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Point-of-care testing improves diabetes management in a primary care clinic in 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 (±SD) HbA1c in this group of diabetes patients (n = 131) fell significantly from 9.7% ± 2.4 (83 mmol/mol) at their first POCT measurement to 8.4% ± 2.4 (68 mmol/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 ≤ 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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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 μL 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

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