

# The effect of the introduction of a standard monitoring protocol on the investigations performed on the metabolic control of type 2 diabetes at Addington Hospital Medical Outpatients Department, Durban, South Africa

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## Abstract

**Background:** A comprehensive approach to the control of type 2 diabetes is required to reduce mortality and morbidity. To improve diabetes management, in 2005 a protocol for the monitoring and management of type 2 diabetes, aligned to the 2003 Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines, was introduced at Addington Hospital Medical Outpatients Department, Durban, South Africa.

**Method:** Data were collected from 120 randomly selected patients with type 2 diabetes. The number of glycosylated haemoglobin (HbA<sub>1c</sub>) and lipid estimations, blood pressure (BP) measurements and body mass indices (BMIs) recorded in 2005 was compared with those recorded in 2008 and 2009. The mean levels of these parameters and the number of patients reaching goal in 2008 were compared with the figures for 2009.

**Results:** In 2005, 18.8% of patients had HbA<sub>1c</sub> levels measured compared with 82.9% in 2009 ( $P < 0.01$ ). The mean HbA<sub>1c</sub> was 6.9% ( $\pm 1.9$ ) in 2008 and 6.4% ( $\pm 2.0$ ) in 2009 ( $P = 0.1$ ). BP and BMI was measured in over 93% of patients in 2005, 2008 and 2009. BP goals were attained by 21% of patients in 2008 and 30% in 2009 ( $P = 0.65$ ). The mean BMI in 2008 was 29.4 kg/m<sup>2</sup> (24% achieved goal), and in 2009 it was 28.6kg/m<sup>2</sup> (29% achieved goal;  $P = 0.267$ ). Lipid estimations rose significantly from 26% in 2005 to 73% in 2009 ( $P < 0.01$ ). There was no improvement in the number of patients reaching target lipid levels between 2008 and 2009.

**Conclusion:** The monitoring protocol improved adherence to the SEMDSA 2003 guidelines from 2005 to 2009. Overall glycaemic control was within target, but attainment of most nonglycaemic goals was suboptimal and did not improve over the study period.

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## Introduction

Diabetes mellitus is a chronic disease, associated with both micro- and macrovascular complications. Previous studies have shown that while the degree of glycaemic control [as measured by glycosylated haemoglobin (HbA<sub>1c</sub>)] is significantly associated with microvascular complications, it has less of an effect on macrovascular complications.<sup>1</sup> Most deaths in subjects with type 2 diabetes occur as a result of macrovascular (predominantly cardiovascular) disease.<sup>2</sup> Therefore, focusing only on glycaemic control may impact less on mortality than on morbidity. Comprehensive management of patients with type 2 diabetes is needed, with emphasis on the management of all risk factors associated with the development of diabetes complications.

Macrovascular complications can be reduced with optimal control of blood pressure (BP) and lipid levels as well as by addressing other risk factors, such as reduction of body mass index (BMI) and cessation of cigarette smoking.<sup>3</sup>

Evidence-based guidelines are available to assist clinicians to manage patients in the most cost-effective and efficient manner. Many clinicians are either unaware of the existence of these guidelines or simply do not follow them. A number of countries, including South Africa, have developed guidelines, based on available evidence, to assist clinicians in the long-term management of patients with type 2 diabetes. However, there is a paucity of literature on adherence to diabetes management guidelines in South Africa.

This motivated the current study to assess the efficacy of clinical management of subjects with type 2 diabetes attending the Medical Outpatients Department (MOD) of Addington Hospital, Durban, South Africa, and to establish whether the introduction of a diabetes monitoring and management protocol had had any effect on the metabolic and nonmetabolic control of these patients.

Addington Hospital MOD is a chronic medical clinic where stable medical patients are monitored and reviewed every six months and treatment is prescribed. Approximately 30% of the 18 000 chronic patients seen annually at the MOD have diabetes mellitus. In September 2005, a protocol for the monitoring of patients with type 2 diabetes was introduced, based on the 2003 guidelines of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA). This report is an analysis of the effect of the introduction and implementation of the monitoring protocol at Addington Hospital MOD, comparing 2008 to 2009. The aim of the study was to determine the effect of the protocol on changes in HbA<sub>1c</sub>, lipid levels, BP, anthropometric parameters as well as the level of compliance of clinic staff in adherence to the guidelines, from 2008 to 2009.

## Method

This was an observational, analytic retrospective study. A sample size of 120 was calculated to give 73 pairs of results, which achieved the necessary power (80%), using a two-sided one-sample t-test. Using a random numbers table, 120 subjects who had been patients at the clinic since 2005 when the protocol for diabetic care was first introduced were selected.

The protocol recommended, in accordance with the 2003 SEMDSA guidelines, that at each six-monthly visit patients should have their BP and weight measured, BMI calculated and serum creatinine and HbA<sub>1c</sub> estimations performed. A fasting lipid profile should be performed either every six months or annually, depending on whether lipid levels were normal or elevated. The clinic doctors were given in-service training and instruction regarding the implementation of the protocol at the end of August 2005, when it was introduced. In 2007, following a routine notes audit, it was noted that investigations were not being performed and so the doctors were again "in-service trained" and the importance of following the protocol was stressed.

Following re-emphasis in 2007, data recorded in 2008 was compared to data recorded in 2009. Data was extracted from each subject's clinical record. Laboratory results not recorded by the attending medical officer were obtained by searching the laboratory databases of Inkosi Albert Luthuli Central Hospital (IALCH, the reference laboratory) and Addington Hospital.

The following data were collected from each patient file and recorded on a Microsoft Excel® spreadsheet:

- HbA<sub>1c</sub>
- Systolic blood pressure (SBP) and diastolic blood pressure (DBP)
- Lipids: total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides

- BMI, derived from the recorded height and weight and calculated as weight (kg) divided by height squared (m<sup>2</sup>)

Compliance with the protocol was judged by the number of HbA<sub>1c</sub> estimations performed in each year, as well as by the number of subjects in whom BMI and BP were measured and lipid profiles were performed.

### Clinical measurements

Body weight and height were measured using electronic scales with height measuring tape. The original (first-measured) height was used throughout, to counter any variation in observer readings. Patients in wheelchairs or those who were unable to stand unaided were not measured.

Welch Allyn® electronic measuring machines were used to measure BP. These machines meet or exceed the SP10: 1992 Association of Medical Instrumentation standard ( $\pm 5$  mmHg mean error, 8 mmHg standard deviation).

### Laboratory measurements

HbA<sub>1c</sub> was measured using an ion-exchange high-performance liquid chromatography (HPLC) with a coefficient of variation (CV) of 1.15% (IALCH laboratory).

*Lipid levels:* Subjects were asked to fast from 22h00 the night before, and blood was taken at 08h00. Lipids were measured on the Beckman Coulter UniCel® Dx C Synchron® 800 analyser (DXC800) in the Addington Hospital laboratory. For total cholesterol, the cholesterol esterase method was used with a CV of 4.5 %. HDL cholesterol was measured employing the direct homogenous method using cholesterol esterase and cholesterol oxidase with a CV of 4.5%. Triglyceride levels were assessed by the glycerol phosphate oxidase method with a CV of 4.5 %. For LDL cholesterol the Friedewald equation [total cholesterol - (HDL cholesterol + triglyceride / 2.2)] was used (Addington hospital laboratory).

Bias was eliminated by the inclusion of all suitable subjects. There were three patients whose files could not be located and two patients whose files were incomplete. These patients were included.

### Statistical analysis

Data was recorded as mean  $\pm$  standard deviation. McNemar's paired t-test was used to compare the means of the parameters measured in 2008 with the corresponding parameters in 2009. Chi-square test was used to compare the percentage of subjects attaining preset goals in 2008 and in 2009. The level of significance was set at 0.05. No confounders were considered or measured.

### Ethics approval

Ethics approval was obtained from the Postgraduate Committee at the Nelson R Mandela School of Medicine, the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (reference number EXP003/06), the Ethics Committee at Addington Hospital and the Provincial Health

Research Committee, and permission to do the study at Addington Hospital was obtained from the acting medical manager.

## Results

Of the 120 randomly selected patients, 117 files were located. Of these, 115 files were complete. In the case of two files, the data for 2005 was missing but the later data (2008 and 2009) was available. These patients were included, as the significant data required was that of 2008 and 2009. The study group comprised 37 men and 82 women. Ages were not recorded.

Table I shows the number of tests performed for each measured parameter. The number of investigations performed in 2005 (before the introduction of the protocol) is included as a comparison with what was done in 2008 and 2009, after the protocol was re-emphasised. Very few HbA<sub>1c</sub> (18.8%) estimations were performed in 2005, but there was a significant improvement in 2008 (74.3%) and 2009 (82.9%,  $P < 0.01$ ).

There was no significant difference in the number of BP measurements performed between any of the years (2008 vs. 2009,  $P = 1.0$ ).

In 2005, only 5% of patients had fasting lipid levels requested with 21% of the subjects having had total cholesterol levels measured only. In 2008, 35% of subjects

had full lipid profiles, with another 36% having had total cholesterol levels measured only. In 2009, 51% of patients had fasting lipid levels estimated, with a further 22% having had total cholesterol levels measured only. There was a significant improvement in the number of fasting lipid profile estimations between 2005 and 2009 ( $P < 0.01$ ) and between 2008 and 2009 ( $P < 0.01$ ).

Table II shows the metabolic and nonmetabolic parameters recorded in the study group in 2008 and 2009. Over the study period, no significant change was observed in HbA<sub>1c</sub>, SBP, DBP or BMI values. Total cholesterol and LDL cholesterol remained virtually unchanged, while triglycerides and HDL cholesterol deteriorated slightly.

The mean HbA<sub>1c</sub> in 2005 was 8.6 ( $\pm 1.9$ ) %, but the mean HbA<sub>1c</sub> for both 2008 and 2009 was within the recommended goal level ( $< 7\%$ ). The reduction of 0.4% in HbA<sub>1c</sub> levels between 2008 and 2009 was not statistically significant ( $p = 0.1$ ). Nonsignificant improvement in SBP, DBP, total cholesterol, LDL cholesterol and BMI occurred from 2008 to 2009 while there was a nonsignificant deterioration in triglycerides and HDL cholesterol.

Table III shows the number of subjects reaching target levels. The number of subjects reaching the goal for HbA<sub>1c</sub> did not improve significantly between 2008 and 2009 ( $P = 0.307$ ). In 2008 only 20% of subjects reached the SBP goal levels while in 2009, 31% did. This trend did not, however, reach significance ( $P = 0.065$ ). There was no significant improvement in subjects reaching goal DBP ( $P = 0.59$ ). Lipid control deteriorated between 2008 and 2009. There was no significant improvement in subjects reaching goal for total cholesterol ( $P = 0.227$ ) while the number for triglycerides ( $P = 0.125$ ), HDL cholesterol ( $P = 0.063$ ) and LDL cholesterol ( $P = 1.0$ ) all deteriorated.

The increase in subjects reaching BMI levels was not significant.

**Table I:** Number of tests performed in 2005 (before the introduction of the protocol), compared with 2008 and 2009 (after the introduction)

	2005 n (%)	2008 n (%)	2009 n (%)	P value*
HbA <sub>1c</sub>	22 (18.8)	87 (74.3)	97 (82.9)	$< 0.01$
Blood pressure measurement	109 (93.1)	115 (98.3)	114 (97.4)	1.0
Total cholesterol levels only	25 (21)	42 (36)	26 (22)	0.71
Fasting lipid profiles	6 (5)	41 (35)	68 (51)	$< 0.01$
Body mass index	108 (92)	108 (92)	110 (94)	1.0

**Table II:** Glycaemic and nonglycaemic parameters in the study population in 2008 and 2009

	SEMDSA 2003 target levels	2008*	2009*	P value
HbA <sub>1c</sub> (%)	$< 7$	6.9 (2.0)	6.4 (1.9)	0.1
SBP (mmHg)	$< 130$	143 (20)	141 (20)	0.065
DBP (mmHg)	$< 80$	79 (11)	78 (10)	0.590
Total cholesterol (mmol/l)	$< 5.0$	5.1 (1.0)	5.0 (1.0)	0.227
Triglyceride (mmol/l)	$< 1.5$	1.7 (0.8)	2.0 (1.2)	0.125
HDL cholesterol (mmol/l)	$\geq 1.2$	1.15 (0.35)	1.03 (0.31)	0.063
LDL cholesterol (mmol/l)	$< 3$	3.06 (0.96)	3.05 (1.05)	1.0
Body mass index (kg/m <sup>2</sup> )	$< 25$	29.4 (9.7)	28.6 (9.74)	0.267

\* Data expressed as mean ( $\pm$  standard deviation)

**Table III:** Number of patients (%) reaching the SEMDSA 2003 goals

Parameter	2008 n (%)	2009 n (%)	P
HbA <sub>1c</sub>	51 (59)	69 (71)	0.307
SBP	23 (20)	35 (31)	0.065
DBP	61 (53)	65 (57)	0.590
Total cholesterol	33 (40)	41 (44)	0.227
Triglycerides	19 (46)	26 (38)	0.125
HDL cholesterol	15 (38)	13 (19)	0.063
LDL cholesterol	24 (60)	29 (45)	1.0
Body mass index	27 (24)	33 (29)	0.267

## Discussion

A number of landmark clinical studies have shown that good glycaemic control in subjects with type 2 diabetes reduces microvascular complications and, to a lesser extent, macrovascular complications. More recently, glycaemic control has been shown to have a beneficial effect on long-term macrovascular complications if good control is achieved from the time of diagnosis.<sup>4</sup> Despite this information being widely known, attainment of metabolic and nonmetabolic targets is often not achieved or sustained. This study aimed to address this important issue through the implementation of a specific guideline protocol in a group of subjects with type 2 diabetes, managed at a primary care level. Each medical practitioner at the site was encouraged to implement the protocol which was based on the existing SEMDSA guidelines. The implementation of the guideline protocol was reinforced through in-service training, and the study sought to measure the efficacy of this intervention, both on metabolic and nonmetabolic parameters.

Addington Hospital MOD caters for a wide range of general medical conditions, including type 2 diabetes. Adherence to the guidelines for the management of type 2 diabetes at a primary health care level put out by SEMDSA in 2003 (that every affected subject requires determination of HbA<sub>1c</sub> at least six-monthly) was shown to be grossly suboptimal when the 2005 statistics were evaluated.

The current data showed that the number of HbA<sub>1c</sub> estimations rose significantly from 2005 (18.8%) to 2008 (74.3%) and to 2009 (82.9%,  $P = 0.01$ ), suggesting an improvement in the level of compliance with the guidelines by the doctors. Notwithstanding this improvement, 17.1% of patients still did not have a single HbA<sub>1c</sub> level measured in 2005, 2008 and 2009. The present study showed that in 2008, 59% of patients were at the SEMDSA target for HbA<sub>1c</sub> and by 2009 this had risen to 72%. However, this difference was not significant ( $P = 0.307$ ). Between 2008 and 2009, the mean HbA<sub>1c</sub> level fell from 6.9% to 6.4%. These observations are difficult to explain, given the preponderance of literature showing the difficulty in attaining and sustaining HbA<sub>1c</sub> levels. One feature of the study population that may have influenced the HbA<sub>1c</sub> results was the fact that the majority of subjects had been attending the clinic since 2005 and were still attending in 2009, indicating a good degree of compliance with clinic attendance and, possibly, also with adherence to treatment regimens. In addition, it is usual for patients with poor glycaemic control to be referred from Addington Hospital MOD to a higher level of expertise for assistance with ongoing care, and thus the remaining clinic attendees were overall more stable, with good glycaemic control.

The study showed that the overall results for HbA<sub>1c</sub> were good with 82.9% of patients having HbA<sub>1c</sub> estimations performed and 72% of patients at target goal. There was significant improvement in HbA<sub>1c</sub> measurement between

2005 and 2008/2009, and this suggests adherence to recommended practice guidelines by the attendant medical officer staff complement and a positive outcome to the implementation of the protocol for the management of type 2 diabetes in Addington Hospital MOD.

Blood pressures are recorded routinely in patients attending Addington Hospital MOD, and so the high levels of compliance achieved for this parameter (in excess of 90%) are expected. There is extensive evidence that targeted antihypertensive treatment is important for cardiovascular risk reduction in patients with type 2 diabetes, and therefore every effort should be made to reach goal levels.<sup>5</sup> Control of SBP has been suggested to be a more important cardiovascular risk-reduction factor than control of DBP, except in patients younger than 50 years, but SBP is more difficult to control.<sup>6</sup> As most patients (especially those younger than 50 years) with hypertension will reach the DBP goal once SBP is at goal, the primary focus should be on achieving the SBP goal.<sup>7</sup> However, in the present study only 30% were in the target range for SBP. There are recommendations that patients adhering to full doses of an appropriate three-drug regimen and who are not reaching goal BP levels should be referred to a hypertension specialist.<sup>7</sup> The present study did not collect information on anti-hypertensive therapy and it is not possible to define the reasons for the lack of uniform attainment of BP goals. This finding nevertheless highlights an important shortcoming in the management of these patients that will require further attention in order that the overall degree of blood pressure control is improved.

Lipids play an important part in cardiovascular and stroke risk. Patients with type 2 diabetes commonly present with atherogenic dyslipidaemia, characterised by elevated triglycerides, low plasma levels of HDL cholesterol and a preponderance of small dense LDL cholesterol particles, which increase the risk of atherogenesis even at normal LDL cholesterol concentrations.<sup>8</sup> Therefore, it is important to attempt to reduce triglyceride and LDL cholesterol levels while elevating HDL cholesterol levels. There is extensive trial evidence that a reduction in lipid levels is important for lowering the cardiovascular risk in patients with type 2 diabetes.<sup>9</sup> The United Kingdom Prospective Diabetes Study (UKPDS 23) showed that a low HDL cholesterol level and an increase in LDL cholesterol levels predicted coronary heart disease to a greater extent than hyperglycaemia.<sup>10</sup> For this reason, obtaining fasting lipid profiles is more relevant than obtaining a total cholesterol level.

In the present study, only 26% of patients had any form of lipid measurement performed in 2005 and of these only 5% were fasting lipid profiles. In 2008, 71% of the study group had lipid estimations performed, but only 35% were fasting lipid profiles. By 2009, 51% of patients had fasting lipid profiles performed although the total lipid tests remained constant at 73%. The improvement between 2005 and 2008

is significant ( $P = 0.01$ ), as is the improvement between 2008 and 2009 ( $P = 0.01$ ), indicating improved compliance on the part of the doctors.

For accurate results, patients need to fast for 10 hours prior to having a fasting lipid profile performed. Patients may forget to fast for the required time period, and this would limit the number of fasting lipid profiles that can actually be performed. At Addington Hospital MOD, total cholesterol estimation is ordered on patients who have forgotten to fast. The mean total cholesterol in 2009 was 5.0 mmol/l, but only 44% of patients achieved the SEMDSA goal. There was no significant improvement compared to the 40% who achieved goal in 2008 ( $P = 0.227$ ). The results of the fasting lipid profile estimations were disappointing, with fewer patients reaching SEMDSA goal levels in 2009 than in 2008.

As with BP recording, height and weight are routinely measured at clinic visits, so the high levels of compliance achieved on these parameters (over 92%) were expected. The mean BMI fell from 29.4 kg/m<sup>2</sup> in 2008 to 28.6 kg/m<sup>2</sup> in 2009, which is a small improvement. The number of patients who achieved goal BMI levels rose from 24% in 2008 to 29% in 2009, but this is not statistically significant ( $P = 0.267$ ). Despite this, these results provide some encouragement in light of the global struggle to contain the epidemic of obesity, from which South African populations are not exempt: in South Africa 30% of adult men and 55% of adult women are overweight.<sup>11</sup> Weight gain is a major contributor to the increasing incidence of type 2 diabetes. Both are independent risk factors for the development of cardiovascular disease.<sup>12</sup> Difficulties in achieving weight loss may be partly cultural, and it has been shown that few overweight black women consider themselves overweight and that thinness is associated with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).<sup>13</sup> A Cape Town study of 240 black girls showed that two-thirds perceived fatness as a sign of happiness and wealth.<sup>14</sup> Three-quarters of the girls associated thinness with ill health, notably HIV/AIDS and tuberculosis.

For any weight-reducing program to work, it needs reasonable weight goals, healthy eating, adequate physical activity and behavioural change.<sup>13</sup> Jackson et al. suggest that obesity cannot be dealt with at a diabetes clinic.<sup>15</sup> At Addington Hospital MOD, obese patients are referred to the dieticians for weight control, but more effort needs to be made to motivate patients to lose weight.

### Study limitations

Information on the doctors was pooled. There may be considerable variation in the adherence to the protocol by different doctors. Unfortunately, patients did not always see the same doctor and may have been treated by different doctors at each visit. Only results that were recorded could be analysed. Information on lifestyle and advice to reduce weight may have been given but not recorded.

## Conclusion and recommendations

The introduction of a protocol does not ensure that doctors will adhere to the protocol, nor does it mean that goals will be met.

This study showed that with repeated emphasis the protocol was accepted and guidelines were followed in relation to the investigation performed, but although overall glycaemic control was within target, attainment of most nonglycaemic goals was suboptimal and did not improve over the study period.

The introduction of a guideline must be accompanied by in-depth education for the doctors concerned, as well as regular re-emphasis of the guideline. Only in this way will guidelines become accepted and implemented. Further studies are needed to determine why guidelines are not routinely followed and whether, with time, more patients in this study will achieve target goals.

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