

Protocol: MMed

Quality of Recovery and Patient Satisfaction after Metabolic Surgery at a Tertiary Hospital in Gauteng: *(QoRPS-MS)*

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Issue date: 4 September 2025

Protocol Amendment Number: _1

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1 Introduction

1.1 Study Background and Literature Review

Obesity is a significant public health issue which puts patients at risk for many non-communicable diseases, such as hypertension, type 2 diabetes mellitus and cardiovascular disease.(1) According to the WHO, obesity is classified according to body mass index, which is calculated by dividing mass over height squared.(2) Patients within 10% of their ideal body weight (IBW) are at lowest risk for weight-associated morbidity, as has been shown in life insurance studies.(3) Incidence of obesity in Sub-Saharan Africa is 42% in women and 13% in men.(4) It is predicted that there will be an increase in incidence of obesity of 47.7% in female patients and 27.6% in male patients in South Africa by 2025. (1)

Bariatric or metabolic surgery is an effective treatment for obesity, resulting in significant weight loss, with the added benefit of reversing non-communicable diseases like diabetes and improving quality of life. (4,5) The increasing number of patients undergoing metabolic surgery has shown its efficacy. (6) Various procedures are included under the umbrella term of metabolic surgery, such as the gastric sleeve, gastric bypass, adjustable banding and bilio-pancreatric diversion with duodenal switch.(5) There are emerging endoscopic options such as the intragastric balloon and endo-plastic sleeve gastroplasty, but these still require further investigation. Roux-enY bypass and biliopancreatic diversion are the two procedures that have shown the most reliable reduction in obesity related disease, especially Type 2 diabetes and related complications.(5)

With metabolic surgery being an elective procedure, usually performed in dedicated units following enhanced recovery protocols, measuring outcomes after the procedure is paramount in order to maintain excellent quality of care.

Surgical outcomes are measured by mortality rate, minor and major complication rate and length of hospital stay. Traditional anaesthetic outcomes are time to extubation, time to swallowing and time spent in the recovery room.

However, with anaesthesia becoming very safe in recent years with limited direct complications, there is a shift to evaluating how quickly the patient returns to their baseline level of functioning. This can be done by evaluating perioperative patient reported outcomes (PROs) which show how the patient experiences their recovery after surgery and anaesthesia.(7)

Patient reported outcomes measures (PROMs) are validated standardised questionnaires completed by a patient, reporting on how they have experienced various factors like pain and nausea, with the aim to improve individual patient care. In other words, with PROMs the patient is reporting on themselves and their progress. This information may help the treating physician to intervene if an individual patient needs help, for example with analgesia. (8)

Patient experience measures (PREMs) on the other hand, are usually anonymously-completed standardised questionnaires that evaluate the system the patient was in with the aim to improve overall patient care. With PREMs the patient is usually reporting on external factors that influenced the quality of the care they received. This information may help healthcare professionals to improve patient care for all patients in the system.(8)

The StEP-COMPAQ group has done much work towards having standardised endpoints for the perioperative setting, including regarding various PROs. They reached a consensus that shortlisted proposed perioperative patient reported endpoints in 2016.(9,10) These endpoints include concepts like quality of recovery (QoR) and patient satisfaction (PS).

Quality of recovery is a multi-dimensional patient reported outcome, assessing recovery after surgery and anaesthesia from the patients' perspective. Assessment of recovery has prognostic and economic importance, which when managed well, may lead to improved patient satisfaction. Having a good understanding of a patient's quality of recovery helps clinicians to better manage the patient perioperatively.(11) The StEP-COMPAQ recommendation is to use the 15-Item Quality of Recovery (QoR-15) questionnaire as developed by Stark et al in 2013, to measure QoR. This questionnaire has good validity and reliability and can usually be completed in 3 minutes.(12) An alternative would be to use the 9-item Quality of Recovery score (QoR-9), but this is an earlier questionnaire with inferior psychometric scoring. (13) QoR is known to be affected by patient sex, duration of anaesthesia, severity of surgery and duration of stay in the post anaesthesia care unit. Age has not consistently been seen to correlate with QoR. The QoR-15 questionnaire has been translated into many international languages, as well as into isiZulu and Setswana in South Africa. (14,15)

Patient satisfaction is often influenced by patient expectations. If these expectations are met, PS is good, even if the actual experience is unpleasant. For example, if a patient has pain postoperatively, but they were warned to expect this by their anaesthetist and they receive pain medication as discussed with them before the procedure,

they may still have a good satisfaction score, even if their quality of recovery score is poor. A systematic review done in 2019 by the StEP-COMPAQ group recommends the Bauer questionnaire to measure patient satisfaction after anaesthesia, as it has good validity and reliability. (16)

The concepts of quality of recovery and patient satisfaction are linked, but do not necessarily influence one another.(17–19) It is therefore important that both aspects should be measured after surgery and anaesthesia in order to improve the quality of perioperative care.

At present, PROMs and PREMs are not routinely measured in South Africa. A number of research studies in South Africa have evaluated quality of recovery, but none have focused on metabolic surgery.(20,21) No published studies could be found on measuring postoperative patient satisfaction with the Bauer measure in South Africa. QoR and PS have been compared in a few studies, but none in South Africa, and none in metabolic surgery.(17,22)

1.2 Study Problem

The end-goal after elective surgery is to have a patient who is comfortable with minimal pain and nausea, who can resume their normal diet and who can mobilise early, so that they can return to their baseline level of functioning as soon as possible. Patient reported outcome and experience measures can help evaluate how patients are doing after surgery and anaesthesia.

In this study, one short term PROM – quality of recovery – and one short term PREM – patient satisfaction – will be evaluated in a patient group coming for elective metabolic surgery. Although outcome measures after metabolic surgery have been widely evaluated internationally, little is known about these outcomes within the South African setting. Given that patients undergoing such procedures often experience stigma and marginalisation, exploring their perioperative experiences, especially interactions with anaesthetists, may identify opportunities to improve care and patient engagement.

Having patient reported outcomes data can be used in improving overall quality of care and in individualising care in a resource limited environment.

This study will be the first to evaluate quality of recovery and patient satisfaction in patients coming for metabolic surgery at a tertiary government hospital.

1.3 Purpose of the Study

1.3.1 Aim

To evaluate quality of care after metabolic surgery at a tertiary Hospital in South Africa from the patient's perspective, using short-term patient reported outcomes and experience measures.

1.3.2 Objectives

- To measure the Quality of Recovery, a patient reported outcome, in patients who undergo metabolic surgery at Dr. George Mukhari Academic Hospital.
- To measure the Patient Satisfaction, a patient experience measure, in patients who undergo metabolic surgery at Dr. George Mukhari Academic Hospital.
- To compare quality of recovery with patient satisfaction.

1.4 Research Question

There are three research questions in this study:

- What is the quality of recovery after metabolic surgery at a tertiary hospital in Gauteng?
- What is the patient satisfaction after metabolic surgery at a tertiary hospital in Gauteng?
- Is there any relationship between quality of recovery and patient satisfaction?

2 Methodology

2.1 Study Design

The study design will be a cross-sectional quantitative study with participants completing standardised questionnaires.

2.2 Setting

This study will be conducted at Dr George Mukhari Academic Hospital, under supervision of the anaesthetic Department. This is a tertiary hospital situated in Ga-Rankuwa, Pretoria North in the Gauteng province with approximately 1500 beds.

2.3 Study Population or Participants

2.3.1 Eligibility

Inclusion Criteria:

- Female and male adult patients over 18 years
- Patients booked for metabolic surgery at Dr George Mukhari Academic Hospital.

Exclusion Criteria:

- Patients with significant psychiatric illness that may impact on their ability to participate in the study.

- Patients who are unable to communicate after their surgery, for example patients who are sedated or intubated and ventilated.
- Any severe preexisting medical condition that limits objective assessment after surgery.
- Patients with any life-threatening postoperative complications.
- Patients with postoperative confusion or delirium
- Incomplete quality of recovery or patient satisfaction questionnaires

2.3.2 Sampling Procedure

Consecutive convenience sampling will be used to recruit patients. Consecutive convenience sampling is appropriate for this study because it allows for the practical and efficient recruitment of participants in a real-world clinical setting. This will minimize selection bias by including all eligible patients who present during the recruitment period, without arbitrary exclusion. It should also ensure that the study population reflects the typical patient flow and case mix, enhancing the generalizability of the findings within the specific healthcare context.

2.3.3 Sample Size

The sample size for this observational study is determined by the expected patient flow over a 12-month period, estimated at approximately 7 patients per month, resulting in an anticipated sample of 84 patients.

As this is an observational study without a primary hypothesis comparing groups, a formal power calculation is not applicable in the same way as for interventional trials. However, we recognize the importance of describing the precision of our estimates. With a sample size of 84, we will be able to estimate proportions such as the prevalence with a margin of error of approximately ±10.5% at a 95% confidence level, assuming a proportion of 50% (which yields the maximum margin of error). For less common outcomes, the confidence intervals will be wider.

The sample size is therefore sufficient to provide reasonably precise descriptive statistics for the population seen over one year at our centre. We have consulted with a statistician to confirm that this approach is appropriate for our study design and objectives.

2.3.4 Recruitment

The principal investigator or their research assistant will recruit patients during the patient's anaesthetic preoperative evaluation the week before their surgery. This consultation takes place in the surgical outpatient's department. Patients will be given information on the study and the concepts of quality of recovery and patient satisfaction will be explained. Willing patients will be recruited and informed consent will be obtained from the participants coming for metabolic surgery.

2.4 Data Collection

2.4.1 Data Collection Tool

The QOR-15 questionnaire has 15 questions graded from 0 (worst score) to 10 (best score). (23)The questions relate to how the patient felt the preceding 24 hours. For questions relating to negative aspects like pain, a score of zero means that the patient was in pain all the time, whereas a score of 10 means that the patient was in pain none of the time. For questions relating to positive aspects like feeling in control, 0 represents not feeling in control at all over the preceding 24 hours, and 10 represents feeling in control all of the time. The scores for the 15 questions are summed together for a maximum QOR-15 score of 150 and a minimum score of 0. This is a continuous, numeric variable. A total score of 118 has been found to be the acceptable symptom limit score, in other words scores below 118 are concerning for poor quality of recovery. The total scores have also been categorised as follows: 0 – 89: poor quality of recovery; 90 – 121: moderate quality of recovery; 122 – 135: good quality of recovery; 136 – 150: excellent quality of recovery. The QOR-15 was developed to be used as a postoperative score, but a preoperative baseline score is often done for comparison and to allow patients to become familiar with the tool.(12)

The Bauer patient satisfaction measure also has 15 questions, divided into two parts. (24)The first part concerns anaesthesia-related discomfort and is measured on a 3-item scale (No / Yes, moderate /Yes, Severe). The second part evaluates patient satisfaction with anaesthesia and is measured on a 4-item scale (Very Satisfied / Satisfied / Dissatisfied / Very Dissatisfied). Data from the Bauer measure is categorical.(24)

2.4.2 Data Collection Procedures

Data collection will be with electronic questionnaires loaded on the REDCap database, using an electronic tablettype device which will be handed to the patient. REDCap (Research Electronic Data Capture) is a is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.(25) If needed, the principal investigator or the research assistant will assist patients to complete the questionnaires.

Each patient will be assigned a study number during their recruitment visit, which will be recorded on the consent form. The study number will be entered into REDCap with their demographic details during the preoperative visit.

The principal investigator will keep all consent forms and a list of patient names and study numbers. This will be stored in a secure location that only the principal investigator has access to.

Patients will be handed an electronic tablet-type device during their preoperative visit, on which they will complete a baseline QoR-15 score, linked to their study number.

The principal investigator and/or the research assistant will see patients the day after surgery in the surgical high care ward before they are discharged home. During this visit, the patient will receive the electronic tablet-type device, on which they will complete the quality of recovery and patient satisfaction questionnaires, linked to their study number.

If needed, the research assistant or principal investigator will assist patients to clarify any questions they may have.

The following table shows the individual patient timeline and when the questionnaires will be completed:

Individual Patient Timeline: QoRPS-MS Study

	STUDY PERIOD			
TIMEPOINT:	**Day -7 Preop**	**Day -1 Preop**	**Day 0 Surgery**	**Day +1 Postop**
ENROLMENT: *Face-to-Face meeting in Bariatric Surgery Outpatient Department*				
Eligibility Screen	X	X (if incomplete)		
Informed Consent	X	X (if incomplete)		
Demographic Data	X	X (if incomplete)		
SURGICAL PROCEDURE:				
Procedure data			X	
ASSESSMENTS:				
Quality of Recovery: QoR-15	X	X (if incomplete)		X
Bauer Questionnaire				X

2.5 Data Analysis

Demographic and clinical characteristics of patients will be summarised descriptively. Continuous variables will be summarised by mean, standard deviation, median, interquartile rage, minimum and maximum values. Categorical variables will be summarised by frequency count and percentage calculations.

All numerical data will be inspected for normality before analysis.

The primary outcome will be reporting on the quality of recovery QoR-15 scores overall, as well as any change from baseline scores. The QoR-15 score is a continuous numerical variable with a range from 0 to 150.

A secondary outcome will be reporting on patient satisfaction, which will be in the form of categorical variables. The first ten questions of the Bauer questionnaire enquire about the presence of symptoms, this data will be split into two categories: either “yes” if the symptom was reported as being present, or “no” if not present. The last five questions relate to satisfaction with different aspects of care, which are rated on a 4-point Likert scale. This data will be transformed into two categories, either “Satisfied” which will include “Satisfied” and “Very satisfied” or “Dissatisfied” which will include "Dissatisfied” and “Very dissatisfied”.(24)

A further secondary outcome will be comparing mean QoR-15 scores with patient satisfaction in general, using data from the last question of the Bauer questionnaire transformed into two categories “Satisfied” and “Dissatisfied”. If QoR-15 scores are normally distributed, the comparison will be performed with the student t-test. If not normally distributed, non-parametric tests like the Mann-Whitney U test will be used. (26)The null hypothesis for this comparison is that there is no association between QoR-15 scores and overall patient satisfaction.

Analysis or comparisons will be made on relevant subgroups, categorised according to sex, duration of anaesthesia, and duration of time spent in the post-anaesthesia care unit. Based on available literature, the expected finding will be that QoR-15 scores are worse in female patients, patients who experience longer anaesthesia and longer duration of time spent in the post-anaesthesia care unit. (13,26)

All statistical analysis will be performed in STATA. Any statistical tests will be two-sided and p values of <0.05 will be considered significant.

2.6 Reliability and Validity

Validity describes the accuracy of a study and the degree to which the measurement reflects the true value of the variables. The QoR-15 scores have been extensively evaluated and has been found to have excellent validity. This has been found both with construct validity (where the QoR-15 scores show a negative correlation with female sex, extent of surgery and duration of surgery or anaesthesia), and with convergent validity where the QoR-15 scores were compared to visual analogue scale. (23)The Bauer questionnaire has been found to have good content validity as it covers several aspects related to patient satisfaction.(24)

Reliability describes consistency or reproducibility of the results from a study. The QoR-15 score has excellent internal consistency (Cronbach alpha 0.85), split-half reliability and test-retest reliability. (26)The Bauer

questionnaire faired well in test-retest assessment with the McNemar test, and it has been shown to have good internal consistency with a Cronbach alpha of 0.84. (24)

2.7 Bias

Sampling bias

Convenience sampling will be used in this study, and there may therefore be an element of sampling bias. Detailing the research plan and data analysis plan will limit the impact of sampling bias on the study.

Recall bias

Using a questionnaire may result in recall bias. To prevent poor memory recall, the questionnaire will be completed on the first post-operative day before discharge. Recall bias should also be reduced by using a validated scoring tool with unambiguous phrases and simple scoring.

Researcher bias

A validated and standardised questionnaire will be used to prevent researcher bias, and a statistician who is not directly involved in patient care or in touch with patients will independently analyse the results.

Publication bias

By pre-registering the study in a public database and making sure the title, abstract, and conclusion provides a fair and representative overview of the findings will help prevent publication bias.

3 Ethical Considerations

This study will only commence after the study protocol has been given clearance by the Head of the Department of Anaesthesia, the University research and ethics committee and the hospital Management. Consent will be obtained from all participants in the research. No participant identifiers will be required on the questionnaire. All information that will be obtained from the questionnaire will be treated as confidential and will be used solely for the purpose of this study.

Before data collection is started permission will be sorted to perform study from the hospital superintendent. Soon after, the study will await approval to the School of Medicine Research Committee (SREC), whereafter it will be submitted for ethical approval to the Sefako Makgatho Health Sciences University Research Ethics Committee (SMUREC).

The study will be registered as a cross-sectional observational trial on the National Health Research Database (NHRD) , as well as on Clinicaltrials.gov.

All participants will be asked to provide written informed consent of voluntary participation. All participants will receive and be required to understand all the information they need to decide whether they want to participate. Information on what the study is about; risks and benefits of taking part in the study; how long the study will take; contact details of the PI and institution's approval number will be made available via a patient information leaflet that will be given to all participants to read. All participants will be free to choose to participate without any pressure or coercion. Refusal to participate will not affect their treatment plan in the hospital. Participants can also choose to opt out at any point of the study without explaining their reasons and may have their study documents destroyed or returned to them. This can be done by contacting the PI, whose contact details will be provided to patients on the patient information leaflet.

Regarding anonymity of patient information, the only documents to contain the patient's name will be the consent form and a sequentially numbered list that will be completed at recruitment that the PI will store to keep track of patients in the study. All data will be de-identified, no personal information (for example name and file number) will be recorded on any of the study documents.

Confidentiality will be ensured by the PI storing all paper documents in lever-arch files in a secure location that only the PI has access to. The sequentially numbered list will be stored electronically in a password controlled online folder that only the PI has access to. Personal information will not be shared without express patient permission. The only situation where it is foreseeable that patient information may be shared, would be if a quality of recovery score is very low and the PI needs to contact the treating physician to intervene.

This is a non-interventional study that does not pose a risk of harm to patients. At most, there may be an inconvenience of completing questionnaires for 10 minutes. Patients will be adequately counselled regarding voluntary participation in the study.

The PI has a valid Good Clinical Practice Certificate.

The results of the study will be published in a peer-reviewed journal and will be presented at local and national research conferences. All supporting documents and de-identified data will be appended as supplements to the publication.

4 Timelines

Gant Chart of Proposed Timeline												
Preparation	**2024**											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Literature Review, First Draft of Protocol												
Protocol Submission to Supervisor												
Corrections												
Year 1	**2025**											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
SREC submission												
SREC Corrections and Response												
SMUREC submission												
Recruitment start												
Data Collection												
Year 2	**2026**											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Recruitment end												
Data Analysis												
Report Writing												
	2027											
	Jan	**Feb**	**Mar**	**April**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Report Submission to Supervisor												
Corrections												
Submission of final report, Preparation for publication												

5 Budget

This study will be self-funded.

No	Item	Description	No of Items	Quantity	Cost	Total
1	**Research Assistant**	To assist with data collection before and after surgery, as needed	1	1	35 000	35 000
2	**Statistician**	Statistical planning and data analysis	1	1	10 000	10 000
3	**Language Editing**	Language editing of the mini dissertation	1	1	2 000	2 000
4	**Dissertation printing and binding**		1	1	2 000	2 000
5	**Printing costs**	Data collection forms, consent forms	1	1	1 000	1 000
					TOTAL	ZAR 50 000

Funding will be applied for through the South African Society of Anaesthesiologists' Jan Pretorius Research Fund, to the value of R50 000, once ethical approval has been obtained. No hospital resources or university resources will be used for this study.

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7 Appendices

7.1 Reporting Guideline Checklist

STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3-4
Methods			

Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	5
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Appendix 7.2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	6

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	

7.2 Variable table

The following variables relating to patient demographics and comorbidities, the procedure and the anaesthetic management will be recorded.

ASA physical status, weight, height, BMI and comorbidities are not expected to affect the outcomes of this study, but it will serve to describe our sample population. Risk factors for nausea and vomiting and the related Apfel score(27) are added as variables, as this may reflect in the QOR-15 and the Bauer questionnaires where questions are asked about post-operative nausea and vomiting. Home language is recorded, as this may help motivate future work to do validated translations of PROMs questionnaires into different local languages.

Nr	Variable	Variable Name	Definition or Calculation	Data source and recording of variable	Data type
1	Age	Age	Age in years	Recorded from file by research assistant	Numerical, continuous
2	Biological sex	Sex	1 = Male 2 = Female	Recorded from file by research assistant	Categorical, nominal
3	Weight	Weight	Weight in kilogram (kg)	Recorded from file by research assistant	Numerical, continuous
4	Height	Height	Height in centimetres (cm)	Recorded from file by research assistant	Numerical, continuous
5	Body Mass Index	BMI	Calculated from weight and height BMI = weight / (height x height)	Calculated in REDCap	Numerical, continuous

6	ASA physical status baseline	ASA_base	1 = I 2 = II 3 = III 4 = IV 5 = V	Recorded in REDCap	Categorical, ordinal
7	Risk factors for PONV	PONV	1 = Female 2 = Previous PONV 3 = Motion Sickness 4 = Non-smoker	Recorded in REDCap	Categorical, nominal
8	Apfel Score for PONV	Apfel	1 = 0 risk factors (10% risk) 2 = 1 risk factor (20% risk) 3 = 2 risk factors (40% risk) 4 = 3 risk factors (60% risk) 5 = 4 risk factors (80% risk)	Calculated in REDCap	Categorical, ordinal
9	Obesityassociated comorbidities	Comorbid_obese	1 = Diabetes Mellitus (DM) 2 = Hypertension (HPT) 3 = Sleep Apnoea 4 = Other	Recorded in REDCap	Categorical, nominal
10	Home language	Language	1=English 2=Setswana 3=Afrikaans 4=Venda 5=Sepedi 6=Sesotho 7=Zulu 8=Other	Verbal question by Research assistant: what language do you speak mostly at home? Recorded in REDCap	Categorical, nominal
11	Procedure	Procedure	Procedure as specified on the consent form	Recorded by research assistant from consent form	Categorical, Nominal
12	Procedure date	Proc_Date	DDMMYYYY as specified on the consent form	Recorded by research assistant from consent form	Numerical, continuous
13	Induction time	Induct_Time	HH:MM as specified on the anaesthetic record or the theatre record form in the patient's file	Recorded by research assistant	Numerical, continuous
18	Last Vitals in Theatre	LastVital_Time	HH:MM as specified on the anaesthetic record or the theatre record form in the patient's file	Recorded by research assistant	Numerical, continuous
19	Drop off Time in Ward	DropOff_Time	Time of First vitals in the high care ward as per the theatre record form in the patient's file	Recorded by research assistant	Numerical, continuous
23	Duration of anaesthesia	Duration_Anaesth	LastVital_time minus Induct_Time	Calculated	Numerical, continuous
24	Duration of Recovery in the	Duration_Recov	Recovery_Time minus Out_Time	Calculated	Numerical, continuous
25	Date of QoR	Date_QoR_Preop Date_QoR_Post	Date the QoR is completed, recorded as DDMMYYYY	Recorded by research assistant	Numerical, continuous
26	Time Since surgery till postop QoR score	Timing_QoR_Post	Date_QoR_Post minus Proc_Date	Calculated	Numerical, continuous
27	QoR15: Able to Breathe easily	QoR_Breath_Preop QoR_Breath_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
28	QoR15: Been able to enjoy food	QoR_food_Preop QoR_food_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
29	QoR15: Feeling rested	QoR_Rest_Preop QoR_Rest_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
30	QoR15: Have had a good sleep	QoR_Sleep_Preop QoR_Sleep_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
31	QoR15: Able to look after personal toilet and hygiene unaided	QoR_Hygiene_Pre QoR_Hygiene_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
32	QoR15: Able to communicate with family or friends	QoR_Comm_Preop QoR_Comm_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous

33	QoR15: Getting support from hospital doctors and nurses	QoR_Support_Preop QoR_Support_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
34	QoR15: Able to return to work or do usual home activities	QoR_Return_Preop QoR_Return_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
35	QoR15: Feeling comfortable and in control	QoR_Comfort_Preop QoR_Comfort_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
36	QoR15: Having a feeling of general well-being	QoR_Well_Preop QoR_Well_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
37	QoR15: Moderate pain	QoR_ModPain_Pre QoR_ModPain_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
38	QoR15: Severe pain	QoR_Severe_Pre QoR_Severe_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
39	QoR15: Nausea or Vomiting	QoR_Nausea_Pre QoR_Nausea_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
40	QoR15: Feeling worried or anxious	QoR_Anxiety_Pre QoR_Anxiety_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
41	QoR15: Feeling sad or depressed	QoR_Sad_Preop QoR_Sad_Post	Score from 0 to 10, as recorded by patient on data collection form	Recorded from questionnaires before and after surgery	Numerical, continuous
42	Total QoR15	Total QoR_Preop Total_QoR_Post	Calculated 0 to 150 from patient responses	Calculated from questionnaires	Numerical, continuous
43	QoR15 Change	QoR15_Change	Total_QoR_Post minus Total_QoR_Preop	Calculated from QoR15 scores	Numerical, continuous
44	Date of Bauer questionnaire	Date_Bauer	Date the Bauer score is completed, recorded as DDMMYYYY	Recorded by research assistant	Numerical, continuous
45	Time since surgery till Bauer questionnaire	Timing_Bauer	Date_Bauer minus Proc_Date	Calculated	Numerical, Continuous
46	Bauer: Have you had Drowsiness at any stage after your operation?	Bauer_drowsiness	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
47	Bauer: Have you had Pain at the site of surgery at any stage after your operation?	Bauer_Pain_Surg	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
48	Bauer: Have you had Thirst at any stage after your operation?	Bauer_Thirst	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
49	Bauer: Have you had Hoarseness at any stage after your operation?	Bauer_Hoareness	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
50	Bauer: Have you had Sore Throat at any stage after your operation?	Bauer_SoreThroat	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
51	Bauer: Have you had Nausea or Vomiting at any stage after your operation?	Bauer_NV	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal

52	Bauer: Have you felt cold at any stage after your operation?	Bauer_Cold	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
53	Bauer: Have you had Confusion or Disorientation at any stage after your operation?	Bauer_Confusion	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
54	Bauer: Have you had Pain at the site of anaesthetic injection at any stage after your operation?	Bauer_Pain_IV	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
55	Bauer: Have you had Shivering at any stage after your operation?	Bauer_Shiver	1=No 2= Yes, moderate 3= Yes, Severe	Recorded from questionnaire	Categorical, ordinal
56	Bauer: How satisfied were you with the information you were given by the anaesthesiologist before the operation?	Bauer_Info	1 = Very dissatisfied 2 = dissatisfied 3 = satisfied 4 = very satisfied	Recorded from Questionnaire	Categorical, ordinal
57	Bauer: How satisfied were you with the emergence from anaesthesia?	Bauer_Emergence	1 = Very dissatisfied 2 = dissatisfied 3 = satisfied 4 = very satisfied	Recorded from Questionnaire	Categorical, ordinal
58	Bauer: How satisfied have you been with pain therapy?	Bauer_Pain	1 = Very dissatisfied 2 = dissatisfied 3 = satisfied 4 = very satisfied	Recorded from Questionnaire	Categorical, ordinal
59	Bauer: How satisfied with the treatment of nausea and vomiting after the operation?	Bauer_Nausea	1 = Very dissatisfied 2 = dissatisfied 3 = satisfied 4 = very satisfied	Recorded from Questionnaire	Categorical, ordinal
60	Bauer: How satisfied were you with the care provided by the department of anesthesia in general?	Bauer_Satisfaction	1 = Very dissatisfied 2 = dissatisfied 3 = satisfied 4 = very satisfied	Recorded from Questionnaire	Categorical, ordinal

7.3 Patient Information Leaflet

STUDY TITLE:

Quality of Recovery and Patient Satisfaction after Metabolic Surgery at a Tertiary Hospital in Gauteng: a Cross-Sectional Study *(QoRPS-MS)*

Principal Investigator: Dr Tsime
Contact Details: 0761031312
Research Assistant: To be confirmed
Format of study: Cross-sectional Single Centre Observational Study

Dear Patient,

You are invited to take part in a research study to be carried out at Dr George Mukhari Academic Hospital by Dr. Tsime. This leaflet will give you background information on what the study is about, how it will work and what your role will be.

Before you decide to participate in the study, it is important that you completely understand what the study is about. It is therefore important to read the following information to make an informed decision.

Approval for this study has been given by Dr. George Mukhari Academic Hospital, Sefako Makgatho Health Sciences University and by the Sefako Makgatho Health Sciences University Research Ethics Committee (SMUREC).

If there are further questions about any aspect of the study, do not hesitate to contact me and ask questions.

Thank you for your time and consideration of this invitation.

PURPOSE OF THE STUDY

The goal of this study is to assess quality of recovery and level of satisfaction after metabolic surgery at a tertiary Hospital in South Africa from the patient's perspective, using 2 questionnaires on how patients recover after a surgical operation. These questions will ask how comfortable you are before and after your surgery. By asking these questions, it will assess if you are able to go back to your normal activities. It will also assess if you have had any pain, nausea or vomiting in the past 24 hours after your operation, and how you were treated during the surgical period.

WHY HAVE I BEEN SELECTED?

This study will be done on patients over the age of 18 presenting for elective metabolic surgery receiving metabolic protocol run anaesthetic. You fit this profile.
In total, we will ask 84 patients to be part of our study.

WHEN WILL THIS RESEARCH BE DONE?
This study will take place from July 2025 until July 2026.

IF I TAKE PART IN THIS STUDY, HOW WILL IT AFFECT MY TREATMENT?

Taking part in this study will not change any of your treatment, your surgery or your anaesthesia.

WHAT DO I NEED TO DO?

On the day before the operation, the private investigator or research assistant will come and see you to explain all the information in this leaflet. They will answer any questions you might have and ask you to sign a consent form showing that you agree to be part of the study.

They will read the questions from 15- item Quality of Recovery (QoR-15) score and you will be asked to record your responses in a score sheet from 0 (worst response) to 10 (best response). First ten questions of the Bauer questionnaire will talk about the presence of particular symptoms, where you will indicate "yes, moderate" or "yes, severe "is the symptom is present, or "no" if not present. The last five questions relate to satisfaction with different aspects of care into "Satisfied" which will include "Satisfied" and "Very satisfied" or "Dissatisfied" which will include "Dissatisfied" and "Very dissatisfied". They will follow up on the first day after your surgical procedure to come and assess how you're recovering. They will again read the questions and ask you to record your responses in the score sheet.

WILL ANY OF MY PERSONAL INFORMATION BE USED?

None of your personal information will be shared as this study will maintain anonymity throughout. Your name will be recorded on the consent form, and the consent forms will be saved securely by Dr. Tsime until the end of the project. We will collect certain information like your age, gender and details of any medical conditions, all this information will be deidentified.

WHAT WILL BE DONE WITH THE RESULTS FROM THIS STUDY?

The results of the study will be published in a medical journal once it is completed.

IF I HAVE MORE QUESTIONS, WHO CAN I CONTACT?

You may contact Dr. Tsime on 0761031312 if you have any further questions.

7.4 Consent Form

APPENDIX 4

SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY CONSENT FORM

You are hereby kindly invited to participate in a research study

Title of Study:

Quality of Recovery and Patient Satisfaction after Metabolic Surgery at a Tertiary Hospital in Gauteng: a Cross-Sectional Study *(QoRPS-MS)*

I have read the information in connection with the intended study and heard the aims and objectives of the intended study and was given the opportunity to ask questions as well as be allowed sufficient time to reflect on the matter. The goal and objectives of the study are clear to me. I was in no way put under any pressure to participate.

I understand that participation in this research study is entirely voluntary and that I may withdraw from it at any time without giving any reasons. It will have no effect on the regular treatment of my condition, nor will it affect the treatment I receive from my own doctor.

I am aware that this study was approved by the 'Sefako Makgatho University Research Ethics Committee (SMUREC)' of the Sefako Makgatho Health Sciences University /Dr George Mukhari Academic Hospital. I am fully aware that the results of this study will be used for scientific purposes, and it may be published. I agree to this, provided that my privacy is guaranteed.

I hereby grant permission to participate in this research.

Participant		
Name of Participant/ Volunteer	Signature of Parent/Guardian	
Place	Date	Signature of Witness

Statement by Researcher			
I provided a spoken and/or written information regarding this study. I declare myself willing to answer any future questions regarding the research to the best of my ability. I will hold myself to the approved protocol.			
Name of Researcher	Signature	Date	Place

7.5 Data Collection Forms / Questionnaires

Case Report Form: Data Collection

Date: ___ / ___ / ___ Study #: _____

SECTION A: PATIENT INFORMATION:

Age:	_____ years				
Biological Sex:	Male	Female			
Weight:	_____	**Height:**	_____		
ASA Status:	I	II	III	IV	V
Risk for PONV:	Female	Previous PONV	Motion Sickness	Non-smoker	
Comorbidities:	Diabetes Mellitus	Hypertension	Sleep Apnoea	Other:	
Home Language:	English	Setswana	Afrikaans	Venda	Sepedi
	Sesotho	Zulu	Other:		

SECTION B: INFORMATION ABOUT PROCEDURE:

Procedure type:	_____	**Procedure date:**	_____
Induction time:[a]	_____	**Theatre out time:**[b]	_____
Time last vitals in recovery room:[c]	_____		
Duration Anaesthesia:[b-c]	_____	**Duration Recovery:**[c-a]	_____

SECTION C: QoR-15 DATA:

Preop QoR date:	_____		**Postop QoR date:**	_____	
Preop QoR-15:[d]	_____		**Postop QoR-15:**[e]	_____	
Score below 118?	Yes	No	**Score below 118?**	Yes	No
Change from baseline: [e-d]	_____				

Note: Refer to QoR-15 question sheets attached for the questions and scoring.

SECTION D: BAUER PATIENT SATISFACTION DATA:

Bauer date:	_____			
General satisfaction?	Very dissatisfied	Dissatisfied	Satisfied	Very Satisfied

Note: Refer to Bauer Patient Satisfaction question sheets attached for the questions and scoring.

QUALITY OF RECOVERY QUESTIONNAIRE

QoR-15 Patient Survey

Date: ___ / ___ / ___ Study #: _____

Pre-Operative ☐ Post-Operative Day 0 ☐ Post-Operative Day 1 ☐

PART A

How have you been feeling in the last 24 hours?

(0 to 10, where 0 = none of the time [poor] and 10 = all of the time [excellent])

1.	Able to breathe easily	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
2.	Been able to enjoy food	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
3.	Feeling rested	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
4.	Have had a good sleep	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
5.	Able to look after personal toilet and hygiene unaided	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
6.	Able to communicate with family or friends	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
7.	Getting support from hospital doctors and nurses	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
8.	Able to return to work or usual home activities	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
9.	Feeling comfortable and in control	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time
10.	Having a feeling of general well-being	None of the time	0	1	2	3	4	5	6	7	8	9	10	All of the time

PART B

Have you had any of the following in the last 24 hours?

(10 to 0, where 10 = none of the time [excellent] and 0 = all of the time [poor])

1.	Moderate pain	None of the time	10	9	8	7	6	5	4	3	2	1	0	All of the time
2.	Severe pain	None of the time	10	9	8	7	6	5	4	3	2	1	0	All of the time
3.	Nausea or vomiting	None of the time	10	9	8	7	6	5	4	3	2	1	0	All of the time
4.	Feeling worried or anxious	None of the time	10	9	8	7	6	5	4	3	2	1	0	All of the time
5.	Feeling sad or depressed	None of the time	10	9	8	7	6	5	4	3	2	1	0	All of the time

Case Report Form: Data Collection

BAUER MEASURE: PATIENT SATISFACTION

PART A: ANAESTHESIA-RELATED DISCOMFORT

	No	Yes: Moderate	Yes: Severe
Have you had Drowsiness at any stage after your operation?			
Have you had Pain at the site of surgery at any stage after your operation?			
Have you had Thirst at any stage after your operation?			
Have you had Hoarseness at any stage after your operation?			
Have you had Sore Throat at any stage after your operation?			
Have you had Nausea or Vomiting at any stage after your operation?			
Have you felt cold at any stage after your operation?			
Have you had Confusion or Disorientation at any stage after your operation?			
Have you had Pain at the site of anaesthetic injection at any stage after your operation?			
Have you had Shivering at any stage after your operation?			

PART B: SATISFACTION WITH ANAESTHESIA CARE

	Very Dissatisfied	Dissatisfied	Satisfied	Very Satisfied
How satisfied were you with the information you were given by the anaesthesiologist before the operation?				
How satisfied were you with the emergence from anaesthesia?				
How satisfied have you been with pain therapy?				
How satisfied with the treatment of nausea and vomiting after the operation?				
How satisfied were you with the care provided by the department of anaesthesia in general?				

7.6 Good clinical practice certificate



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Onalenna Tsime

to certify your completion of the six-hour required course on:

GOOD CLINICAL PRACTICE

MODULE:	STATUS:
Introduction	N/A
Institutional Review Boards	Passed
Informed Consent	Passed
Confidentiality & Privacy	Passed
Participant Safety & Adverse Events	Passed
Quality Assurance	Passed
The Research Protocol	Passed
Documentation & Record-Keeping	Passed
Research Misconduct	Passed
Roles & Responsibilities	Passed
Recruitment & Retention	Passed
Investigational New Drugs	Passed

Course Completion Date: 22 June 2024

CTN Expiration Date: 22 June 2027

Eve Jelstrom

Eve Jelstrom, Principal Investigator

NDAT CTN Clinical Coordinating Center

Good Clinical Practice, Version 5, effective 03-Mar-2017

This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272012010000024C.

7.7 Other relevant documents

- **Turnitin Report**
- **Hospital permission letter**

- **Departmental research committee**
- **Statistician letter**