satisfaction with POC testing • Patient appointment times <p>Other outcomes which could be a barrier to POC testing: Costs to practice and patient Consultation time (patient) Care pathway</p>

interviewed before their first POC appointment. The second study visit (visit 2) took place around 12 weeks after the baseline visit. During this visit a POC HbA_{1c} test was performed using a fingerprick blood sample, clinicians were asked to feedback and discuss the result with the patient, and make treatment changes or provide advice during the appointment. Patients completed one questionnaire on medication adherence. The third and final study visit (visit 3) took place around 24 weeks after the baseline visit. Study procedures were identical to visit 2, but at the end of the visit patient weight was re-measured and all four questionnaires were completed by patients. The same fifteen patients were interviewed for a second time after completion of visit 3. Fig. 1 shows the study timeline.

Clinicians involved in the study were asked to complete a short survey at the end of the study. The survey consisted of multiple choice or tick box questions on ease of use of the POC device, its impact on patient care and the perceived barriers to POC testing. Space was provided to give more detailed free-text feedback if required.

2.4. Data collection and analysis

Demographics and baseline characteristics of the study participants collected during visit 1 included patients' sex, age, ethnicity, diabetes duration, smoking status, level of education, weight and height as well as relationship to people living in the same household. In visits 2 and 3, data from the POC consultations was collected on location of POC device, patient appointment duration, sequence of the consultation, POC HbA_{1c} test result and medication changes or advice given. Problems encountered with the device operation and any cartridge failures were reported by clinic staff running the tests, and were recorded.

All recruited patients were asked to complete four questionnaires at the baseline visit and again at the end of the study to measure levels of satisfaction, knowledge of diabetes, motivation to self-manage diabetes and medication adherence, before and after receiving POC testing (see [Supplementary material](#) for copies of questionnaires). The questionnaires used were Diabetes Treatment Satisfaction

Questionnaire [21] appended with questions relating to understanding of HbA_{1c} and satisfaction with clinic visit (DTSQ+), Revised Illness Perception Questionnaire (IPQ-R) [22,23], Patient Activation Measure (PAM) [24] and Morisky Medication Adherence (MMAS) [25].

Mean \pm standard deviation (SD) HbA_{1c} was summarised for each study visit, mean \pm SD body mass index (BMI) was summarised at baseline and visit 3, medication changes and advice given at POC visits were recorded. Duration of POC appointments were summarised. Data on cartridge failures, connectivity of devices, uploading of results, protocol deviations and incomplete follow-up were recorded. Explanations for any problems encountered were sought through discussion with clinic staff. Aggregated questionnaire scores were calculated (details are given in the [supplementary material](#)). Changes between baseline and visit 3 were compared; statistical significance was set at p -value < 0.05 for all changes. Differences in outcomes between clinics were explored. Qualitative data collection methods and results are reported separately.

3. Results

3.1. Clinics and patients

Two clinics in Oxfordshire and one in Berkshire participated in the study. Two clinics were run by nurses and one was run by a GP. In all cases, the POC device was located in the nurse or GP's office. Thirty patients were recruited between May and October 2015. Clinic 1 recruited 14 patients, Clinic 2 recruited 11 patients and Clinic 3 recruited 5 patients. Baseline characteristics of the 30 recruited patients are shown in [Table 2](#). Approximately equal numbers of men and women were recruited to the study. Mean age was 57.8 years, twenty-eight patients were white and two were Asian, mean

diabetes duration was 6.7 years and mean \pm SD BMI was 32.2 ± 3.5 kg/m². Mean \pm SD HbA_{1c} at baseline was $8.21 \pm 0.98\%$ (66.3 ± 10.7 mmol/mol).

3.2. Follow-up

Baseline questionnaires were not returned by one study patient. One patient withdrew before the second study visit without providing a reason and all five patients recruited in Clinic 3 missed the second study visit due to high workloads experienced in the clinic during the study. The remaining 23 patients completed all three study visits and questionnaires.

There were eleven cartridge failures and error messages during the study ([Supplementary Material – Table 4](#)). Nine of these were resolved by replacing a box of cartridges, which may not have been stored correctly. One patient did not receive a POC test result at the second study visit because the device gave error messages at three attempts before a venous blood sample was taken for laboratory analysis of HbA_{1c}. Two other error messages resulted from application of too little blood to one cartridge and another cartridge still being too cold after removal from refrigeration. Forty-seven POC HbA_{1c} test results for 24 patients in two clinics were electronically downloaded and synchronised with their hospital records.

3.3. Outcomes

The HbA_{1c} result was fed back to, and discussed with patients during each of the POC consultations ([Table 3](#)). Results were acted on in 30 of the 52 POC consultations (58%) to provide lifestyle advice or a change in medication ([Table 3](#)); all of which took place in the nurse-led consultations. In the nurse-led appointments the POC test appointment fully replaced the patients usual appointments, which usually

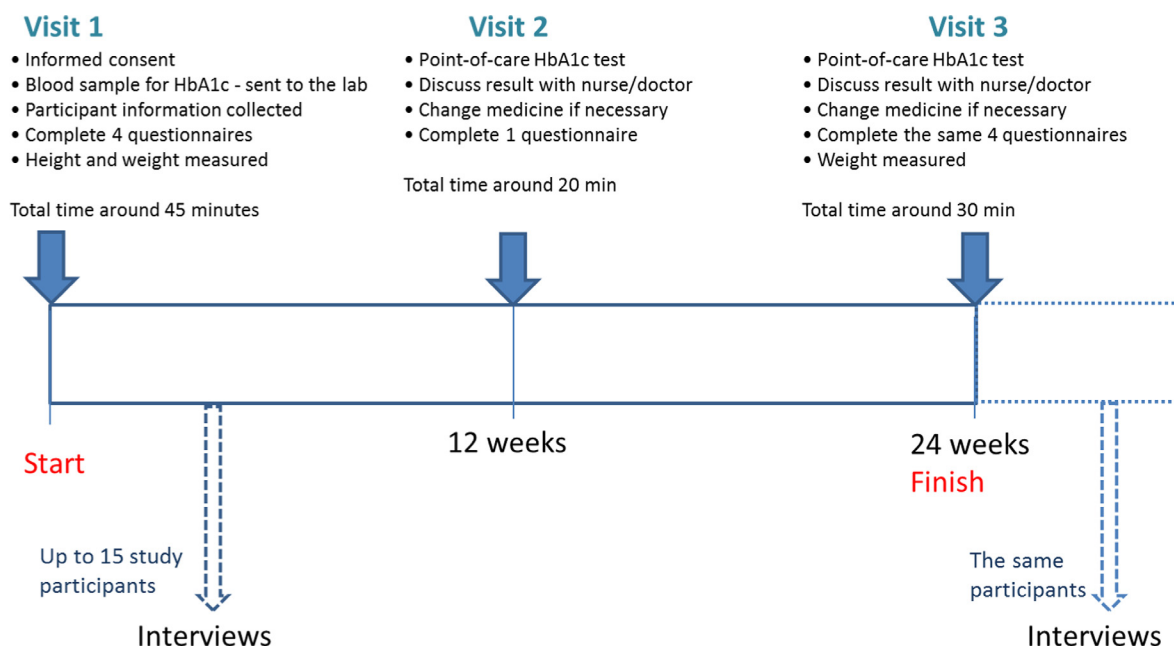


Fig. 1 – Patient study timeline.

comprised a visit to take blood followed by a consultation with the nurse, around two weeks later. In GP-led appointments, POC testing was carried out in parallel to the patients' routine diabetes visits with the practice nurse.

Mean \pm SD appointment time in visit 2 was 24.1 ± 6.2 min, compared with 20.1 ± 6.0 min for visit 3. In study visit 2 the appointment length ranged from 15 to 45 min. One appointment lasted 60 min after three cartridge failures requiring the nurse to take a venous blood sample. Another appointment lasted 45 min because two cartridges failed before a result was obtained using a third cartridge. The next longest appointment time was 35 min. In all cases the POC consultations were significantly longer in the nurse-led consultations (23.8 ± 7.7 min) compared with the 5 GP appointments (11.4 ± 0.9 min) ($p < 0.0001$). Appointments in which clinical decisions were made were longer than those in which no clinical decisions were made (23.2 ± 4.8 min versus 20.1 ± 7.9 min).

There was no significant difference in HbA_{1c} at the end of the study compared with baseline ($p = 0.45$) (Table 3). Results were similar when only patients with full follow-up data were included in the analysis.

3.4. Questionnaires and surveys

Questionnaire results are shown in [Supplementary data, Tables 5–9](#). Other than a significant increase in treatment satisfaction at visit 3 compared to baseline ($p = 0.01$) ([Supplementary data, Table 5](#)), there was no difference between baseline and visit 3 for any of the aggregated questionnaire scores.

Four healthcare professionals completed a survey at the end of the study; all reported that the device was easy to use, had very positive feelings about POC testing and believed it to be accurate. Opinions on convenience ranged from very convenient to a perception that it was less convenient for the clinician. Feelings about the effect on patient care ranged from no difference, to improved care. The responses to a question on concerns about cost ranged from 'some concerns' to 'too expensive'. Suggested benefits of POC testing were that the instant result could promote positivity between healthcare professional and patients, and that it would reduce anxiety patients experience waiting for the result. One clinician

said quality control requirement was a concern and another said the space the device took on the desk was a problem.

4. Discussion

4.1. Summary and key findings

This study, in which POC HbA_{1c} testing was introduced in UK GP practices, found that the POC test result was fed back to patients in 100% of consultations and clinical decisions were made in over 50% of the consultations. Appointment duration ranged from 10 to 45 min, but clinical decisions were only made during consultations of 15 min or longer. Nurses integrated the POC testing into their routine patient appointments, using the result for clinical decision-making within the allotted 20 min consultation time, whereas the POC HbA_{1c} test result was not used to make clinical decisions during the GP-led appointments. It was demonstrated that data could be successfully uploaded and synchronised with patient hospital records via a secure Ethernet connection. Clinicians reported that they found the device easy to use but the costs associated with POC testing were reported by all clinicians to be a concern.

We have demonstrated that POC HbA_{1c} testing can be successfully integrated into UK primary care consultations. Results indicate that the successful implementation of these technologies may be dependent on the clinician delivering the intervention. Nurses used results for making treatment decisions during POC appointments, which completely replaced usual care appointments during this study. On the contrary, GP appointments in one site ran alongside usual care appointments in which clinical decisions were made, suggesting that POC testing may not have been optimally implemented in this site. This difference may be related to the longer consultation times with nurses, and thus fewer time constraints. Therefore, the way these technologies are used may need to vary across different settings to ensure that their implementation is optimised.

4.2. Strengths and limitations

We have examined how some of the individual components of POC HbA_{1c} testing may impact on the delivery of these tests in primary care consultations. This approach has made it possible to identify aspects of the implementation, which worked well, but has also identified potential problem areas where improvements could be made. Three sites were selected in two different counties serving different populations, which enabled comparisons to be made between GP and nurse-led consultations. Having the support of hospital laboratory staff benefitted this study by enabling connectivity to transfer results to patient records and bar-code scanning for operators. Moreover, this collaboration made the logistics of implementing this type of testing easier for the clinicians carrying out the tests, and has demonstrated how POC hospital teams could contribute to the management, training and quality control of devices if POC testing is adopted in primary care settings. This could provide a realistic model for GP practices wishing to use POC testing, in allowing full connectivity and

Table 2 – Demographics of recruited patients.

Sex	14 female, 16 male
Age (years), mean (range)	57.8 (30–79)
Ethnicity	28 white, 2 Asian
Diabetes duration	6.7 ± 4.3 years
Smoking status	17 former smokers 13 never smoked
Highest level of education	7 University 10 College 13 Secondary school
BMI (kg/m ²) Mean \pm SD (range)	32.2 ± 3.5 (25.1–40.7)
Living in the same household, n	Alone 3 Partner 25 Other family > 18 9 Children < 18 5

Table 3 – Summary of POC consultations and HbA_{1c} at all study visits.

		Visit 2 (n = 23)	Visit 3 (n = 29)
Mean ± sd POC HbA _{1c}		64.9 ± 15.7	63.2 ± 13.0
Results fed back to patient		23	29
Result discussed with patient		23	29
Action taken:		12	18
Medication change		5	7
Lifestyle advice		7	11
Mean appointment time in minutes (range)		24.1 mins (15–45)	20.1 mins (10–35)
Mean (SD) HbA _{1c} at baseline and follow-up visits			
	Visit 1 (n = 30)	Visit 2 (n = 23)	Visit 3 (n = 29)
HbA _{1c} (%)	8.21 ± 0.98%	8.09 ± 1.44%	7.93 ± 1.19%
HbA _{1c} (mmol/mol)	66.3 ± 10.7	64.9 ± 15.7	63.2 ± 13.0
BMI (kg/m ²)	32.2 ± 3.5 kg/m ²	–	32.6 ± 3.6 kg/m ²

synchronisation of results with patient records, whilst relieving clinic staff of the burden of training and quality control, which could be a barrier to the adoption of POC testing [13].

A single clinician carried out the POC testing at each of the sites, meaning that finding a convenient location to situate the device was straightforward. It is recognised that locating a POC device in a setting with multiple users would require more thought. Siting the device in a location remote from the patient consultation could result in logistical problems, which may impact on patient flow or waiting times. These could potentially be minimised by locating the device in a central location easily accessible to the clinician usually responsible for care of diabetes patients, involving healthcare assistants in the testing process [26] or development of hand-held technologies which can more easily be moved between locations.

All three GP practices in this study were located in relatively rural settings and only two non-white participants were recruited to the study. GP practices in urban settings may differ in terms of patient proximity and ease of access to the clinic, as well as numbers of ethnic minorities and levels of deprivation. There may be other implementation issues in some settings which could not be fully explored in the current study.

The questionnaires were selected to measure behaviour change which may result from POC testing. However, at baseline, study participants were already satisfied with their usual care and highly motivated, meaning there was little room for improvement. There were no differences in patient satisfaction, understanding of diabetes, motivation or medication adherence over the course of the study. Use of qualitative methods is needed to better understand how POC testing may have impacted on patient satisfaction and behaviour [27]. This study was not powered to detect changes in clinical outcomes such as HbA_{1c}, nor was follow-up long enough to examine longer-term health outcomes such as hospitalisations, cardiovascular events or death. These would need to be addressed in a larger, longer-term randomised trial.

4.3. Comparison with the literature

There are few examples of studies, which have explored how POC testing can be integrated into patient consultations. Crocker et al. found that using the DCA Vantage for HbA_{1c} or lipid testing in a US primary care setting resulted in fewer tests

overall being performed, and thus may lead to potential cost savings [28]. However, cost reimbursement structures differ greatly between the US and the UK, therefore these savings may not be seen if implemented in a different setting. A trial of POC HbA_{1c} testing in UK primary care [16] found that clinicians delivering the POC testing found it difficult to change their usual practice and did not always use the results of the test to base clinical decisions during the POC appointment. This perceived lack of capacity to alter consultations was also reported in results from a survey on barriers to POC testing [29].

Results from our study have demonstrated that carrying out a POC test and acting on the result during the consultation may sometimes be challenging for GPs, particularly when workloads are high. GP practices in the UK are inherently over-stretched, with many juggling too many patients and unrealistic workloads [30]. Successfully implementing a new intervention in an environment with competing demands is contingent on health professionals adopting the intervention and abandoning old practices, but this may be particularly difficult in over-constrained systems [31,32]. Time constraints by clinicians is reported to be one of the major barriers to adoption of innovation [33]. Overcoming inertia to encourage the adoption and correct use of a new intervention may in some cases only take place if incentives are offered [31].

This work has identified that POC HbA_{1c} testing within nurse consultations may operate better than GP consultations. In Denmark, GP practices with nurse-led diabetes care were found to have a lower proportion of patients with HbA_{1c} > 8% and patient monitoring was more likely to have taken place within guidelines [34]. A meta-analysis of trials of adults with type 2 diabetes mellitus managed in general practice found significant improvements in blood pressure and cholesterol in those who received nurse care compared with GP care [35]. Full explanations for these apparent benefits of nurse-based care for some conditions are not provided in the reports, but the longer consultation times with nurse appointments may be a contributing factor.

Although this study was not powered to detect changes in HbA_{1c} or behaviour measured by questionnaires, POC testing has been linked to improved medication adherence, communication with health care professional and engagement of patients [12,36]. There is evidence that those who are aware of their HbA_{1c} are more likely to have a better understanding of diabetes and how to manage it [37].

4.4. Clinical implications

Nurses who participated in this study and operated the point-of-care devices were diabetes-specialist nurses whose responsibilities included making treatment decisions and medication changes. If healthcare workers who perform the test are not able to make treatment decisions, then the process of care may require the patient to see multiple members of staff, which may result in longer consultation times.

Quality control is an area which needs to be carefully considered by GPs who are planning to use these technologies. A batch acceptance process is usually required by hospital laboratories when taking delivery of new cartridges, strips or other consumables, as there may be lot to lot variability. This would be difficult for GP practices to administer and it is possible that many central laboratories with active point-of-care teams may be able to manage POC devices in primary care settings. This could provide the lab with control over the technology used, quality control and connectivity to ensure that patient health records are automatically updated, as well as maintaining a source of revenue for the lab [38]. Moreover, laboratories could play a role in circulating material from national quality assurance schemes, collating reports and implementing any corrective actions required. This model would provide GPs with assurance for result quality and comparability with laboratory methods. Involvement of hospital laboratories in procurement, evaluation and implementation of POC testing has been recommended by an expert committee in a recent report commissioned by the NHS [39].

This study has shown that POC HbA_{1c} testing has potential for full integration into UK primary care settings, though the way it is implemented may vary depending on the clinician who is delivering the intervention. Typically, GP appointments are time-restricted and pressures to keep to a 10-min consultation may be too great to allow optimal implementation of POC testing during the consultation. It may be preferable for the test to be administered by a healthcare assistant immediately prior to the GP appointment to allow sufficient time with the GP for discussion of the result and clinical decision-making. Nurse-led appointments in primary care are usually around 20 min, which may be more realistic for an appointment in which a test is administered, discussed and acted upon. Therefore, how much the optimal implementation of these technologies is dependent on the clinician conducting the consultation or the appointment duration is not clear. Further work to explore this, as well as the impact of POC HbA_{1c} testing on long-term health outcomes, is now warranted.

Through this work we have provided data to help design a service pathway for using POC HbA_{1c} testing. It has identified challenges that could be overcome with an intervention, and provided data that can be used to inform the design of a pragmatic trial on the implementation of POC HbA_{1c} testing.

Author contributions

JH designed the study, collected the data and wrote the manuscript, RS contributed to the study design, reviewed and edited manuscript and contributed to the discussion. IS

contributed to the data collection and reviewed/edited manuscript, TJ contributed to the data collection and reviewed/edited manuscript. BG contributed to the study design and management, reviewed and edited manuscript, AF contributed to the study design, reviewed and edited manuscript and contributed to the discussion.

Conflicts of interest

None.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.diabres.2017.05.014>.

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