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Point-of-care testing improves diabetes management in a primary care clinic in South Africa

Lara A. Motta^{a,*}, Mark D.S. Shephard^a, Julie Brink^b, Stefan Lawson^c, Paul Rheeder^d

^a Flinders University International Centre for Point-of-Care Testing, Sturt Campus, West Wing, Level 3, Flinders University, Bedford Park, South Australia 5042, Australia

^b Project HOPE South Africa, Wild Fig Business Park, Block F, Unit 54, 1494 Cranberry Street, Honeydew, Johannesburg 2170, South Africa

^c Project HOPE, 255 Carter Hall Lane, Millwood, VA 22646, USA

^d Dept. Internal Medicine, Steve Biko Academic Hospital, University of Pretoria, Bophelo Road, Pretoria, South Africa

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ABSTRACT

Introduction: Diabetes is a major health problem in South Africa. DiabCare Africa found just 47% of diabetes patients had a hemoglobin A1c (HbA1c) test for their management in the previous year.

Methods: Patients attending an urban diabetes clinic near Johannesburg, run by Project HOPE, accessed HbA1c (and urine albumin:creatinine ratio) point-of-care testing (POCT) as part of a quality-assured international program called ACE (Analytical and Clinical Excellence). Patients who had two or more HbA1c POC tests from 2012 to 2014 were assessed to determine their change in glycaemic control.

Results: The mean (\pm SD) HbA1c in this group of diabetes patients ($n=131$) fell significantly from $9.7\% \pm 2.4$ (83 mmol/mol) at their first POCT measurement to $8.4\% \pm 2.4$ (68 mmol/mol) at their most recent POCT measurement (paired t-test $p < 0.01$). The average time between first and most recent HbA1c test was 15 months. The number of diabetes patients achieving optimal glycaemic control ($HbA1c \leq 6.5-7.5\%$ [48–58 mmol/mol]) increased by 125%, while the number with very poor glycaemic control ($HbA1c > 10\%$ [86 mmol/mol]) halved. An association was observed between degree of glycaemic control and increasing albuminuria in this cohort.

Discussion: POCT has promoted change in clinical practice by facilitating greater accessibility to HbA1c testing.

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* Corresponding author. Fax +61 8 8201 7666.

E-mail addresses: Lara.Motta@flinders.edu.au (L.A. Motta), Mark.Shephard@flinders.edu.au (M.D.S. Shephard), jbrink@projecthope.org (J. Brink), slawson@projecthope.org (S. Lawson), Paul.Rheeder@up.ac.za (P. Rheeder).
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1. Introduction

Once an uncommon disease in Africa, type 2 diabetes has now become a major public health problem with its prevalence expected to increase by 110% over the next two decades, from 19.8 million individuals in 2013 to 41.5 million by 2035 [1]. In this time period, non-communicable diseases are also expected to overtake infectious diseases as the leading cause of mortality in this region. The diabetes epidemic in Africa, like the rest of the world, is driven by rapid globalization, an aging population and urbanization, which is evident by the increase in diabetes prevalence with economic development. In the Africa region, prevalence ranges from 4.4% in low-income countries to 7.0% in the upper-middle income countries [1]. In 2013, South Africa ranked in the top 5 African countries for individuals with diabetes at 2.6 million and prevalence of diabetes at 9.3% [2].

A recent study by DiabCare Africa reported that diabetes care in six sub-Saharan African countries (Cameroon, Ghana, Kenya, Nigeria, Senegal and Tanzania) was suboptimal with just 47% of patients having had a hemoglobin A1c (HbA1c) test for their management in the previous year [3] in regions where rates of micro-vascular complications (retinopathy and persistent proteinuria) approach 25% [4].

Current guidelines for the management of diabetes prepared by the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) recommend that HbA1c should be measured three- or six-monthly (if at target), with target levels being individualized depending on age, length of onset, and risk of complications, while urine albumin:creatinine ratio (ACR) is the preferred marker for early renal disease and should be measured at an initial visit and then annually [5]. The latter recommendation is consistent with the current global guidelines purported by the International Diabetes Federation [6]. The SEMDSA guidelines also recommend that all diabetes clinics in South Africa should have 'HbA1c testing equipment to enable on-site testing' [5].

On-site pathology testing, or point-of-care testing (POCT), is now becoming more widely available in primary care settings in many developed and developing countries. POCT can provide innovative and practical opportunities to improve delivery of pathology services in disadvantaged settings globally and can deliver operational, cultural and clinical benefits to assist in bridging the gap in health equity in such settings [7,8].

In Australia, the Flinders University International Centre for Point-of-Care Testing (ICPOCT) manages a national POCT program for diabetes management in Indigenous communities called QAAMS (Quality Assurance for Aboriginal and Torres Strait Islander Medical Services). QAAMS now operates in over 180 Aboriginal and Torres Strait Islander medical services, more than 70% of which are in rural and remote locations, with trained Indigenous health workers conducting HbA1c and urine ACR tests using the DCA Vantage point-of-care (POC) device (Siemens Healthcare Diagnostics) under a quality managed framework [8–11].

In 2012, following many requests from overseas countries for assistance with POCT, the Flinders ICPOCT launched the ACE (Analytical and Clinical Excellence) Program, an

international POCT model for diabetes management [12,13]. The ACE Program has a strong emphasis on community engagement and empowerment and has been built on the successful quality elements of the Australian-based QAAMS Program. Thirty three communities from 7 countries (Canada, Thailand, East Timor, Solomon Islands, Papua New Guinea, Samoa and South Africa) now participate in ACE. To facilitate community engagement, the Flinders ICPOCT formed partnerships with regional international universities to reach out and support the local communities. In South Africa, the University of Pretoria partnered with the Flinders ICPOCT. This study describes the introduction of the ACE POCT Program into one of the participating South African communities – an urban primary care diabetes clinic in Zandspruit, 30 km from Johannesburg, run by Project HOPE. Project HOPE is a global public health non-government organization (NGO) which provides medical training and health education, as well as conducting humanitarian assistance programs, in more than 35 countries [14].

2. Methods

2.1. Participating communities

Zandspruit has a population of approximately 70,000 and is a town which typifies the growing peri-urban sprawl on the fringe of Johannesburg. Made up of predominantly metal shacks with limited public infrastructure, health services are very limited to basic primary care. Project HOPE through The HOPE Centre in Zandspruit aims to improve access to quality patient services for diabetes and hypertension, and runs a clinic three days a week where the POCT described in this study took place. As part of The HOPE Centre, Project HOPE also runs health promotion programs in the community to improve awareness and testing for non-communicable diseases and provides health education services including a patient self-care curriculum called *5 Steps to Self-Care*, urban food gardening, cooking classes and exercise support for patients.

2.2. Ethics

Ethics approval for the ACE program was granted by the Government of South Australia's Southern Adelaide Clinical Human Research Ethics Committee (application 051.12) and by the University of Pretoria's Faculty of Health Sciences Research Ethics Committee (application 204/2012).

2.3. POCT device, equipment and consumables

The Siemens DCA Vantage (Siemens Healthcare Diagnostics, Tarrytown, NY, USA) measures HbA1c on one microlitre of capillary whole blood with the result available in six minutes, while urine ACR is performed on 40 μ L of urine with results available in seven minutes. The immunoassay method principle used for measuring HbA1c on the DCA Vantage is not affected by the most commonly occurring haemoglobinopathies which can interfere with some HbA1c chromatographic assays. Factors which impact erythrocyte

Table 1 – Characteristics of diabetes patients from the HOPE clinic.

	All diabetes patients	Diabetes patients who had one HbA1c test	Diabetes patients who had repeat HbA1c tests	
			First test	Last test
Number	211	75	131	131
Gender	Male: 35% Female: 65%	Male: 29% Female: 71%	Male: 38% Female: 63%	Male: 38% Female: 63%
Age	51.9 years Range: 27–85 years	53.3 years Range: 28–85 years	51.1 years Range: 27–78 years	52.3 years Range: 29–79 years
Mean HbA1c	9.7% (83 mmol/mol) Range: 6.5–14% (48–130 mmol/mol)	9.8% (84 mmol/mol) Range: 6.5–14% (48–130 mmol/mol)	9.7% (83 mmol/mol) Range: 6.5–14% (48–130 mmol/mol)	8.4% (68 mmol/mol) Range: 5.0–14% (31–130 mmol/mol)

Table 2 – Change in glycaemic control in 131 diabetes patients over 15 months following the introduction of POCT at the HOPE clinic (Wilcoxon Signed Rank test $p < 0.0005$).

		Glycaemic control most recent HbA1c test									
		Very poor		Poor		Controlled		Target		Total	
		n	%	n	%	n	%	n	%	n	%
Glycaemic control first HbA1c test	Very poor	16	12.2%	15	11.5%	5	3.8%	16	12.2%	52	39.7%
	Poor	4	3.1%	4	3.1%	1	0.8%	10	7.6%	19	14.5%
	Controlled	5	3.8%	5	3.8%	6	4.6%	16	12.2%	32	24.4%
	Target	1	0.8%	2	1.5%	4	3.1%	21	16.0%	28	21.4%
	Total	26	19.8%	26	19.8%	16	12.2%	63	48.1%	131	100.0%

lifespan, such as anemia, may affect interpretation of HbA1c results [15]; however this is not a common occurrence in this clinic. Urine dipstick tests were used to exclude patients with urinary tract infections, with urine ACR tests only performed on patients who tested negative to nitrites and leukocytes. The analytical performance of the DCA Vantage in the HOPE clinic was constantly monitored through a quality control testing program, in which operators tested artificial samples with known values of HbA1c and urine ACR (as part of an overarching quality management framework provided to all ACE participants) [12].

2.4. Education and training

Point-of-care testing operators at the HOPE clinic (n=7 local Indigenous health workers and nurses) completed training in the principles and practice of POCT for HbA1c and urine ACR on the DCA Vantage and were awarded competency certification under a web-based ACE training program developed and delivered by the Flinders University ICPOCT [12].

2.5. Patient data collection

Results of de-identified patient HbA1c and urine ACR POCT were recorded onsite onto an electronic patient result sheet which was then forwarded to the ACE Program Coordinator (first author). Diabetes patients (HbA1c $\geq 6.5\%$ [48 mmol/mol]) who had two or more HbA1c tests performed by POCT from October 2012 to December 2014 were assessed to determine their overall change in glycaemic control by comparing (i) the absolute change in HbA1c values and (ii) the change in clinical category of glycaemic control between their first and most recent POC HbA1c test. Diabetes patients were split into four clinical categories according to their HbA1c result: target glycaemia (6.5–7.5% [48–58 mmol/mol]); controlled

glycaemia (7.6–8.5% [59–69 mmol/mol]); poor glycaemic control (8.6–10% [70–86 mmol/mol]); very poor glycaemic control (>10% [>86 mmol/mol]). As the HbA1c POC test was being used for diagnostic purposes as well as for the management of existing diabetes patients, patients who had HbA1c levels of less than 6.5% (48 mmol/mol) were removed from this diabetes patient dataset. Initial POC urine ACR results, split by clinical category of normoalbuminuria (≤ 3.5 mg/mmol female; ≤ 2.5 mg/mmol male), microalbuminuria (3.6–35 mg/mmol female; 2.6–25 mg/mmol male) and macroalbuminuria (36–100 mg/mmol female; 26–100 mg/mmol male) [6,16], were also correlated with diabetes patients' first HbA1c POCT values.

3. Results

A total of 332 patients presenting at the HOPE Centre clinic had 595 HbA1c tests performed by POCT during the study period (October 2012 to December 2014). Of these patients, 211 (64%) were classified as having diabetes [6]. Over 60% (n=131) of these diabetes patients returned to the clinic for repeat HbA1c POCT (range 2–5 tests) during the study period (Table 1). The mean (\pm SD) HbA1c in this group of diabetes patients fell significantly from $9.7\% \pm 2.4$ (83 mmol/mol) at their first POCT measurement to $8.4\% \pm 2.4$ (68 mmol/mol) at their most recent POCT measurement (paired t-test $p < 0.01$); with the average time between first and most recent HbA1c test being 15 months (± 6 months; range: 4–24 months). In terms of categorization of glycaemic control, 48% of patients (n=63) improved their glycaemic control, 36% (n=47) remained stable and 16% (n=21) worsened over the study period (Wilcoxon Signed Rank test $p < 0.0005$) (Table 2). In addition, the total number of diabetes patients achieving target glycaemia increased by 125% (from 28 to 63); including 16 who improved from very poor

Table 3 – Association between degree of glycaemic control and albuminuria status in 149 diabetes patients from the HOPE clinic.

Hemoglobin A1c	Urine albumin:creatinine ratio (mg/mmol)					
	Normal kidney function (ACR \leq 3.5 F; \leq 2.5 M)		Microalbuminuria (ACR 3.6–35 F; 2.6–25 M)		Macroalbuminuria (ACR 36–100 F; 26–100 M)	
	n	%	n	%	n	%
Target glycaemia (HbA1c \leq 7.5% [58 mmol/mol])	36	80.0%	9	20.0%	0	0.0%
Controlled glycaemia (HbA1c \leq 8.5% [69 mmol/mol])	14	63.6%	8	36.4%	0	0.0%
Poor glycaemic control (HbA1c 8.6–10% [70–86 mmol/mol])	25	62.5%	12	30.0%	3	7.5%
Very poor glycaemic control (HbA1c >10% [86 mmol/mol])	20	47.6%	20	47.6%	2	4.8%

Table 4 – Assessment of analytical quality of point-of-care testing conducted by Hope clinic (n = 10 repeats).

Test	Lot number	Normal/low quality control		Abnormal/high quality control		Imprecision goal
		Mean	Imprecision (CV%)	Mean	Imprecision (CV%)	
HbA1c (%)	0101	5.1	2.3	10.8	3.8	4%
Albumin (mg/L)	0044	32.7	4.5	216.8	2.9	10%
Creatinine (mmol/L)		8.8	3.7	35.3	3.4	6%
ACR (mg/mmol)		3.7	5.0	6.15	3.2	12%

glycaemic control to target; while the number of patients with very poor glycaemic control fell by 50% (from 52 to 26) over the study period.

During the study period, 149 diabetes patients had at least one urine ACR test conducted by POCT. The association between degree of glycaemic control and albuminuria status (using the first HbA1c and urine ACR POC test result performed) is shown in Table 3. The mean HbA1c was $8.9\% \pm 2.2$ (74 mmol/mol) for patients with normoalbuminuria (n=95), $10.1\% \pm 2.6$ (87 mmol/mol) for patients with microalbuminuria (n=49) and $11.1\% \pm 2.7$ (98 mmol/mol) for patients with macroalbuminuria (n=5). The difference in HbA1c between normo- and microalbuminuria groups was statistically significant (unpaired t-test $p < 0.01$).

The POC device's performance was shown to be analytically sound, with both levels of quality control achieving the minimal goal for imprecision (CV) of 4% for HbA1c and the desirable goals of 10%, 6% and 12% for albumin, creatinine and ACR, respectively [11]. Table 4 shows the analytical performance for the lot number of quality control with the highest number of repeat tests performed during this study.

4. Discussion

Diabetes is a major health issue for the developing world. Experts predict that, by the year 2020, mortality from non-communicable diseases in sub-Saharan Africa will out-strip those from infectious diseases such as HIV, malaria and tuberculosis [17].

Improved access to HbA1c testing is a factor that is consistently highlighted in discussion papers about better quality

of care for diabetes patients in this region [3–5,18]. POCT is a diagnostic tool that can potentially bridge that divide in access. The Australian-based QAAMS, and now the international ACE, programs provide frameworks for supporting and sustaining large networks of primary care sites to conduct quality-assured POCT for HbA1c and urine ACR, both key pathology markers of diabetes management. While most of the participating sites in these two programs are from rural and remote settings, this study examines the use of POCT in an urban primary care setting with a high burden of chronic disease.

Two years since the introduction of the program in the HOPE Centre clinic, there has been a 1.3% (15 mmol/mol) reduction in the mean HbA1c level of diabetes patients accessing this service, with a doubling of the number of patients achieving optimal diabetes control and a halving of those patients exhibiting very poor glycaemic control. Previous large clinical trials have shown that a 1% reduction in HbA1c equates to a 25–35% reduction in risk of microvascular complications of diabetes [19,20]. It should be noted that the only medication available to diabetes patients in this clinic are oral hypoglycaemic agents. The burden of diabetes complications can have significant financial (loss of productivity) and personal health consequences (such as blindness, kidney damage and amputation) for the patient. Therefore the cost of early and effective screening for, and management of, diabetes using POCT is more than compensated by the savings in avoiding long term complications [21].

Urine ACR POC testing has provided a useful adjunct to HbA1c testing used for managing diabetes patients at the HOPE clinic, with 36% of its diabetes patients found to

have micro- or macroalbuminuria, a number consistent with literature reporting 10–42% of diabetes patients as having increased albuminuria [22]. The correlation observed between degree of glycaemic control and increasing albuminuria in this cohort of patients is likely to be due to their duration of diabetes and resultant decline in kidney function, in addition to their generally poor diabetes control [22].

From a POCT operator perspective, POCT has been well accepted within the clinic, while the convenience of POCT has delivered practical benefits for diabetes patients, as evidenced by the following quote:

‘Having the machines in our clinic is helping us a lot. By doing the test ourselves, we can give treatment right away and we don’t send the patient away to wait for results which can take 2–3 months, wasting time. With ACR testing, we can check the kidneys right away and send the patient to the hospital if needed. Overall, the machines help us to avoid wasting time and make our patients happy because they can get testing, results and treatment all in one visit. Most of our patients are working and cannot take off work to come for many different appointments.’

Project HOPE Lab & Pharmacy Assistant and POCT operator

The portability and ease of use of POCT has enabled the device to be used in the clinic’s small lab where POCT has been performed by a trained local health worker. This has eased the time pressures on HOPE Centre professional nursing staff. In a recent development, the POCT program is being expanded to a second Project HOPE clinic at Itsoseng, a community neighboring Zandspruit where Project HOPE was invited by another NGO, Fodisong Community & Health Centre, to provide services one day per week for patients with diabetes and hypertension.

The success of the program to date has largely been due to the strength of the partnership between the Flinders University International Centre for Point-of-Care Testing, the University of Pretoria and Project HOPE, with the specialist quality-assured POC services provided by Flinders complementing the clinical support from the University of Pretoria and the global commitment of Project HOPE as a NGO providing health expertise, medical training and promoting wellness in the communities they support.

There have been a number of challenges for the program at the HOPE Centre clinic as it has evolved. Continuity of the supply of HbA1c and urine ACR testing cartridges/reagents from the local distributor was initially poor; however once the primary manufacturer (Siemens) was engaged in the supply process, this issue was speedily resolved. Reagents for the study were initially provided in-kind and are now being purchased by Project HOPE. The current cost per HbA1c and urine ACR test is approximately R100 (US\$6) and R87 (US\$7) respectively. Quality control kits to conduct HbA1c and urine ACR testing cost approximately R3000 (US\$200) every six months. Currently there is no Government rebate available to reimburse costs associated with delivering POCT services in South Africa and, for this reason, cost still remains a major barrier for the implementation of POCT in most smaller, less well-resourced diabetes primary care clinics in South Africa. Generally one of the major challenges facing sustainability of a POCT program is high rates of staff turnover and maintenance

of training standards (particularly in rural and remote settings) [23,24]; however, in this urban HOPE clinic setting, there has been a relatively stable and committed pool of POCT device operators which has certainly contributed to the success of the study to date. In this study just over 60% of patients returned for a follow-up POCT testing; clinic staff continue to encourage patients to return for repeat testing but this can be difficult due to other competing social and cultural priorities of patients.

In summary, the introduction of POCT to the Project HOPE clinic has promoted change in clinical practice by facilitating greater accessibility to HbA1c testing that is so critically needed and that has resulted in a clinically significant improvement in the glycaemic control of diabetes patients using this service.

Conflict of interest

The authors state that there are no conflicts of interest. Research support provided by Siemens Healthcare Diagnostics played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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