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

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Declaration

I, the undersigned, declare hereby 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: Reference number N13/02/026)

Signature:……..

Date:……

Abstract

Background
HbA1c testing helps to reduce the risk of complications associated with diabetes mellitus and is accepted to be an accurate measure of long-term glycaemic control. Immediacy of results through point of care testing can promote early treatment intensification and lifestyle modification. Currently point of care (POC) testing for HbA1C is not available in primary health care facilities in the Western Cape.

Aim and objectives
The main aim was to explore the effect of POC testing for HbA1C on treatment intensification, patient education, glycaemic control and the amount of patients who would receive an annual HbA1C test. Cost implications and technical quality was also assessed.

Methods
This was a quasi-experimental study comparing clinics with and without POC testing over a period of 1-year. This assignment reports on half of the larger study and presents data from two clinics. A POC machine for HbA1C was introduced at the intervention site. 150 patients (N=300) were randomly selected from each site. Data was collected retrospectively from the patient records for the preceding 12 month period at baseline and follow up. A peer focus group at the intervention site explored experience and perceptions of staff with POC testing. Technical quality was assessed by monitoring compliance with internal and external quality control.

Results
There was a significant increase in the % of patients receiving an annual HbA1C (control - 8%, POC +24%; $p<0.001$). The turn-around time for HbA1C results was greatly reduced (control 38.2 days, POC 1.2 days; $p<0.001$). There was no effect on intensification of treatment or counselling. The effect on glycaemic control must be followed up later. Staff reported that the POC testing was feasible. There was poor compliance with quality control checks. There was an incremental cost to POC testing of R1451 per 100 tests.

Conclusion
The increase in patients having an annual HbA1C test and reduced turn-around time for results will hopefully result in improved feedback to patients and glycaemic control. The lack of a response in terms of treatment and counselling to the results suggests a degree of clinical inertia that should be addressed in other ways. The initial results do not suggest a favourable cost to benefit ratio.

Introduction

Diabetes is a metabolic disorder which is associated with a significant morbidity and mortality; there are 415 million people with diabetes in the world. It is estimated that there will be 642 million people with diabetes in the world by 2040. [1] In addition, the impact will be significant in developing countries where the majority of people with diabetes will be 45–64 years old, typically a person's most productive working years.[2]

The estimated diabetes prevalence for South Africa is 6.5% for adults aged 20-79 years (approximately 1.9 million of 30 million adults).[3] It is a leading cause of blindness, lower extremity amputation, and end-stage renal and cardiovascular disease.[4] For each of these micro- and macro-vascular complications, higher levels of risk have specifically been linked to HbA1c levels >7%; which indicates poor glycaemic control.[5][6]

HbA1c is a valid measure of glycaemic control and in 1993 the Diabetes Control and Complications Trial (DCCT) established that the development and progression of complications of diabetes is closely related to HbA1c levels.[7] HbA1c is an indicator of long-term glycaemic control that healthcare professionals can use to make treatment decisions. The amount of glycated haemoglobin is directly related to the average level of glucose in the blood. Since circulating erythrocytes have an average half-life of 60–90 days, HbA1c can indicate glycaemic control over a 2–3-month period.[8] For this reason measurement of HbA1C has been recommended as an alternative to the traditional random "finger prick" blood glucose level, which provides very limited information of long-term glucose control.

National clinical guidelines from both the United States and South Africa recommend that glycaemic control should be defined as a HbA1c of <7%, with HbA1c levels of > 8% indicating a definitive need for a change in therapy.[9][10][11] Lowering HbA1C, ideally to less than 7%, has been shown to reduce microvascular and neuropathic complications in people with both type 1 and type 2 Diabetics.[12] Patients with type 2 diabetes mellitus with HbA1c levels >7.5% have a 2.5 to 5 fold greater relative risk of developing microvascular complications [7][8] and a 5 fold greater risk of developing peripheral artery disease.[10][11] If the patient's HbA1c is at target and the treatment has not been altered, the HbA1c can be checked every six months.[3][9] If HbA1c is above the target or the treatment has been altered or intensified, the HbA1c should be re-checked after three months.[9][14]

Monitoring has traditionally been via laboratory testing in primary care and in the Western Cape only one test is allowed per year per patient. Results from laboratory testing arrive after the consultation and are therefore unavailable at the time clinical decisions are made regarding ongoing management. Patients must then make an additional visit to receive the result, which creates extra workload for both patients and health workers, or return for their next routine appointment after 3-6 months. At this point the result may not be filed in the patient record and if it is available is somewhat out of date. Clinical decisions based on random blood glucose may be wrong a quarter of the time, which makes this approach difficult to justify.[15] A possible solution to this could be to ask patients to have the HbA1c test done when they collect their last CDU, results will then be available at the clinical visit.

Limitations have been identified in terms of treatment intensification due to traditional laboratory testing including long waiting periods for results and poor follow up of these results with patients. Point of care (POC) testing, however, provides rapid diagnostic information in the clinic in order to enable clinical decisions to be made at the earliest opportunity during patient care and treatment. The rapid processing time of POC HbA1c assays generates HbA1c results in minutes and provides test results during patients' visits. Evidence supports that POC HbA1c testing improves glycaemic control, not only in the short term (less than 1.5 years), but also the long term (3.5 years), potentially delaying the onset and magnitude of complications from the disease.[7] In addition to improving glycaemic control, studies have shown that POC HbA1c testing helps improve communication and collaborative efforts between physicians and patients in managing the disease and results in positive patient satisfaction. [9][12]

Concerns about POC testing include feasibility and costs of introducing it in public sector primary care facilities in the Western Cape. Technical quality of POC testing and the effect on glycaemic control and treatment intensification for patients with diabetes in this setting also needs to be explored and that is the reason for doing this research.

Aim and objectives

This study aimed to evaluate the cost and consequences for quality of care and glycaemic control when introducing point of care (POC) testing for HbA1c amongst patients with type 2 diabetes at community health centres in the Western Cape. Specific objectives were:

1. To evaluate the technical quality of POC testing for HbA1c in primary care
2. To explore the feasibility of introducing POC testing for Hba1c in primary care
3. To evaluate the effect of POC testing for HbA1c on the percentage of patients receiving an annual HbA1c test
4. To evaluate the effect of POC testing for HbA1c on treatment intensification and patient counselling
5. To evaluate the effect of POC testing for HbA1c on glycaemic control as measured by HbA1c
6. To evaluate the cost implications of introducing POC testing for HbA1c in primary care

Methods

Study design

This research assignment reports on part of a larger quasi-experimental study that compared two intervention and two control sites. This research assignment reports on one of the pairs of control and intervention sites, as the other pair was co-ordinated by a separate registrar. The work will be integrated for publication after independent examination of the assignments. Data was collected at baseline and again after a 12-month period for comparison.

Setting

The study took place in the Metropolitan District Health Services, which caters for patients with diabetes through a network of 45 community health centres. Community health centres usually see patients with diabetes on a specific "club" day and can have between 500 and 1500 patients on the club register. Patients have routine tests performed by nurses when they attend the club (urine, blood pressure, weight, random capillary blood glucose) and are then 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 the blood sample is sent away to the laboratory. The most recent audit of diabetes in the Metropolitan District found that 47% of patients had received an HbA1c test in the previous year. The result is returned to the health centre a few days later and given to the clerks to file in the patient record. The result is then only available when the patient is next reviewed. Most patients are seen routinely 3-6 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. Health education is provided by the clinical nurse practitioners or doctors individually on an ad hoc basis. In some centres health promoters provide talks to the waiting room on diabetes or group diabetes education. Health promoters and visiting dieticians may also be referred to for individual consultations. Occupational therapists in some centres have also taken initiatives around patient education and lifestyle.

Study population

The study population included adult patients (> 18 years of age) with type 2 diabetes who had been attending the community health centre for treatment for at least 1-year prior to 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 intervention groups (total of 212). If we assume that only 40% of the patients selected will have had an HbA1c test in the last year then a sample of 265 is required in each arm to achieve a sample of 106 with an HbA1c result. In order to ensure a sufficient sample size with an HbA1c result we will select 300 patients in each arm or 600 in total. As this assignment reports on only one of the pairs the sample size in this study was 150 patients in each arm or 300 in total.

Selection

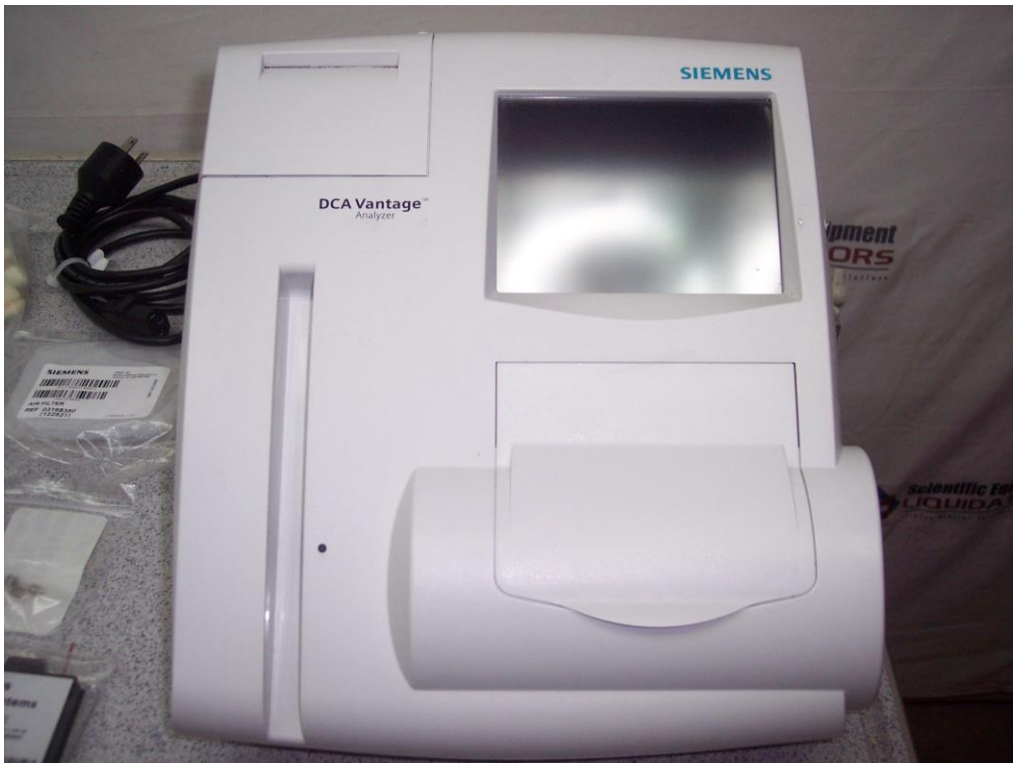
Four community health centres from Helderberg sub-district that were willing to participate were selected from the eight community health centres available. Coming from the same sub-district they were similar in terms of the communities served and services for diabetes. Two health centres were selected for this part of the study: Grabouw Community Health

Centre (intervention) and Macassar Health Care Centre (control). Grabouw Community Health Centre was chosen as the intervention site as it is the clinic I work in as part of the Family Medicine registrar programme; it would make it easier to oversee and facilitate the introduction of POC testing. The intervention centres were therefore selected in terms of the availability of a registrar in family medicine to assist with the research at that location.

At each health centre 150 patient records were randomly selected using computer generated random numbers from the club register for inclusion in the study. Staff members were blind as to which patients were selected.

Intervention

A Siemens DCA Vantage Point of Care test (POCT) analyser was used during the study. The time to obtain an HBA1c result is 6 minutes and it 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**.**



At the health centre that was selected for the intervention two members of staff were identified to perform the POC testing. These staff members were identified with the help of the facility manager and chronic care team. These staff members were trained on how to operate the POC machine by technicians from Siemens who provided a teaching workshop at Helderberg Hospital prior to installation of the POC machine for the study.

The location of the POC machine and its integration into the process of care was negotiated with the local chronic care team so that it made sense for their specific setting. It was decided that the POC machine would be installed in the Chronic Care Unit at Grabouw Community Health Centre for the part of the study that I was involved in. Practically this was the best place to put the machine as we wanted to use the device in the routine

management of the diabetic patients who came for follow up at this clinic. Our clients with diabetes were organised in a "club" system. POC testing for HbA1C would form part of the routine "vitals" done for each patient presenting to this clinic; ensuring that each patient had an annual HbA1C. This ensured the least disruption to the "flow" in the clinic. The clinic staff agreed that this also eliminated "time wastage" for the 6 minutes that it would take to do the POC HbA1C as they could do other interventions such as foot and eye examinations and counselling during this time.

When POC testing is performed it is not necessary to also perform a random blood glucose using the glucometer. The time taken to perform POC test is therefore offset by the time taken to perform random blood glucose and this will reduce the perception that this is additional work. In addition, the cost of performing the random blood glucose test will also be saved and helped to negate any additional cost of the HbA1c test strip. POC testing was performed according to a standardised operating procedure. The goal was to perform a routine HbA1c test once a year in all patients. Additional tests could be performed if the doctor felt it was clinically necessary.

Assessment of the quality of the HbA1c results provided by the POC machine was assessed using internal quality control and external quality control measures. Internal quality control involved using normal and abnormal control reagents; the aim was to do this test twice a week for the first month and subsequently on a weekly basis. External quality control involved doing a POC test which would be compared with a laboratory HbA1c test; this was to be done monthly and the patient would be randomly selected from the patients attending the clinic on the diabetes club day.

The HbA1c test result was entered into the medical record. According to local protocols, those with an HbA1c $\leq$8% were regarded as reasonably controlled, while those with an HbA1c >8% were seen as poorly controlled. Those with an HbA1c >10% were prioritised for intensification of treatment and/or education by the clinical nurse practitioner or doctor.

Data collection

For this part of the study data was collected at 2 intervals in order to allow a comparison of results over time and between the 2 facilities involved. Initially results were collected at baseline with the second set of data being collected after the POC testing machine had been in operation at the intervention site for 12 months. The following data was collected from the medical records and then again retrospectively after the one year period. Data was collected from the medical records using a standardised data collection form.

Data Collected at Baseline:

- Demographic data at baseline (age, sex)
- Clinical data at baseline (type of diabetes, other co-morbid conditions or complications, random blood glucose, weight, blood pressure, total cholesterol, creatinine, proteinuria)

Data Collected at Baseline and Follow Up

- Number of HbA1c tests performed in the previous 12 months
- Last HbA1c test result (in prior 12 months)
- Medication prescribed at baseline and at 12 months (Metformin, Glibenclamide, Gliclazide, Insulin)
- Dose of medications prescribed at baseline and at 12 months
- Referral for diabetes counselling recorded during previous 12 months (this is from the practitioner to another counsellor in or outside the health centre such as a health promoter or dietician.
- Recording of diabetes counselling during consultations during previous 12 months by the practitioner

After the chronic care team had used the POC testing machine for 12 months a focus group interview was held with them to explore their experience of using the POC machine. The chronic care team included one of the family physicians who worked at Grabouw Community Health Centre as well as the nursing staff who were trained in using the POC machine. The invitation to attend the interview was also extended to the facility manager but he was unable to attend. The interview was held at Grabouw Community Health Centre in September 2014 and was conducted in English. The interview was facilitated by an independent research assistant who was also a registrar in family medicine. This focus group interview was semi-structured with an interview guide and explored the practical issues faced in introducing and using the POC machine, the perceived impact on the quality of care, and the perceived cost implications. The interview was audio recorded.

The cost of POC testing was determined by directly observing the time taken to perform the test and by obtaining the costs of the equipment and materials used to perform and record the test. The cost saved of any materials that were not used (i.e. 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, Glibenclamide, 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 then entered into an excel spread sheet by the researcher and checked for any errors. Data analysis was performed by the Biostatistics Unit at Stellenbosch University using the Strata Version 13 analysis program.

Descriptive statistics were used to report continuous data as means with standard deviation and to report categorical data as frequencies and percentages. Inferential statistics were used to compare paired data at baseline and follow up. Normally distributed continuous data was analysed using a t-test and if not normally distributed using Two-sample Wilcoxon rank-sum (Mann-Whitney) test. Categorical data was compared using Pearson's Chi Square Test. Statistical significance was determined as $p < 0.05$.

The costs 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 compared to any costs saved in terms of not performing the laboratory test and random blood glucose.

The single qualitative data source was transcribed verbatim and checked against the original audio recording. The data was then analysed using the framework method (familiarisation, thematic index, and coding, charting, interpretation) and interpreted in terms of the range and nature of opinions, any associations between opinions or explanations for particular viewpoints held.

Ethical considerations

Ethical approval was obtained from the Health Research Ethics Committee at Stellenbosch University with Reference number N13/02/026. The Department of Health and the facility managers of the involved Community Health Centres gave permission for the study to be conducted at the selected sites.

Results

Three hundred patients with type 2 diabetes were randomly selected from two community health centres: 150 from the control site (Macassar Community Health Clinic) and 150 from the intervention site (Grabouw Community Health Centre). Tables 1 and 2 present the baseline profile of this sample with their key diabetes indicators, known co-morbidities and complications.

Table 1: Profile of study sample at baseline

Variable	**All N=300**	**Intervention N=150**	**Control N=150**
Male: n (%)	95 (31.7)	48 (32.0)	47 (31.3)
Female: n (%)	205 (68.3)	102 (68.0)	103 (68.7)
Mean age: years (SD)	55.6 (13.2)	53.6 (12.9)	57.6 (13.3)
Mean BMI: kg/m2 (SD)	31.2 (6.6)	31.9 (5.5)	30.8 (7.0)
Mean weight: kg (SD)	80.2 (17.5)	80.3 (17.4)	80 (17.7)

Mean systolic blood pressure: mmHg (SD)	142.9 (26.3)	148.8 (28.0)	137 (23.0)
Mean diastolic blood pressure: mmHg (SD)	81.6 (12.0)	82.6 (13.8)	80.6 (9.9)
Mean serum creatinine: umol/l (SD)	86.5 (70.0)	71.9 (34.1)	96.4 (85.1)
Mean serum cholesterol: mmol/l (SD)	5.2 (1.4)	5 (1.2)	5.3 (1.6)
Mean HGT: mmol/l (SD)	10.5 (5.0)	11.4 (5.6)	9.5 (4.1)
Mean HbA1c: % (SD)	9.9 (2.8)	9.9 (2.6)	9.9 (3.0)

Table 2: Known co-morbidities and complications in the study sample

Co-morbidities and complications	**Total N=300 n (%)**	**Intervention N=150 n (%)**	**Control N=150 n (%)**
Hypertension	217 (93.1)	90 (84.9)	127 (100)
Hypercholesterolaemia	62 (71.3)	22 (46.8)	40 (100)
Retinopathy	14 (4.7)	4 (2.7)	10 (6.8)
Cataracts	4 (1.4)	2 (1.3)	2 (1.4)
Peripheral Neuropathy	14 (4.7)	3 (2.0)	11 (7.4)
Foot Ulcers	9 (3.0)	1 (0.7)	8 (5.4)
Amputation	5 (1.7)	1 (0.7)	4 (2.7)
Nephropathy	23 (7.7)	4 (2.7)	19 (12.8)
Cardio Vascular Accident	13 (4.4)	2 (1.3)	11 (7.4)
Ischaemic Heart Disease	17 (5.7)	5 (3.4)	12 (8.1)
Congestive Cardiac Failure	22 (7.4)	5 (3.4)	17 (11.5)

Tables 3 present the results for the control and intervention groups for the key outcome variables at baseline and follow up. Table 4 compares the change from baseline to follow up for the two groups where there was paired data and whether there was any statistically significant difference. When the groups were compared at follow up there was a significant difference in turn-around time (control group mean of 38.1 days (SD 29.2), intervention group mean of 1.2 days (SD10.4); $p<0.001$).

Table 3: Measurement of outcomes at baseline and follow up in control and intervention groups

Variable	Control baseline N=150	Control follow up N=150	Intervention baseline N=150	Intervention follow up N=150
HbA1c Results				
Frequency of HbA1C testing in last year n (%)	73 (48.7)	61 (40.7)	49 (32.7)	85 (56.7)
Frequency of more than one HbA1C test in last year n (%)	2 (1.3)	3 (2.0)	0 (0.0)	10 (6.7)
Turn around time for HBA1c result mean days (SD)	52.3 (57.7)	38.2 (29.9)	56.7 (73.1)	1.2 (10.4)
Treatment Intensification				
Frequency of prescribing Metformin n (%)	123 (82.0)	97 (84.4)	132 (88.6)	119 (89.5)
Frequency of prescribing Gliclazide n (%)	67 (44.67)	61 (53.0)	78 (52.70)	77 (57.9)
Frequency of prescribing Protophane n (%)	16 (10.67)	15 (13.6)	28 (18.8)	28 (21.7)
Frequency of prescribing Actraphane n (%)	39 (26.0)	26 (22.8)	25 (16.8)	24 (18.6)
Lifestyle Modification				
Referral for counselling n (%)	27 (18.4)	53 (38.7)	21 (14.1)	25 (19.1)
Counselled in consultation n (%)	82 (55.8)	99 (72.3)	55 (36.9)	88 (66.7)

Table 4: Comparison of control and intervention groups for the change from baseline to follow up

Variable	Change in control Diff [N] (SD) or n/N (%)*	Change in intervention Diff [N] (SD) or n/N (%)*	p-value
HbA1C Results			
Change in frequency of HbA1C testing (change in %)	-12/150 (-8.0)	36/150 (24.0)	<0.001
Change in frequency of more than one HbA1C test (change in %)	1/150] (0.7)	10/150 (6.7)	0.053
Change in mean HbA1C (HbA1c %)	-0.2 [26] (2.1)	-0.01 [26] (1.7)	0.740
Change in Treatment Intensification			
Change in mean dose of Metformin (mg)	-1132.4 [51] (1355.0)	-816.2 [34] (1299.1)	0.209
Change in mean dose of Gliclazide (mg)	-38.1 [32] (176.4)	-4 [20] (179.8)	0.350
Change in mean dose of Protophane (IU/ml)	-6.9 [14] (27.5)	-2.9 [11] (13.5)	0.912
Change in means dose of Actraphane (IU/ml)	-29.6 [26] (35.9)	-1.2 [10] (47.0)	0.152
Change in frequency of prescribing Metformin (% change)	-4/115 (-3.5)	-2 [133] (-1.5)	0.313
Change in frequency of prescribing Gliclazide (% change)	6/115 (5.2)	4 [132] (3.0)	0.108
Change in frequency of prescribing Protophane (% change)	4/114 (3.5)	2 /129 (1.6)	0.555
Change in frequency of prescribing Actraphane (% change)	-2/114 (-1.8)	2 /129 (1.6)	0.162

Comparison in Change of Lifestyle Modification			
Change in frequency of referral for counselling (% change)	27 [134] (20.2)	6 [130] (4.6)	<0.001
Change in frequency of counselling in consultation (% change)	23 [134] (17.2)	34 [131] (26.0)	0.184

For continuous data: Diff = change in the mean; N=number of patients with paired data; SD=standard deviation of the change in mean
For categorical data: n=number of patients that changed; N=number of patients with paired data, %= % of patients that changed

Technical Quality

A total of 54 tests for internal quality control were expected to be done throughout the 12 month period (2 weekly in first month and then weekly for the other 11 months). Only 15 tests were performed, which equates to 29% of the expected tests. Of the tests done all (100%) were within the acceptable range. The acceptable range for normal control was HBA1c 4.2% to 6.4% while the range for abnormal control was HBA1c 8.9% to 13.3%. The NHLS has major concerns about maintenance and calibration of equipment used for POC testing, and these findings would justify their concern.

Only 2 out of the 12 (17%) expected tests for external quality control were performed. These two tests were well correlated (9.8mmol/l for laboratory vs. 10mmol/l for POC; and 7 mmol/l vs. 7 mmol/l). There was insufficient data for a statistical correlation to be analysed.

Costing

The additional costs of testing were analysed based on the additional time taken to perform the test and the salary of the nurse performing the test as well as the costs of all additional materials used (Table 7). These costs were compared to costs saved in terms of not performing the laboratory test and random blood glucose (Table 8). Costs were extrapolated to costs for 100 tests and the final incremental cost calculated as the additional costs of testing minus the costs saved.

Table 7: Cost of performing 100 HbA1c tests using the Point of Care Machine

Item	**Cost per unit for calculation** **Rand**	**Cost of 100 tests** **Rand**
POCT Analyser (with lifespan of 7.5 years)	24200	3227
Cartridges	68	6800
Lancets	2.28	228

Incremental salary cost to perform test if other tasks are performed and testing only requires 3.5 minutes of a staff nurse's time	6.71	671.24
Total cost	109.97	10996.47

Table 8: Costs saved if HBA1c tests performed by POC testing

Item	**Cost per unit for calculation** **Rand**	**Cost for 100 tests** **Rand**
Laboratory HbA1c test	87.69	8769.00
Blood glucose machine test strips	2.90	290.00
10 ml syringes	0.33	33.00
Needles	0.10	10.00
Tubes	0.00	0.00
Salary costs taken to do finger prick blood glucose test on average it takes 2 minutes to do this test	3.84	383.57
Total Cost		9544.97

This calculation is based on the assumption that regardless of the POC machine being available to perform HbA1c tests, an annual Creatinine and Cholesterol blood test would still have to be performed. So currently the costs of performing a blood test as well as the transportation of them will not be saved. The annual HbA1c test is usually taken at the same time as the Creatinine and Cholesterol serum tests but money will be saved when a HbA1c test is requested on more than one occasion during the year in order to assess glycaemic control. The Glucometer is also a valuable tool for the acute management of complications associated with diabetes and would therefore still be required.

Overall POC testing was R1451,50 more expensive per 100 tests performed when calculations are based on the assumptions above. A significant reduction in the costs of the cartridges use for POC testing may be possible if there is a large scale "roll-out" of POC testing and equipment and cartridges are bought in bulk on tender. This could significantly reduce the incremental costs of the test. We also anticipate that the future POC machines will be able to do multiple tests (such as Creatinine and Cholesterol levels) thereby further decreasing the costs of formal testing.

Themes from qualitative interview

The interview group consisted of two members of the chronic care team namely the senior Family Physician who was involved in patient care and the Professional Nurse who was trained to work with the POC machine on a daily basis. The interview was recorded and transcribed by a professional transcriber appointed by the University of Stellenbosch.

Generally there was a positive response in the interview towards POC testing for HbA1c. The perception that the wait time for HbA1c test result was greatly reduced from traditional formal blood testing was the most prominent benefit expressed.

> *"It saves time"*
>
> *"The patients' results are available immediately"*

In terms of organisation the 6 minutes that the test took to execute allowed for foot and eye screening, which was often previously neglected.

> *"While the patients wait for their result, you can do their feet or you can do their eyes, test their urine. I could do any other stuff on the diabetic patients, whilst they were waiting for the result, because the result takes 6 minutes."*

The usage of the POC machine for HbA1c testing led to the formulation of a "register" in which all the HbA1c test results done with the POC machine were recorded. The "register" served as a reference resource that health care professionals were able to consult and this was believed to be a very positive contribution in terms of clinical governance. Patients who had abnormally high HbA1c results and who were "missed" in terms of referral could be identified.

> *"Sister Adonis has created a register which I can consult and have a look and pick up those results that are above a certain level, just to make sure that those are all being identified . So that I've seen as a very positive contribution"*

The staff felt that the machine was very easy to use especially after training.

> *"this machine…. it just is very easy. It's quick and it's fast, and it's easy."*

The test was described as *"a good visual motivator to modify lifestyle habits"* and it was believed to make a significant difference in improving glycaemic control as it *"engaged the patient in the process of glycaemic control"*. Immediate test results made it easier to convey the importance of glycaemic control to the patient as the long wait-time for formal blood test results was reduced.

> "*If you do a test, and the result comes back three months later, the connection between pricking the finger and the urgency in what you're looking for is lost, to an extent. I think the meaning for the patient is possibly easier to convey the importance of what one is dealing with."*

> *"In general, I think the test is a very powerful test, because if we tell somebody now, as you're sitting in front of me, "the test we'll do will reflect the performance plus minus in the last three months," that's a very powerful statement to make.*
>
> *And to engage somebody in this process, because you can analyse it, you can think of the behaviour, you can think of the doctor's input, and I think if it's a test done amongst many, and sent away, the meaning of it is lost."*
>
> *"They were very positive about it, because they were waiting and they were watching the machine, because they want to see their results. The patients were very interested in knowing their result now."*

The patients' experience was described as an *"increased interest in knowing their result and a more positive feeling toward improving their health".*

The Family Physician who was interviewed asked to be included in the training process as he felt that it was a *"powerful tool in motivating lifestyle modification".* He also felt that *"in terms of overall management and overall picture of glycaemia control at the facility the POC HbA1c hadn't made that much of a difference"* and suggested that follow up audits be done in order to assess the long-term benefit of the intervention. Problems that were identified in terms of logistics were that there was a period of 2 weeks during the study that cartridges for the machine were not available due to a delay in supply.

Discussion

The study showed a significant improvement in the primary outcome, which was an increase in the percentage of patients receiving an annual HbA1c test. As the current guideline is an annual HbA1c test for all patients with diabetes this is a marked improvement [10]. There was also no significant increase in the number of additional tests, which implies that health workers adhered to the local policy of one test per patient per year.

A marked reduction in the turn-around time was also seen. Providing test results during patient visits can improve glycaemic control and potentially delay the onset and magnitude of complications [7]. The effect of this on glycaemic control must still be evaluated in this study by collecting additional data 6-months after the end of the study. The need for registrars to graduate precluded including this data in the research assignment, but these results will be available at the time of publication.

Despite the positive outcomes above there was no impact on treatment intensification or counselling. The lack of improvement in treatment intensification and lifestyle modification can possibly be attributed to a number of issues related to patient care such as large patient volumes, lack of appropriate theoretical knowledge or burn out of health care providers [16][17][18][19]. Patient resistance to initiation of insulin therapy and fear of insulin administration (needles) is also an important factor that needs to be considered [20].

There was a generally positive response from the chronic care team to the POC HbA1c testing. Studies have shown that POC testing helps improve communication and collaborative efforts between physicians and patients in managing the disease [9][12] and this was the perception of the staff who worked with the POC machine. They felt that the

machine was easy to operate and made a significant contribution to improving the quality of care. The improvement in care was attributed to the immediate availability of results, feedback to patients and improved clinical decision making. It was seen as evoking a positive response from the patients who became better "collaborators" in their own health care.

We were unable to show a decrease in overall cost related to POC testing; in fact it appears to be R1451.50 more expensive per 100 tests than traditional testing. We were therefore unable to demonstrate savings in incremental costs. There could be a significant decrease in costing if the programme is "rolled out" on a larger scale and equipment is bought in bulk on "tender". The potential of the POC machine to do multiple tests (including Creatinine and Cholesterol) could also further reduce costs.

There was poor adherence to quality control measures and these would need closer supervision if POC testing is implemented even though the few tests that were done for this study suggested that the quality of POC testing was acceptable. Poor adherence to the quality control measures may be contributed to large patient volumes and work load and a lack of trained staff.

Quality data obtained through peer interviewing may have been biased due to personal opinion; even though the interview was conducted by an "independent" researcher; the interviews included staff members who were personally involved in the research (daily POC testing, Quality Control testing) and this may have resulted in personal interest in positive feedback related to the research.

The impact of POC testing may be related to the selection of community health centres. More organised or less organised chronic care teams might have responded differently to the provision and use of the POC tests. It is possible therefore that different results could have been obtained if different health centres were selected. Nevertheless it was thought that these health centres were typical of current organisation and quality of care in the public sector. The number of people interviewed was small and it is possible that other opinions would be obtained if a broader range of staff had been included. The final conclusion on the costs and consequences depends on the measurement of any effect on glycaemic control. At present however the initial results suggest that incremental costs may not be worth the measured benefits due to the lack of treatment and counselling intensification.

The DOH has a service level agreement with NHLS and there is a guideline document for POC testing. HbA1c is not on the approved list of POC tests, if it were to be recommended then it would have to be proposed to a number of committees including the PPTC.

Conclusion

There was significant increase in the percentage of patients receiving an annual HbA1C test and in the turn-around time for receiving the results. There was no change in the number of patients receiving more than one test in line with current department of health policy. There was no effect on intensification of treatment or counselling suggesting a degree of clinical inertia. Further data must still be collected to determine any effect on glycaemic control. There was poor adherence to the quality control measures and the POC testing results in an estimated incremental cost of R 1451,50 per 100 tests performed. Staff were positive about the POC testing in terms of its feasibility and likely impact on patient's self-management.

The results do not support the implementation of POC testing. Future research should explore whether an intervention to improve the clinical response to poor control was amplified or not by combination with POC testing.

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