


# Implementation of self-monitoring of blood glucose for patients with insulin-dependent diabetes at a rural non-communicable disease clinic in Neno, Malawi

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**Background.** Self-monitoring of blood glucose (SMBG) is a widely accepted standard of practice for management of insulin-dependent diabetes, yet is largely unavailable in rural sub-Saharan Africa (SSA). This prospective cohort study is the first known report of implementation of SMBG in a rural, low-income country setting.

**Objectives.** To evaluate adherence and change in clinical outcomes with SMBG implementation at two rural hospitals in Neno, Malawi.

**Methods.** Forty-eight patients with type 1 and insulin-dependent type 2 diabetes were trained to use glucometers and logbooks. Participants monitored preprandial glucose daily at rotating times and overnight glucose once a week. Healthcare providers were trained to evaluate glucose trends, and adjusted insulin regimens based on results. Adherence was measured as the frequency with which patients checked and documented blood glucose at prescribed times, while clinical changes were measured by change in glycated haemoglobin (HbA1c) over a 6-month period.

**Results.** Participants brought their glucometers and logbooks to the clinic 95 - 100% of the time. Adherence with measuring glucose values and recording them in logbooks eight times a week was high (mean (standard deviation) 69.4% (15.7) and 69.0% (16.6), respectively). Mean HbA1c decreased from 9.0% (75 mmol/mol) at enrolment to 7.8% (62 mmol/mol) at 6 months (mean difference 1.2% (95% confidence interval (CI) 0.6 - 2.0;  $p=0.0005$ ). The difference was greater for type 1 diabetes (1.6%; 95% CI 0.6 - 2.7;  $p=0.0031$ ) than for type 2 diabetes (0.9%; 95% CI 0.1 - 1.9;  $p=0.0630$ ). There was no documented increase in hypoglycaemic events, and no hospitalisations or deaths occurred.

**Conclusion.** SMBG is feasible for patients with insulin-dependent diabetes in a rural SSA population, and may be associated with improved HbA1c levels. Despite common misconceptions, all patients, regardless of education level, can benefit from SMBG. Further research on long-term retention of SMBG activities and the benefits of increasing frequency of monitoring is warranted.

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Diabetes is a chronic non-communicable disease (NCD) of growing public health concern and with an increasing incidence worldwide. Africa has the fastest-growing prevalence of diabetes, with estimates predicting a 47.5% increase by 2030 to 28.6 million people.<sup>[1]</sup> Furthermore, the rural poor bear a disproportionate burden of NCDs without typical risk factors associated with urbanisation, such as obesity.<sup>[2,3]</sup> While it is unclear whether the aetiology of diabetes in the sub-Saharan African (SSA) setting differs from that in North America and Europe, cases are still typically classified as type 1 and type 2 diabetes.<sup>[4]</sup> In Malawi, 84% of the population lives in rural settings and 65% survive on less than USD1 per day.<sup>[5,6]</sup> While the national burden of diabetes in adults is estimated to be 1.4 - 3.0%,<sup>[1]</sup> a recent population-based study found that 41% of participants with diabetes were undiagnosed, suggesting that the actual burden may

be much higher.<sup>[7,8]</sup> Human insulin is procured by the Malawian government and provided free of charge to patients through public facilities, although availability can be limited.<sup>[9]</sup> Home glucometers and test strips must be purchased privately and are inaccessible and unaffordable to most patients living in rural communities.

There are two forms of diabetes that require exogenous insulin administration. Type 1 diabetes is an autoimmune condition characterised by impaired secretion of insulin from pancreatic islet cells and is typically diagnosed in childhood or young adulthood. Type 2 diabetes is characterised by resistance to insulin and is typically diagnosed in adulthood. Although type 2 diabetes can initially be managed with lifestyle modifications and oral medications that increase insulin sensitivity or production, exogenous insulin administration is often required as the condition progresses.

Uncontrolled diabetes is common in SSA and leads to individual disability, mortality, and strain on health systems.<sup>[10]</sup> All patients who use insulin face an increased risk of severe hypoglycaemia and increased self-care challenges, including the necessity for frequent self-monitoring of blood glucose, multiple daily injections, and strict dietary management.<sup>[2,10,11]</sup>

Glycaemic control is an essential element of diabetes care and reduces the risk of short- and long-term complications.<sup>[12]</sup> While insulin is increasingly being considered an essential medicine and is supplied by health systems in many countries, access to blood glucose meters and test strips remains extremely limited.<sup>[13,14]</sup> Self-monitoring of blood glucose (SMBG) has been the standard of care for diabetes in high-income countries since the transition from self-monitoring of urinary glucose in the 1980s.<sup>[15]</sup> SMBG impacts on glycaemic control both by increasing patient awareness of blood glucose levels and by providing information to healthcare providers that enables more accurate titration of insulin doses. Monitoring blood glucose levels at home has proved to be feasible and acceptable in high-resource settings, and an increased frequency of SMBG is linked to lower levels of glycated haemoglobin (HbA1c).<sup>[12,16]</sup> Global guidelines emphasise the value of SMBG for ensuring safety, preventing complications, and promoting individual self-management in patients with diabetes, especially those using insulin.<sup>[16-18]</sup> Despite these clear guidelines, SMBG use remains infrequent in low-income rural settings. To our knowledge, there are no current data on adherence to and the clinical impact of SMBG for the rural poor living with diabetes in SSA, and this is the first study to measure adherence to and effectiveness of SMBG in rural low-income SSA.

Cost, access, patient literacy and adherence are all potential or perceived barriers to SMBG in low-resource settings. Previous research on SMBG in the African region has focused on urban or tertiary care facilities.<sup>[14,19-23]</sup> In Malawi, in a recent cross-sectional survey of adolescents with type 1 diabetes receiving care at tertiary hospitals, only 20% were using glucose meters.<sup>[24]</sup> Variability in criteria used to define adherence makes comparison across studies difficult. Studies focusing on glycaemic control in SSA have not been conclusive in demonstrating a correlation between SMBG and glycaemic control. However, these studies have primarily been carried out at urban medical centres, demonstrated low adherence to SMBG, and included patients with non-insulin-dependent type 2 diabetes.<sup>[19,25]</sup> The impact of SMBG on HbA1c has been shown to be stronger for type 1 than type 2 diabetes.<sup>[19,26]</sup> Studies based in urban medical centres may not be generalisable to rural populations, given the increased challenges of care provision and reduced literacy in the rural setting. A randomised controlled trial evaluating SMBG feasibility in rural patients with insulin-dependent type 2 diabetes in Rwanda is in progress.<sup>[27]</sup> As previous research on SMBG has not included patients in resource-limited rural communities and perceived barriers to quality care have not been examined, it is necessary to evaluate adherence to and the impact of SMBG for these patients. We present the findings of a cohort study examining adherence and clinical outcomes with introduction of SMBG to insulin-dependent patients in a rural district hospital clinic in Malawi.

## Methods

### Setting and population

Neno is a rural district with a population of 138 291 according to the Malawi census of 2018, located in the southern region of Malawi.<sup>[6]</sup> Most people in Neno rely on subsistence agriculture and fewer than 5% have access to electricity. The literacy rate, defined as being able to read and write a simple sentence, is 70%.<sup>[6]</sup> Neno's local health

system is primarily public and comprises a district hospital in Neno centre, a smaller community hospital in the town of Lisungwi, and 12 additional healthcare centres distributed throughout the district. Partners in Health (PIH), a US-based non-governmental organisation known locally as Abwenzi Pa Za Umoyo, has partnered with the Ministry of Health (MoH) since 2007 in order to improve healthcare and socioeconomic development in Neno.

In Malawi, like many parts of SSA, it is difficult for patients in rural districts to receive care for severe NCDs, including type 1 and insulin-dependent type 2 diabetes, sickle cell disease and rheumatic heart disease, because most specialty clinics are at central referral hospitals. Most decentralised models of care, such as the World Health Organization (WHO) Package of Essential Non-communicable Disease Interventions (WHO PEN), focus on addressing common NCDs, such as hypertension and non-insulin-dependent type 2 diabetes, at primary healthcare centres.<sup>[28]</sup> In Neno, patients with common NCDs are treated at the Integrated Chronic Care Clinics, a unique model that provides longitudinal care for patients with HIV and NCDs.<sup>[29]</sup> At the same time, integrated services for more severe and complex NCDs, such as insulin-dependent diabetes, are provided through the PEN-Plus model. PEN-Plus is a strategy for providing outpatient treatment of chronic, severe NCDs at specialised clinics based in rural district hospitals.<sup>[3,30]</sup> This model builds on the WHO PEN approach and promotes decentralisation through structured training of nurses and other mid-level healthcare providers.<sup>[31-36]</sup>

Two PEN-Plus clinics, known locally as advanced NCD (aNCD) clinics, have been operating in Neno since November 2018. The clinics are run by clinical officers and nurses, with supervision by a doctor and a nurse mentor. Patients with diabetes who use insulin are seen at the clinics on a monthly basis. Insulin regimens are created and titrated based on clinical protocols that take into account multiple factors including patient symptoms, monthly fasting blood sugar levels taken at the clinic, and twice-yearly HbA1c levels. Most insulin regimens include a combination of intermediate-acting insulin (neutral protamine Hagedorn, NPH) and short-acting insulin (regular). Patients typically inject a fixed dose of intermediate- and short-acting insulin twice a day, before breakfast and before dinner. Oral regimens for patients with type 2 diabetes are adjusted as necessary.

### Study design

This was a prospective 6-month cohort study evaluating patient adherence and clinical outcomes with introduction of home SMBG among patients with insulin-dependent diabetes in a rural NCD clinic setting. Prior to SMBG implementation, patients used symptom monitoring while at home and received a fasting blood sugar check monthly during clinic visits. Data collection was done at the same time as site-wide implementation of SMBG for all patients with insulin-dependent diabetes. All insulin-dependent patients aged  $\geq 18$  years receiving care at the aNCD clinic were invited to participate in the study. Children were given the same standard of care but were not included in the study. Twenty-five adults with type 1 diabetes and 23 adults with insulin-dependent type 2 diabetes were eligible and attended their appointment to be enrolled in the study. The aNCD clinic is the only chronic care clinic in Neno treating patients with insulin-dependent diabetes, so all patients in the district were evaluated for enrolment.

Prior to study initiation, NCD clinicians and nurses were trained on the correct technique for using glucometers and providing patient education on glucometer use. Clinicians were further trained to use logbook data to inform insulin dosing decisions. At the start of the study, patients received a half-day training session led by

NCD nurses. They were taught how to use the glucometer, check blood glucose and document values in the logbook. Education also reinforced recognition and treatment of low blood glucose levels. However, the education did not instruct patients to self-adjust insulin dosing outside of clinic visits. This was decided on because there was concern about possible hypoglycaemia if insulin was adjusted based on one blood glucose measurement per day, particularly given that some patients faced inconsistent food availability. Patients were followed up at the aNCD clinic 2 weeks after initial training to ensure that the glucometers were being used appropriately and blood glucose values documented correctly. After the 2-week follow-up, patients returned monthly for regularly scheduled care, data collection, education and insulin titration. Additional patient education was provided as needed.

Glucometers, test strips and lancets were provided to all patients enrolled in the study. Logbooks were created to help guide the patients on when to check their blood sugar levels and record the results (Fig. 1). Participants were asked to check preprandial blood sugar once a day, rotating through breakfast, lunch and dinner. They were also asked to check one additional overnight blood glucose per week, resulting in a total of eight prescribed checks per week. HbA1c was measured at baseline and 6 months. Logbooks were used throughout the course of the study to help inform changes to insulin regimens.

**Data collection**

Demographic data were obtained from structured patient intake forms during enrolment. Point-of-care HbA1c was obtained at baseline and endline using a point-of-care device. Because the glucometers did not have capability to upload to a computer, study staff compared the time-stamped

values from the glucometer with those recorded in the logbook, then manually entered glucometer values into an Excel spreadsheet, version 16 (Microsoft, USA). If blood glucose was checked more than once in a day, only the value within an hour of the prescribed time was recorded. At each visit, the interval since the previous visit was noted and all data since the previous visit were collected so that no data were missed if participants missed an appointment.

**Outcomes of interest**

Adherence was the primary outcome of interest, and was measured by the following variables: (i) whether patients brought their glucometers to the clinic; (ii) whether patients brought their logbooks to the clinic; (iii) the number of days the patients checked their blood glucose during the previous month; (iv) the number of days the patient entered the glucose value correctly in the logbook during the previous month; and (v) the number of days patients both correctly checked their glucose and entered the data into the logbook. HbA1c was the primary clinical outcome of interest. Glycaemic variability, the secondary clinical outcome of interest, was calculated by identifying the percentage of values in a visit interval <70 mg/dL, >180 mg/dL, and in range (70 - 180 mg/dL).

**Statistical analysis**

Data were analysed using Stata version 15.1 (StataCorp, USA). Owing to the low sample size, demographic variables were grouped into binary or three-tiered groups. For example, education level was grouped by binary groups of none or primary education and secondary or higher. Adherence to SMBG activities was calculated as a proportion by comparing the number of times an activity was completed correctly with the number of times that activity was

expected to have been completed. Change in HbA1c from baseline to endline at 6 months was calculated using a paired *t*-test.

**Ethical considerations**

All participants were instructed about the benefits and risks of the study and signed consent forms before starting. Participants were not compensated, because this cohort study was evaluating a new standard of care being implemented for all diabetes patients in the clinic. All patient data were kept secure by password encryption. Ethics approval was obtained from the Malawi National Health Sciences Research Committee (NHSCR) (ref. no. 19/05/2340) and the MoH-PIH Malawi Research Committee.

**Results**

**Study population**

A total of 48 participants were enrolled in and completed the study (Table 1). About half (52.1%; *n*=25) had type 1 diabetes and the other half (47.9%; *n*=23) had insulin-dependent type 2 diabetes. The median patient age was 47 years (range 21 - 86), and 52.1% (*n*=25) of participants were female. Most participants were married (68.8%; *n*=33) and had no or only primary education (66.7%; *n*= 32). Participant occupation was evenly divided between subsistence farmer (31.2%; *n*=15), formal employment (35.4%; *n*=17) and unemployment (33.3%; *n*=16). The mean time since diabetes diagnosis was 5 years (range 7 months - 22 years) for participants with type 1 diabetes and 8 years (range 1 - 21 years) for those with type 2 disease. Most participants were using intermediate-acting (NPH) and short-acting (regular) insulins to manage their diabetes (77.1%; *n*=37), while the remainder were using intermediate-acting insulin only (22.9%; *n*=11). Twelve patients (25.0%) were also taking metformin. Fifty-four percent of participants (*n*=26) had one or more comorbidities, the most common being hypertension, while 45.8% (*n*=22) had no comorbidities (Table 1).

**Adherence**

Most patients brought their glucometers and logbooks to the clinic, ranging from 94% to 100% at each visit, with an overall average of 98%. For monthly adherence to scheduled glucose checks, accuracy of logbooks and both these variables, mean (standard deviation) percentages of participants were 69.4% (15.7), 69.0% (16.6) and 66.4% (17.0), respectively (Table 2). Trends highlighted by stratification by education and diabetes type show that participants with primary or

	Before breakfast		Before lunch		Before dinner		Overnight	
	Time	BG	Time	BG	Time	BG	Time	BG
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								
Sunday								

Fig. 1. Weekly blood glucose logbook provided to participants.

no education and those with type 2 diabetes had improved adherence to scheduled checks and accuracy of logbooks over time; however, owing to high levels of variability, these trends were not statistically significant (Table 2).

### Clinical data

Change in HbA1c was the primary clinical outcome of interest. Mean HbA1c for the cohort decreased from 9.0% (75 mmol/mol) at enrolment to 7.8% (62 mmol/mol) at 6 months (mean difference 1.2%; 95% confidence interval (CI) 0.6 - 2.0;  $p=0.0005$ ). Enrolment mean HbA1c was consistent with HbA1c levels of insulin-dependent patients at the clinic over the previous year, which averaged 9.3% (78 mmol/mol) from January to June 2019 ( $n=18$ ) and 8.8% (73 mmol/mol) from July to December 2018 ( $n=8$ ). The mean difference between baseline and endline was greater for patients with type 1 diabetes (1.6%; 95% CI 0.6 - 2.7;  $p=0.0031$ ) than for those with type 2 disease (0.9%; 95% CI 0.1 - 1.9;  $p=0.0630$ ) (Fig. 2). When stratified, a significant decrease was seen from baseline to endline for all education levels (Table 1).

Description of any change in glucose variability from initiation to completion of the intervention was a secondary clinical outcome of interest. Glucose levels ranged from 20 mg/dL to 523 mg/dL over the 6 months of data collection (Table 3). For both type 1 and type 2 diabetes, the percentage of low values (<70 mg/dL) remained consistent, between 6.8% and 10.3%. The percentage of values >180 mg/dL increased slightly for type 2 diabetes (24.6% v. 36.9%), although it remained below the overall mean for type 1 diabetes (45.3%). The percentage of values in range (70 - 180 mg/dL) increased for type 1 diabetes from 35.5% to 52.2%, although this was not statistically significant and remained below the overall mean for type 2 diabetes (65.2%) (Table 3). There were no adverse events (hospitalisation or death) during the 6 months of data collection.

### Discussion

This is the first study conducted on SMBG for type 1 diabetes in a rural, low-income setting. Our cohort study demonstrated that SMBG is feasible in a rural SSA setting. Participants enrolled in this study demonstrated a reduction of HbA1c over 6 months, and showed good adherence to SMBG, particularly as the study progressed. Overall adherence to SMBG was high, with a total of 69.4% of prescribed checks completed and 69.0% of checks accurately transcribed from glucometers to logbooks. Initially there

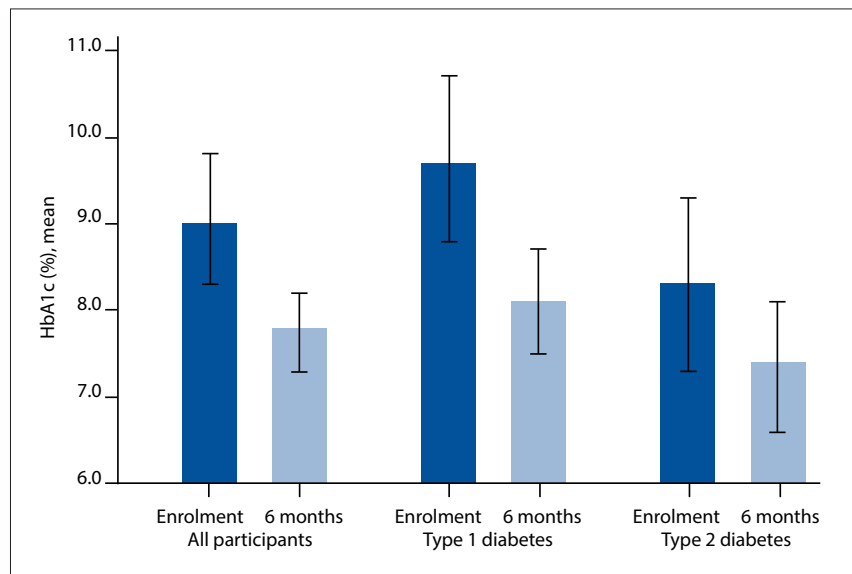


Fig. 2. Change in mean HbA1c by diabetes type (with 95% confidence intervals). (HbA1c = glycated haemoglobin.)

were concerns about adherence to SMBG in participants with limited literacy and numeracy. During the first months of the study, participants with primary school or no education had lower adherence than those with secondary or higher education. However, with close follow-up and re-education, adherence levels became the same in both groups. Cumulatively, these findings suggest that with sustained patient education and a patient-centred approach, all patients can benefit from SMBG technology regardless of education levels.

Previous studies conducted in SSA have used different methodologies to measure adherence. One study measured adherence to seven blood glucose checks per week and had 15.1% of participants meet this criterion,<sup>[21]</sup> and another measured adherence as >80% of blood glucose checks completed, with 34% of participants meeting the criterion.<sup>[22]</sup> We found it difficult to make direct comparisons with these studies because we collected data differently. Our analysis measured the number of prescribed checks completed (69.4%) and the number of checks accurately transcribed from glucometers to logbooks (69.4%). While comparison with published studies is difficult without an established metric or cut-off, the data suggest that our study achieved higher adherence.

Clinical impact was measured primarily by change in HbA1c, with a mean decrease of 1.2% ( $p<0.005$ ) from baseline to endline. This difference was greater in participants with type 1 diabetes than in those with type 2 disease (1.6%;  $p<0.005$ ), which may reflect the higher baseline HbA1c in this population and increased complexity of

insulin regimens and disease management. Consistency of baseline HbA1c with clinical data from the past year implies that this change was not due to potential confounding factors such as seasonality, which can affect food security and therefore diabetes management. Charity *et al.*<sup>[22]</sup> found a similar mean decrease in HbA1c (1.2%; 95% CI 0.8 - 1.7) 6 months after implementation of an SMBG programme in western Kenya. The post-intervention average HbA1c level of 7.8% (62 mmol/mol), while not meeting target levels of 7.0% (53 mmol/mol), demonstrates remarkable improvement in control compared with previous studies in the region. An assessment of youth with type 1 diabetes at a central hospital in Malawi found a mean HbA1c level of 13.2% (121 mmol/mol),<sup>[37]</sup> while a cohort of type 1 and 2 diabetes patients at PEN-Plus clinics in Rwanda had a median HbA1c of 8.6% (70 mmol/mol) 24 months after entry into care.<sup>[32]</sup>

Importantly, no severe adverse events (defined as hospitalisation or death) occurred during the study. One serious concern with lower HbA1c is increased hypoglycaemia, especially in a setting with limited monitoring capability. Prior to the initiation of this study, there were no data on the severity or frequency of hypoglycaemia in rural SSA. Over the course of the study, neither participants with type 1 nor those with type 2 diabetes had a statistically significant change in the percentage of values <70 mg/dL recorded, suggesting that increased glycaemic control and lower HbA1c were obtained without increasing the risk of hypoglycaemia in this population. However, the presence of values <50 mg/dL during all 6 months of the study



**Table 1. Sociodemographic characteristics and mean HbA1c levels of participants, N=48**

Characteristics	n (%)*	HbA1c (%), mean (95% CI)		p-value
		At enrolment	At 6 months	
All participants	48 (100)	9.0 (8.3 - 9.8)	7.8 (7.3 - 8.2)	0.0005
Gender				
Female	25 (52.1)	9.3 (8.3 - 10.2)	7.9 (7.3 - 8.6)	0.0037
Male	23 (47.9)	8.8 (7.6 - 10.0)	7.5 (6.8 - 8.3)	0.0417
Marital status				
Married	33 (68.8)	9.0 (8.1 - 9.9)	7.5 (6.9 - 8.0)	0.0008
Not married	15 (31.2)	9.0 (7.7 - 10.4)	8.3 (7.2 - 9.3)	0.1753
Education level				
None or primary	32 (66.7)	9.0 (8.1 - 9.9)	7.8 (7.2 - 8.4)	0.0117
Secondary or higher	16 (33.3)	9.5 (8.2 - 10.8)	7.9 (7.1 - 8.6)	0.0119
Occupation				
Farmer	15 (31.2)	8.9 (7.5 - 10.3)	8.0 (7.1 - 8.8)	0.2488
Formally employed	17 (35.4)	9.9 (8.4 - 11.3)	8.0 (7.1 - 8.8)	0.0091
Unemployed	16 (33.3)	8.4 (7.4 - 9.4)	7.4 (6.5 - 8.3)	0.0130
Diabetes type				
Type 1 diabetes	25 (52.1)	9.7 (8.8 - 10.7)	8.1 (7.5 - 8.7)	0.0031
Type 2 diabetes	23 (47.9)	8.3 (7.3 - 9.3)	7.4 (6.6 - 8.1)	0.0630
Insulin use				
NPH and regular	37 (77.1)	9.3 (8.5 - 10.2)	7.9 (7.3 - 8.4)	0.0010
NPH only	11 (22.9)	8.1 (6.6 - 9.5)	7.4 (6.4 - 8.4)	0.2576
Comorbidities				
One or more	26 (54.2)	8.9 (7.9 - 9.9)	7.6 (6.9 - 8.2)	0.0154
None	22 (45.8)	9.4 (8.4 - 10.4)	8.1 (7.4 - 8.8)	0.0108
BMI (kg/m <sup>2</sup> )				
Underweight (<18.5)	2 (4.2)			
Healthy weight (18.5 - 24.9)	25 (52.1)			
Overweight (25 - 29.9)	8 (16.7)			
Obese (>30)	13 (27.1)			
Age (years), median (range)	47 (21 - 86)			
Type 1 diabetes	34 (21 - 45)			
Type 2 diabetes	60 (43 - 86)			
Time since diabetes diagnosis, median (range)	6 years (7 months - 22 years)			
Type 1 diabetes	5 years (7 months - 22 years)			
Type 2 diabetes	8 years (1 - 21 years)			

HbA1c = glycated haemoglobin; NPH = neutral protamine Hagedorn (intermediate acting); BMI = body mass index.  
\*Except where otherwise indicated.

remains a critical finding. Some of these values may have been due to transcription errors when transferring values from glucometers to data collection tools. Nevertheless, it is likely that some of these are true values <50 mg/dL and further support the need for increasing SMBG for patients using insulin, since some patients were probably experiencing undetected symptomatic or asymptomatic hypoglycaemia at home prior to initiation of the study. Further research using increased SMBG or continuous glucose monitoring would be valuable to assess the true extent of previously undetected hypoglycaemia in this population.

The most significant limitation to this study was the small sample size. The number of patients on insulin in the aNCD clinic limited the ability for more detailed analysis into predictors and for analysing subgroups of the population. However, despite this limitation, there was still a significant improvement in mean HbA1c in the population. Additionally, the primary outcome of assessing adherence to prescribed variables was able to be met.

The cohort design of the study was influenced by the clinical goal of providing SMBG to all patients. There was a statistically significant

improvement in HbA1c before SMBG and after 6 months, but external factors could have influenced the results given the cohort design. The 6 months of data collection do not allow for conclusions on whether the observed clinical and behavioural changes can be sustained over time. Furthermore, because the glucometers were not able to upload directly to a computer for analysis, data were manually transcribed from logbook data and cross-checked with the glucometers. This process may have led to transcription errors (e.g. 20 mg/dL range instead of 200 mg/dL range).

While this study found significant clinical improvement with a model using one glucose test strip per day, best practice and previous research have shown that increasing glucose checks per day is correlated with lower HbA1c.<sup>[16,17]</sup> While cost was not an outcome of this study, it is a primary barrier to use of SMBG in SSA.<sup>[13,19-23]</sup> Neno is the first district in Malawi to provide glucometers to all patients on insulin, but the cost of test strips limited testing to once per day. Although multiple glucose checks per day is the optimal treatment strategy for patients on insulin, this study shows that testing once a day is associated with blood sugar control to near-normal levels.

**Table 2. Adherence to self-monitoring of blood glucose tasks**

	Total (N=48), % (SD)	Visit 1 (N=34), % (SD)	Visit 2 (N=38), % (SD)	Visit 3 (N=42), % (SD)	Visit 4 (N=41), % (SD)	Visit 5 (N=41), % (SD)	Visit 6 (N=43), % (SD)
Adherent to scheduled checks	69.4 (15.7)	69.8 (26.8)	64.4 (24.8)	71.3 (24.5)	76.6 (14.2)	74.3 (22.0)	72.7 (19.5)
Education							
Primary or less	68.5 (15.7)	65.6 (28.6)	63.6 (25.3)	72.7 (24.4)	76.3 (15.8)	74.0 (22.2)	74.4 (19.2)
Secondary or more	71.2 (16.7)	81.6 (18.6)	63.5 (23.8)	74.0 (15.4)	77.4 (11.1)	73.4 (22.9)	75.2 (21.1)
Diabetes type							
Type 1	67.5 (16.7)	70.7 (30.2)	64.3 (24.0)	73.0 (21.0)	74.1 (9.3)	69.7 (23.6)	69.9 (21.3)
Type 2	71.5 (14.7)	69.0 (24.6)	64.5 (26.2)	69.3 (28.6)	78.7 (17.3)	79.1 (19.5)	77.1 (16.6)
Accuracy of logbook	69.0 (16.6)	68.2 (28.0)	64.8 (28.2)	72.8 (23.9)	70.9 (19.0)	76.1 (20.6)	75.9 (17.9)
Education							
Primary or less	68.9 (15.4)	66.5 (27.3)	64.9 (28.1)	74.3 (23.2)	70.0 (20.9)	76.6 (20.3)	74.4 (16.9)
Secondary or more	69.3 (19.6)	72.3 (33.4)	62.0 (29.3)	75.4 (16.4)	73.0 (15.6)	73.5 (22.6)	78.2 (20.4)
Diabetes type							
Type 1	67.2 (17.4)	72.3 (23.7)	65.3 (25.7)	73.9 (20.3)	68.2 (17.2)	71.0 (22.8)	72.2 (19.3)
Type 2	71.1 (15.7)	65.0 (31.3)	64.3 (31.2)	71.5 (28.2)	73.3 (20.6)	81.4 (17.0)	80.0 (15.5)
Adherent to schedule and logbook correct	66.4 (17.0)	65.8 (27.6)	61.8 (28.2)	69.4 (25.2)	70.3 (18.8)	73.4 (22.6)	72.7 (19.5)
Education							
Primary or less	65.4 (16.6)	60.4 (29.0)	61.3 (28.8)	69.8 (25.7)	70.0 (20.9)	73.0 (23.0)	71.1 (18.9)
Secondary or more	68.3 (18.7)	80.9 (18.2)	60.3 (27.9)	74.0 (15.4)	70.6 (14.8)	73.2 (23.3)	75.7 (21.3)
Diabetes type							
Type 1	64.8 (17.7)	65.8 (30.5)	62.7 (26.2)	72.7 (21.0)	68.2 (17.2)	68.4 (23.9)	68.8 (21.2)
Type 2	68.1 (16.5)	65.7 (25.9)	60.9 (30.8)	65.4 (29.6)	72.0 (20.4)	78.7 (20.5)	77.1 (16.6)

SD = standard deviation.

**Table 3. Blood glucose variability**

	N	Blood glucose level (mg/dL), mean (IQR)	<70 mg/dL, n (%)	70 - 180 mg/dL, n (%)	>180 mg/dL, n (%)
Visit 1	858	171 (20 - 519)	88 (10.3)	453 (52.8)	317 (36.9)
Visit 2	944	166 (25 - 514)	73 (7.7)	523 (55.4)	348 (36.9)
Visit 3	1 099	166 (23 - 523)	86 (10.4)	628 (57.1)	385 (35.0)
Visit 4	1 111	155 (21 - 473)	115 (6.8)	667 (60.0)	329 (29.6)
Visit 5	1 266	169 (23 - 489)	86 (6.8)	673 (53.2)	507 (40.0)
Visit 6	1 221	173 (26 - 499)	80 (6.8)	657 (53.8)	453 (38.5)
Total	6 499	166 (20 - 523)	528 (8.2)	3 601 (55.4)	2 338 (36.2)
Type 1 diabetes					
Visit 1	386	200 (20 - 519)	48 (12.4)	137 (35.5)	201 (52.1)
Visit 2	493	180 (25 - 514)	50 (10.1)	224 (45.4)	219 (44.4)
Visit 3	544	181 (25 - 523)	48 (8.8)	251 (46.1)	245 (45.0)
Visit 4	482	172 (21 - 473)	63 (13.1)	228 (47.3)	191 (39.6)
Visit 5	688	185 (30 - 489)	49 (7.1)	295 (42.9)	344 (50.0)
Visit 6	617	174 (26 - 499)	40 (6.5)	322 (52.2)	255 (41.3)
Total	3 210	179 (20 - 523)	298 (9.3)	1 457 (45.4)	1 455 (45.3)
Type 2 diabetes					
Visit 1	472	149 (27 - 387)	40 (8.5)	316 (66.9)	116 (24.6)
Visit 2	451	151 (26 - 498)	23 (5.1)	299 (66.3)	129 (28.6)
Visit 3	555	150 (23 - 508)	38 (6.8)	377 (67.9)	140 (25.2)
Visit 4	629	141 (21 - 399)	52 (8.2)	439 (69.8)	138 (21.9)
Visit 5	578	151 (23 - 431)	37 (6.4)	378 (65.4)	163 (28.2)
Visit 6	604	172 (35 - 449)	40 (6.6)	335 (55.5)	229 (37.9)
Total	3 289	152 (21 - 508)	230 (7.0)	2 144 (65.2)	915 (27.8)

IQR = interquartile range.

We therefore believe that testing blood sugar daily is a reasonable monitoring strategy until resources allow patients to have enough test strips to check blood sugar multiple times per day.

Free provision of glucometers and strips to participants for the duration of the study is likely to have influenced the higher levels of adherence seen in these results compared with previous studies in SSA. Further research would be valuable to understand the feasibility and document the cost-effectiveness of increasing the number of glucose checks per day in this setting. As continuous glucose monitors become cheaper and more widely utilised in high-income settings, comparative studies with current SMBG models evaluating cost, feasibility, and clinical impact in low-resource settings are warranted.

Our findings suggest that use of SMBG with one strip per day at rotating times is an effective strategy to improve glycaemic control for patients with insulin-dependent diabetes in low-resource, rural populations in SSA. Low literacy and numeracy should not be reasons to avoid use of SMBG, although clinics planning to implement it should take care to provide frequent follow-up, patient support and re-education. Further research would be helpful to evaluate the effect on long-term adherence and the impact and cost-effectiveness of increasing the number of glucose checks per day. This study adds to the growing body of literature and global guidelines supporting integration of SMBG as a minimum health system requirement for patients with insulin-dependent diabetes.

## Conclusion

SMBG with one glucose check per day, at rotating times, is feasible in rural SSA. Despite common misconceptions, all patients, regardless of education level, can benefit from SMBG. Implementation of SMBG is associated with a decrease in the mean HbA1C level. Further research, including randomised controlled trials with larger sample sizes, is warranted to define a causal relationship between SMBG and improved clinical outcomes in this setting, and to understand long-term retention of SMBG activities, and the benefits of increasing frequency of monitoring.

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