EVALUATING POINT OF CARE TESTING FOR GLYCOSYLATED HAEMOGLOBIN IN PRIMARY CARE FACILITIES IN THE WESTERN CAPE

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Declaration

I, the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval for the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number: N13/02/026)

Signature

Date: 15/06/2015

ABSTRACT

Introduction: Diabetes Mellitus makes a significant contribution to the burden of disease in South Africa. Monitoring of glycaemic control with HbA1c is imperative in the management of diabetes. Presently, there are no facilities for point of care testing for HbA1c in Western Cape and there are concerns about the cost, feasibility and technical quality of point of care testing.

Aims and objectives: The study aimed at evaluating the costs and consequences for quality of care of introducing point of care testing for HbA1c in patients with diabetes at community health centres in the Western Cape.

Methods: This was a quasi-experimental study with four community health care centres, two matched control sites and two intervention sites. A point of care testing machine for HbA1c was introduced to the intervention sites for 12 months. Patients were randomly selected from the diabetes register in the intervention (N=150) and control sites (N=151) respectively and data collected from patient records. Focus group interviews were done at the intervention sites. Technical quality and cost implications were also evaluated.

Results: Point of care testing for HbA1c in primary health care was feasible and resulted in more immediate feedback to the patients about their level of control ($p<0.05$). The point of care group had better glycaemic control ($p=0.02$) though this needs further follow up. Point of care testing did not lead to any change in the frequency of testing or change in clinical practice. Cost analysis showed that R824.33 was saved per 100 tests by using the point of care testing machine when compared with laboratory testing for the same number of tests.

Conclusion: The study demonstrated the feasibility of introducing point of care testing for HbA1c in primary care. Point of care testing resulted in more immediate feedback of results to the patient and possibly better glycaemic control. It however did not lead to change in clinical practice and patient education. The technical quality compared favourably with laboratory testing for HbA1c.

INTRODUCTION

Diabetes Mellitus is a complex, chronic condition requiring routine monitoring to ensure disease control and to minimise, avoid or delay associated complications. These complications include retinopathy, renal failure, neuropathy, foot ulceration and limb amputation, heart failure, myocardial infarction and cerebrovascular events.(1) The International Diabetes Federation estimated that in 2011, 366 million people worldwide were living with diabetes mellitus, 80% in low and middle income countries, and gave a projected estimate of 552 million people by 2030. Diabetes Mellitus is an important contributor to the burden of disease in South Africa with an estimated prevalence of 6.5% for adults aged 20 to 79 years.(2) Significant disparities exist between the different population groups, with prevalence of up to 33% being recorded in at least one urban community.(3) In addition, 50 to 85% of people with DM (especially in rural areas) remain undiagnosed.(4)

Glycosylated haemoglobin (HbA1c) measurement shows the average blood glucose levels over the last three months, corresponding with the half-life of red blood cells. In the South African public sector, random blood glucose is commonly used to make clinical decisions about glycaemic control in order to guide treatment during patient visits. This is because HbA1c tests have either not been done, or the results are not yet available or are out of date. The best value of random blood glucose to predict control (HBA1c <7%) is 9.8mmol/l with a sensitivity of 77% and a specificity of 75% (5), which implies that even in the best of circumstances the assessment of control will be wrong in up to a quarter of patients. This highlights the importance of having HbA1c tests as a more accurate assessment of glycaemic control over the previous 3-4 months and to guide treatment decisions during patient consultations. It has been shown that the development and progression of complications in people with diabetes, particularly micro-vascular conditions, are closely related to glycaemic control and HbA1c levels.(6) American guidelines recommend checking HbA1c levels twice a year in diabetic patients who have good glycaemic control and quarterly in diabetic patients whose treatment changes or who are not controlled.(7) South African guidelines recommend that HbA1c be checked every three months if uncontrolled or whenever treatment changes. It should be checked at least six monthly if HbA1c meets the target of <7%.(4) Small but sustained reductions in HbA1c over 10 years can lead to significant reduction in risks as follows: 25% for micro-vascular risks, 16% for myocardial infarctions, 21% for retinopathy, 33% for albuminuria and 12% for all risks.(8) For each 1% reduction in HbA1c, there is a relative risk reduction of 21% for any diabetes related end point, 21% for diabetes related death, 14% for myocardial infarctions and 37% for micro-vascular complications.(9)

The American Diabetes Association recommends the use of point-of-care testing for HbA1c to allow for timely decisions on therapeutic changes. (7) Point-of-care testing is investigation at or near the site of patient care. The aim is to provide accurate test results that are convenient and immediately available. Point-of-care testing for HbA1c has evolved and resulted in relatively cheap and portable hand held instruments, which have been shown to be reliable and accurate.(12) Research has shown that availability of HbA1c point-of-care test results during the same visit is associated with improvement in glycaemic control of up to 2% in HbA1c over 90 days.(6,10) Point-of-care HbA1c testing improves glycaemic control on a short term basis (<1.5 years) as well as on long term basis (3.5 years), thus delaying the onset and extent of complications.(11) In a pilot study in Atlanta,

United states of America, point-of-care testing has also been linked to improved primary health outcomes in an urban community health centre that served low income patients.(11) Point-of-care testing can improve communication and collaboration between the patient and provider on management of the disease (17), and ensures significant benefit from immediate education and treatment adjustment during scheduled doctor visits.(15) Point-of-care testing for HbA1c can also save the patient time by reducing the number of clinic visits and save the health care practitioner the administration time of obtaining laboratory results telephonically, reviewing patient records or mailing the patient.(15) Point of care testing has been found to be acceptable and feasible to physicians and other staff members.(15) Point of care testing has also been associated with improved patient experience and satisfaction with their healthcare.(17) Despite these advantages, the cost of point of care testing on site may be up to three times the cost of using the normal laboratory service.(10)

Despite the evidence base outlined above, most of the research has been performed in high-resource settings and more developed primary healthcare systems. There is little evidence on whether such testing can achieve similar benefits for patients in low resource settings and whether investing in this would be a cost-effective strategy. The local Department of Health have specifically requested that research be done in our context into the feasibility, technical quality, costs and consequences of using point of care testing for HbA1c.

AIM AND OBJECTIVES

The study aimed to evaluate the costs and consequences for quality of care and glycaemic control of introducing point-of-care testing for HbA1c in diabetic patients at community health centres in the Western Cape. Specific objectives included:

1. To evaluate the technical quality of point-of-care testing in primary care.

2. To explore the feasibility of introducing point-of-care testing for HbA1c in primary care.

3. To evaluate the effect of point-of-care testing for HbA1c on the percentage of patients receiving an annual HbA1c test.

4. To evaluate the effect of point-of-care testing for HbA1c on treatment intensification and patient education.

5. To evaluate the effect of point-of-care testing for HbA1c on glycaemic control as measured by HbA1c.

6. To evaluate the cost implications of introducing point-of-care testing for HbA1c in primary care.

METHODS

STUDY DESIGN

This was a quasi-experimental study with purposively selected control and intervention health centres. This research assignment reports on half of the study which was conducted by the registrar

responsible for two of the paired community health centres. The results from the other two sites will be reported by another registrar. Once the two research assignments have been independently examined the results will be combined for publication. Both registrars conceptualised the methods to ensure compatibility, but conducted the study and analysed the results independently.

SETTING

The study was located in the Cape Town Metropolitan District Health Services, which cater for patients with diabetes through a network of 45 community health centres. These community health centres usually see patients with diabetes on a specific "club" day and have between 500 and 1500 patients on the club register. Patients have routine tests performed by nurses when they attend the club (e.g. urinalysis, blood pressure, weight, random capillary blood glucose) and are then usually seen either by a clinical nurse practitioner, if reasonably well controlled, or by a doctor if poorly controlled. HbA1c is meant to be checked once a year to assess overall control and a blood sample taken and sent away to the laboratory. Audits of diabetes in the metropolitan district found that 47% of patients had received an annual HbA1c test in 2012, 59% in 2013 and 70% in 2014 (16). The results from the laboratory are returned to the health centre a few days later and given to the clerks to file in the patient records. The result is then only available when the patient is next reviewed. Most patients are seen routinely three to six monthly, but if poorly controlled, may be seen sooner. Well controlled patients receive pre-packaged medication from the chronic dispensing unit and obtain their medicines directly from the pharmacy or even from community based support groups who deliver the medicines to them at home. Health education is provided by the clinical nurse practitioners or doctors individually on an ad hoc basis. In some centres, health promoters provide talks in the waiting rooms on diabetes or hold group diabetes education. Referral to health promoters and visiting dieticians for individual consultations are also done. Occupational therapists in some centres have also taken initiatives around patient education and lifestyle. In the two community health centres in this article, the patients received talks in the waiting room on chronic diseases and lifestyle modifications in general. Appointments had to be made to see the dietician on another clinic day and most of the counselling and patient education around diabetes care happened during consultations with nurses or doctors.

STUDY POPULATION

The study population was adult patients (>18 years of age) with type 2 diabetes mellitus, who had been attending the community health centres for treatment for at least a year prior to commencement of the study.

SAMPLE SIZE CALCULATION

A sample size calculation was based on having 90% power to detect a 1% difference in HbA1c (SD 2.229) with a p value of 0.05 as significant. This outcome was chosen for the calculation because we had accurate data on its standard deviation and it would require a larger sample size than was likely to be needed for the other outcomes.

This calculation suggested that 106 patients were required in the control and in the intervention groups (total of 212). If we assume that only 40% of the patients selected had an HbA1c test in the last year, then a sample of 265 in each arm would achieve a sample of 106 with an HbA1c result. In

order to ensure a sufficient sample size with an HbA1c result, 300 patients were randomly selected in each arm.

SELECTION

The community health centres (CHC) were chosen from the same sub-district and therefore served similar communities. Selection of the intervention site was based on the presence of the registrar at that site and the control site was selected to be as similar as possible in terms of the service provided. Health centres also had to be willing to participate. This research assignment reports on Strand CHC (intervention site) paired with Gustrouw CHC (control site).

At each health centre, 150 patient records were randomly selected from the club register using computer generated random numbers for inclusion in the study. The staff at the health facilities were not aware of which patients were selected for the study.

INTERVENTION

The machine used in this study was the Siemens DCA Vantage point of care (POC) test analyser. It has a time to HbA1c result of six minutes and is able to detect results within the range of 2.5% to 14%. It weighs 3.8kg and power requirements are 100-240 Volts Amperes. Figure 1 shows the analyser in situ at the health centre.

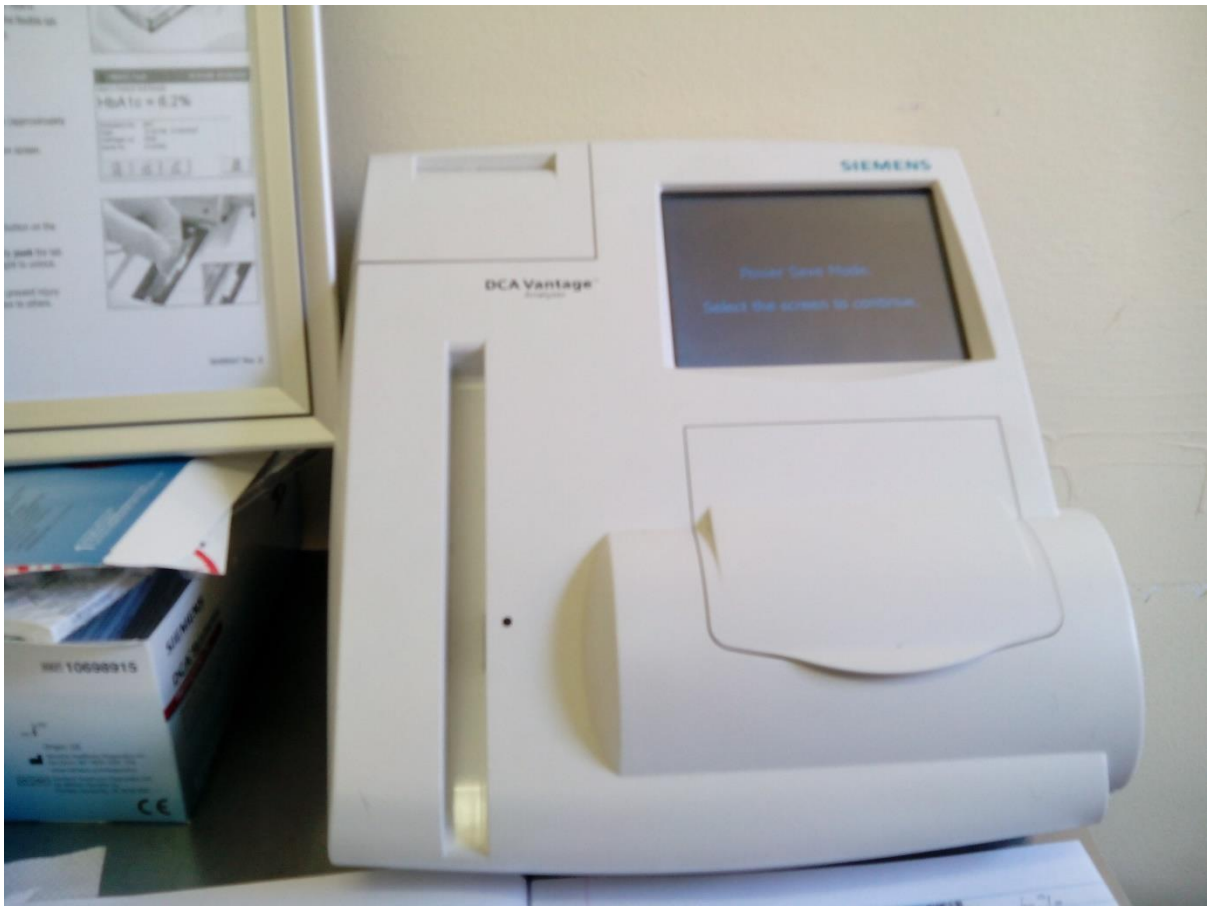

Figure 1: The Siemens DCA Vantage point of care (POC) test analyser

At the two health centres that were selected for the intervention, two to three members of the chronic care team were identified to perform the POC testing. They were trained on how to operate the POC machine by trainers from Siemens and received certificates of competency on completion of training. The location of the POC machine and its integration into the process of care was negotiated with the local chronic care team during a site visit so that it was appropriate for their specific context.

When the POC testing was implemented, it eliminated the need for random blood glucose testing with the glucometer at that visit. The time taken to perform the POC test was offset by the time taken to perform a random blood glucose and reduced the perception that the POC testing was additional work. In addition, the cost of performing a random blood glucose test was saved and may partly negate any additional cost of the HbA1ac test strip. POC testing was performed according to a standardized operating procedure with the goal of performing a routine HbA1c test once a year in all patients as recommended by the Metropolitan District Health Services in Western Cape. Additional tests could be performed if the doctor felt it was clinically necessary. One annual test was expected as this was the policy of the local District Health services, despite guidelines recommending more frequent testing.

The HbA1c test result was entered into the patient record and the patient was then managed according to the usual guidelines and management practice at the health facility. No attempt was made to provide additional training in the management of diabetes and interpretation of the HbA1c test result as the study aimed to investigate the effect of providing POC testing and not more intensive guideline implementation.

The technical quality of the point of care machine for HbA1c was assessed using internal quality assessment which involved using control reagents and external quality assessment which involved doing a point of care test as well as a laboratory HbA1c on a chosen patient. It was agreed on that the internal quality assessment be done twice a week for the first month and then weekly subsequently. The external quality assessment was to be done monthly on one of the usual club days for diabetics.

The researcher was a family medicine registrar working at the community health centre, who was able to assist with the introduction of POC testing and provide regular support during the year of the study.

DATA COLLECTION

Data was collected retrospectively from medical records. Baseline data was collected for the 12 months prior to commencement of the study as well as after the POC testing machine had been operational at the health centre for 12 months. The following data were collected from the medical records at baseline:

- Demographic data (age, sex)
- Clinical data (height, weight, blood pressure, random blood glucose, presence or absence of proteinuria, serum creatinine, total cholesterol, other co-morbid conditions and presence or absence of associated diabetic complications)

The following data was collected from the medical record at baseline and follow up:

- Number of HbA1c tests performed in the previous 12 months
- Last HbA1c test result (within previous 12 months)
- Medication prescribed (metformin, gliclazide, insulin)
- Dose of medication prescribed (metformin, gliclazide, insulin)
- Referral for diabetes counselling recorded during the previous 12 months (this was from the practitioner to a counsellor in or outside the health centre such as a health promoter or a dietician).
- Record of diabetes counselling by the practitioner within consultations during the previous 12 months

Data was also collected on tests done to assess the quality of the POC tests:

- Results of weekly control tests for normal and abnormal values (internal quality control tests)
- Results of tests done on a monthly basis where a patient sample was sent to the lab for HbA1c test as well as a POC test and both results documented (external quality control).

After the chronic care team had used the POC testing machine for 12 months, a focus group interview was held to explore their experience. The focus group interview explored the practical issues faced in introducing and using the POC machine and the perceived impact on the quality of care. The interview was conducted by an independent interviewer, audio recorded and then transcribed.

The cost of POC testing was determined by directly observing the time taken to perform the test and by obtaining the costs of equipment and materials used to perform and record the tests. The cost saved of any materials that were not used (random blood glucose strips) was also determined. The cost of the laboratory test was also determined for comparison.

DATA ANALYSIS

The primary outcome of the study was the difference in % of patients who received an HbA1c test to accurately determine their glycaemic control in the last 12 months.

Secondary outcomes included:

- Difference in % of patients receiving more than one HbA1c test in the previous 12 months
- Difference in treatment intensification as measured by the % of patients started on a new medication to lower glucose
- Difference in treatment intensification as measured by the difference in mean dose of metformin, gliclazide or insulin
- Difference in the % of patients referred for counselling (diabetes health education)
- Difference in the % of patients with counselling recorded in the consultation
- Difference in the mean HbA1c result

Data was entered into an Excel spread sheet by the researcher. Data was cleaned and checked by the researcher prior to analysis. Data analysis was performed by the Biostatistics Unit at the Faculty of Medicine and Health Sciences using Statistica version 13.

Descriptive statistics reported on frequencies and percentages or means and standard deviations. Both categorical and continuous data were paired at baseline and follow up and any change in category or numerical difference evaluated. Inferential statistics were then used to compare the differences between the intervention and control groups. Pearson chi square test was used to compare categorical variables between the two groups. Continuous numerical data were analysed using the t -test of proportion if normally distributed. If not normally distributed, the two sample Wilcoxon rank-sum (Mann Whitney) test was used for analysis. Statistical significance was determined by a p value<0.05.

The cost of testing was analysed based on the time taken to perform the test and the salary of the nurse performing the test, as well as the costs of all materials used. These costs were then compared to the costs of laboratory testing and any costs saved in terms of not performing the random blood glucose.

Qualitative data was transcribed verbatim and checked against the original audio recording. The data was then analysed using an abbreviated Framework Method (familiarization, thematic index, coding, charting, interpretation) as there was only one data source.

ETHICAL CONSIDERATIONS

The Health Research Ethics Committee at Stellenbosch University approved the study (Ref N13/02/026). Permission to conduct the study was also obtained from the Department of Health and the facility managers of the health facilities.

RESULTS

STUDY SAMPLE

Data was obtained from 301 patients with type 2 diabetes in the two community health centres, 150 from the intervention site and 151 from the control site. The mean age of the study sample was 57.9 years, 181 (60.1%) were females and 120 (39.9%) were males. Table 1 presents a profile of key diabetes indicators in the study sample.

Table 1: Baseline profile of the study sample

Variable	All N= 301 Mean (SD)	Intervention N= 150 Mean (SD)	Control N= 151 Mean (SD)
Age	57.9 (12.6)	56.5 (13.2)	59.3 (11.8)
Body Mass Index (Kg/m2)	32.6 (7.0)	33.1(7.3)	31.9 (6.6)
Random blood glucose (mmol/L)	10.4 (4.4)	10.8 (4.5)	9.9 (4.3)
Systolic BP (mmHg)	146.7 (22.3)	145.8 (22.5)	147.5 (22.5)
Diastolic BP (mmHg)	83.8 (13.1)	84.0 (14.2)	83.5 (11.9)
Total cholesterol (mmol/L)	5.0 (1.1)	5.0 (1.0)	5.0 (1.3)
Creatinine (mmol/L)	78.8 (67.5)	75.6 (57.3)	83.7 (80.9)
	n (%)	**n (%)**	**n (%)**
Male	120 (39.9)	60 (40)	60 (39.7)
Female	181 (60.1)	90 (60)	91 (60.3)

Table 2 presents comparative data between the two community health centres showing baseline data and follow up data in the facilities.

Table 2: Comparative data for control and intervention sites at baseline and follow up

Variable	Control Baseline N=151 n (%)	Control Follow up N=151 n (%)	Intervention Baseline N=150 n (%)	Intervention Follow up N=150 n (%)
Metformin (Yes)	138 (91.4)	133 (88.1)	133 (88.7)	134(89.3)
Gliclazide (Yes)	74 (49)	82 (54.3)	63 (42)	72 (48)
Protaphane (Yes)	28 (18.5)	30 (19.9)	34 (22.7)	38 (25.3)
Actraphane (Yes)	39 (25.8)	44 (29.1)	30 (20)	28 (18.7)
Had test for HbA1c (Yes)	77(51)	65 (43)	132 (88)	100 (66.7)
More than 1 HbA1c (Yes)	4 (2.6)	3 (1.99)	8 (5.3)	2 (1.33)
HbA1c result given (Yes)	59 (39.1)	50 (33.1)	123 (82)	86 (57.3)
Referred for counselling (Yes)	2 (1.2)	0 (0)	13 (8.7)	2 (1.33)
Counselled in consultation (Yes)	49 (32.5)	64 (42.3)	111 (74)	105 (70)
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
HbA1c result (%)	9.1 (2.3)	9.3 (2.4)	8.4 (2.02)	8.1 (2.1)

As seen in table 2, fewer patients had HbA1c tests done in both groups at follow up. However, at follow up, there were 61 (40.7%) patients in the intervention group who received their result on the same day compared to 0 (0.0%) patients in the control group (p -value=0, <0.05). This shows statistical significance. POC testing results in more immediate feedback to the patients about the level of their glycemic control.

Table 3 presents differences in health care workers' use of HbA1c testing in both groups. There was no statistical difference in terms of the frequency of testing, which was the primary outcome for the study. There was, however, a significant difference in the mean value of HbA1c (p=0.02) due to a small decrease in the intervention group combined with a small increase in the control group.

Table 3: Comparing use of HbA1c testing in intervention and control groups

Variable	Change in Intervention N=150 n (%)	Change in control N=151 n (%)	P value
HbA1c test done (Yes)	-32 (21.3)	-12 (7.9)	
More than 1 HbA1c test performed (Yes)	-6 (4)	-1 (0.67)	0.45
HbA1c result given (Yes)	-37 (24.7)	-9 (5.96)	0.55
	Mean (SD)	**Mean (SD)**	
HbA1c (%)	-0.6 (1.8)	0.4 (2.0)	0.02

Table 4 compares the two groups in terms of treatment intensification and only shows a statistical significance for use of Metformin (p=0.03). This difference however was due to treatment reduction in the control group rather than intensification in the intervention group. The difference in use of

Actraphane approached statistical significance (p=0.06), but there was no other effect on treatment intensification.

Table 4: Comparing intervention and control groups for treatment intensification

Variable	Change in intervention N =150 n (%)	Change in control N= 151 n (%)	P value
On Metformin (Yes)	1 (0.7)	-5 (3.3)	0.03
On Gliclazide (Yes)	9 (6)	8 (5.3)	0.83
On Protaphane (Yes)	4 (2.6)	2 (1.3)	0.81
On Actraphane (Yes)	5 (3.3)	-2(1.3)	0.06
	Mean (SD)	**Mean (SD)**	
Metformin dose (mg)	148.1 (768.7)	-132.1 (910)	0.18
Gliclazide dose (mg)	75.2 (168.7)	55.5 (163.2)	0.44
Protaphane dose (IU)	5.2 (11.1)	3.4 (12.4)	0.76
Actraphane dose (IU)	-53.6 (32.5)	-63.5 (40.4)	0.20

Table 5 shows the differences in patient education and counselling between the groups. Although the groups differed significantly, this was due to deterioration in referrals for counselling in the intervention group and an improvement in counselling in the consultation for the control group.

Table 5: Comparing intervention and control groups in terms of patient education and counselling

Variable	Change in control N=151 n%	Change in intervention N=150 n%	p value
Referred for counselling	-2 (1.3)	-11 (7.3)	0.01
Counselling in consultation	15 (9.9)	-6 (4)	0.008

TECHNICAL QUALITY

For the internal quality assessment of the expected tests, only 19.6% of the normal controls and 23.2% of the abnormal controls were done. All the values (100%) of the control tests were within the acceptable range for normal (between 4.2 and 6.4%) and abnormal controls (between 8.9 and 13.3%). The mean HbA1c result for the normal control values was 5.3% with a standard deviation of 0.42 while the mean for the abnormal control values was 10.8% with a standard deviation of 0.29.

For the external quality assessment only 33.3% of the expected tests were done. The Spearman correlation coefficient between the laboratory tests and point of care test results in the external quality assessment was 0.8, indicating a strong association**.**

COST ANALYSIS

Table 6 shows the cost of performing 100 HbA1c tests with the point of care machine and can be compared to Table 7, which shows the possible costs associated with performing 100 laboratory test as well as random blood glucose tests. The difference in cost was R824.33, showing that point of care testing for HbA1c saved costs. Time and costs of drawing annual bloods (for creatinine and

cholesterol) was included as this would still have to be done routinely. Time required to draw bloods and do tests were based on the observation and timing of the health care workers as they routinely carried out these procedures. Other saved costs include papers for printing laboratory results and associated costs of transport of blood specimens to the laboratory. The cost of electricity to run the machine was difficult to calculate and was not included, but would not add significantly to the cost. Point of care testing did not result in increase in the cost of additional medical waste.

Table 6: Cost of performing 100 HbA1c tests using the point of care machine

ITEM	RATIONALE FOR COST CALCULATION	COST OF 100 TESTS
POC test Analyzer	Cost of machine R24,200 Average lifespan of 7.5 years 476 tests done in 12 months	R677.94
Cartridges	Unit cost of R68	R6800
Lancets	Unit cost of R2.28	R228
Cotton swabs	Unit cost of R0.60	R60
Webcols	Unit cost of R0.11	R11
Cost of incremental time taken to run test (4minutes)	Based on salary scale of a professional nurse	R965.30
Cost of time taken to draw blood for cholesterol and creatinine (5minutes per patient)	Based on the salary scale of a professional nurse	R1206.58
Total		R9948.82

Table 7: Cost of performing 100 laboratory tests and random glucose tests

ITEM	RATIONALE FOR COST CALCULATION	COST OF 100 TESTS
Laboratory HbA1c test	R87.69 per test	R8769
Blood glucose machine strips	Unit cost of R3	R300
10 ml syringe	Unit cost of R0.33	R33
Needles	Unit cost R0.10	R10
Cotton swabs	Unit cost of R0.60	R60
Webcols	Unit cost of R0.11	R11
Cost of time taken to draw blood for HbA1c, creatinine and cholesterol(5 minutes per patient)	Based on the salary scale of a professional nurse	R1206.58
Cost of time taken to do finger prick blood glucose test (2 minutes per patient)	Based on the salary scale of a staff nurse	R383.57
Total		R10,773.15

OBSERVATIONS AND FEEDBACK FROM STAFF

The point of care machine was put in place at the intervention site immediately after the training. The initial machine provided was faulty and was replaced within 2 days during the first week of the study. There were no further technical faults reported during the rest of the year.

At the beginning of the study, the machine was kept in the consultation room of the clinical nurse practitioner in charge of the diabetes club. Later in the year, other nurse practitioners and professional nurses were trained on the use of the machine and the machine was subsequently moved to the preparation room to ensure a smoother flow in the organization of care for the patients. The cartridges were delivered to the facility on a monthly basis. There was, however, a six week period where cartridges were not delivered to the facility, but were erroneously delivered to another facility instead.

The following themes were derived from the focus group interview.

Ease and feasibility of using the machine

The respondents reported that the point of care machine was quite easy to use and introduce into primary care practice. They also saw the benefits for the patients of being able to do the test on site and have results immediately available:

> *"The test was easy and quick, and my, the other sisters also quickly adapted to using it".*

> *"It was a very, it's an easy test, it's not difficult".*

Benefits of the point of care testing for the patients

The respondents reported that patients benefited from having the test done and receiving the result on the same day as their clinical visit. These benefits included reducing number of visits, saving time and being able to have treatment modified on the same visit based on the result of the test.

> *"Okay, well, it did definitely benefit, particularly in patients where you, where you had to start them on insulin and you've, you're not sure for a while whether the oral medication was sufficient. And then you could just right there, start them with insulin, instead of letting them come back in a month or two".*

> *"Saves time and a lot of complications for the patient".*

> *"And then, if we can do the HbA1c immediately, we can adjust the medication immediately".*

Time required to carry out test and effect on organization of care

The respondents reported that the test usually took about ten minutes or less. This was inclusive of the six minutes that it took for the machine to run the tests.

> *"It's a prick and it takes six minutes, and to write it down in the folder, a turn-around time of no more than ten minutes".*

The actual time taken on the test itself was six minutes. However, during the six minutes in which the machine was running the test, the nurse was able to do other things for the patient. The incremental time to do the test was thus, four minutes.

> *"…because when I pricked the patient, and the machine was running, I would do other things- fill in forms, do my notes, weigh the patient…".*

> *"When I do the tests, when I'd run my club, I do my own observations in the room. So while I'm pricking the finger, and doing the BP and measuring and weighing the patient..."*

Point of care testing and patient experience

The respondents said that patients were more satisfied with the point of care testing because it felt like the service was improving and they did not have to have a formal blood sample taken:

> *"The patients feel that we are very scientific and they feel that we are advancing, progressing".*

> *"And it's also, they prefer it, because they don't have to, you know, blood doesn't have to be taken. Here, it's just a finger prick test".*

The health care workers also believed that having the point of care machine is a good motivation for the patients to maintain good glycaemic control.

> *"And the people are talking about the machine as a 'catching you out when you cheat' machine".*

> *"You know, it's good for them to know, okay, what they've done is working and the life style changes has made a difference and so on. And then, they are encouraged to keep it up, I think".*

Point of care testing and health care workers' recommendations

The health care workers also expressed the wish to have point of care testing, not just for HbA1c, but for serum cholesterol and creatinine as these needed to be done on an annual basis:

> *"The not so good thing was that I did an HbA1c today, but I still had to draw blood to have the creatinine and the cholesterol done, which is like double work".*

> *"So if, it would be wonderful, you could swipe it, and it does all three. I mean, that would be wonderful".*

DISCUSSION

Point of care testing for HbA1c resulted in significantly more immediate feedback to the patients about the level of their glycaemic control. However POC testing did not lead to an increase in the percentage of patients who had the test and the availability of POC testing did not tempt staff to break with the policy of the district health services and perform testing more frequently. The use of POC testing did not lead to any effect on treatment intensification, patient education or counselling.

Although there was a significant difference in glycaemic control, it is hard to attribute this to the effect of the intervention and further follow up of the groups will be needed. Studies, however, have demonstrated that the availability of HbA1c test results provided during the same visit is associated with improvement in glycaemic control. (10) Four observational studies of over 5700 patients with diabetes, in which there was immediate feedback of results to patients, all showed significant reductions in the HbA1c results. (11, 19-21) One of these studies demonstrated maintenance of improved HbA1c concentrations for a period of four years. (21)

This study also showed that point of care testing is feasible in primary care as the introduction of a point of care testing machine for HbA1c was acceptable to the health care workers and the patients. It provided the convenience of knowing the test result in one clinic visit. It fitted well into the daily routine of care at the clinic when located in a central triage room and was associated with reduced patient visits and improved patient satisfaction. Studies have shown that patient satisfaction is improved using point of care testing and personal knowledge of an individual's HbA1c levels is associated with better outcomes (reduced HbA1c levels).(25-27)

This study showed a cost savings of R824.33 per 100 tests with the use of point of care testing machine compared to laboratory testing. . A Swedish before and after study compared the economic costs and benefits of implementing HBA1c home testing and found a reduction in costs due to fewer clinic visits, reduction in total treatment costs, time saved and reduced labour costs in administration and sampling, reduced travel costs and a reduction in mean HbA1c levels. (24) Another study where patients were randomised to receive instant results for HbA1c or routine care found a non-statistical cost difference of diabetes related care of 390 pounds in the control group and 370 pounds in the point of care testing group. (10)

The internal and external quality assessments were not done as frequently as required, which suggests that stronger supervision of the technical quality requirements was needed. Nevertheless the results suggested that the technical quality was adequate. The DCA Vantage and similar devices have been shown to have an acceptable technical quality when compared to laboratory tests. (22-23)

The study was a quasi-experimental design and one of the limitations of the design is the lack of random allocation to intervention or control groups which makes the possibility of confounding factors more likely. The presence of confounding factors in the organisation of care or behaviour of health workers is seen in the unexpected improvement in counselling in the control group. The improvement in turn-around time however is consistent with the expected effect. The quality of medical records was not always adequate and the researcher sometimes struggled with extracting the needed information from the medical records. The focus group discussions were conducted by the other registrar who was conducting the study at the alternative sites. He was unknown to the interviewees, but may have had a bias towards more positive feedback.

No definitive recommendations can be made as yet from the results presented here. The point of care testing resulted in more immediate feedback to the patient and further follow up is required to determine if this translates into better glycaemic control. The test is feasible to perform and appears to be cheaper overall than the laboratory testing. The availability of the HbA1c result could not overcome clinical inertia in terms of treatment intensification or additional patient education and counselling. Likewise, it appears that the frequency of testing may be more related to the way care is

organised than the availability of point of care testing. If point of care testing was implemented, more attention would be needed to ensure compliance with the requirements for technical quality control.

CONCLUSION

This study showed that introducing point of care testing for HbA1c in primary care is feasible. The test was positively received by the health care workers as well as the patients. There was a small improvement in the glycaemic control of the point of care testing group, which requires further follow up. Point of care testing for HbA1c did not lead to increased treatment intensification or patient education and counselling. The annual percentage of patients receiving the HbA1c test did not increase as a result of point of care test availability. Although there was insufficient compliance with the technical quality control, the results obtained suggested the quality was acceptable. The study also showed that R824.33 was saved per 100 tests performed by using a point of care machine versus laboratory testing. This suggests that point of care testing may be more cost effective relative to laboratory testing. Point of care testing for all three annual bloods (HbA1c, cholesterol and creatinine) may be more cost effective and time saving. It is recommended that further follow up of the HbA1c levels of the study groups be done for a further 6 to 12 months to evaluate any emerging differences in glycemic control between the groups.

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