# CHAPTER 4

# Management of inpatients with diabetes who are able to eat meals: An audit before and after the implementation of a standardised inpatient management protocol.

## *Abstract*

**Background:** Globally the prevalence of diabetes is increasing, which results in more patients with diabetes being admitted to hospital for diabetes related and diabetes unrelated causes. There are good reason for blood glucose to be controlled in hospital because of an increased risk of mortality and morbidity associated with hyperglycaemia. Current guidelines exist, detailing management of blood glucose in hospitalised patients. The implementation of these guidelines are often problematic and the guidelines are often not followed.

**Objectives:** This study attempted to implement a structured inpatient management protocol to assess if glucose control in hospital would be improved.

**Methods:** This was a quasi-experimental study with a before and after design. An audit of glycaemic control was done before and after physicians' and nurse training program as well as the introduction of a standardised inpatient management protocol. A second audit was done to assess the impact of the intervention on glycaemic control.

**Results:** The first audit included records of 164 patients and the second audit 199 patients. Of these, 150 records from audit one, and 183 records from audit two were eligible for inclusion in the study. On the first full day of hospitalisation the mean blood glucose was significantly higher in the second audit (1.72 mmol/L higher) ($p < 0.001$). This could be attributed mostly to patients admitted to internal medicine in whom the average blood glucose was 2.07 mmol/L higher ($p < 0.001$). A significant improvement in mean blood glucose was seen from day one to day seven within audit two (-1.88 mmol/L, $p < 0.001$), within audit one this change was not significant (-0.88 mmol/L, $p = 0.33$). Despite the higher mean blood glucose at day one, the proportion of patients that achieved a mean daily blood glucose of less than 10 mmol/L during hospital admission was very similar (43.0% versus 43.7%, $p = 0.97$). The number of hypoglycaemic events (blood glucose less than 4 mmol/L) per day of

hospitalisation increased significantly during audit two (19.6 versus 17.2 events per 100 patient days, p = 0.048). After adjustment for age, diabetes related admission or not and known with diabetes before admission or not mean blood glucose values was still higher in audit 2 than in audit 1 over time.

**Conclusion:** This study found no evidence that implementation of a standardised management protocol reduces hyperglycaemia and achieves earlier target blood glucose levels, in comparison to a free unstructured approach in inpatient glycaemic management.

## *Introduction*

The global prevalence of diabetes is estimated to be 6.6% of the population, amounting to a staggering 285 million people. It is estimated that the prevalence will increase to 7.8% by the year 2030 (438 million people). The prevalence in Southern Africa is estimated at 4.5 to 5% and is expected to increase to 5 to 7% by 2030.[1] The increased prevalence of diabetes results in an increase in hospital admissions of patients with diabetes for diabetes related or unrelated problems.

Umpierrez et al.[2] studied admissions (medical and surgical) in a community hospital in the USA and found 26% of inpatients were known to have diabetes and 12% were newly diagnosed with diabetes in hospital. From the mentioned study patients with newly diagnosed hyperglycaemia were at higher risk of being admitted to ICU compared to patients with known diabetes and non-diabetic patients (29%, 14%, and 9% respectively). Inpatients with newly diagnosed hyperglycaemia were also at significantly higher risk of death (16%) in comparison to patients with known diabetes (3%) and non diabetic patients (1.7%). The reason for the excessively high mortality and morbidity rate in the newly diagnosed patients was that the hyperglycaemia was often left untreated (only 13% of these patients had a diabetic diet prescribed, 2% were prescribed oral hypoglycaemic agents, 6% received scheduled insulin dosages, and 35% were prescribed a sliding scale). However no randomised trial has been published examining the effect of intensive glycaemic control on outcomes in hospitalised patients outside ICU.

A number of observational studies have demonstrated a correlation between hyperglycaemia in peri-operative inpatients and adverse outcomes. Pomposelli et al.[3] found that a single blood glucose measurement in the first post-operative day of more than 12.2 mmol/L amounted to a 2.7 times higher risk of nosocomial infections. Similar findings were reported after trauma independent of the injury characteristics.[4] In patients with pneumonia the risk of

death also increased with an increase of blood glucose on admission; it seemed that the risk of in-hospital death increased by 8% for every one mmol/L increase in blood glucose after adjustment for the pneumonia severity.[5]
Zerr et.al.[6] conducted a study in cardiac surgery patients from 1991 to 2001 with management of blood glucose to a target range of: 8.3 - 11.1 mmol/l. An optimal blood glucose in the first 2 days post surgery resulted in a reduction of deep wound infections from 2.4% to 1.5% ($p \leq 0.02$).

In contrast, prospective randomised controlled trials attempting to obtain good glycaemic control show conflicting results for critically ill patients. If all ICU patients are included the RR for mortality between patients on intensive insulin treatment and conventional insulin treatment is 0.93 (CI 0.83 to 1.04). For purely medical ICUs the RR is 1 (CI 0.78 to 1.28), for mixed medical and surgical ICUs the RR for mortality is 0.99 (CI 0.87 to 1.12), and, for purely surgical ICU's the RR for mortality is 0.63 (CI 0.44 to 0.91). In this latter group one study by van den Berghe [7] explains this beneficial effect - all other studies were small and non-significant.[8]

Olson et. al.[9] analysed the impact of a hospital-wide diabetes management program on quality of care, length of stay and cost. They concluded that when more patients with diabetes were identified earlier during hospital stay, care was better as measured by lower mean blood glucose concentration (from 13.5 mmol/L to 8.21 mmol/L) and length of stay was reduced (8 days to 4.3 days).

We conducted this study to evaluate the effectiveness of the implementation of a structured protocol for management of blood glucose in inpatients with diabetes who are not critically ill.

## *Methods*

### Setting and participants

The study was conducted on patients admitted to Kalafong hospital, a large secondary hospital in the west of Tshwane district. A cross sectional audit of hospital records was done on two occasions. The first audit was done on records of patients admitted from May 2005 to December 2005 (reported in Chapter 2 of this thesis). The second audit was done on records of patients admitted from November 2006 to October 2007. Between the two audits a physician and nurse training programme was implemented.

The physician training programme consisted of formal lectures on how to manage non-fasting diabetic patients in the general wards. These lectures were presented at each department's regular meetings where all doctors of the department were present. The nurses were trained in the wards by a nurse educator who went from ward to ward offering nurses in-service training. All wards were issued with a poster with the diabetes management protocol; the protocol was put up against the wall at a conspicuous place in each ward. A new glucose monitoring sheet was introduced on which glucose monitoring in the wards was captured as well as record was kept of basal, prandial and supplemental insulin administered (see attached appendix).

All diabetic patients qualified for inclusion in the study provided they were eating and not on an insulin infusion. Patients who were admitted to the high care and intensive care units were included only after discharge to the wards. All records of diabetic patients were audited irrespective of the severity of the underlying disease and the reason for admission. Patients were prospectively identified for inclusion in the second audit on admission to the hospital. However, the researcher made no attempt to interfere or intervene in the management of the treating physician or caring nurses.

## Measurements and data collection

Data was extracted from patient records for each of the patients included in the study. The data sources utilised were nursing notes and record sheets, medication administration sheets, vital sign and glucose monitoring sheets as well as physicians' clinical notes. All capillary blood glucose measurements and blood pressure measurements were recorded from patients' records for day one, three, seven and the last day of admission.

The outcome measures were: The mean blood glucose of patients on the first, third and seventh full day of hospitalisation and the time to glycaemic control. Glycaemic control was defined as the mean of all capillary glucose measured in 24 hours less than 10 mmol/L. The number of hospital days until glycaemic control was achieved was recorded. The proportion of patients who achieved glycaemic control according to the above mentioned criteria at discharge were determined. The number of inpatient hypoglycaemic events was counted for each patient. Hypoglycaemia was defined as finger prick blood glucose of less than 4 mmol/L.[10] Other patient information that was collected included: age, gender, reasons for admission, treatment before admission, unit and discipline admitted to, duration of diabetes since diagnosis, length of hospital stay, and patient outcome.

## Statistical analysis

Data was captured electronically in a Microsoft Access database. Statistical analysis was done utilising SPSS 17 for Windows (SPSS Inc, 2008) and STATA 12 statistical software (StataCorp. 2011. *Stata Statistical Software: Release 12*. College Station, TX: StataCorp LP). All proportions are reported as percentages and continuous variables are reported as means and standard deviations (SD) except where data is ordinal or skew in which case it is reported as medians and inter-quartile ranges (IQR).

The analysis within each audit was done comparing. blood glucose change (delta) of day 1 to day 3 and day 3 to day 7 with a paired t-test.

Comparison between audit one and two were done as follows:

The repeated mean daily glucose profiles over time (day1, day 3 and day 7) were analysed using a covariance pattern model in STATA. Firstly, a saturated model including all the clinically important variables and the audit*time interaction was compiled. Based on Wald tests the fixed effects with highest p values were dropped from the model. An exchangeable covariance structure was used utilising maximum likelihood estimation. The model with and without the interaction term was assessed with a likelihood ratio test. Least square means contrasts between the two audits at different times were tested using the contrast option after the mixed model.

Secondly, the difference in time from admission to glycaemic control between the two audits was determined using survival analysis with Cox-proportional hazards modelling. For this analysis glycaemic control was defined as a mean blood glucose of all glucose measurements done per day, less than 10 mmol/L.

## *Results*

### Patient characteristics (Table I)

The records of 150 patients were evaluated in the first audit, with 11 patients from the department of Ophthalmology and 3 from the department of Gynaecology excluded in the analysis because of the lack of patients of similar departments in audit two. The second audit evaluated 184 patient records, with 15 pregnant patients from the Obstetrics unit and 1 patient from the department of Gynaecology excluded because the first audit did not include any obstetric patients and very few gynaecology patients. Figure 1 indicates the numbers of patients included and excluded to the study as well as the distribution between departments for both the first and second audits.

Baseline characteristics of all patients, reasons for admission and co-morbidities are given in table I.

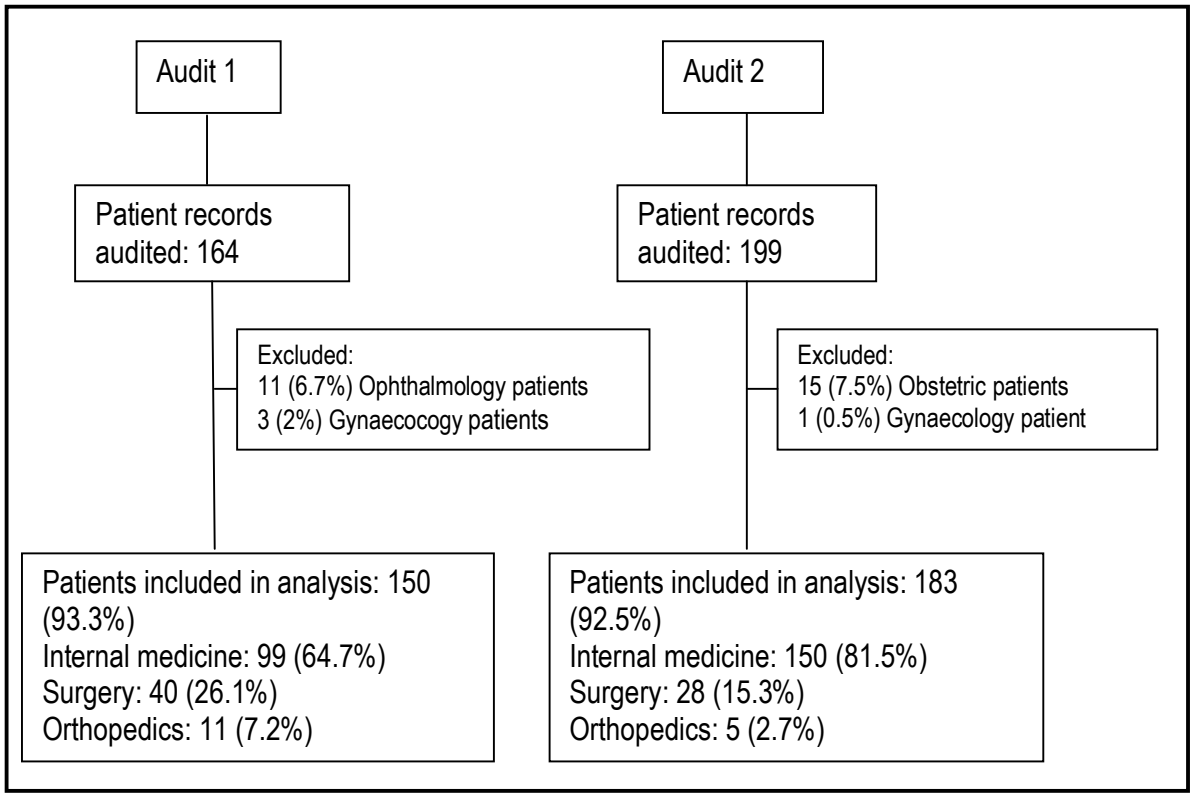


**Figure 1: Flow of patients for analysis**

## Blood glucose

The mean blood glucose on the first full day of admission was significantly higher for audit two in comparison to audit one (delta: 1.7 mmol/L, $p < 0.001$). For patients admitted to the internal medicine units the difference between audit one and two were 2.1 mmol/L ($p = 0.001$) (Table II). The difference in baseline blood glucose between audit one and two was significantly different for the internal medicine units in comparison to that of the surgery and orthopaedic units together (2.0 mmol/L, $p < 0.001$).

For both audits the blood glucose change within the audit from day one to day three was not statistically significant ($p = 0.227$ for audit one and $p = 0.163$ for audit two). However the decrease in mean blood glucose from day one to day seven and from day one to the last day was significant for audit two (Delta: -1.9 $p < 0.001$ and delta: -2.2 $p < 0.001$ respectively). For Audit one the change in mean blood glucose from day one to day three increased non- significantly (Delta: 0.1 $p = 0.227$).

**Table I: Patient characteristics in audit 1 and 2**

| Audit of diabetic inpatients | Audit 1 All N=150 | Audit 2 All N = 183 | P |
|---|---|---|---|
| Patient age (years) | | N = 177 | 0.012 |
| mean (SD) | 58.1 (15.1) | 53.6 (16.7) | |
| Duration of hospitalisation (days) median (IQR) | 8 (4 – 14) range 1 - 87 | 8 (6 – 12) range 2 – 40 | 0.185 |
| Duration of Diabetes (years) diagnosed before admission median (IQR) | N = 76/132 6 (2.25 – 12) | N = 120/142 5 (1 – 11) | 0.253 |
| Newly diagnosed | 19 (12.6%) | 42 (23%) | 0.016 |
| Gender Male | 41 (27.3%) | 75 (41%) | |
| Female | 109 (72.7%) | 108 (59%) | 0.013 |
| Diabetes treatment before admission (newly diagnosed cases excluded) | N = 138 | N = 136 | |
| No treatment | 20 (14.5%) | 4 (2.9%) | <0.001 |
| Diet only | 12 (8.7%) | 0 | |
| Oral treatment only | 74 (53.6%) | 69 (50.7%) | |
| Insulin only | 20 (14.5%) | 37 (27.2%) | |
| Combination oral and insulin | 12 (8.7%) | 26 (19.1%) | |
| Department hospitalised to | | | |
| Internal Medicine | 99 (64.7%) | 150 (82%) | 0.001 |
| Surgery | 40 (26.1%) | 28 (15.3%) | 0.015 |
| Orthopaedics | 11 (7.2%) | 5 (2.7%) | 0.09 |
| Primary reason for admission: | | | |
| Hyperglycaemia (excluding DKA and ketosis) | 34 (22.7%) | 92 (50.3%) | <0.001 |
| Hypoglycaemia | 10 (6.7%) | 14 (7.6%) | 0.718 |
| DKA or ketosis | 12 (8%) | 38 (20.7%) | 0.002 |
| Leg and foot problems | 17 (11.3%) | 23 (12.57%) | 0.861 |
| Uncontrolled hypertension | 13 (8.6%) | 14 (7.6%) | 0.892 |
| Cardiovascular disease and stroke | 22 (14.6%) | 11 (6.01%) | 0.015 |
| Renal disease | 7 (4.6%) | 5 (2.73%) | 0.518 |
| Respiratory disease including pneumonia | 13 (8.6%) | 9 (4.92%) | 0.251 |
| Tuberculosis | 4 (2.6%) | 3 (1.64%) | 0.79 |
| Infections excluding respiratory and tuberculosis | 3 (2%) | 5 (2.73%) | 0.941 |
| Malignancy | 4 (2.6%) | 2 (1.1%) | 0.51 |
| Gastro-intestinal problems | 12 (8%) | 6 (3.3%) | 0.098 |
| Retroviral disease (HIV) | 1 (0.67%) | 4 (2.2%) | 0.496 |
| Orthopaedic related excluding leg and foot problems | 16 (10.6%) | 5 (2.73%) | 0.006 |
| Other | 10 (6.7%) | 8 (4.4%) | 0.498 |
| Patient outcomes | N = 144 | N = 183 | |
| Discharged | 126 (87.5%) | 169 (92.3%) | 0.201 |
| Died | 12 (8.3%) | 8 (4.4%) | 0.44 |
| Self discharged* | 6 (4.1%) | 6 (3.3%) | 0.85 |
| HbA1c on admission (%) | N = 71 | N = 115 | |
| Mean (SD) | 11.3 (4.3) | 13.3 (3.6) | 0.139 |

*patients who refuse further hospital treatment

However, a significant decrease in mean blood glucose was evident from day one to the last day of hospitalisation (Delta: −2.0, $p < 0.001$). (See Figure 2) The change in mean blood glucose from day one to day seven in audit one (−0.88

mmol/L, p = 0.33) was significantly less than that of audit two (−1.9 mmol/L) (p = 0.031).

The improvement in mean blood glucose from day one to day seven was not consistent for all four departments. In audit one for internal medicine the mean blood glucose increased first (Delta: 0.1 p = 0.277) to day three and then decreased (delta: -1.0 p = 0.358), however the decrease from day one to the last day before discharge was significant (Delta: -2.0, p < 0.001). Audit two showed an initial slow decline in blood glucose from day one to day three (delta: -0.5, p = 0.163), the decline steepened to day seven (Delta: -1.9, p < 0.001) and a significant decline was observed from the first day to the last day of admission (Delta: -2.2, p = < 0.001) (Figure 2 and Table II).

**Table II: Median duration of hospitalisation and comparison of unadjusted mean blood glucose for day 1, day 3, day 7 and the last day hospitalised for disciplines separately and together**

| | Audit 1 | | Audit 2 | | p |
|---|---|---|---|---|---|
| **Internal Medicine** | N | | N | | |
| Length of hospital stay median (IQR) (days) | 99 | 8 (5 to 13) | 150 | 8 (6 to 11) | 0.494 |
| Mean (SD) glucose day 1 (mmol/L) | 91 | 10.7 (4.7) | 150 | 12.8 (4.7) | 0.001 |
| Mean (SD) glucose day 3 (mmol/L) | 78 | 10.9 (4.6) | 139 | 12.1 (4.5) | 0.056 |
| Mean (SD) glucose day 7 (mmol/L) | 49 | 9.9 (4.4) | 76 | 10.5 (3.9) | 0.44 |
| Mean (SD) glucose last day (mmol/L) | 81 | 9.0(3.6) | 150 | 10.2 (3.2) | 0.006 |
| **Surgery** | | | | | |
| Length of hospital stay median (IQR) (days) | 40 | 5 (2 to 17) | 28 | 11 (6. to 15) | 0.034 |
| Mean (SD) glucose day 1 (mmol/L) | 34 | 10.7 (3.3) | 28 | 10.3 (4.0) | 0.671 |
| Mean (SD) glucose day 3 (mmol/L) | 19 | 11.1 (4.9) | 27 | 10.9 (3.7) | 0.839 |
| Mean (SD) glucose day 7 (mmol/L) | 12 | 9.4 (3.3) | 19 | 10.6 (4.1) | 0.376 |
| Mean (SD) glucose last day (mmol/L) | 33 | 7.9 (0.3) | 28 | 9.9 (4.3) | 0.047 |
| **Orthopaedics** | | | | | |
| Length of hospital stay median (IQR) (days) | 11 | 5 (4 to 12) | 5 | 18 (11 to 26) | 0.031 |
| Mean (SD) glucose day 1 (mmol/L) | 9 | 9.3 (2.7) | 5 | 11.5 (4.0) | 0.261 |
| Mean (SD) glucose day 3 (mmol/L) | 6 | 8.2 (1.4) | 5 | 11.7 (3.3) | 0.043 |
| Mean (SD) glucose day 7 (mmol/L) | 4 | 9.4 (4.7) | 5 | 10.1 (2.0) | 0.754 |
| Mean (SD) glucose last day (mmol/L) | 8 | 7.9 (3.3) | 5 | 10.3 (2.6) | 0.0204 |
| **All disciplines** | | | | | |
| Length of hospital stay median (IQR) (days) | 150 | 8 (4 to 14) | 183 | 8 (6 to 12) | 0.185 |
| Mean (SD) glucose day 1 (mmol/L) | 134 | 10.7 (4.0) | 183 | 12.3 (4.6) | <0.001 |
| Mean (SD) glucose day 3 (mmol/L) | 103 | 10.8 (4.5) | 171 | 11.9 (4.4) | 0.042 |
| Mean (SD) glucose day 7 (mmol/L) | 65 | 9.8 (4.2) | 100 | 10.5 (3.9) | 0.255 |
| Mean (SD) glucose last day (mmol/L) | 122 | 8.6 (5.5) | 183 | 10.2 (3.4) | <0.001 |

For patients admitted to the surgery department in audit one a non-significant increase in mean blood glucose was seen from day one to day three (Delta: 0.42, p = 0.328). This increase was not maintained and the mean blood glucose

to day seven decreased (Delta from day one: -1.4, p = 0.55). The mean blood glucose on the last day before discharge was significantly lower compared to day one (Delta: -2.8, p <0.001). At the second audit the mean blood glucose increased from day one to day three (Delta: 0.5, p = 0.484), from day 3 to day seven (Delta: 0.2, p = 0.983). The mean glucose however decreased non-significantly by 0.4 mmol/L (p = 0.68), from day one to the day before discharge. The trends for orthopaedics can be seen in figure 3 but is not reliable because of small numbers.

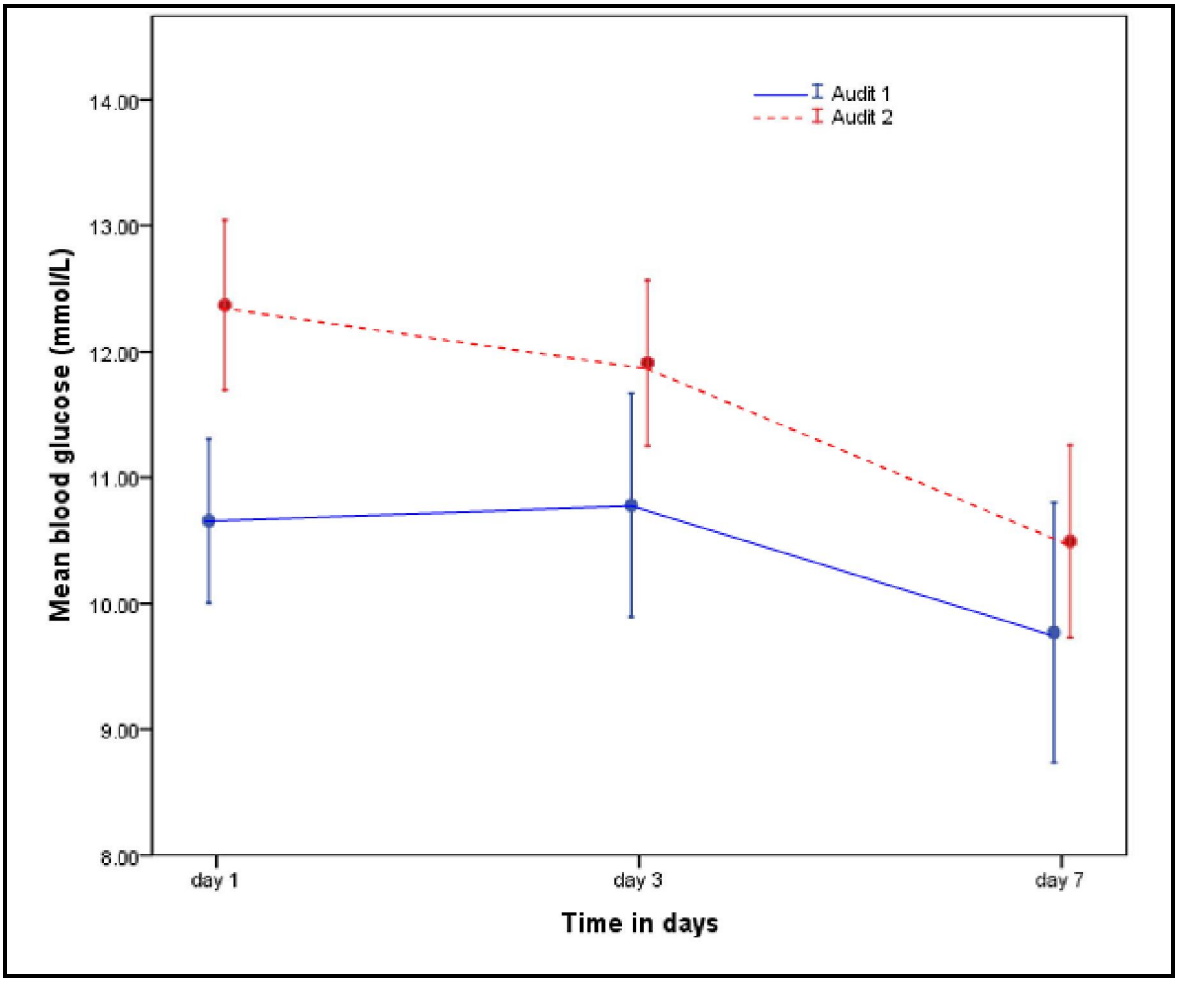


**Figure 2: Unadjusted change in mean blood glucose from day one to day seven of hospital admission**

## Hypoglycaemia

The number of hypoglycaemic events per hospital day in audit two (19.6 events per 100 patient days) was significantly more than in audit one (17.2 events per 100 patient days) (p = 0.048). Hypoglycaemic events during the day of admission were not included in the analysis to prevent bias introduced by patients admitted for hypoglycaemia.

## Adjusted between audit analysis of glycaemic control

Audit one and two was done more than a year apart and from the audits it seems that a significant change occurred in patient demographics and severity of disease (Tables I, II). Baseline (day 1) blood glucose in audit two were significantly higher than in audit one. Therefore an adjusted analysis was done. The final model was adjusted for age, diabetes related admission or not and, known diabetes before admission or not. Hyperglycaemia as primary reason for admission was not adjusted for because it was probably under reported in audit one, and therefore not comparable to that of audit two. The model with the interaction term (audit*time) included is shown below.

**Table III: Saturated model with interaction term**

| Variables included in the model | Coefficient | P | 95% Conficence interval |
|---|---|---|---|
| Age | -0.05 | <0.001 | -0.1 to -0.0 |
| Diabetes related admission | 1.3 | 0.001 | 0.5 to 2.1 |
| Audit (Reference audit is audit 1) | 0.8 | 0.083 | -0.1 to 1.8 |
| Time with reference time day 1 | | | |
| Day 3 | 0.2 | 0.689 | -0.7 to 1.0 |
| Day 7 | -0.7 | 0.138 | -2.6 to -0.0 |
| Interaction (audit*time) reference audit 1 and time day 1 | | | |
| At day 3 | -0.6 | 0.266 | -1.7 to 0.5 |
| At day 7 | -1.3 | 0.049 | -2.6 to -0.0 |
| Diabetes known before admission | -1.7 | <0.001 | -2.6 to -0.7 |
| Constant | 14.7 | <0.001 | 13.0 to 16.5 |

The coefficient for audit can now be seen as the unweighted average of the audit effect obtained from each time point (0.8 mmol/l higher in audit 2 versus

audit 1). However as the 95% CI indicates this was just not statistically significant (-0.1 to 1.8)

Based on the model the predicted values for each audit at day 1, day 3 and day 7 are presented in table IV and graphically in figure 4

**Table IV: Predicted mean glucose values for day 1, day 3 and day 7 based on model in table III**

| Time | Audit | Predicted mean blood glucose | 95% confidence interval |
|---|---|---|---|
| Day 1 | 1 | 11.2 | 10.5 to 11.9 |
| Day 1 | 2 | 12.0 | 11.4 to 12.6 |
| Day 2 | 1 | 11.4 | 10.6 to 12.2 |
| Day 2 | 2 | 11.6 | 11.0 to 12.2 |
| Day3 | 1 | 10.5 | 9.5 to 11.4 |
| Day 3 | 2 | 10.0 | 9.2 to 10.8 |

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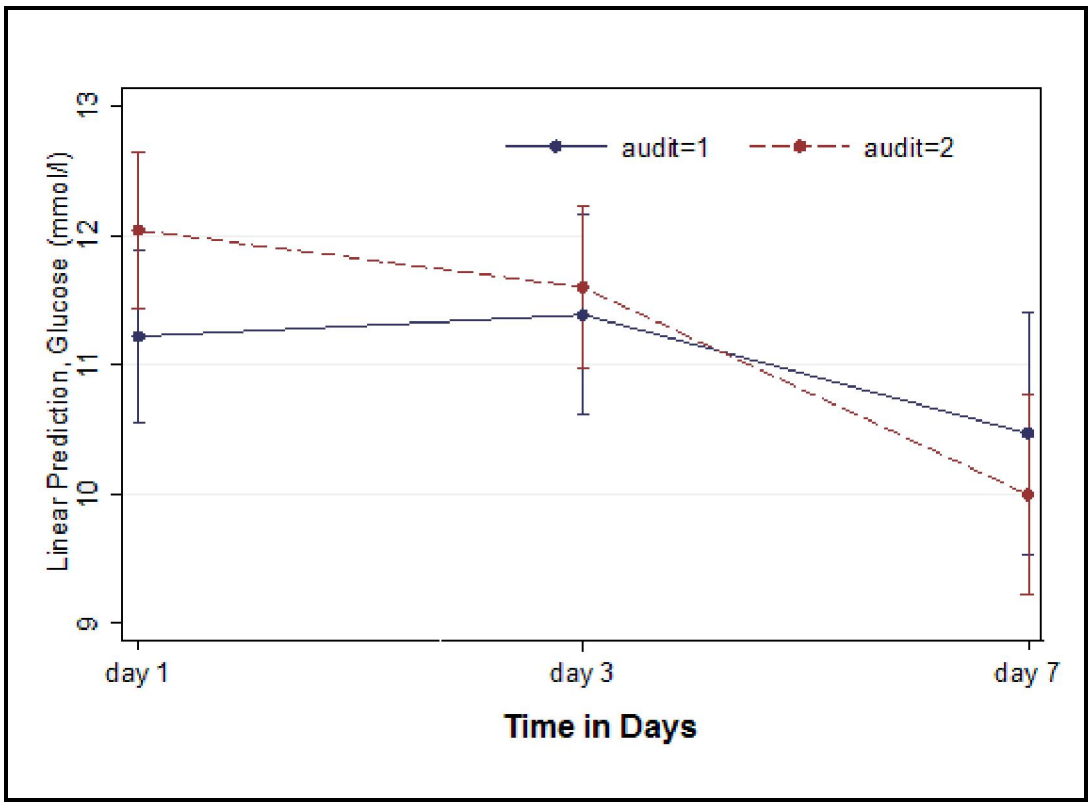


**Figure 3: Predicted mean blood glucose for Audit 1 and 2 at day 1,3 and 7**

For the model described in table III the contrasts over time are reflected in table V.

**Table V: Contrasts between audits for mean glucose predicted for Day 1, 2 and 3**

| Time | Contrast between Audit 1 and 2 | Standard error | 95% Confidence interval | p |
|---|---|---|---|---|
| Day 1 | 0.8 | 0.5 | -0.1 to 1.8 | 0.083 |
| Day 3 | 0.2 | 0.5 | -0.8 to 1.2 | 0.685 |
| Day 7 | -0.5 | 0.6 | -1.7 to 0.8 | 0.453 |

Since none of the contrasts were statistically significant no corrections for multiple testing were done. The likelihood ratio P value for the interaction term was 0.13. If the interaction term was dropped from the model the results were as follows

**Table VI: Revised model without the interaction term**

| Variables included in the model | Coefficient | P | 95% Conficence interval |
|---|---|---|---|
| Age | -0.1 | <0.001 | -0.1 to -0.0 |
| Diabetes related admission | 1.4 | 0.001 | 0.6 to 2.2 |
| Audit (Reference audit is audit 1) | 0.4 | 0.350 | -0.4 to 1.1 |
| Time with reference time day 1 | | | |
| Day 3 | -0.2 | 0.493 | -0.7 to 0.3 |
| Day 7 | -1.5 | <0.001 | -2.1 to -0.9 |
| Diabetes known before admission | -1.7 | <0.001 | -2.6 to -0.7 |
| Constant | 15.0 | <0.001 | 13.3 to 16.7 |

With the interaction term removed the coefficient for audit represents a weighted average of the audit effect for each time point (0.4, 95% CI -0.4 to 1.1 mmol/l). The predicted mean blood glucose values for the two audits at day 1, 2 and 3 for the revised model are reflected in table VII and figure 6.

**Table VII: Predicted mean glucose values for day 1, day 3 and day 7 based on the revised model in table VI**

| Time | Audit | Predicted mean blood glucose | 95% confidence interval |
|---|---|---|---|
| Day 1 | 1 | 11.5 | 10.9 to 12.1 |
| Day 1 | 2 | 11.8 | 11.3 to 12.4 |
| Day 2 | 1 | 11.3 | 10.6 to 11.9 |
| Day 2 | 2 | 11.6 | 11.1 to 12.2 |
| Day3 | 1 | 10.0 | 9.2 to 10.7 |
| Day 3 | 2 | 10.3 | 9.7 to 11.0 |

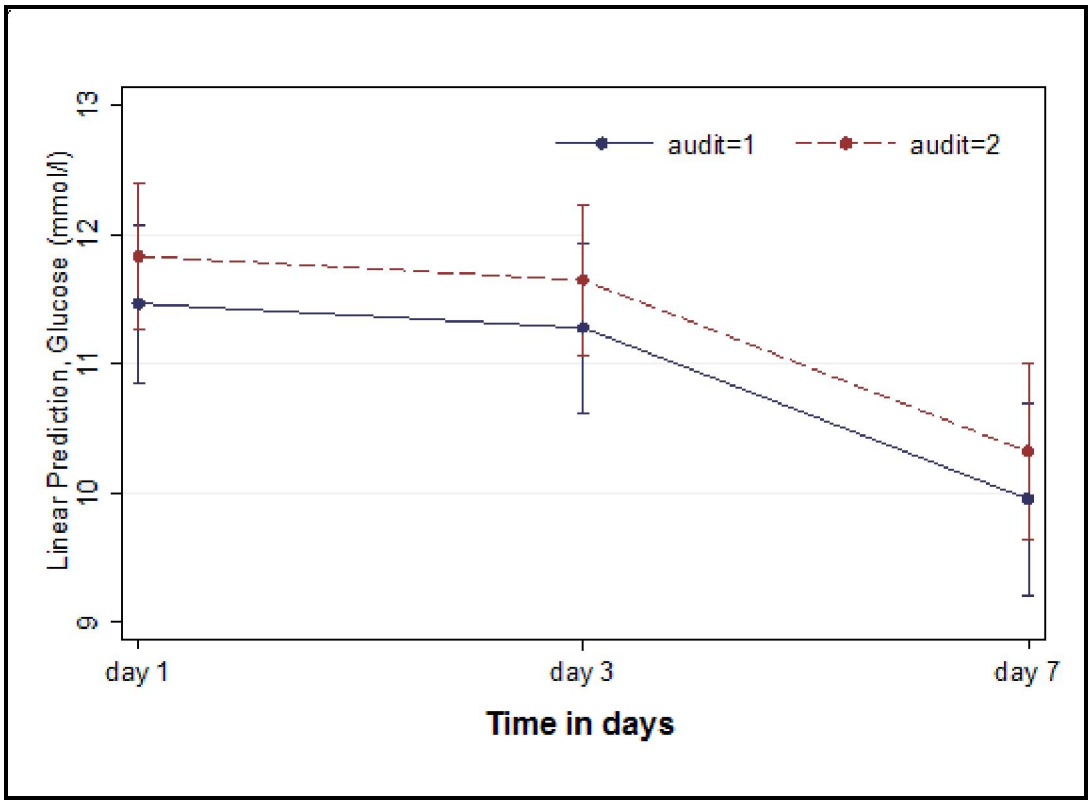


**Figure 4: Predicted mean blood glucose from the revised model (without interaction term) for Audit 1 and 2 at day 1, 3 and 7**

These results thus show that the audit did not have an effect over days of measurement and neither was the mean difference over time significant between the 2 audits.

## Time to glycaemic control

There was no significant difference in the proportion of patients between the two audits who achieved control (audit one: 43%, audit two: 43.7%, p = 0.97)

The median time to achieve glycaemic control in an unadjusted Kaplan Meyer analysis, for the patients that achieved control was 14 days (95% CI: 6.8 to 21.2) for audit 1 and 15 days (95%CI: 9.8 to 20.2) for audit 2. The median time to glycaemic control if unadjusted was non-significantly longer in audit 2 than in audit 1 (p = 0.189). A Cox proportional hazards model was compiled to compare the time in hospital to achieve glycaemic control (a mean blood glucose of less than 10 mmol/L) between the two audits, adjusted for the significant difference in baseline mean blood glucose (HR: 0.77, p = 0.124). The difference in time to glycaemic control between audit one and two was completely explained by the

difference in baseline blood glucose (-Log Likelihood: 1443.018, Chi-square: 26.159. p <0.001). Thus, after adjustment for the difference in baseline glucose no difference in time to glycaemic control between audit one and two could be demonstrated.

## *Discussion*

The results of this study failed to show that the implementation of an inpatient diabetes management protocol and a physician and nurse education programme improved blood glucose control as measured by the change in mean blood glucose from admission to day seven after admission. It could also not indicate any improvement in the time to achieve glycaemic control before and after the implementation of the intervention.

On admission patients in audit two had poorer pre-admission glycaemic control (baseline HbA1c) (although not statistically significant), as well as higher mean blood glucose values on the first full day in hospital.

In audit one there was an initial slight increase in blood glucose to day three where after the blood glucose decreased. In audit two there was an initial slight decrease in blood glucose to day three, which accelerated to day seven. In both audits the most improvement in mean blood glucose seemed to occur after day three.

For both audits, the patients with the highest blood glucose on admission were admitted to the Internal Medicine department, because most patients were specifically admitted for poor glycaemic control. All the other departments admitted patients for reasons other than diabetes control but with diabetes related or diabetes unrelated diseases. This different spectrum of patients may also explain the difference seen in blood glucose improvement between patients admitted to Internal Medicine and the other departments. This discrepancy between patients admitted to internal medicine versus surgical departments is

not unique to this study; it was also seen in a Swiss study.[11] The admission blood glucose in the Swiss study was also significantly higher in patients admitted to medical units. The increase in blood glucose from the first to the second audits for the first day of hospitalisation may indicate an increase in the glycaemic threshold for admission by clinicians. The increase was also seen in the Swiss study[11] where the baseline glucose increased from 11.3 mmol/L in 2002, to 13.5 mmol/L in 2005.

This was a quasi-experimental study with a before and after design. This design is not the ideal study design, but because of limitations in the study setting this was the only design to prevent cross contamination of the intervention. The reason for this is that the doctors' work in more than one of the hospital units, and it would be unethical to give training to one group of doctors and nurses working in the same clinical departments and not to others.

Part of the intervention was to implement a meal related blood glucose monitoring system instead of the previously used four or six hourly system. The implication of this change is that ascertainment bias may have been introduced due to the difference in timing of blood glucose monitoring between audit one and two. However this would introduce a random rather than a systematic error.

For this study, glucose control was defined as the mean of all blood glucose measurements in 24 hours of less than 10 mmol/L. At present there are no clear criteria for what would constitute good glycaemic control in diabetic patients in hospital. The reason for this uncertainty is that patients in hospital usually have multiple blood glucose measurements, some of these measurements are fasting, some post prandial and some random. Because of this a number of performance measures are proposed, of which one is the mean daily blood glucose. The mean daily blood glucose was used in this study is because it gives a good reflection of the glycaemic exposure.[12]

In the study reported here nurses and physicians were trained and protocols for treatment were made available in all units, but doctors and nurses were free to adjust treatment as they deemed appropriate. A limitation of this study was that the appropriateness of treatment decisions regarding glycaemic control made by clinicians and nurses were not evaluated. The suspicion is that as in other studies there was a lack of treatment intensification despite the availability of treatment protocols.[13]
During the second audit, nurses and doctors may have been aware of the audit taking place and therefore could have changed there behaviour (Hawthorn effect), however in the light of the results of this study it unlikely played a significant role.

In a similar study which used a retrospective observational design to compare blood glucose control pre and post implementation of a diabetes management protocol the hyperglycaemic control was poorer (Mean blood glucose 9.6 mmol/L before versus 10.4 mmol/L afterwards), but less hypoglycaemia episodes occurred.[14] In our study there was also a decline in glycaemic control, but blood glucose on admission was significantly higher at the onset of the second audit. In a cluster randomised controlled trial published by Schnipper et. al.[15] who used a computer based patient order set as intervention compared to usual care, the improvement of the patient-day weighted mean blood glucose control was significant (8.2 mmol/L versus 8.7 mmol/L in the control group). In our study no measurement of compliance to the implemented protocol by medical and nursing staff was made, furthermore the effect of staff turnover was not assessed. These factors might explain the lack of an improvement in mean blood glucose.

From the literature glycaemic control and the risk of errors occurring in patient management can be improved with the use of a structured protocol or order set for the management of inpatients with diabetes. A protocol can also reduce the risk of hypoglycaemia and it can result in increased patient, nurse and doctor satisfaction in diabetes management.[16 17]

**Conclusion:** From this study no improvement in mean blood glucose could be demonstrated by the introduction of a standardised inpatient diabetes management protocol. There was also no evidence for achieving glycaemic control more often and earlier in patients treated with a standardised inpatient management protocol.

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