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Point-of-care HbA_{1c} testing in an urban primary care diabetes clinic in South Africa: a mixed methods feasibility study

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ABSTRACT

Introduction Monitoring and treatment of type 2 diabetes in South Africa usually takes place in primary care using random blood glucose testing to guide treatment decisions. This study explored the feasibility of using point-of-care haemoglobin A1c (HbA_{1c}) testing in addition to glucose testing in a busy primary care clinic in Cape Town, South Africa.

Subjects 185 adults aged 19–88 years with type 2 diabetes.

Materials and methods Participants recruited to this mixed methods cohort study received a point-of-care HbA_{1c} test. Doctors were asked to use the point-of-care HbA_{1c} result for clinical decision-making. Qualitative interviews were held with clinical staff.

Results Point-of-care HbA_{1c} test results were obtained for 165 participants of whom 109 (65%) had poor glycaemic control (>8% HbA_{1c}, 64 mmol/mol). Medical officers reported using a combination of HbA_{1c} and blood glucose 77% of the time for clinical decision-making. Nurses found the analyser easy to use and doctors valued having the HbA_{1c} result to help with decision-making.

Discussion Our results suggest that 30% of patients may have received inappropriate medication or not received necessary additional medication if random blood glucose alone had been used in routine appointments. Clinicians valued having access to the HbA_{1c} test result to help them make treatment decisions.

Strengths and limitations of this study

- This work demonstrated that point-of-care (POC) haemoglobin A1c testing can be integrated into patient appointments and used for clinical decision-making.
- It presents a realistic care pathway which can be used in future research or roll-out of POC testing on a wider basis.
- This study did not include any follow-up, so we could not establish whether POC testing had an impact on glycaemic control or long-term health outcomes.
- Paper-based records meant that it was difficult to retrieve missing and incomplete data.
- For qualitative data collection, we interviewed clinicians working at the clinic at the time of the study and views may not represent all clinical staff.

INTRODUCTION

Diabetes is highly prevalent in South Africa, and is increasing over time.[1–3] An estimated 2.6 million people are living with the condition and there are estimated to be a further 1.2 million who have undiagnosed diabetes.[3] Diabetes is the second most common non-communicable disease in people attending primary care,[4] accounts for 5.7% of all deaths in South Africa, and was the second most common cause of death after tuberculosis overall and leading cause of death in women in 2017.[5] There is a substantial unmet need for diabetes care in the South African population and levels of glycaemic control are suboptimal in studies in the community and primary care.[3] Assessing whether glucose levels, which are directly related to occurrence of disease complications, are adequately controlled requires monitoring tests.

Glycated haemoglobin or haemoglobin A1c (HbA_{1c}) reflects average plasma glucose over the previous eight to 12 weeks[6 7] and is the preferred test for monitoring glycaemic control and making treatment decisions in people with diabetes.[8] Monitoring of HbA_{1c} in most settings usually requires the patient to have a venous blood sample taken, which is then sent for analysis in a central laboratory. The test result is reported back to the clinician within a few days and the patient will receive the result at a follow-on visit when any necessary adjustments to medication are made.

Local clinical guidelines in South Africa recommend random blood glucose (RBG) testing at every clinic visit for monitoring diabetes control. A random glucose above 10 mmol/L is considered uncontrolled

glycaemia and indicates the need for a medication review and treatment change.[9] RBG levels can, however, fluctuate substantially depending on the length of time since the patient last ate and the type of food ingested, meaning they are difficult to interpret and have poor agreement with HbA_{1c}.[9–11] HbA_{1c} testing is recommended at 6-monthly intervals unless there has been a medication change, in which case HbA_{1c} should be retested after 3 months.[12 13]

In primary care settings in South Africa, HbA_{1c} testing is performed in centralised laboratories and consequently, results are not available for immediate or same day review by healthcare workers. Review takes place at the next patient appointment, which may be up to 6 months later. This limits the use of HbA_{1c} for informing clinical decisions as results are outdated and patients are not able to link their lifestyle behaviours with their HbA_{1c} control.[14]

The emergence of point-of-care (POC) technologies has the potential to improve healthcare and patient-centred outcomes in diverse settings, including those with limited resources. POC testing may particularly lend itself to diabetes management in low-income settings because equipment maintenance requirements are low and there are no sample storage or transport requirements, but costs may be a barrier.[15] This is particularly pertinent, as while clinics in South Africa are often located within a small radius of the community they serve which makes patient access easy, clinic visits can be long, resulting in patient dissatisfaction and non-adherence.[16]

There are some reports that POC HbA_{1c} testing may improve HbA_{1c} in South African settings,[17 18] but this is not supported by randomised trial evidence from other settings.[19] However, it may obviate the need for additional visits to specifically review glycaemic control and medication if this is thought to be indicated by the health provider.

POC HbA_{1c} testing is used as standard practice in tertiary care clinics in Cape Town, particularly in paediatric clinics. A recent South African study followed up 300 patients with diabetes in primary care clinics who received POC HbA_{1c} testing for 18 months with the ultimate objective of improving glycaemic control and quality of care. They found that introducing POC HbA_{1c} testing resulted in lower HbA_{1c} and more patients receiving immediate feedback, but it did not change clinical practice.[17] The researchers concluded that there was currently insufficient evidence to support the implementation of POC HbA_{1c} testing in public sector primary care in South Africa. To benefit from the immediate result from a POC test, it is important that results are fed back to patients and clinical decisions take place during the POC appointment[20] to help the patient understand how their behaviour may affect their diabetes control.[14] The work presented here builds on this previous study to understand how a POC test could be effectively integrated in a primary care appointment and how it may influence patient flow and clinical decision-making.

The aim of this study was to explore the feasibility and acceptability of implementing and using an HbA_{1c} POC analyser in the routine care of patients with type 2 diabetes at a busy primary care outpatient clinic in Cape Town.

MATERIALS AND METHODS

Setting

This study took place in Gugulethu Community Health Centre, a busy primary care clinic serving a low income community of about 98 000 people with an average headcount of 22 000 per month in the Western Cape, South Africa.

Patient population

Adults (≥18 years) diagnosed with type 2 diabetes and receiving routine clinic care who were willing and able to provide written informed consent were eligible for the study. We included all possible treatment and monitoring regimens. Diabetes diagnosis was based on a measurement of HbA_{1c} with a threshold of ≥6.5%.

We excluded people who were unable to speak one of the study languages (English, Afrikaans or iXhosa), women who were pregnant or recently pregnant (within 3 months post partum) by self-report, people with known renal failure (creatinine >125 µmol/L), those with significant iron deficiency anaemia (Hb <10 g/dL) or known haemoglobinopathy (eg, sickle cell disease). We also excluded people who did not receive usual care from the clinic.

Recruitment and consent

Participants were recruited between mid-November 2016 and mid-February 2017 (with a break during the Christmas period). Patients attending their routine scheduled appointments for diabetes care were identified in the waiting room by a trained research assistant and invited to participate in the study. Written and verbal versions of the participant information sheet and informed consent were presented to the participants detailing the exact nature of the study, what it would involve for the participant and the implications and constraints of the protocol. Both documents were available in English, Afrikaans and iXhosa. The participant was allowed as much time as they needed to consider the information, and had the opportunity to question the study investigator, their doctor or nurse, or other independent parties to decide whether they were happy to participate in the study. A copy of the signed informed consent was given to the participant. The original signed form was retained at the study site in the patient folder. Each participant was given a unique and anonymous patient identifying number which was used on the data collection form.

Embedding the intervention into the clinic workflow

We placed an Afinion HbA1c assay POC analyser (Abbott, Chicago, Illinois) in the clinic room where nurses

admit and register patients for their diabetes clinic visit. Training and support were provided by the manufacturer to nurses who would be responsible for diabetes clinic appointments during the study.

To minimise the potential impact of the analyser on clinic workflow, we obtained finger prick blood sample for the RBG (usual care) and the POC (intervention) at the same time. The POC analyser provided an on screen result within 3 min. Both results were recorded in the patient's medical records folder and on the study data collection form.

Patients returned to the waiting area where they waited to be seen by a family doctor or nurse practitioner. During this appointment, the HbA_{1c} result, as well as other data collected and recorded by the nurse, were reviewed. Clinicians were asked to base treatment decisions on the POC HbA_{1c} result using local treatment protocols.[13] Any clinical decisions made during the appointment were recorded on the data collection sheet. The clinician was also asked to indicate whether they had used the RBG or HbA_{1c} to base their clinical decision and record the length of time until the patient's next appointment.

Data collection and analysis

Quantitative data

We collected basic demographic data as well as RBG test result, POC HbA_{1c} test result, any clinical decisions made (medication change, advice, combination of advice and treatment change or nothing). We also recorded the time interval until the next appointment, any cartridge or analyser failures, error messages, the temperature in the room where the POC analyser was kept and the gender of people in the waiting area.

Analysis

Results on participants characteristics, current medication use, RBG and HbA_{1c} test results, and all other data collected in the study were tabulated for the full cohort of patients and stratified by diabetes control, defined as controlled (HbA_{1c}≤8%), high HbA_{1c} (HbA_{1c}>8% and ≤10%) and very high HbA_{1c} (HbA_{1c}>10%). A threshold of 8% was selected to define uncontrolled diabetes because it is in line with targets in local guidelines for treatment.[13]

Quantitative data were analysed using Stata version 16SE (StataCorp, Texas). Descriptive results were presented in a table as mean and SD or percentages. Scatter plots were used to compare RBG with HbA_{1c} in each individual and highlight which participants received a medication change. Numbers above and below the treatment threshold of 8% (64 mmol/mol) correctly diagnosed with RBG were plotted in a 2×2 table to demonstrate how RBG performs in comparison to HbA_{1c} to guide treatment.

Qualitative data

Data on the usual care process of the participants were collected during the study by observation and by speaking to patients and clinicians to understand patient flow. These included appointment sequence, the number of patients in the waiting area, the number of staff working in the clinic and the number of clinicians usually seen by each patient during a routine visit.

At the end of the study, focus groups were held with doctors and enrolled nurses who were working in the clinic at the time of the study to get their perspectives of having access to a POC HbA_{1c} analyser in the clinic and their confidence in making patient management decisions with the result. Clinicians were provided with an information sheet and informed consent was taken. Structured questions were posed to a group of five doctors who had seen patients who received a POC HbA_{1c} test during the study, and with two nurses who registered patients, operated the POC analyser and recorded the results in the diabetes clinics. Topic guides informed by previous work in this area were used.[14] The doctors were asked open questions about their feelings of having the HbA_{1c} test result in the appointment with the patient, and how this compared with having the RBG result alone in terms of communication with the patient and patient management decisions. Nurses were asked about the patient flow in the clinic and what they felt about patient perception of receiving the test. Interview recordings were transcribed and checked. Initial transcripts were coded in NVivo.

A thematic analysis approach was applied to the open-ended responses. Once coded, Microsoft Excel was used to group responses. The codes were grouped into themes and themes were then compared back to the data to ensure that it had been sufficiently captured. The results are presented to highlight the main analytical findings, and quotations are provided to substantiate the findings for each theme.[21 22]

Patient and public involvement

No patient involved.

RESULTS

Workflow and processes

In Gugulethu Community Health Centre, routine diabetes care is provided through diabetes-specific clinics (diabetes chronic care club) which are run two mornings a week. The morning is divided into 3 clinic sessions and, on average, 90 patients with type 2 diabetes will be seen seen over a morning.

The patient flow is a follows: on arrival at the health centre, patients are given their clinic folder in the waiting area before measurement and recording of vital signs by a clinic nurse in a staging room. This included measurement of weight, blood pressure, urine dipstick and a random finger-prick blood glucose measured. The results are written into the patient record in their clinic folder. Thereafter, patients are seen either by medical officers and interns for clinical review. This includes a previous HbA_{1c} if the results are in the file or was requested at the previous visit and subsequent medication adjustment, and a new prescription is completed if deemed necessary. An HbA_{1c} test may be requested by the medical officer, which

requires them to have a venous blood sample drawn in another part of the clinic. The results will be available at the patient's next scheduled appointment (routinely once per month but may be up to 6 months' time).

Patients may spend as much as 3 hours in the clinic on one occasion depending on waiting times to receive care or medications. All care, laboratory tests and treatment are provided free of charge.

Quantitative results

One hundred and eighty-five participants were recruited to the study over 13 days between 21 November 2016 and 10 February 2017. There were 18 missing forms, so completed data collection forms were received for 168 participants. Three participants did not receive their HbA_{1c} result due to analytical errors, leaving 165 participants with both an HbA_{1c} and blood glucose test result. The flow chart for participant recruitment is shown in figure 1.

Mean±SD age of recruited participants was 56.2±12.6 years with a range of 19–88 years. Sex was recorded for 43 participants, of whom 28 (65%) were women. The mean±SD (range) RBG was 11.3±5.1 mmol/L (3.3–31 mmol/L) and mean±SD (range) HbA_{1c} was 9.5%±2.6% (80±28 mmol/mol) (range 5.4%–18.5%, 36–179 mmol/mol). Poor glycaemic control (defined as >8%, 64 mmol/mol HbA_{1c}[23]) was recorded in 109 (65%) of the recruited participants, and 65 (39%) had an HbA_{1c} above 10% (86 mmol/mol). Current medication use was recorded for 111 (66%) of the participants, over half of whom (58%) were taking metformin alone. Characteristics of included participants are shown in table 1 for the full cohort and stratified by whether participants had controlled HbA_{1c} (HbA_{1c}≤8%, 64 mmol/mol), high HbA_{1c} (HbA_{1c} >8%, 64 mmol/mol and ≤10%, 86 mmol/mol) or very high HbA_{1c} (HbA_{1c}>10%, 86 mmol/mol).

The plot of RBG versus HbA_{1c} for the 165 participants in figure 2 demonstrates the numbers of participants who would have received correct and incorrect assessments or characterisation if only RBG at a threshold of 10 mmol/L were used to make treatment decisions. These numbers are presented in table 2. Overall, 116 people (70%) were correctly diagnosed by the RBG test and would have received appropriate treatment using the RBG alone. Forty-nine (30%), however, were incorrectly identified as needing treatment, and if RBG alone were used, 11 would have been overtreated, and a further 38 would have been undertreated. The RBG test had a sensitivity of 66% and specificity of 79% compared with POC HbA_{1c} testing.

Mean±SD clinic temperature across each of the days of data collection was 25°C±1.6°C (range 24–32°C). Gender ratio of 80 people in the waiting area over 2 days was 74% women to 26% men.

Clinical decision-making

Of the 168 participants for whom results had been received, 13 participants (8%) received a medication change alone, 48 participants (29%) received adherence advice alone, 63 participants (37%) received both and 44 participants (26%) received no treatment or advice. Results stratified by diabetes control are presented in table 1. Clinicians reported that 14% of clinical decisions were made on HbA_{1c} alone, 7% on RBG and 77% on both HbA_{1c} and RBG.

Figure 3 shows clinical decision making by each participant's blood glucose and HbA_{1c}. It shows that 5 participants (3%) who had an HbA1c below 8% (64mmol/mol) and blood glucose above 10 mmol/L received a medication change, and 42 participants (25%) with HbA_{1c} above 8% (64mmol/mol) did not receive a medication change, but they may have received advice on medication adherence. There were 8 participants (5%) with HbA1c above 8% (64 mmol/mol) who neither received medication adherence advice nor treatment change.

Figure 1 Patient flow chart. HbA1c, haemoglobin A1c; POC, point of care.

Table 1 Patient characteristics and management decisions stratified by haemoglobin A1c (HbA1c) (excluding 18 participants with missing data)

	All patients (N=168)	Controlled HbA1c (≤8%, 64 mmol/mol) (N=56)	Poor control (HbA1c >8% 64 mmol/mol and ≤10%, 86 mmol/mol) (N=44)	Very poor control (HbA1c >10%, 86 mmol/mol) (N=65)
Age (mean±SD)	56.3±12.6	60.6±13.6	55.51±10.5	53.3±12.1
Sex (N, % female) (N=43)	28 (65%)	10 (62%)	9 (64%)	9 (69%)
HbA1c (%) (mean±SD)	9.5±2.6	6.8±0.7	9.1±0.6	12.1±1.6
Random blood glucose (mmol/l) (mean±SD)	11.3±5.1	8.0±2.4	11.2±4.5	14.4±5.5
Treatment recorded	**111 (66%)**	**33 (59%)**	**30 (68%)**	**48 (74%)**
Diet only	2 (2%)	2 (6%)	0	0
Metformin	64 (58%)	21 (64%)	17 (57%)	26 (54%)
Oral (not specified)	12 (11%)	5 (15%)	4 (13%)	3 (6%)
Glimipiride and metformin	5 (5%)	2 (6%)	0	3 (6%)
Insulin	6 (5%)	0	3 (10%)	3 (6%)
Metformin and insulin	22 (20%)	3 (9%)	6 (20%)	13 (27%)
Medication not recorded	70 (42%)	23 (41%)	14 (32%)	17 (26%)
Clinical decisions				
Medication change	13 (8%)	0	3 (7%)	10 (15%)
Counselling on adherence	48 (29%)	15 (27%)	20 (45%)	11 (17%)
Combination	63 (38%)	6 (11%)	15 (34%)	42 (65%)
None	44 (26%)	35 (63%)	6 (14%)	2 (3%)
Decision based on				
HbA1c result	23 (14%)	6 (11%)	8 (18%)	9 (14%)
RBG result	12 (7%)	3 (5%)	2 (5%)	4 (6%)
Both	130 (77%)	46 (82%)	34 (77%)	50 (77%)

Study limitations

Some participants were uncertain whether they had diabetes. Two participants who were recruited and reported that they did have diabetes were subsequently reported by doctors to not have diabetes, though one of these had a POC HbA_{1c} of 7.7%, which meets to WHO criteria for diabetes.[8]

Information on gender of participants was only captured for the final 2 weeks of data collection, but broadly reflected the sex ratio of those in the waiting area of the clinic.

There were three cartridge failures: two because HbA_{1c} was too high (HbA_{1c}>18%, 173 mmol/mol) and one because insufficient blood was applied to the cartridge.

Missing records from the 18 participants were sought in the clinic document area where patient folders are stored

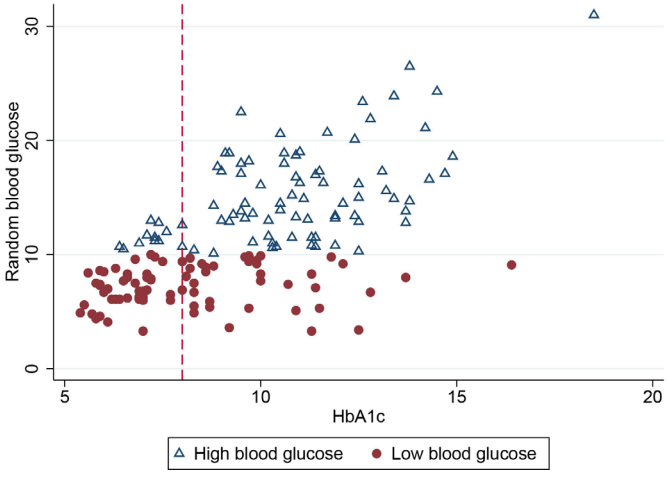

Figure 2 Random blood glucose versus haemoglobin A1c (HbA_{1c}), stratified by random blood glucose levels using 10 mmol/L as the treatment decision threshold. Dotted line represents the threshold between controlled and uncontrolled HbA_{1c} (8%, 64 mmol/mol).

Table 2 Correct diagnoses between random blood glucose and haemoglobin A1c (HbA1c) (n=165)

	HbA1c		
Blood glucose	≥8% (64 mmol/mol)	<8% (64 mmol/mol)	Total
≥10 mmol/L	75	11	86
<10 mmol/L	38	41	79
Total	113	52	165
	Sensitivity=0.66	Specificity=0.79	

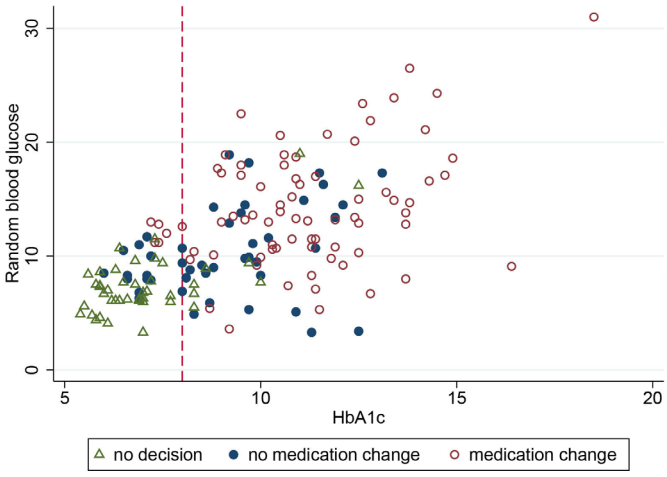

Figure 3 Random blood glucose versus haemoglobin A1c (HbA1c) stratified by clinical decisions or medication change (triangle=no medication change or advice, hollow circle=medication change, solid circle=no medication change).

but could not be located. Discussion with clinic staff revealed that patient folders were frequently misplaced, meaning that sometimes patients have to be seen by clinic staff with a new, blank folder which did not contain their medical history.

Qualitative results

Five doctors participated in the focus group which centred around feelings about having the HbA_{1c} test result in the appointment and the effect this may have on management decisions and patient behaviour. Overall, the doctors found having the HbA_{1c} result in the appointment helpful. They reported that some patients will try to manipulate their blood glucose levels by fasting before their appointments to receive different care in the clinic.

> You don't know what the patient is going to do before they come here. Some people will eat before they come in, others won't eat and take their medication. So you don't know what you are going to get on the fingerprick glucose that they do on the day, so sometimes their fingerprick will be 6 but their HbA_{1c} will be 15 because they haven't eaten before they came in or whatever the case may be. Having had HbA_{1c} at the time has been helpful."

Usually, the doctors only have the HbA_{1c} from the previous appointment which may be 6 months out of date; it is therefore of very little use for making a clinical decision on the day, so the blood glucose levels are prioritised.

> I think it's a very luxury, it's nice to have the value when you are seeing the patient it's a relevant value now and it's not 6 months old so we do it anyway to get the labs, when we see the patients we tick the lab form to get the HbA_{1c}, but to have it on the day we see them is perfect.

Some scenarios where there were discordant results between RBG and HbA_{1c} were discussed:

> Interviewer: There was one person here with an HbA_{1c} of 12.5 and a random blood glucose of 3.4. So, would you have chosen to change their medication?
>
> Doctor 1: Obviously not controlled
>
> Doctor 2: I would have changed the medication; they are clearly not controlled. A lot of the patients, they know they are seeing the doctor, so well, in my experience, the night before they drink lots of water, a litre, or 2 litres of water, in the morning they wouldn't eat, just because they know they are seeing the doctor. As long as their test the next morning is under 5 then they know they are in the clear. And who knows what they do for the previous 6 months before they saw the doctor. So that value is actually is 12 and lets me know what happens for 3 months before.

Interview with two nurses

Nurses found the analyser easy to use and enjoyed using it.

> I said I'm not interested because this machine is taking long, but the minute I started I am enjoying this much.

The nurses found that they could perform the test in their busy clinics despite only a short time with each patient. They explained that some patients had to wait for the test to finish running so they could record the result before the patient returned to the waiting room:

> It was a good experience, though it was very time consuming because the patient had to wait. We took all the vitals and we then we did the HbA_{1c} lastly, if the doctor came in and take the other patients so this one would have to wait until the machine is finished because it takes time.

They pointed out that it was important to have two of them in the clinic as they could work together to take measurements, do the tests and make sure the patient flow was not disrupted.

> Because, since its 2 of us, one will do the Hb what what and the other will be doing all the vitals. So it's not really that difficult

DISCUSSION

This study has found that use of POC HbA_{1c} testing could have potentially averted 30% of patients receiving inappropriate medication or not receiving additional medication. It provides evidence of the scale of incorrect identification of controlled or uncontrolled diabetes that would result from measurement of RBG alone in a real clinical setting. We have established that RBG has a sensitivity of 66% and specificity of 79% compared with POC

HbA_{1c} using a treatment cut-off at HbA_{1c} 8% (64mmol/mol) in this busy diabetes clinic.

The qualitative work found that nurses liked using the analyser and were able to effectively carry out the POC HbA_{1c} testing during routine appointments without holding up clinics. Doctors reviewing the results valued having access to the HbA_{1c} test result to help them make treatment decisions, but the empirical data suggest that they were influenced by blood glucose results in their clinical decision-making.

Comparison with the literature

Previous studies have explored how POC HbA_{1c} testing can be integrated into primary care consultations in low-resource settings in South Africa.[17 18 24] One study demonstrated that POC HbA_{1c} testing leads to more patients receiving immediate feedback and resulted in a small statistically significant reduction in HbA_{1c} of 0.44% (4.8 mmol/mol) after 12 months of POC testing, but the POC testing group did not receive any additional treatment intensification.[17] Furthermore, this reduction in HbA_{1c} may not be clinically significant. The researchers concluded that their work did not support the implementation of POC HbA_{1c} testing in public sector primary care in South Africa. More recently, a trial combining treatment intensification (frequent appointments, feedback of HbA_{1c} and education) and POC testing found that treatment intensification had an impact on HbA_{1c} levels, but POC testing on its own did not.[24] However, immediate feedback of HbA_{1c} was part of both the intervention and control groups, and there is unlikely to be any added benefit from performing the test on a POC device.[20] A third study, which implemented POC testing near Johannesburg,[18] found that participants who received two HbA_{1c} tests showed a significant improvement in HbA_{1c}. In that study, HbA_{1c} fell from 9.7%±2.4 (83 mmol/mol) at their first POC test to 8.4%±2.4 (68 mmol/mol) at the second test, but all participants received POC testing and there was a 38% dropout rate. A qualitative study from 2017 reporting the perceptions of different stakeholders on the implementation of POC testing in rural primary care settings in South Africa, found that there was a need for scale-up of POC testing in rural clinics, but there were some concerns about the reliability of the technologies.[15]

Glycaemic control in our cohort was overall poor, with 65% of people presenting with HbA_{1c}>8%. Poor diabetes control has been reported in other African countries: in Ethiopia 78% of people tested in an outpatients clinic had HbA_{1c}>10%.[25] A chart review in a South African clinic found that 87% of patients had HbA_{1c} above 7%.[26] Other studies have explored how health service organisational factors contribute to patient's dissatisfaction leading to irregular clinic attendance and lying about medication adherence.[16]

Documentation of the analyser recommend a maximum operating temperature of 25°C, yet temperatures in the nurses' treatment room reached 32°C during this study. We do not know whether this may have affected the performance of the analyser but this is something which would need to be considered before roll-out of these technologies, as many clinics do not have temperature control and may reach high temperatures in summer months.[27]

Our qualitative work demonstrated that clinicians could integrate these tests into their clinical practice to deliver testing and act on results. Other researchers have reported that POC testing can improve disease management and access to healthcare in resource-limited settings.[15]

Our study found that in many patients, there was little correlation between RBG and HbA_{1c} which is consistent with previous work in South Africa.[9–11] Data from our cohort gave a sensitivity of 66% and specificity of 79% of using RBG compared with HbA_{1c} at an HbA_{1c} treatment cut-off of 8% (64mmol/mol). Another study reported a higher sensitivity of 77% and a lower specificity of 75%,[9] but they used HbA_{1c} of 7% (58 mmol/mol) as a cut-off for good control.

Costs of these technologies may still be prohibitively high,[17 28] but as technologies develop and costs come down, there is scope for widespread rollout in rural and low-resource settings. Haemoglobinopathies, which are common in some parts of the world, are frequently linked to altered HbA_{1c}. The Afinion analyser used in this study has been shown to perform well in bloods with haemoglobinopathies and does not show any clinically significant biases.[29]

Strengths and limitations

Our study has demonstrated that POC HbA_{1c} testing can be integrated into patient appointments and used for clinical decision-making during the same consultation in a South African primary care setting. Furthermore, it has quantified the degree of incorrect treatment decisions arising from monitoring RBG in a real-world clinical setting.

Our study did not include any follow-up, so it was not possible to establish whether POC testing had an impact on glycaemic control or whether it changed longer-term health outcomes. It has, however, demonstrated that the POC test can be delivered within the timeframe of existing appointments and clinicians reported that they were comfortable making clinical decisions on the POC test result. It presents a realistic care pathway which can be used in future research or roll-out of POC testing on a wider basis.

We did not collect data on frequency of appointments for these participants so we did not know how long since their previous appointment or previous HbA_{1c} test. We did, however, collect information on when the next appointment was scheduled, which allowed us to make a judgement on whether this was congruous participants' RBG and HbA_{1c} test result.

Paper-based records meant it was difficult to retrieve missing data and resulted in incomplete data collection. Paper-based patient records are a real limitation of healthcare in this resource-limited setting and the impact

missing patient folders has on care has been reported in other studies.[16]

In the qualitative data collection, we were limited to the clinicians who were working at the clinic while the study was ongoing. That means that we only collected views from two nurses and five doctors, whose views may not be representative of all clinical staff.

Clinical implications and future research

In our study, clinicians clearly recognised the limitations of using blood glucose for making their clinical decisions as they could not be sure whether the patient had eaten before attending the clinic. Although clinicians understood the value of having an HbA_{1c} test result, some clinicians were still heavily influenced by RBG when making clinical decisions evidenced by the quantitative findings. This study has found that there was discordance between what clinicians said in qualitative interviews and how they acted to make treatment decisions. The reasons for this remain unclear, but this may be because HbA_{1c} results which clinicians usually have access to, are from the patient's previous appointment which may have been several months ago. This means they may be reluctant to place too much importance on this in their clinical decision-making compared with the blood glucose level from that day in their usual care practices. A future POC HbA_{1c} intervention should provide comprehensive guidance and training to clinicians on decision-making on the test result and consider not giving clinicians access to RBG results. For those who are insulin treated, an alternative to POC HbA_{1c}, where it is unavailable or information about glucose levels are needed, may be structured self-monitoring of blood glucose where there is some proof-of-principle evidence of its use to improve glycaemic control in similar settings.[30] As technologies develop and become cheaper, non-invasive, continuous or flash monitoring could become an option for use in low-resource settings.[31]

Conclusion

This work demonstrates the importance of having an HbA_{1c} test result for clinical assessments in primary care diabetes appointments. It confirms previous reports that a single RBG result should not be relied on to make valid decisions about diabetes control and suggests that the use of POC HbA_{1c} testing should be considered for diabetes monitoring and management.[9]

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