AN AUDIT OF THE PREVALENCE OF ABNORMAL FASTING BLOOD GLUCOSE LEVELS IN PATIENTS PRESENTING FOR ELECTIVE SURGERY AT A SELECTION OF WESTERN CAPE GOVERNMENT HOSPITALS.

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"A MULTICENTRE PROSPECTIVE OBSERVATIONAL STUDY OF THE PREVALENCE AND GLYCAEMIC CONTROL OF DIABETES MELLITUS IN ADULT NON-CARDIAC ELECTIVE SURGICAL PATIENTS IN WESTERN CAPE HOSPITALS."

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DECLARATION

I, Tessa Biesman-Simons, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

Background. Diabetes mellitus (DM) is a common condition. The high burden of undiagnosed DM and lack of large population studies make accurate prevalence estimations difficult, especially in the surgical environment. Furthermore, poorly controlled DM is associated with an increased risk of perioperative complications and mortality.

Objectives. The primary objective was to establish the prevalence of DM in elective adult non-cardiac, non-obstetric surgical patients in Western Cape hospitals. The secondary objectives were to assess the glycaemic control and compliance with treatment of known diabetics.

Methods. This was a five-day, multicentre, prospective observational study performed at six government-funded hospitals in the Western Cape. Screening for DM was done using finger-prick capillary blood glucose (CBG) testing. Patients found to have a CBG of ≥ 6.5 mmol/L had an HbA_{1c} level done. DM was diagnosed based on the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) diagnostic criteria. Patients known with DM had an HbA_{1c} performed and Morisky Medication Adherence Scale (MMAS-4) questionnaires completed, to assess glycaemic control and compliance with treatment.

Results. Of the 379 participants, 61 were known diabetics (16.15%; 95% CI 12.4-19.8%). After exclusion of eight patients with incomplete results, a new diagnosis of DM was made in five out of 310 patients (1.6%; 95% CI 0.2-3.0%). Overall prevalence of DM was 17.8% (66/371; 95% CI 13.9-21.7%). HbA_{1c} results were available in 57 (93.4%) of the 61 known diabetics. Of these 27 (47.4%; 95% CI 34.4-60.3%) had an HbA_{1c} level≥8.5% and 14 (24.6%; 95% CI 13.4 – 35.8%) had an HbA_{1c} ≤7%. Based on positive responses to two or more questions on their MMAS-4 questionnaires, 12 out of 60 participants (20%) were deemed non-compliant.

Conclusion. There is a low rate of undiagnosed DM in our elective surgical population; however there is a large proportion of poorly controlled DM. Since poorly controlled DM is known to increase postoperative complications, this likely increases the burden of perioperative care. Resources should be focused on improvement of long-term glycaemic control in patients presenting for elective surgery.

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LIST OF ABBREVIATIONS

DM: diabetes mellitus

HbA1c: glycated haemoglobin

MMAS-4: Morisky medication adherence scale – 4

CRF: case report form

SEMDSA: society for endicronology, metabolism and diabetes of South Africa

CBG: capillary blood glucose

REDCap: research electronic data capture

SD: standard deviation

ASA: American society of anaesthesiologists

SANHANES: South African national health and nutrition examination survey

PUBLISHED ARTICLE

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Conclusion. There is a low rate of undiagnosed DM in our elective surgical population; however there is a large proportion of poorly controlled DM. Since poorly controlled DM is known to increase postoperative complications, this likely increases the burden of perioperative care. Resources should be focused on improvement of long-term glycaemic control in patients presenting for elective surgery.

INTRODUCTION

Diabetes mellitus (DM) is a common condition, affecting an estimated 15.5 million people in Africa. Importantly, the prevalence of DM across the continent is expected to double by 2045.[1] Since 2015, this condition has been ranked as the second most common cause of natural death in South Africa, and the impact on health care provision is substantial.[2] Accurate assessment of prevalence is difficult due to the high burden of undiagnosed DM (estimated at 69% in Africa), and the lack of large population studies.[1] In South Africa, the prevalence of DM is estimated to be between 5.4% and 9.2%.[1,3] There is limited data reporting the prevalence of DM in the Western Cape, South Africa, and minimal information with regards to elective surgical patients. Many studies have shown that DM, especially if poorly controlled, is associated with an increased risk of perioperative complications and mortality.[4-9] In South Africa, insulin dependent surgical patients are twice as likely to die in hospital than non-diabetics.[10]

The objective of this study was to establish the prevalence of DM in patients presenting for elective surgery over a one-week period in six Western Cape hospitals. The secondary objectives were to assess; i) the glycaemic control of known diabetics presenting for surgery, using the HbA_{1c} level, and ii) the compliance with treatment, by means of the Morisky Medication Adherence Scale (MMAS-4).[11]

METHODS

Study approval was obtained from the University of Cape Town Faculty of Health Science Human Research Ethics Committee (UCT HREC: 386/2017), the Western Cape Department of Health, as well as institutional approval from all participating centres (NHRD:WC_201709_018). The study was registered on Clinicaltrials.gov (NCT03318055). Written informed consent was provided by all participants prior to enrolment. This study is presented according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[12]

This was a multicentre, prospective observational study performed at six government-funded hospitals in the Western Cape, South Africa: Groote Schuur-, Somerset-, Paarl-, Victoria-, Mitchell's Plain- and George Hospital. A pre-study power calculation based on an expected prevalence in the South African surgical patient population of DM of 10%[10] and an estimated sample size of 500 (expected number of elective surgical procedures in the participating hospitals) allowed for an estimate of the prevalence with a 95% confidence interval of ± 2.65%, i.e. 7.35%-12.65%. Convenience sampling was practised, during the daytime hours (07:00-19:00) of a calendar week (Monday 16 October to

Exclusion criteria were patient refusal or inability to consent, emergency and cardiac surgery, and pregnant and paediatric (<18 years old) patients. All participants were seen preoperatively by the anaesthesia medical staff, and after written consent was obtained, demographic and baseline data was collected and recorded on the case report form (CRF) (see Appendix).

The diagnosis of DM in our study was based on recommendations of the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA)[13], which states that the diagnosis can be made in 'an asymptomatic patient when any one of the following tests, repeated on separate days within a two-week period are confirmed: i) fasting plasma glucose ≥ 7.0 mmol/L, ii) 2 hour-post glucose load ≥ 11.1 mmol/L, or iii) HbA_{1c} ≥ 6.5%. In the event that both a glucose-based test and the HbA_{1c} test are measured, if both are 'diagnostic' for diabetes, then the diagnosis of diabetes is confirmed.'

An HbA_{1c} level was measured in known diabetics who did not have a test result within the preceding 90 days. As HbA_{1c} levels reflect glycaemic control over the preceding

12 weeks, if a recent result was available, the test was not repeated to save on costs. Screening for DM was done using finger-prick capillary blood glucose (CBG) testing in all consenting participants undergoing elective surgery. The mandatory starvation period of at least six hours for elective surgical patients was used as the fasting period for the fasting glucose measurement. Based on the recommended correction of CBG to reflect a true plasma glucose (plasma glucose (mmol/L) = 0.102 + 1.066 x CBG)[13] a capillary glucose level of ≥ 6.5 mmol/L was taken as a cut-off to reflect a plasma level ≥7.0 mmol/L. Patients found to have a CBG of ≥ 6.5 mmol/L had an HbA_{1c} level done to confirm the diagnosis of diabetes.

HbA_{1c} results were linked via a unique CRF-generated laboratory number. Data was recorded on paper CRFs, and captured electronically onto the Research Electronic Data Capture (REDCap) application. Access to REDCap was protected by username and password. Patient confidentiality and anonymity were protected through unique numerical code generation during electronic data capturing. Patients identified as having raised fasting CBG were given referral letters to their primary health care facilities for further investigations and management.

The primary objective of this study was to determine the prevalence of diabetes in the elective surgical population. This included patients with a previous diagnosis of DM, and a new diagnosis based on the screening CBG and confirmatory elevated HbA_{1c} level. The secondary objectives of this study were to assess: i) the glycaemic control and, ii) the compliance with treatment of participants already known with DM. Glycaemic control was determined by the HbA_{1c} levels. SEMDSA advocates aiming for an HbA_{1c} of ≤7% in most patients (well controlled DM). An HbA_{1c} level of 7.1 to 8.5% is considered moderate control and may be acceptable in the following patient categories: elderly, frail, limited life expectancy, multiple co-morbidities, severe vascular disease, advanced chronic kidney disease, recurrent severe hypoglycaemia, or unawareness of hypoglycaemia.[13] An HbA_{1c} of ≥8.5% is considered poor control. Compliance with treatment was assessed using the MMAS-4 score.[11] Non-compliance was taken as a positive response to two or more of the four questions in the MMAS-4.

STATISTICAL ANALYSIS

Continuous variables with normal distribution were described as mean and standard deviation (SD). Between-group comparisons were performed using Fisher's exact test, except for age (t-test) and in contingency tables which were more than 2 by 2 comparisons (ASA classification and functional status) where the Pearson's Chi-Square test was used. The Statistical Package for the Social Sciences (SPSS) version 24 (SPSS Inc., Chicago, IL, USA) was used for data analysis.

RESULTS

The study flow diagram is shown in Figure 1. The breakdown of contribution to final participant numbers from each hospital is displayed in Table 1. Participants known to have DM comprised 16.1% (61/379; 95% CI 12.4-19.8) of the study population. Of the 318 participants who were not previously diagnosed with DM, 310 (97.5%) had CBG and, where appropriate, HbA_{1c} results available. A new diagnosis of DM was made in an additional 1.6% (5/310; 95% CI 0.2-3.0) of participants not previously known with DM. Therefore, the overall prevalence of DM was 17.8% (66/371; 95% CI 13.9-21.7). Of the 66 diabetic participants, 7.5% (5/66; 95% CI 1.2-13.9) were diagnosed during the study.

The demographic details of the study population are shown in Table 2. Univariate analysis showed an association between DM and increasing age, increasing American Society of Anesthesiologists' Physical Status (ASA) classification, decreasing functional status, and co-morbidities. Based upon positive responses to two or more questions on the MMAS-4 questionnaires, 12 out of 60 participants (20%) were non-compliant on therapy for DM.

DISCUSSION

Principal findings

In our study population, one in six participants presenting for surgery was diabetic. Of the participants with DM, 92.5% were known diabetics prior to surgery, but almost one in two had poor glycaemic control as reflected by an HBA_{1c} level ≥8.5%.

Strengths of the study

The strength of this investigation was that it was a multicentre, prospective study that involved several regions in the Western Cape, South Africa. The research provided the most comprehensive data to date of the prevalence of diabetes in this elective adult surgical patient population, and therefore has implications for determining appropriate management plans for this population. In comparison with some previous prevalence studies, this study did not rely solely on self-reporting of DM or single CBG results; therefore we believe it is a more accurate representation of the true prevalence of diabetes and the degree of glycaemic control in these elective surgical patients.

Relation to other studies

The prevalence of DM in our study was higher than reported in non-surgical South African population studies. The International Diabetes Federation country level DM estimates (5.4% for South Africa) were based on the weighted average of the scores of all data sources in the adult population.[1] The South African National Health and Nutrition Examination Survey (SANHANES) utilised a multi-stage disproportionate, stratified cluster sampling approach to the general population based on census data, and demonstrated a 9.2% prevalence of DM (self-reported, and HbA_{1c} ≥6.5%) in the adult population.[3] The prevalence of DM increases with age, and the higher mean age of our study population than that of the general South African population likely contributes to the higher prevalence of DM reported.[14]

Studies of surgical patients report a higher prevalence of DM than in the population overall. The South African Surgical Outcomes Study (SASOS) reported a South African national prevalence of self-reported DM of 10.1%.[10] This is considerably lower than we have shown.

When investigating elective surgical patients in the Western Cape, van der Spuy et al. showed a prevalence of 16% of self-reported DM, which is in keeping with our findings.[15] However, neither of these studies evaluated the prevalence of undiagnosed DM at the time of surgery, nor the degree of glycaemic control.

Using CBG and HbA_{1c} level as screening and diagnostic tools, our study identified a low prevalence of undiagnosed DM of 1.6% (5/310) in this surgical population. This is a considerably lower value than reported in a general population study by Bailey et al, which estimated an undiagnosed prevalence of DM, (based on random CBG measurement) in the Western Cape, of 12.7%.[16] In 2012 Erasmus et al found a prevalence of undiagnosed DM (based on oral glucose tolerance tests and HbA_{1c}) of 18.2% in adults in a community in Bellville, Western Cape.[17] The reasons for the lower prevalence in our study likely include: i) the stringent diagnostic criteria applied in our study, and ii) the fact that all participants in our study had been assessed preoperatively by multiple health care practitioners.

Clinical implications

Our data suggest that DM screening for patients accessing elective surgery (often via primary health care) is well-established in the studied health care services. Based on our findings, we suggest that screening for DM is not a priority in the preoperative period. This is in keeping with conclusions from a systematic review that routine blood glucose or HbA_{1c} levels are not needed in otherwise well non-diabetic patients presenting for general (non-orthopaedic or vascular) surgery.[18] Cognisance must be taken of the fact that a small number of patients present with undiagnosed DM. The prevalence of DM and access to primary health care and hospitals are extremely variable within South Africa, and care must be taken in generalising these findings over too broad a population base.

Multiple studies have shown that poor glycaemic control in the preoperative period is associated with increased complication rates in the perioperative period. These include increased length of stay,[4] higher risk of failure of total ankle replacements,[5] increased infection rates in hip and knee arthroplasty,[6] and raised risk of poor postoperative glycaemic control and postoperative complications.[7]. In 2015 Kallio et al demonstrated that referral of poorly controlled diabetic patients (HbA_{1c} >10%) to primary health care services for

optimisation of glycaemic control before proceeding with total joint arthroplasty resulted in lower complication rates and shorter hospital stays.[19]

The United Kingdom National Health Service (NHS) Consensus Guidelines of 2011,[20] endorsed by the Association of Anaesthetists of Great Britain and Ireland Working Party,[21] recommend postponing elective surgery in patients with an HbA_{1c} level ≥8.5%, to allow for improved glycaemic control. In our study, 47% of diabetic participants had an HbA_{1c} exceeding this level. If these guidelines were to be adopted in the Western Cape, it is likely that a significant proportion of diabetic patients would have their surgery postponed.

In our resource-limited environment patients may experience long delays accessing elective surgery. Last minute postponement of surgery to allow for improved glycaemic control may not be practical. If poor control is timeously identified, the long waiting period presents an opportunity for optimisation of treatment without increasing the delay before surgery. Limited access to good quality diabetes care is a major concern: an analysis of data from the SANHANES study estimated that only 19.4% of patients with DM in South Africa are both identified and well controlled,[22] which is in keeping with our findings, where only 24.6% of patients known with DM had good control (HbA_{1c} level ≤ 7%).

As a secondary outcome, compliance was assessed, using the MMAS-4 questionnaire. Only one of every five participants was noted to be non-compliant, which is similar to the prevalence of self-reported non-compliance to DM medication of 30% in the Limpopo province.[23] In our study, no conclusions could be drawn with respect to correlation between compliance and glycaemic control. Verbal questionnaires to establish compliance have limited reliability. We employed the MMAS-4 questionnaire since this tool has been described as the nearest to the gold standard.[24] Despite the reported compliance rate of 80% in our study population, 47.4% of the diabetic participants were found to be poorly controlled, with an HbA_{1c} level of ≥8.5%. Interpreting the reasons for the disparity between reported medication compliance and glycaemic control is complex. Factors contributing to glycaemic control may include the prescribing and availability of correct medication, as well as lifestyle factors, such as exercise and diet.

Limitations of the study

This study has some limitations. Smaller patient numbers were recruited than expected (379 versus 500) due to the withdrawal of one of the hospitals initially planned to be an active site. This minimally increased the 95% CI associated with the estimation of the prevalence of diabetes in this population from 5,3 to 8%.

Nil per os guidelines followed in the participating hospitals were a minimum of six hours for solid food, and two hours for clear fluids. In practice, most patients had longer nil per os times than this minimum requirement. SEMDSA guidelines state that 'fasting is defined as no caloric intake for at least eight hours'.[13] It is possible that participants may have had oral or intravenous glucose containing fluids within eight hours preoperatively, which might have affected the CBG result. Fasting status would not affect HbA_{1c} level results. Since HbA_{1c} was used as a defining result for DM, we are confident that we did not overestimate the prevalence of DM in our study population.

The SEMDSA guidelines advise that bedside tests (glucose and HbA_{1c} level) should not be used to diagnose DM unless laboratory-based tests are unavailable.[13] For reasons of clinical convenience, and to make our study practicable, we used finger-prick CBG levels. We conducted laboratory HbA_{1c} testing as a defining result to diagnose DM. The SEMDSA guidelines also state that 'if only one of these tests is abnormal, a second abnormal result of the same testing method is required to confirm the diagnosis of diabetes on a different day, preferably within two weeks'.[13] Fourteen of our participants had a raised CBG level, with an HbA_{1c} level <6,5%, and were not followed up. Our results may therefore underestimate the prevalence of undiagnosed diabetes in this surgical population.

Suggested further research

This study provides an objective assessment of the prevalence and glycaemic control of DM in the perioperative patient population in the Western Cape, South Africa. The poor control of DM in the perioperative period suggests that further research is needed to evaluate the perioperative complication rates in these patients. Interventions to improve long term glycaemic control should be identified in elective surgical patients, and the effects of their introduction studied.

CONCLUSION

DM is a common disease that is associated with increased perioperative complications. It is well diagnosed, but poorly managed in our study population. We recommend that early identification of poorly managed DM (by HbA_{1c} measurement) should be prioritised in elective surgical patients. This could result in timeous referral to the appropriate services for improvement of glycaemic control before surgery, and in turn allow time for improvement of preoperative management of DM, without causing a significant increase in surgical waiting times. Overall, the goal would be lower perioperative complication rates.

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Conflicts of interest: None

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TABLES AND FIGURES

Table 1: Participating hospitals

Hospitals	Number of participants (n= 379)
Groote Schuur	176
George	58
Paarl	42
New Somerset	40
Victoria	35
Mitchell's Plain	28

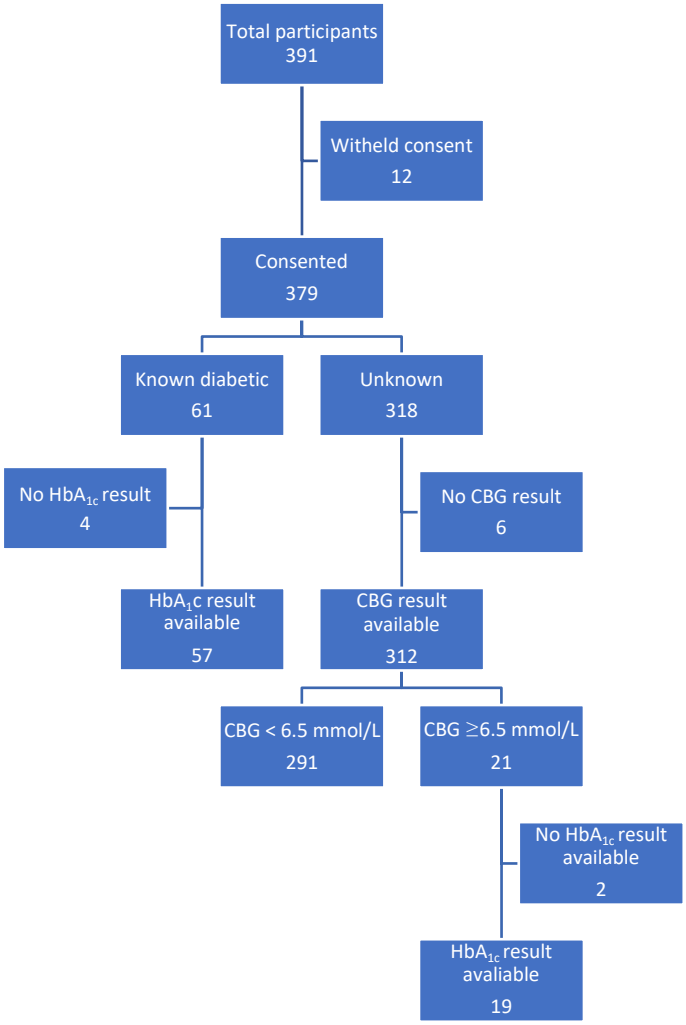

Figure 1: Study flow diagram

CBG: capillary blood glucose

Table 2: Characteristics of the study population. Data are presented as n (%) or mean (SD)

	Patients n=371	**Diabetic** n=66 (17.8)	**Non-diabetic** n=305 (82.2)	**p-value**
Age (years) mean, (SD)	50.6 (16.5)	60.0 (11.9)	48.6 (16.7)	<0.001
Male gender, n (%)	133/371 (36.4)	22/66 (33.3)	113/305	0.672
Major surgery, n (%)	40/371 (10.8)	5/66 (7.6)	35/305 (11.5)	0.511
ASA classification, n (%) ASA 1	90/368 (24.5)	0/65 (0)	90/303 (29.7)	<0.001
ASA 2	193/368 (52.4)	32/65 (49.2)	193/303 (53.1)	
ASA 3	80/368 (21.7)	29/65 (44.6)	51/303 (16.8)	
ASA 4	5/368 (1.4)	4/65 (6.2)	1/303 (0.3)	
Co-morbid conditions, n (%) Smoker	128/367 (34.9)	16/66 (24.2)	112/301 (37.2)	0.047
History of coronary artery disease	17/371 (4.6)	7/66 (10.6)	10/305 (3.3)	0.018
History of congestive heart failure	5/371 (1.3)	3/66 (4.5)	2/305 (0.7)	0.041
Stroke/TIA	15/371 (4.0)	8/66 (12.1)	7/305 (2.3)	0.002
Chronic renal disease	18/371 (4.9)	7/66 (10.6)	11/305 (3.6)	0.026

Peripheral arterial disease	3/371 (0.8)	2/66 (3.0)	1/305 (0.3)	0.083
Hypertension	165/371 (44.5)	55/66 (83.3)	110/305 (36.1)	<0.001
Advanced retinopathy	13/371 (3.5)	13/66 (19.7)	0/305 (0)	<0.001
Functional status, n (%)				<0.001
Totally independent	324/370 (87.6)	46/66 (69.7)	278/304 (91.4)	
Partially dependent	39/370 (10.5)	19/66 (28.8)	20/304 (6.6)	
Totally dependent	7/370 (1.9)	1/66 (1.5)	6/304 (2.0)	

ASA American Society of Anaesthesiologist's physical status classification system; TIA transient ischaemic attack

Denominators vary as patients with missing data excluded.

Table 3: Glycaemic control of known diabetics based on HbA_{1c} results n (%; 95% CI)

	HbA_{1c} ≤7	**HbA_{1c} 7.1-8.4**	**HbA_{1c} ≥8.5**
Known diabetics	14 (24.6; 13.4 – 35.8)	16 (28.1; 16.4-39.7)	27 (47.4; 34.4-60.3)

APPENDIX 1 **EPIC I - Study**

Consent given □ Yes □ No

Preoperative data capture

Age ☐☐☐ **years** **Gender □ M □ F** **Current smoker □ Y □ N**

Ethnicity: □ Black □ Coloured □ Asian □Caucasian

Height ☐☐☐ **cm** **Weight** ☐☐☐ **kg ASA □ I □ II □ III □ IV □ V**

Most recent formal blood results (no more than 3 months before surgery): No recent formal bloods □

Haemoglobin ☐☐.☐ **g/dL** **HbA1c** ☐☐.☐ **%** **s - Ferritin** ☐☐.☐ **µg/L**

MCV ☐☐.☐ **%** **Creatinine** ☐☐.☐ **µmol/L** **Transferrin saturation** ☐☐.☐ **%**

Chronic co-morbid disease (tick all that apply):

- **□ Coronary artery disease**
- **□ Stroke or Transient ischaemic attack**
- **□ Known hypertension**
- **□ Diabetes (without insulin)**
- **□ Diabetes (requiring insulin)**
- **□ Heart failure**
- **□ COPD / Asthma**
- **□ Chronic renal disease**
- **□ Peripheral arterial disease**
- **□ Advanced retinopathy**
- **□ Known HIV / AIDS**
- **□ Current TB**
- **□ Previous PTB**

Functional status:

□ Totally independent **□ Partially dependent** **□ Totally dependent**

Surgical procedure category (select *single* most appropriate):

- **□ Anorectal**
- **□ Brain**
- **□ Aortic**
- **□ Breast**
- **□ Bariatric**
- **□ ENT (except thyroid/parathryroid)**

□ Foregut (hepatopancreaticobiliary) □ Gallbladder, appendix, adrenal, spleen □ Hernia (ventral, inguinal, femoral)

- **□ Intestinal**
- **□ Orthopaedic/ nonvascular extremity**
- **□ Skin**
- **□ Vein**
- **□ Neck (thyroid/parathyroid)**
- **□ Other abdominal**
- **□ Spine**
- **□ Urology**
- **□ Gynaecology**
- **□ Peripheral vascular**
- **□ Non-oesophageal thoracic**
- **□ Eye surgery**

Current medications taking for at least 30 days prior to hospital admission (tick all that apply):

□ Any Sulfonylurea (glibenclamide/ glimepiride/ glipizide/ glyburide/ gliclazide)

- **□ Metformin**
- **□ Iron**
- **□ Insulin**
- **□ Folate**
- **□ Other**

EPIC I unique patient ID ☐☐☐☐☐☐☐☐☐☐

□ ----------

Patient name:_____ **DOB** d d m m y y y y

Drug compliance (tick all that apply)? :

1) Do you ever forget to take your medication? □ Y □ N

2) Are you careless at times about taking your medication? □ Y □ N

3) When you feel better, do you sometimes stop taking your medication? □ Y □ N

4) Sometimes if you feel worse when you take the medicine, do you stop taking it? □ Y □ N

This questionnaire applies to: □ Both diabetic and anaemia therapy □ Anaemia only □ Diabetic therapy only Reasons for non-drug compliance (only answer if 2 or more drug compliance questions above marked 'Yes'): Health system □ Condition □ Patient □ Therapy □ Socioeconomic □

Perioperative data capture

Surgery performed: □Yes □No:

If No, state reason for cancellation □ Poor diabetic control □ Low haemoglobin □ Other reason

Blood/products ordered for theatre: □ Group & Screen only □ Blood Cross-matched □ Blood in theatre

Major surgery: □ Y □ N

Expected blood loss > 500ml: □ Y □ N

Ward results (only if done preoperatively in ward)

Haemoglobin ☐☐.☐ **g/dL** **Glucose** ☐☐.☐ **mmol/L**

Blood transfusion prior to surgery (on this admission): □ Y □ N

If known diabetic, was the patient on a perioperative sliding scale □ Y □ N

Pre-induction Finger prick blood results

Haemoglobin ☐☐.☐ **g/dL** **Glucose** ☐☐.☐ **mmol/L**

If Haemoglobin ≤ 13 g/dL (M) or ≤ 12 g/dL (F) - □ Purple and Yellow top blood samples **taken**

If Glucose ≥ 6.5 g/dl - □ Purple top blood samples **taken**

NB ! Document the PID number here ☐☐☐ ☐☐☐

Note: if bloods taken for both anaemia and diabetes, there need to be two separate 'Purple top' tubes please

Post operative Follow-up of Formal Blood Results (to be completed by EPIC Investigators

Haemoglobin ☐☐.☐ **g/dL** **Transferrin saturation** ☐☐.☐ **% s - Ferritin** ☐☐.☐ **µg/L**

MCV ☐☐.☐ % **HbA1c** ☐☐.☐ **%**

EPIC I unique patient ID ☐☐☐☐☐☐☐☐☐☐

□ ----------

Patient name:_____ **DOB** d d m m y y y y

Guidance for use of paper Case Record Form (CRF)

1. **Baseline data on page one and consent should be collected on the preoperative anaesthetic visit the day before surgery.**
2. **Baseline data on page two should be collected by the anaesthetist who provides the anaesthetic for the patient.**
3. **Ward blood results are referring to the routine ward Hb and glucose performed by the ward staff and documented on the preoperative checklist form.**
4. **"Finger-prick" blood and samples to be taken pre-induction at time of intravascular access. Additional blood sample for formal blood results should be collected if:**
    a. **Haemoglobin ≤ 13 g/dl (M) or ≤ 12 g/dl (F) for formal HB, MCV (purple top tube) and transferrin saturation and ferritin (yellow top tube)**
    b. **Glucose ≥ 6.5 g/dl for formal HbA1C (purple top tube)**

    Please Note: this CRF
    i) Remember to copy the Patient ID nr (PID) on the blood sample tubes and this CRF
    ii) Bloods taken for both anaemia and diabetes, there need to be two separate 'purple top' tubes
    iii) Follow-up of these formal bloods (bottom of page 2) will be done by the EPIC investigators
5. **Definitions:**
    a. **Major surgery:** defined as Aortic and other major vascular surgery, peripheral vascular surgery, or intraperitoneal or intrathoracic surgery with major fluid shifts
    b. **Non-drug compliance definitions;**[2]
        i. **Health system:** Poor quality of provider-patient relationship; poor communication; lack of access to healthcare; lack of continuity of care
        ii. **Condition:** Asymptomatic chronic disease (lack of physical cues); mental health disorders (eg, depression)
        iii. **Patient:** Physical impairments (eg, vision problems or impaired dexterity); cognitive impairment; psychological/behavioural; younger age)
        iv. **Therapy:** Complexity of regimen; side effects
        v. **Socioeconomic:** Low literacy; higher medication costs; poor social support
6. **Please ensure complete data capture. If blood results are not available at the time of the preoperative anaesthetic assessment, please can the anaesthetist for the operative procedure complete these data.**

APPENDIX 2

INFORMED CONSENT FORM

EPIC 1 - Evaluating Perioperative Interventions to improve patient outComes 1

Title of Studies:

Study 1: An audit of the prevalence of anaemia in patients presenting for elective surgery in selected hospitals in the Western Cape

Study 2: An audit of the prevalence of abnormal fasting blood glucose levels in patients presenting for elective surgery at a selection of Western Cape government hospitals.

Investigators: Dr Willem Conradie, Dr Tessa Biesman-Simons, Dr Marcin Nejthardt, Dr Francois Roodt, Prof Bruce Biccard, Prof Robert Dyer, Dr Margot Flint

Department of Anaesthesia and Perioperative Medicine, University of Cape Town, South Africa

INFORMATION

The doctors in this study are trying to find out how common **diabetes** and **anaemia** are in patients coming for surgery.

Diabetes is a condition whereby the blood sugar is too high. If left untreated it increases the risk of heart attack, stroke, kidney failure and blindness. Anaemia is when the blood is 'too thin' which can lead to feeling fatigued and increase the chance of needing a blood transfusion during surgery. Anaemia can also increase complications after surgery. There are many causes of anaemia but one of the common reasons is a low iron level in the blood.

By understanding how common the two conditions are will allow doctors and to set up programs to manage these treatable conditions more effectively.

Taking part is purely voluntary and by not agreeing to take part will not affect your normal care for surgery. The results of the tests may however be of great benefit to you.

What will happen?

A blood test is needed to test for diabetes and anaemia. In diabetes, the blood sugar level is high whilst in anaemia haemoglobin is low. Haemoglobin is a normal substance made up of iron that carries oxygen in the blood. This is the reason why iron is measured to check if the blood is too thin.

As part of normal preparation for surgery blood tests are taken to test haemoglobin concentration. This blood test may be done as either as a finger prick to get a drop of blood or a small tube of blood may be needed to test other things that your doctor thinks is necessary.

The only additional inconvenience to you is a finger prick to test for blood sugar just before surgery. If the sugar is high, this may indicate that you have diabetes. The doctor would then

need to take a blood sample to confirm that the result is accurate and also get an impression of how high your sugar has been in the last 3 months. This would be done at the same time as the drip so no additional needle sticks should be necessary. The testing of low iron would be done at the same time.

As part of normal care, doctors discuss any medical problems that you may have. This information is used to plan appropriately for your procedure. In the study, the doctor would do exactly the same but ask you a few additional questions about the medication that you're taking. The details of the discussion would be recorded on a page which would have no personal identifiers, in other words the information would be anonymous and could not be traced back to you.

Is there any benefit to me?

Yes.

By knowing if you are diabetic or at risk of diabetes can lead to appropriate life style changes and treatment, both of which have proven effect to minimise complications such as heart atttacks, strokes, kidney failure and blindness. By knowing that you have thin blood and finding out that the cause is low iron can lead to effective treatment to improve fatigue and improve circulation. You would also be given a referral letter to your local day hospital/healthcare provider informing them of your abnormal sugar or anaemia which will enable appropriate follow up.

Is there any potential harm to me?

A finger prick carries an extremely low risk of infection. Also, the additional blood that may be taken if your blood is thin or you have a high sugar is very small amount (less than a tablespoon) which will have no effect on your body. We believe that the benefits far outweigh any risk.

The information from this study will be used to publish in a medical journal and presented at professional meetings in order to improve patient care.

The investigators have received permission for this research from the Human Research Ethics Committee (HREC no: 386/1017). If you have any concerns or questions regarding the study you can contact the researchers directly on 021 404 5001. If you have any ethical concerns you can contact the Human Ethics Research Committee on 021 406 6338.

Please read this form carefully and ask the investigator (study doctor) to explain any words or information that are not clear to you. This will help to ensure you understand the details of your participation before you give your consent. You will be given a copy of this consent form to take home with you. The doctors will answer any questions you may have about this consent form and about the studies

CONSENT STATEMENT

I therefore certify the following:

- I have read the above information form and understand that the study involves research.
- I understand that the doctors will make a copy of some of my routinely recorded data from my standard patient care.

- I have had the opportunity to ask questions. All my questions have been answered to my satisfaction.
- I understand that any information that leaves the doctor's office will be de-identified (i.e., identifying information will be removed from the documents).

_____YES _____NO

Participant/Legal Representative's name (printed) Signature Date:

Name of person obtaining consent (printed) Signature Date:

APPENDIX 3

To: Primary Health Care Facility

Re:

Patient Sticker/ Name and Folder Number

Please note that the above patient participated in the ***Evaluation of Perioperative Interventions (EPIC 1)*** study to screen for diabetes mellitus and anaemia in patients presenting for elective surgery.

It was found that the patient had the following abnormal blood result/s

☐Fasting finger prick **glucose** ..... mmol/l ☐Pre-operative **haemoglobin**..... g/dl

☐ **HbA1c** .....%

Normal values:

Fasting Glucose: Normal 2.9-6.0mml/l
Impaired 6.1-6.9 mmol/l
Diabetic ≥7.0 mmol/l

Haemoglobin: Males >13g/dl
Females > 12g/dl

Implication of theresults:

☐ The elevated finger prick glucose and HbA1c reflect a poor glucose control. The patient will require appropriate long term follow up and management of possible diabetes mellitus.

☐ The low haemoglobin defines an anaemia and the most likely cause in a postoperative patient would be iron deficiency. The patient will require oral iron supplementation and subsequent rechecking of their haemoglobin.

☐ The patient was given information about the implication of the abnormal result and is being referred to you as the primary care facility that will take over ongoing review and appropriate treatment.

If you have any queries related to the study or the implication of the result you can contact the investigators on the following number:

Telephone: 021 404 5001

With best intentions
The EPICInvestigators

APPENDIX 4

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

25 August 2017

HREC REF: 386/2017

Dr M Nejthardt
Anaesthesia & Perioperative Medicine
D23, NGSH

Dear Dr Nejthardt

PROJECT TITLE: EPIC 1- AN AUDIT OF THE PREVALENCE OF ABNORMAL FASTING BLOOD GLUCOSE LEVELS IN PATIENTS PRESENTING FOR ELECTIVE SURGERY AT A SELECTION OF WESTERN CAPE GOVERNMENT HOSPITALS (MMed-candidate-Dr T Biesman-Simons)

Thank you for submitting your response to the Faculty of Health Sciences Human Research Ethics Committee dated 4 August 2017.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

To provide insight into why we have made an issue of race as a research criterion, the following comments have been provided.

- There are many complex ethical issues associated with the inclusion of race as a variable for analysis, which should ideally be addressed in a research proposal.
- A case for biological plausibility for the inclusion of race as a variable for analysis should to be specifically articulated. Without such biological plausibility, the scientific validity of the related research aim and objectives is limited. It is acknowledged that you have provided a reference that suggests an altered prevalence of diabetes in certain racially categorised population groups in South Africa. This provides some level of justification for examining the crude and relatively ill-defined criterion of race.
- You also indicate that there are several lifestyle-associated factors that may be relevant that are independent of race, which may potentially be more relevant than a categorisation of race itself. Variability in ancestry, socioeconomic status, environmental biological and genetic factors mean that there can be little homogeneity within a group classified according to a crude ethnic or racial marker. If race is of secondary importance to such factors, then it is preferable that these factors should rather be used as research criteria. However, existing clinical data may not always include information about such factors.
- There are significant risks of using such a crude marker such as race to make generalisations. These risks include possible misrepresentation and stigma. In addition, the use of population group, race or ethnicity may discriminate for or against individuals who are crudely categorised using a criterion that is too non-specific and flawed.
- To respect individual autonomy, race should be self-identified, as you have indicated will be the case in this study. Individuals should also have the right not to choose a category that may

associate them with such a poorly generalised group as race, which may potentially disadvantage them as individuals by potentially inappropriately guiding general health policies through misrepresentation or exposing them to stigma.

Approval is granted for one year until the 30 August 2018.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

The HREC acknowledge that the student,* Dr T Biesman-Simons *will also be involved in this study.

Yours sincerely

Signature removed to avoid exposure online

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

APPENDIX 5

SAMJ GUIDELINES TO AUTHORS

Taken from http://www.samj.org.za/index.php/samj/about/submissions#Research

Publication Fees

All articles published in the South African Medical Journal are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R5 250 (ex vat) for each research article published. The charge applies only to Research articles submitted after 1 March 2017. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

When submitting a Research article to the SAMJ, the submitting author must agree to pay the publication fee should the article be accepted for publication. The publicaiton fee is payable when your manuscript is editorially accepted and before production commences for publication. The submitting author will be notified that payment is due and given details on the available methods of payment. Prompt payment is advised; the article will not enter into production until payment is received.

Queries can be directed to claudian@hmpg.co.za.

Please refer to the section on 'Sponsored Supplements' regarding the publication of supplements, where a charge is applicable. Queries can be directed to dianes@hmpg.co.za or claudian@hmpg.co.za

Authorship

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conceptualisation, design, analysis and interpretation of data; (ii) drafting or critical revision of important scientific content; or (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org)

If authors' names are added or deleted after submission of an article, or the order of the names is changed, all authors must agree to this in writing.

Please note that co-authors will be requested to verify their contribution upon submission. Non-verification may lead to delays in the processing of submissions. Author contributions should be listed/described in the manuscript.

Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors' or reviewers' opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication's message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the

editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

If the study was carried out using data from provincial healthcare facilities, or required active data collection through facility visits or staff interviews, approval should be sought from the relevant provincial authorities. For South African authors, please refer to the guidelines for submission to the National Health Research Database. Research involving human subjects must be conducted according to the principles outlined in the Declaration of Helsinki. Please refer to the National Department of Health's guideline on Ethics in Health research: principles, processes and structuresto ensure that the appropriate requirements for conducting research have been met, and that the HPCSA's General Ethical Guidelines for Health Researchers have been adhered to.

Clinical trials

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. All clinical trial reports must also contain a data sharing statement as per the recommendations of the ICMJE. Statements are to indicate:

whether individual deidentified participant data will be shared;

what data in particular will be shared; whether additional, related documents will be available;

when the data will become available and for how long; by what access criteria data will be shared.

Please see the ICJME announcement for further details and illustrative examples of data sharing statements: ICMJE Data Sharing Statements for Clinical Trials.

Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register. The SAMJ therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrollment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

Patient Consent

Information that would enable identification of individual patients should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given informed written consent for publication and distribution. We further recommend that the published article is disseminated not only to the involved researchers but also to the patients/participants from whom the data was drawn. Refer to Protection of Research Participants. The signed consent form should be submitted with the manuscript to enable verification by the editorial team.

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To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.

Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.

Mask self-citations by referring to your own work in third person.

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Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

Manuscripts must be written in UK English.

The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).

Please make your article concise, even if it is below the word limit.

Qualifications, full affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state ‘none’.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).

Litres is denoted with an uppercase L e.g. 'mL' for millilitres).

Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.

Please be sure to insert proper symbols e.g. µ not u for micro, a not a for alpha, b not B for beta, etc.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the only exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.

- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

**NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'

- Use the latest approved gene or protein symbol as appropriate:

Human Gene Mapping Workshop (HGMW): genetic notations and symbols

HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature

OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions

Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text.

Structured abstract

This should be 250-400 words, with the following recommended headings:

Background: why the study is being done and how it relates to other published work.

Objectives: what the study intends to find out

Methods: must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.

Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.

Conclusion: must be supported by the data, include recommendations for further study/actions.

Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.

Do not include any references in the abstracts.

Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed

Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.

Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.

Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc)that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.

Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.

Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any

Results.

Start with description of the population and sample. Include key characteristics of comparison groups.

Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.

Do not replicate data in tables and in text.

If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:

E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).

Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

Statement of principal findings

Strengths and weaknesses of the study

Contribution to the body of knowledge

Strengths and weaknesses in relation to other studies

The meaning of the study – e.g. what this study means to clinicians and policymakers

Unanswered questions and recommendations for future research

Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

APPENDIX 6

Review: A multicentre prospective observational study of the prevalence and glycaemic control of diabetes mellitus in adult non-cardiac elective surgical patients in Western Cape hospitals (manuscript draft SAMJ013898)

1. **This article attempts to establish the prevalence of diabetes mellitus in adult patient for elective, non-cardiac and non-obstetric surgery in the Western Cape; with secondary objectives to assess the degree of glycaemic control and treatment compliance of known diabetics. This study is certainly appropriate for this journal – diabetes is an epidemic according to the WHO and is one of the medical conditions responsible for an enormous burden of disease internationally; and the complications of which are particularly onerous to treat in a resource-constrained country like South Africa and its African counterparts.**
   This study is also original research albeit in familiar and relevant territory, and has produced some interesting findings with smallish numbers. It would be very interesting to see it used as a pilot for a national study, or to see the findings investigated further e.g. evaluating the efficacy of interventions (particularly in the waiting period between booking an elective surgical case and it actually being performed) to try to increase treatment compliance in an effort to reduce the incidence of perioperative complications.

2. **The article is well-written, concise and focussed. As a whole, spelling and grammar errors are minimal although any article worth publishing requires a thorough line-by-line beta by the editor.**

3. **Introduction: It is concise and to-the-point, as is suited to its nature.**

4. **Methods: It is gratifying to note that informed consent was obtained from the patients and ethics approval obtained. The description of the study is detailed but well laid out, logical and easy to read. The study itself follows simple and elegant lines, taking nothing away from the enormous amount of work it must have taken to complete. The methods described are quite straightforward.**

5. **Results: Regarding Table 2 – as convention, and to improve readability, numbers are right-justified and words are left-justified.**

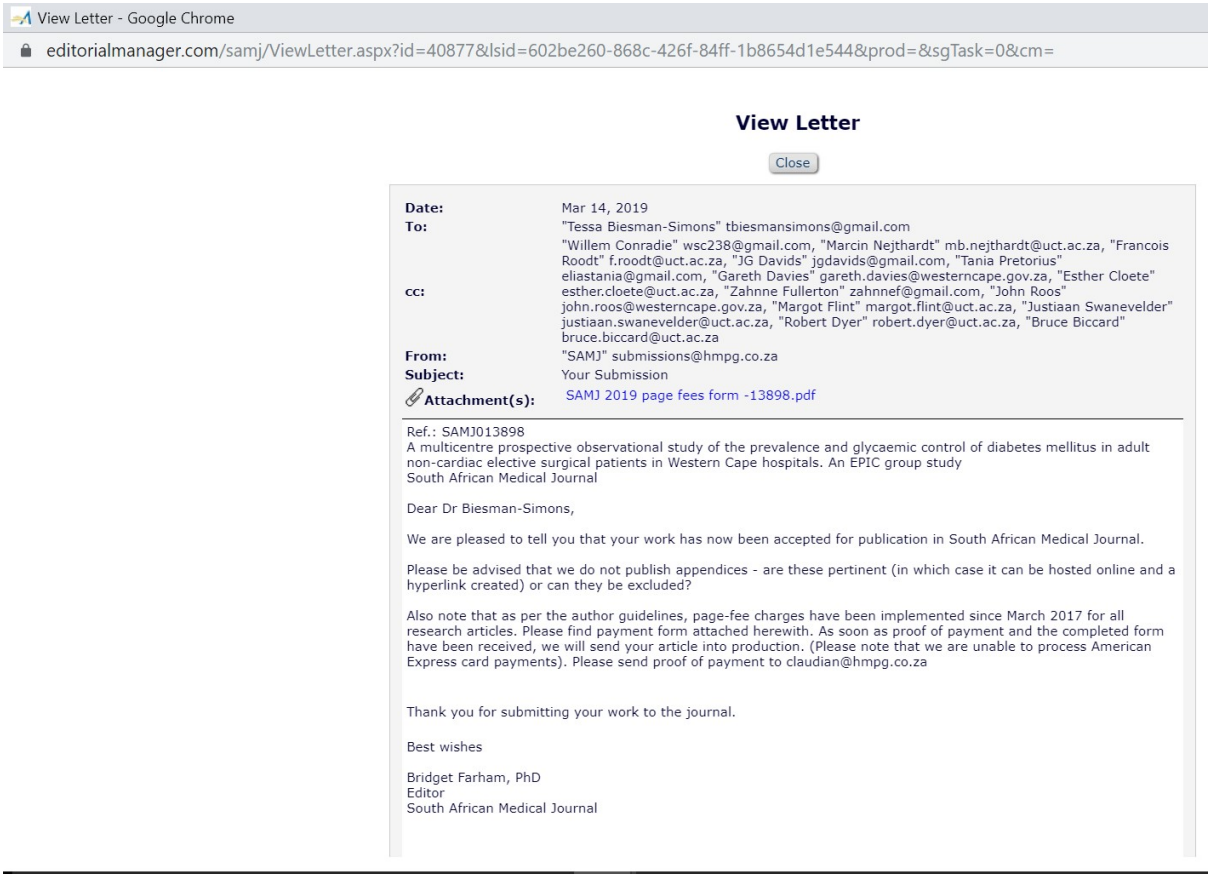
   Under statistical analysis, Lines 57-59 look as though they may be have been minimally changed from the original protocol (as a guess) and more information and detail is needed here. They need to justify or explain when and why Pearson's and Fisher's were used. This same level of detail should be represented in Table 2 where the statistical tests used should be added, as well as in the p-value calculation column.

6. **Discussion: As a general comment, the discussion is appropriate; and is essentially a revision and extension of the work presented in the introduction, and a summary of the important and significant findings of the study. The author(s) does well to include the limitations of the study and to suggest areas of further research.**
   It is also gratifying to note that cognisance is taken of the fact that although the incidence of undiagnosed DM in the Western Cape in THIS study was relatively low, it may not be so in

the rest of South Africa due to the very variable quality of primary health care provision nationally.

7. <u>References:</u> standard format; only 7 of 24 references are more than five years old.

APPENDIX 7



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Ref.: SAMJ013898
A multicentre prospective observational study of the prevalence and glycaemic control of diabetes mellitus in adult non-cardiac elective surgical patients in Western Cape hospitals. An EPIC group study
South African Medical Journal

Dear Dr Biesman-Simons,

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Thank you for submitting your work to the journal.

Best wishes

Bridget Farham, PhD
Editor
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