SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY

Protocol

Validation of the Setswana-Translated Quality of Recovery Questionnaire in Orthopaedic Patients at a Tertiary Hospital in South Africa: a Cross-Sectional Observational Study

ClinicalTrials.gov:

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1 Administrative Information

1.1 Trial Registration

Registered in ClinicalTrials.gov with reference number:

1.2 Revision Chronology

Date	Protocol Amendment Number	Description
23 Aug 2024	1	Original version of protocol
11 Oct 2024	2	Revision after feedback from School Research Committee
16 April 2025	3	Provisional approval pending minor revisions after meeting with School Research Committee

2 Introduction

2.1 Study Background

In perioperative medicine, quality of recovery is a patient reported outcome that evaluates physical and psychological well-being after a surgical procedure.(1) Effective assessment of postoperative recovery is crucial for patient-centered care and clinical decision-making.(2,3) Accurate assessment of postoperative recovery can help to evaluate surgical outcomes and can guide rehabilitation. This is especially relevant in orthopaedic surgery, which accounts for a large proportion of surgical case load in South Africa (4) and involves procedures that significantly impact mobility, function, and quality of life. In this context, patient-reported outcomes are essential for capturing the patient's perspective on pain, functional improvement, and return to daily activities, factors that are not always fully reflected in clinician-reported outcomes or radiological assessments. (3,5) Evaluating quality of recovery in the short term after orthopaedic surgery enables clinicians to identify patients at risk of poor postoperative outcomes, and may facilitate targeted interventions to improve patient care.(6)

Quality of recovery can be measured with a validated multidimensional questionnaire called the 15-Item Quality of Recovery questionnaire (QoR-15).(7) The original questionnaire was developed in English, but cultural and language barriers may impact the use of the tool among non-English speaking populations.(8) Multiple translations of the QoR-15 have been developed and validated internationally over the past few years with only one South African translation into isiZulu being done to date.(9) South Africa is a multicultural, multilingual country where language discordance may pose significant challenges in our healthcare system.(10) In the perioperative setting, language barriers may make it difficult for patients to communicate with their healthcare providers about how they are recovering after a procedure. Effective communication of health status requires assessment tools that are both culturally relevant and in the patient's preferred language.(11)

In South Africa, where Setswana is widely spoken, there is a need for validated Setswana versions of PROMs to ensure accurate and meaningful patient feedback. Setswana is part of the Sotho-Tswana language group, which includes closely related languages such as Sesotho and Sepedi. Given the linguistic similarities within this group, this tool may also prove useful among Sesotho and Sepedi speaking populations.(9,12) A recent randomised control trial evaluating quality of recovery after volatile anaesthesia for ophthalmological surgery translated the English Quality of Recovery questionnaire into Setswana, but the translation could not be validated in that study as only two patients in the study used the translation.(13)

This study is designed to validate the Setswana translation of the 15-Item Quality of Recovery questionnaire in a predominantly Setswana-speaking population, undergoing orthopaedic surgery.

2.2 Literature Review

2.2.1 Quality of Recovery as a Patient Reported Outcome in Perioperative Medicine

The patient's perspective of their health care is recognized as an important factor in assessing and ensuring good quality healthcare services. Much research is being done on the use of patient reported outcomes (PROs) and patient reported outcomes measures (PROMs).(14–17) PROMs are self-reported questionnaires that gather information and report on specific outcomes directly from the people who encounter them. Broadly speaking, PROMs may be condition specific, for example to assess outcomes after hip arthroplasty; or it may be more universal and used across different conditions by assessing constructs like health-related quality of life. (18)

Several patient-centered and patient reported outcomes exist in the perioperative sphere.(17,19) Quality of Recovery (QoR) is one such a patient reported outcome, and it is a multi-faceted concept that evaluates patient comfort in the short term after surgery, within 24-48 hours postoperatively. It encompasses recovery from a physical, emotional and economic point of view.(16,20) There are a number of anaesthetic, surgical and patient factors that may have an impact on quality of recovery, for example: type and severity of surgery (21–24), duration of anaesthesia (9,16,21,22,24,25), time spent in the recovery room (23,24) and sex (21,23,24,26). More severe surgery and longer procedures are associated with worse quality of recovery. Likewise, longer time spent in the recovery room has also been associated with worse quality of recovery. Some studies indicate that female patients and older patients have overall worse quality of recovery scores, but this is not a universal finding.

In orthopaedic patients specifically, quality of recovery is influenced by patient sex, surgical site, use of regional anaesthesia, postoperative pain, and postoperative nausea and vomiting.(6,27–29) Patients with low preoperative QoR-15 scores are also at risk for worse postoperative quality of recovery.(6) Evaluating quality of recovery in the short term after orthopaedic surgery enables clinicians to identify patients at risk of poor postoperative outcomes, and may facilitate targeted interventions to improve patient care.(6,15) This may hold benefit for a large surgical population, as orthopaedic patients account for a large proportion of the South African surgical population.(4) For example, providing timely pain relief or treatment for nausea and vomiting may improve early mobilization which may lead to faster discharge from hospital. Being able to educate patients on what to expect after a procedure based on feedback from other patients speaks to patient-centered care.

There are many different tools that have been developed over the years to measure quality of recovery. In 1999, the 9-item quality of recovery (QoR-9) score was constructed from an initial 61 item questionnaire.(23) It was developed by taking the 9 most highly rated items on the questionnaire. It was evaluated in a group of 136 diverse participants and there was a positive correlation with a visual analogue scale for the patient's perception of their

recovery and a negative correlation with the duration of hospital stay. However, the score had only moderate validity and was thought to be better suited for group assessments.(23,30)

The following year, Myles et al developed the 40-item quality of recovery score (QoR-40). This was developed by recruiting 160 participants who were asked to complete a 100-mm visual analogue scale, the QoR-9 and a fifty-item questionnaire. The questionnaires were repeated later the same day. From the results, a 40-item questionnaire was developed. It showed a positive correlation with the visual analogue scale and a negative correlation with the duration of hospital stay. There was good convergent validity, good test-retest reliability and internal consistency. It was concluded that the QoR-40 was a good objective measurement tool in quality of recovery following anaesthesia and surgery. The only drawback of the QoR-40 is that it takes around 10 minutes to complete.(30)

In 2013, Stark et al developed the 15-item quality of recovery score (QoR-15) by using the best psychometrically performing items from each of the five domains of the 40-item score. This was then tested in 127 surgically heterogenous adult patients after general surgery and anaesthesia. Most patients completed the questionnaires independently, with patients who were discharged same-day being contacted for a telephonic interview. It showed good convergent validity between the QoR-15 and a global quality of recovery visual analog scale. Most patients could complete the questionnaire in under 3 minutes. It was concluded that this score provided a valid, reliable and efficient way of evaluating quality of recovery.(24)

Kleif and Gögenur conducted a study with the aim of classifying the QoR-15 into poor, moderate, good and excellent classes of recovery. This was done on 276 participants who were undergoing laparoscopic appendicectomies under general anaesthesia. They concluded that the QoR-15 scores for excellent, good, moderate and poor recovery were 136 to 150, 122 to 135, 90 to 120 and 0 to 89 respectively.(31)

Through its development, the QoR-15 and QoR-40 scores have been extensively validated in English.(16,24,26,30) A systematic review by Kleif et al used the COSMIN checklist to evaluate the measurement properties and interpretability of the QoR-15 questionnaire.(32) The QoR-15 was again found to have good validity and reliability, and using the COSMIN four-point checklist it was also shown that the questionnaire fulfils the requirements to be included in a “core outcome set”.(16)

There has been limited work on quality of recovery in South Africa. A study in Johannesburg evaluated quality of recovery in orthopaedic patients at Helen Joseph hospital and found that low pre-operative baseline QoR-15 scores predicted worse postoperative scores. It was suggested that being able to identify patients with low pre-operative scores may help to focus limited resources on them in order to improve their post-operative course.(6)

A prospective clinical audit at New Somerset hospital in Cape Town in an undifferentiated surgical population, showed that most patients experienced “moderate” quality of recovery, with a QoR-15 score of 90-121, and the majority of patients achieved an acceptable symptom score of 118 or more. (33) A Study of quality or recovery after general anaesthesia for ophthalmological surgery at Dr George Mukhari Academic Hospital showed most patients had “excellent” quality of recovery, which may have been due to the minimally invasive nature of the surgery.(13) All of these studies used the English translation of the QoR-15 questionnaire.

2.2.2 Need for Translation of the 15-Item Quality of Recovery Questionnaire

Effective communication of health status requires assessment tools that are both culturally relevant and in the patient's preferred language.(11) In South Africa, where Setswana is widely spoken, there is a need for validated Setswana versions of PROMs to ensure accurate and meaningful patient feedback.(9,12) Language concordance can improve patient satisfaction and optimize health outcomes.(34)

Quality of recovery is not currently routinely captured as an outcome in daily practice in South Africa. Not having material available in a patient’s home language and low levels of literacy may present a barrier to widespread implementation of questionnaire-based assessments. In 2021, it was estimated that approximately 4 million adults were functionally illiterate. Black South Africans are more likely to be illiterate, with an illiteracy rate of 11.9% as opposed to 0.1% for white South Africans. (35) The Progress in International Reading Literacy Study in 2021 revealed that 81% of Grade 4 learners in South Africa struggled to achieve the lowest benchmark of reading to find specific information. The lowest mean achievement scores were attained in Setswana speaking learners. (36)

Utilizing the English version of patient-reported outcome measures (PROMs) with third-party assistance from an interpreter may seem practical. However, this approach presents several challenges, including the risk of misinterpretation, cultural and linguistic barriers, patient comfort and privacy, consistency and standardization, and regulatory compliance.(16,37) For instance, interpreters may inadvertently alter the meaning of questions or responses, leading to inaccuracies in data collection.(38) Regarding cultural and linguistic barriers, PROMs often contain culturally nuanced items.(39) Direct translation during interviews might not convey these subtleties effectively, leading to misunderstandings or incomplete data.(40) Discussing personal health information through an interpreter may make patients uncomfortable, potentially causing them to withhold sensitive details.(41) Self-administration of PROMs in the patient's native language fosters a sense of privacy and encourages honest reporting.(37) Using interpreters can introduce variability in how questions are presented and answered, affecting the reliability of the data. On the other hand, validated translations ensure that all patients receive the same questions, maintaining consistency across responses.(42,43)

The QoR-15 has been translated into many different languages internationally, including French, Danish, Dutch, and recently Arabic.(44–46)

De Vlieger et al aimed to validate the Dutch translation of the QoR-15 score across multiple surgical disciplines, where all patients received general anaesthesia. The questionnaires were completed independently by patients who received their questionnaires by mail. Convergent validity was displayed by a good correlation between the translated QoR-15 with the VAS for general recovery. The reliability indices of the score were also high with a Cronbach's alpha and split half reliability of 0,87 and 0,8 respectively. The Dutch translation was found to have good validity and reliability and was easy to use with high responsiveness.(45)

Demumieux et al translated the QoR-15 scale into French. In this validation study, a trained assessor read the questions to patients who then responded with their rating per item. The translated version was found to have good convergent and discriminatory validity, as well as good internal consistency and test-retest reliability. Responsiveness and acceptability were also found to be fair. Overall, these psychometric properties of the French version of the QoR-15 were comparable to the original English version.(44)

South African work has also been done on translating the original English version of the QoR-15. A randomized quantitative observational study conducted by Sikhakhane et al translated the QoR-15 score into isiZulu and validated both the English and the translated versions in an isiZulu speaking population. The study was designed to compare the quality of recovery scores between the English and isiZulu translations, and against a general visual analog scale of overall sense of recovery. Patients were randomized into 2 groups: one receiving the English version of the questionnaire first, and 40 minutes later the isiZulu version, and the other receiving the isiZulu and later the English. The time between questionnaires was an arbitrary decision by the investigators. The finding from this study was that there was good correlation and agreement between the English original and the isiZulu translation, and both were suitable to be used in an isiZulu speaking population. The authors admit that the educational background of respondents was not assessed, instead self-professed literacy in English and isiZulu was used as inclusion criterion, which may impact the validity of the result. (9)

In order to comply with ethics committee requirements, the QoR-15 questionnaire was translated from English into Afrikaans and Setswana during the recent Desflurane-Isoflurane Quality of Recovery (DIQoR) study performed at Dr. George Mukhari Academic Hospital. These translations could not be validated during the study as the English version was used in all but 2 patients who requested the Setswana translation. The purpose of the DIQoR study was not to validate the translations. Most patients in the DIQoR study needed help from a research assistant to complete their questionnaires. Visual disturbance after ophthalmological surgery as well as limited written literacy in the study population were barriers to the patients completing the questionnaires independently. The results of

the QoR-15 questionnaires were used to evaluate the patient's perspective of their anaesthetic management, and the tool was found to be overall useful.(13)

2.2.3 Evaluating Patient Reported Outcomes Measures or Questionnaires

Whenever a questionnaire is being developed or evaluated, it is important to ensure that the information gathered is valid and reliable. Validity considers what a specific tool measures (the so-called "construct") and the precision with which it is measured, whereas reliability refers to repeatability, whether a tool will get the same answer when repeated over time.(47) Furthermore, responsiveness can be evaluated which refers to the ability of a questionnaire to detect a change. Feasibility and acceptability can also be assessed by evaluating patient recruitment rate, completion rate and time taken to complete a questionnaire.

Different aspects of validity can be evaluated. Construct validity refers to how well a questionnaire measures the theoretical concept it is designed to assess. For QoR, this has been evaluated by looking for negative associations between QoR score and among others age, sex, severity and duration of surgery. Convergent validity is the degree to which two measures of the same construct are related. In QoR studies, convergent validity is determined by comparing QoR scores with a Visual Analog Scale (VAS) for general recovery. Discriminant validity confirms that the instrument measures what is intended without mistakenly capturing overlapping aspects. For QoR, discriminant validity is tested by evaluating QoR scores of patients with complications who are expected to have worse quality of recovery.

Reliability can be tested with internal consistency using Cronbach's alpha statistic, split-half reliability and test-retest reliability. The Cronbach's alpha statistic estimates how well a set of questions measures a unidimensional construct by looking for correlation between questions. For split-half reliability, the questions in a questionnaire are split into two equal halves, and the correlation between the scores for the two halves is calculated. Test-retest reliability is assessed by having patients repeat a questionnaire after a specified time period, and then evaluating responses with the Spearman's rho correlation coefficient.

Responsiveness is measured with the Cohen effect size, which is the average change of scores from pre-test to post-test.

2.2.4 Study Problem

Patient-reported outcomes are seen as important in perioperative research, but they are not yet in widespread use in clinical practice in South Africa. While quality of recovery measures have been widely applied in general and ambulatory surgery settings, there is a relative paucity of data specifically addressing orthopaedic populations. Orthopaedic surgical procedures are associated with significant postoperative pain, functional limitations and

extended rehabilitation periods, all of which can substantially impact the patient's overall recovery experience. Evaluating a short-term postoperative outcome like quality of recovery in this surgical cohort may help to tailor postoperative care to patient needs, which may lead to better patient-clinician communication, better surgical outcomes and better patient satisfaction.(48)

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A Setswana translation of the QoR-15 questionnaire exists from a previous study (13), which may be of use in Ga-Rankuwa, which is home to a Setswana speaking population. This translated questionnaire is yet to be validated in this population. For PROMs to be effective in non-English-speaking populations, rigorous linguistic and cultural adaptation is necessary.(49)

2.2.5 Study Rationale

Patients coming for orthopaedic procedures make up a large percentage of the surgical patients at any facility.(4) Surgery ranges from minor to major procedures. Being able to evaluate quality of recovery on the first day after surgery in the orthopaedic surgery population will help improve patient care and levels of patient satisfaction.(6,48) By having standardized questionnaires covering different aspects of recovery, like pain, comfort and nausea, it is less likely that symptoms that patients are experiencing are overlooked in a postoperative consultation. Any patient whose quality of recovery deviates from the expected trajectory can be identified and can be given additional care to improve their condition.(6) Besides the benefit to patients or evaluating quality of recovery, orthopaedic patients also present an ideal patient population to do this validation study in, as male and female patients of all ages present for orthopaedic surgery, and procedures vary from minor to intermediate to major in terms of severity, so one can expect to find a wide range of quality of recovery in this patient population.

South Africa has a diverse language heritage with 11 official languages and high rates of functional illiteracy. While many South Africans are able to communicate in English, only a small minority reports English as the primary language used most often outside the household. For black South Africans the most languages spoken outside of the home most commonly are isiZulu, isiXhosa and the Sotho-Tswana languages.(50) Studies on the impact of language barriers in healthcare are very limited in South Africa, and mostly being done on isiXhosa in the Western Cape province.(51)

In this study quality of recovery will be measured with the Setswana translation of the QoR-15 questionnaire, as well as with a visual analogue scale on which patients can rate their overall postoperative recovery from 0 (bad recovery) to 10 (good recovery).

By showing that the Setswana translation of the QoR-15 has good reliability, validity and ease of use in an orthopaedic population, we hope to add another tool to evaluate the patient reported outcome of quality of recovery in our local population.

2.3 Purpose of Study

2.3.1 Aim

The aim of this study is to determine if the Setswana translation of the 15-Item Quality of Recovery Questionnaire (QoR-15), is a valid, reliable and easy-to use outcome assessment tool in a Setswana speaking population undergoing orthopaedic surgery.

2.3.2 Objectives of the Study

- To evaluate construct, convergent and discriminant validity of the Setswana translation of the 15-Item Quality of Recovery questionnaire in Setswana speaking patients undergoing orthopaedic surgery.
- To evaluate reliability with internal consistency and test-retest reliability of the 15-Item Quality of Recovery questionnaire in Setswana speaking patients undergoing orthopaedic surgery.
- To evaluate responsiveness with change from preoperative to postoperative scores of the 15-Item Quality of Recovery questionnaire in Setswana speaking patients undergoing orthopaedic surgery.
- To evaluate acceptability and feasibility of the 15-Item Quality of Recovery questionnaire in Setswana speaking patients undergoing orthopaedic surgery.

2.4 Research Question

Is the Setswana translation of the 15-Item Quality of Recovery Questionnaire a valid, reliable and easy to use measure of quality of recovery in a Setswana speaking patient population undergoing orthopaedic surgery at a tertiary hospital in Gauteng Province, South Africa?

3 Methods

3.1 Study Design

This study will be a cross-sectional single-centre observational study.

3.2 Setting

The study will be conducted in the orthopaedic wards at Dr. George Mukhari Academic Hospital, a 1500 bed tertiary hospital in Gauteng province in South Africa. There are approximately 150 orthopaedic beds in the hospital, and an estimated 250 of orthopaedic procedures being performed at the hospital per month.

3.3 Study Population or Participants

The study population will consist of adult patients (aged 18 years and older) who are fluent in Setswana and are scheduled for elective orthopaedic surgery at the hospital. The population is expected to be diverse in terms of gender, age, and socioeconomic background, reflecting the typical demographic of Setswana-speaking patients. These patients are expected to be conscious and alert in the postoperative period, able to provide informed consent, and cognitively capable of understanding and responding to a questionnaire. Participants with known cognitive impairments, severe postoperative complications that impair communication, or those unwilling to participate will be excluded. A detailed inclusion and exclusion criteria has been outlined below:

3.3.1 Eligibility

Inclusion Criteria:

- Adult patients over 18 years
- Scheduled elective orthopaedic surgery at Dr George Mukhari Hospital

Exclusion Criteria:

- Patients who are not fluent in Setswana
- Patients booked for emergency procedures where a delay to surgery could be detrimental
- Patients where the surgery is delayed beyond 10 days of the initial assessment and preoperative quality of recovery measurement.
- Patients with a psychiatric disturbance that precludes complete cooperation
- Patients with a severe debilitating medical or surgical condition that may limit objective assessment after surgery
- Patients with any life-threatening postoperative complication
- Postoperative confusion or delirium

- Patients with a history of recent drug or alcohol abuse which may render responses unreliable
- Incomplete quality of recovery questionnaires
- Patients who do not have complete preoperative and postoperative questionnaires

3.3.2 Participant timeline

TIMEPOINT:	Pre-op Day -1	Surgery Day 0	Postop Day 1
RECRUITMENT:			
Eligibility Screen	X		
Informed Consent	X		
PREOPERATIVE ASSESSMENT:			
Preoperative Quality of Recovery score	X		
SCHEDULED SURGERY		X	
POSTOPERATIVE ASSESSMENT:			
Postoperative Quality of Recovery score			X
Visual Analog Scale			X

Table 1: Participant timeline

3.3.3 Sampling Procedure

Non-probability convenience sampling will be used to recruit patients on consecutive weekdays.

3.3.4 Sample Size

The recommended sample size to validate a questionnaire is 10 participants per item, which would be 150 patients.(52,53). This fits well with the average number of patients recruited in recent validation studies.' (9,22,44–46). All 150 patients will complete all 15 questions on the preoperative and the postoperative questionnaires. Any incomplete forms will result in the patient being excluded from analysis.

3.3.5 Recruitment

The Principal Investigator (PI) will screen the elective theatre lists on a daily basis and record detail of eligible patient on an electronic spreadsheet stored on a password protected device that only the PI and research assistant have access to. The PI or the research assistant will then visit eligible patients in the ward, and counsel them regarding voluntary participation in the research study, with the help of a patient information leaflet to ensure complete information sharing. The concept of quality of recovery will be explained to consenting patients, as well as the way that the questionnaires work, scoring a particular aspect from 0 to 10, with 0 being the worst score and 10 being the best score. The visual analog scale will also be explained to them with 0 reflecting the worst recovery and 10 the best recovery. Consenting patients will be allocated a sequential study number which will be recorded on all study documents relating to a particular patient.

Should patients not be operated the following day, the PI will review the orthopaedic theatre registers on a daily basis to confirm when patients that were recruited come to theatre. The operative date will be recorded on the electronic spreadsheet, and the PI or the research assistant will follow-up with patients on day 1 after their surgery.

3.4 Data Collection

3.4.1 Data Collection Procedures

Patients will be assessed before their procedures, as well as on day 1 after their procedures. Where possible, patients will be assessed on the day before their scheduled surgery, but if cases are cancelled and rebooked, the interval before the procedure may be longer. Patients are usually rebooked within a week of their initial scheduled surgery, depending on availability of theatre time. Occasionally patients will be done on an after-hours list. Patients who are rebooked more than 10 days after their initial consultation and baseline QoR-15 assessment will be excluded from further participation.

For the pre-operative visit, each patient will receive a hard copy of the Setswana translation of the QoR-15 questionnaire on which they will record their response from 0 (worst response) to 10 (best response) on the paper form. The PI or research assistant will explain to the patient how to complete the form and may read the questions out to the patient as they are written without any interpretation but will offer no further assistance to limit bias.

For the postoperative visit, each patient will receive a hard copy of the Setswana translation of the QoR-15 questionnaire as well as the Visual Analog Scale. The PI or research assistant will explain to the patient how to complete the forms and may read the questions out to the patient as they are written without any interpretation but will offer no further assistance to limit bias.

Once the forms are completed, the PI or research assistant will collect the forms which be identified with the patient's sequential study number. The forms will be kept in a dedicated lever arch file in a secure location that the PI and research assistant have access to.

The PI or research assistant will explain the scoring system to the patient, ensuring that they understand that in the QoR-15 questionnaire, 0 relates to the worst score per item and 10 to the best score per item. Different aspects of recovery are evaluated over the preceding 24-hour period. For the first 10 questions of the QoR-15 questionnaire, 0 means the patient experienced a particular aspect (for example "Feeling rested") none of the time and 10 means they experienced that aspect all of the time. For the last five questions the scoring is reversed, with zero still being the worst score, but now meaning that a patient experienced a negative aspect of recovery (for example nausea) all of the time.

Once the patients have completed the postoperative QoR-15 questionnaires, they will be asked to rate their quality of recovery on a 10-point visual analogue scale with 0 being the worst recovery and 10 being the best possible recovery. By comparing the QoR-15 total scores and the VAS scores it will be possible to assess convergent validity of responses to the Setswana translation.

Every 6th patient that is recruited, will be asked to complete a second QoR-15 questionnaire 30-60minutes after completing their postoperative questionnaire. This data will be used to determine test-retest reliability. The same data collection procedures will be followed. In total 25 patients will be asked to complete a second QoR-15 questionnaire.

3.4.2 Data Collection Tools

The QoR-15 questionnaire consists of 15 statements relating to how the patient felt the previous 24 hours, and each question is rated from 0 to 10, with 0 being the worst score and 10 being the best score. Patients will receive paper questionnaires to complete their scores on, after having the questions read to them as detailed above.

A translation of the English QoR-15 questionnaire into Setswana was done in a previous study at DGMAH.(13) Forward translation was done by an accredited medical translator, and back-translation was done by three first language speakers with the final translation being approved by all three reviewers. The Setswana version was reviewed again during the planning phases of the current study by three different first language Setswana speakers, who were all satisfied with the original translation.

3.4.3 Data management

The data from paper forms will be captured electronically on the REDCap database by the research assistant. (54) REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 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 importing data from external sources.

The patient's study number assigned at recruitment will be used to identify all documents in REDCap relating to a particular patient.

Study documents will be stored securely by the Principal Investigator. Hard copy documents will be kept in a dedicated lever-arch file and will be arranged sequentially according to study number. All study documents relating to a single patient will be stored together. The forms will be kept in a dedicated lever arch file in a secure location that the PI and research assistant have access to. The electronic database used for screening and recruitment

will be stored on a password protected device that only the PI and research assistant have access to. Data in REDCap is also password protected.

The principal investigator will monitor the completed study documents and the REDCap entries to ensure accurate capture of results. In case of incomplete data on the Data Collection Form, the principal investigator will review the source documents in the order listed to obtain the missing information. In case of incomplete quality of recovery questionnaires, patients will be asked to complete any blank questions. Cases with incomplete data collection forms will still be included in final analysis, but cases with incomplete quality of recovery questionnaires will not be included in final analysis.

3.4.4 Data sources

The following documents will be used to source information:

- Patient file:
    - Patient demographic data
- Surgical consent form:
    - Procedure name, date, type of anaesthesia
- Anaesthetic form:
    - Induction time, theatre out time, urgency of surgery, type of anaesthesia
- Theatre record form:
    - Induction time, theatre out time, time of last vitals in recovery room, type of anaesthesia

3.4.5 Study documents

The following documents will be used as study documents to record relevant information:

- Case Report Form: Data collection
- Case Report Form: VAS
- Case Report Form: Quality of Recovery Questionnaires
- Consent Form
- Patient Information Leaflet

3.4.6 Variables

<u>Patient-related variables</u>

Patient age, sex and level of education will be recorded. Age will be recorded in years. Biological sex will be recorded as male or female.

American Society of Anaesthesiologists classification of Physical State (ASA Score) will be recorded as follows: ASA 1: healthy normal patient, ASA 2: patient with mild systemic disease, ASA 3: patient with severe systemic disease, ASA 4: patient with severe systemic disease that is a constant threat to life, ASA 5: a moribund patient who is not expected to survive without surgery.

Surgery-related Variables

In this study, we will grade the magnitude or severity of orthopaedic procedures depending on the estimated length of time required to complete the procedure and the complexity of the procedure.

- Minor orthopaedic surgery: Quick procedures, lasting 30 minutes or less. This may include incisions and drainages, realigning a dislocated joint and repairing a tendon.
- Intermediate orthopaedic surgery: More complex procedures, typically taking between 30 – 90 minutes in the operating room. Common examples include rotator cuff repair, carpal tunnel release and open reduction and internal fixations.
- Major orthopaedic surgery: This necessitates the skill and experience of highly qualified surgical teams, and often necessitates several hours of operating time. Major orthopaedic operations include joint replacement, spinal fusion and limb restoration.

Anaesthesia-related Variables

The following variables relating to anaesthetic management will be recorded:

- Duration of anaesthesia: measured from theatre entry time until theatre exit time
- Duration of stay in the post-anaesthesia recovery room: measured from theatre exit time until the time last vitals are recorded in the recovery room, as this is when patient is deemed ready to go to the postoperative surgical ward.
- Type of anaesthesia: general anaesthesia, regional anaesthesia, sedation with monitored anaesthesia care, combination general anaesthesia and regional anaesthesia, combination sedation with regional anaesthesia.

Quality of Recovery

The QoR-15 is a 15-item post-operative questionnaire evaluating physical and mental well-being by assessing five aspects of patient recovery: emotional state, physical comfort, psychological support, physical independence and pain. The 15 questions are scored by the patient from 0 (worst score) to 10 (best score), giving a lowest possible score of 0, and a highest possible score of 150. This continuous composite score allows comparisons between intervention groups. The minimal clinically important difference (MCID) is 6 and patient acceptable symptom state score for the QoR-15 score has been found to be 118. The QoR-15 has good scaling properties, with scores showing a normal distribution during development and testing. Floor and ceiling effects have not been observed with the QoR-15. (55,56)

The time it takes a patient to complete each version of the questionnaire will also be recorded.

Visual Analogue Score (VAS)

A 10-point visual analogue score will be given to patients to grade their overall postoperative recovery. This will give an objective measure of postoperative recovery against which to compare the quality of recovery scores measured with the QoR-15. Zero points will be the worst quality of recovery, and 10 points will be the best quality of recovery.

3.5 Data Analysis

3.5.1 Outcomes

The outcomes of the study are as follows:

- To evaluate construct validity by looking for associations between QoR-15 scores and age, gender, duration of surgery, severity of surgery, and duration of stay in the recovery room.
- To evaluate convergent validity by comparing it with a visual analogue scale of quality of recovery in general.
- To evaluate discriminant validity by assessing QoR-15 scores in patients low VAS scores for general recovery.
- To evaluate internal consistency with Cronbach's alpha using the average correlation between the questions of the QoR-15.
- To evaluate test-retest reliability in a subset of 25 patients who will be asked to have a repeat assessment 60 minutes after their post-operative questionnaire.
- To evaluate responsiveness by calculating the Cohen effect size of change from preoperative to postoperative scores.
- To evaluate acceptability and feasibility by calculating patient recruitment rate, completion rate and time taken to complete the questionnaire.

3.5.2 Statistical Methods

Data will be summarised with descriptive statistics and presented as mean ± standard deviation (SD), median (interquartile range (Q3-Q1)) or number (percentage) as appropriate to data type and distribution. Normal distribution will be assessed with the Shapiro–Wilk test.

Psychometric evaluation of the scores will include construct validity, reliability and feasibility. Construct validity will be evaluated by looking for associations between total QoR-15 scores and severity of surgery, duration of surgery, duration of stay in the recovery room and sex using Spearman's rank correlation. Very strong correlation will be defined as a Spearman's rho of 0.90 – 1.0, strong correlation will be defined as 0.70 – 0.89, and moderate

correlation will be defined as 0.40 – 0.69.(45). Convergent validity of the QoR-15ST will be assessed in a similar way by comparing total postoperative QoR15 scores with the patient VAS scores of quality of recovery. Discriminant validity will be by assessed by reporting QoR-15 scores of patients with low VAS scores for general recovery. Internal consistency as a measure of reliability will be calculated using Cronbach's alpha statistic, with 0.70-0.90 considered good.(45) Test-retest reliability will be evaluated by comparing the postoperative QoR15 scores 60 minutes apart in a subset of patients who will be asked to have a repeat assessment. Responsiveness will be calculated with the Cohen effect size of change from preoperative to postoperative scores.

Feasibility will be assessed by calculating recruitment rate, completion rate, time taken to complete the questionnaires, and by evaluating scores for floor and ceiling effects. Floor or ceiling effects will be deemed to be present if >15% of respondents give the lowest or highest scores, respectively.(45) The recruitment rate will be calculated as the percentage of eligible patients who were approached and who agreed to participate in the study. The completion rate will be calculated as the percentage of patients completed both pre- and postoperative questionnaires.

3.6 Reliability and Validity

Construct validity will be tested by evaluating if the quality of recovery scores in this study show negative correlation with duration of surgery, extent of surgery and female sex. To determine convergent validity of the QoR-15 scores, total scores will be compared with the visual analogue score using Spearman's rank correlation.

Reliability testing of the individual items from the questionnaires will be tested using internal consistency evaluated with Cronbach's alpha.

Feasibility will be assessed based on completion rate and on the time taken to complete the questionnaires.

3.7 Bias

Sampling bias will be avoided by submitting a well-designed research protocol clearly outlining data collection and analysis. Due to the nature of the project, convenience sampling will be used.

Recall bias is possible with the use of a questionnaire. This will be minimized by offering the questionnaire on Day 1 post operatively, prior to discharge to prevent poor memory recall. The use of a validated scoring tool that uses clear statements and easy to understand scoring should also minimize recall bias.

Researcher bias will be avoided by using a validated and standardized questionnaire, and by having the PI and research assistant read questions to patients without interpretation. Independent analysis of the results will be done by a statistician who will not be in contact or directly involved in patient care.

Publication bias will be avoided by pre-registration of the study in public databases and by ensuring that the title, the abstract and conclusion present a well-balanced and representative summary of the results.

4 Ethical Considerations

Prior to commencing data collection, permission to perform study at Dr George Mukhari Academic Hospital will be obtained from the hospital superintendent. Thereafter, the study will be submitted for 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 an observational trial 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 other 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 and research assistant 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 for a small subset of patient who will be asked to complete questionnaires 30-60 minutes apart. Patients will be adequately counselled regarding voluntary participation in the study.

The PI will obtain a Good Clinical Practice Certificate before commencing data collection.

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.

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5 Timelines

Gant Chart of Proposed Timeline												
Preparation	**2025**											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
SREC corrections and response												
Protocol Submission to Supervisor												
Corrections												
SREC submission												
SREC Corrections and Response												
SMUREC submission												
Recruitment starts												
Data collection												
Recruitment ends												
Data Analysis												
Report writing												
Year 2	**2026**											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Report writing												
Report submission to supervisor												
Corrections												
Submission of final report, Preparation for publication												

6 Budget

Expense	Personal	JPRF
Research Assistant		R 39 000
Printing costs		R 1 000
Statistician		R 10 000
Total		**R 50 000**

Once ethical approval for the study has been obtained, the PI will apply for funding through the SASA Jan Pretorius Research Fund, to the value of R 50 000. No hospital or university resources will be used for the study.

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8

9 APPENDICES

9.1 Data Collection Form

Date: ___ / ___ / ___ Study #: _____

Age: _____ years

Sex:	Male	Female

Home Language:	Setswana	English	IsiZulu	IsiXhosa	Tshivenda	Xitsonga
	Sepedi	Sesotho	isiNdebele	siSwati	Afrikaans	Other:

ASA Status:	I	II	III	IV	V

Level of Education:	After School Qualification	Secondary School Completed	Primary School Completed	No Formal Education Completed	Other:

Literacy Setswana:	Speak	Read	Write

Literacy English:	Speak	Read	Write

Pre-op assessment date: _____

Pre-op QoR-15 Score:			

Start Pre-Op QoR:		**Done Pre-Op QoR:**	

Procedure: _____

Procedure Date: _____ **Induction Time (a):** _____ **Out Time (b):** _____ **Time last vitals in Recovery (c):** _____

Duration of Anaesthesia (min):	= b – a	**Duration of Stay Recovery Room (min):**	= c – b

Severity of Surgery:	Minor	Intermediate	Major

Type of Anaesthesia:	General	Neuraxial alone	Regional alone	General & Neuraxial	General & Regional
	Sedation	Sedation & Neuraxial	Sedation & Regional		

Post-op assessment date: _____

Post-op QoR-15 Score:			

Start Post-Op QoR:		**Done Post-Op QoR:**	

STUDY TITLE:
Validation of the Setswana translated Quality of Recovery Questionnaire in orthopaedic patients at a Tertiary Hospital in South Africa: a Cross-sectional Observational Study

Principal Investigator: Dr. Unathi Mzinyathi
Contact Details: 0711436058
Research Assistant: To be confirmed
Format of study: Cross-sectional Observational Study

Dear Patient,

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

Before you decide whether to take part in the study, it is important that you fully 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

This research study aims to test a Setswana translation of a questionnaire with 15 questions examining how patients recover after a surgical operation. These questions will ask how comfortable you are before and after your surgery, by asking you how well you are breathing, eating, sleeping and 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 surgical operation.

WHY HAVE I BEEN SELECTED?

This study will be done on patients over the age of 18 presenting for any elective orthopaedic procedure receiving any form of anaesthetic. You fit this profile.
In total, we will ask 150 patients to be part of our study.

WHEN WILL THIS RESEARCH BE DONE?
This study will be taking place from February 2025 until April 2025.

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 the Setswana translation of the 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). 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. Additionally, they will ask you to rate your overall recovery by using a visual analog scale with 0 indicating the worst recovery and 10 indicating the best recovery.

WILL ANY OF MY PERSONAL INFORMATION BE USED?

Your participation in this study is anonymous. This means that none of your personal information will be shared. Your name will be recorded on the consent form, and the consent forms will be saved securely by Dr. Mzinyathi until the end of the project. We will collect certain information like your age, gender and details of any medical conditions, but none of this information can be used to identify you.

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. Unathi Mzinyathi on 0711436058 if you have any further questions.

9.3 SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ENGLISH CONSENT FORM

We kindly invite you to participate in a Research Project,

Title of Study:

Validation of the Setswana translated Quality of Recovery questionnaire in orthopaedic patients at a Tertiary Hospital in South Africa: a Cross-Sectional Observational Study

I have read the information / heard the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I know that photographs / electronic images / sound recordings will be taken of me. I am aware that this material may be used in scientific publications which will be electronically available throughout the world. I consent to this provided that my personal information is not revealed. Regarding images of the face, I understand that it may not always be possible to disguise my identity, and I consent to the use of these images.

I understand that participation in this study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this study has been approved by the Sefako Makgatho University Research Ethics Committee (SMUREC), 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 may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this study.

Participant		
Name of participant/volunteer	Signature of participant or guardian	
Place	Date	Signature of Witness

Statement by the Researcher			
I provided verbal and/or written* information regarding this study I agree to answer any future questions concerning the study as best as I am able. I will adhere to the approved protocol.			
Name of Researcher	Signature	Date	Place

9.4 ENGLISH QoR-15

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

QoR-15 Patlisiso ya Molwetse

Letlha: ___ / ___ / ___ # ya Thutopatlisiso: _____

Pele ga karo ☐ Letsatsi 0 Morago ga karo ☐ Letsatsi 1 Morago ga karo ☐

KAROLO A

O ntse o ikutlwa jang mo diureng tse 24 tse di fetileng?

(0 go fitlha ka 10, moo 0 = le e seng ka nako epe [maemo a a bokoa] mme 10 = ka dinako tsotlhe [maemo a a gaisang])

1.	Ke kgona go hema bonolo	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
2.	Ke kgonne go natefelelwa ke dijo	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
3.	Go utlwala ke ikhuditse	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
4.	Ke nnile le boroko jo bo monate	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
5.	Ke kgona go ikisa kwa ntlwanaboithusetsong ka sebele le go ela tlhoko bophepa kwa ntle ga thuso	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
6.	Ke kgona go buisana le balelapa kgotsa ditsala	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
7.	Ke bona tshegetso mo dingakeng le baoki ba kwa bookelong	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
8.	Ke kgona go boela kwa tirong kgotsa kwa ditirong tsa gale tsa fa gae	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
9.	Ke ikutlwa ke phuthologile e bile ke kgona go laola maemo	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe
10.	Ke na le maikutlo a boitekanelo ka kakaretso	Le e seng ka nako epe	0	1	2	3	4	5	6	7	8	9	10	Ka dinako tsotlhe

KAROLO B

A o nnile le sepe sa dilo tse di latelang mo diureng tse 24 tse di fetileng?

(10 go fitlha ka 0, moo 10 = le e seng ka nako epe [maemo a a gaisang] mme 0 = ka dinako tsotlhe [maemo a a bokoa])

1.	Setlhabi/botlhoko jo bo mo magareng	Le e seng ka nako epe	10	9	8	7	6	5	4	3	2	1	0	Ka dinako tsotlhe
2.	Setlhabi/botlhoko jo bo tseneletseng	Le e seng ka nako epe	10	9	8	7	6	5	4	3	2	1	0	Ka dinako tsotlhe
3.	Go feroga sebele kgotsa go tlhatsa	Le e seng ka nako epe	10	9	8	7	6	5	4	3	2	1	0	Ka dinako tsotlhe
4.	Go ikutlwa o tshwenyegile kgotsa o tlhobaela	Le e seng ka nako epe	10	9	8	7	6	5	4	3	2	1	0	Ka dinako tsotlhe
5.	Go ikutlwa o hutsafetse kgotsa o na le kgatelelo ya maikutlo	Le e seng ka nako epe	10	9	8	7	6	5	4	3	2	1	0	Ka dinako tsotlhe

9.5

9.6 VARIABLE TABLE

9.6.1 Variable Table

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 or PI	Numerical, continuous
2	Biological sex	Sex	1 = Male 2 = Female	Recorded from file by research assistant or PI	Categorical, nominal
3	Home Language	Language	1 = Setswana 2 = English 3 = IsiZulu 4 = IsiXhosa 5 = Tshivenda 6 = Sepedi 7 = Sesotho 8 = Xitsonga 9 = isiNdebele 10 = siSwati 11 = Afrikaans 12 = Other	Recorded by research assistant	Categorical, nominal
4	ASA physical status	ASA	1 = I 2 = II 3 = III 4 = IV 5 = V	Recorded from anaesthetic chart by research assistant. If not recorded, PI will review anaesthetic chart and assign ASA score based on history.	Categorical, ordinal
5	Level of Education	Education	1 = After School Qualification 2= Secondary School Completed 3 = Primary School Completed 4 = No Formal Education Completed 5 = Other	Recorded by research assistant	Categorical, nominal
6	Literacy level Setswana	Lit_Setswana	1 = Speak 2 = Read 3 = Write	Recorded by research assistant	Categorical, nominal
7	Literacy level English	Lit_English	1 = Speak 2 = Read 3 = Write	Recorded by research assistant	Categorical, nominal
8	Procedure	Procedure	Procedure as specified on the consent form	Recorded by research assistant or PI from consent form	Categorical, nominal
9	Procedure date	Proc_Date	DDMMYYY as specified on the consent form	Recorded by research assistant or PI from consent form	Numerical, continuous
10	Induction time	Induct_Time	HH:MM as specified on the anaesthetic record or the theatre record form in patient's file	Recorded by research assistant or PI	Numerical, continuous
11	Out time	Out_Time	HH:MM as specified on the anaesthetic record or the theatre record form in patient's file	Recoded by research assistant	Numerical, continuous
12	Time last vitals in recovery room	Recovery_Time	Time of last vitals in recovery room as per the theatre record form in the patient's file.	Recorded by research assistant or PI	Numerical, continuous
13	Duration of Anaesthesia	Duration_Anaesth	Out_Time minus Induct_Time	Calculated	Numerical, continuous
14	Duration of Stay in Recovery Room	Duration_Recov	Recovery_Time minus Out_Time	Calculated	Numerical, continuous
15	Severity of Surgery	Severity	1 = Minor 2 = Intermediate 3 = Major	Assigned by research assistant or PI based on type of procedure, according to ASOS trial definitions.	Categorical, ordinal
16	Type of Anaesthesia	Anaesth_Type	1 = General 2 = Neuraxial alone 3 = Regional alone 4 = General & Neuraxial 5 = General & Regional 6 = Sedation 7 = Sedation & Neuraxial 8 = Sedation & Regional	Recorded from the anaesthetic chart by the research assistant. If any uncertainty, PI will review the anaesthetic chart and assign type of anaesthetic.	Categorical, nominal
18	Pre-Op Date	Pre_Op_Date	DDMMYYY as specified on the data collection form	Recorded by research assistant or PI from consent form	Numerical, continuous
19	Time start Pre-op	Start_Pre-op	HH:MM recorded on data collection form	Recorded by research assistant or PI	Numerical, continuous

16	Time finish Pre-op	Done_Pre-op	HH:MM recorded on data collection form	Recorded by research assistant or PI	Numerical, continuous
20	Post-Op Date	Post_Op_Date	DDMMYYY as specified on the data collection form	Recorded by research assistant or PI from consent form	Numerical, continuous
21	Time to complete pre-op questionnaire	Duration_Pre-op	Done_Pre-op minus Start_Pre-op	Calculated	Numerical, continuous
22	Time start post-op	Start_Post-op	HH:MM recorded on data collection form	Recorded by research assistant or PI	Numerical, continuous
23	Time finish Post-op	Done_Post-op	HH:MM recorded on data collection form	Recorded by research assistant or PI	Numerical, continuous
17	Time to complete post-op questionnaire	Duration_Post-op	Done_Post-op minus Start_post-op	Calculated	Numerical, continuous
24	Days since surgery till QoR score	Timing_QoR	Post_Op_Date minus Proc_Date	Calculated	Numerical, continuous
27	Visual Analogue Score	VAS	0-10	Recorded by research assistant or PI from data collection form	Categorical, ordinal
28	Total Pre-op QoR-15 score	Total_QoR_Pre-op	0 to 150, calculated in RedCAP from patient responses to questions 1 to 15	Calculated from questionnaires	Numerical, continuous
29	Total Post-op QoR-15 score	Total_QoR_Post-op	0 to 150, calculated in RedCAP from patient responses to questions 1 to 15	Calculated from questionnaires	Numerical, continuous
30	Pre-op: Able to breathe easily	Pre-op_Breathe	Score from 0 to 10, as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
31	Pre-op: Been able to enjoy food	Pre-op_Food	Score from 0 to 10, as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
32	Pre-op: Feeling rested	Pre-op_Rest	Score from 0 to 10, as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
33	Pre-op: Have had a good sleep	Pre-op_Sleep	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
34	Pre-op: Able to look after personal toilet and hygiene unaided	Pre-op_toilet	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
35	Pre-op: Able to communicate with family or friends	Pre-op_Comm	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
36	Pre-op: Getting support from hospital doctors and nurses	Pre-op_Support	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
37	Pre-op: Able to return to work or usual home activities	Pre-op_Home	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
38	Pre-op Feeling comfortable and in control	Pre-op_Comfort	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
39	Pre-op: Having a feeling of general well-being	Pre-op_Well	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
40	Pre-op: Moderate pain	Pre-op_Mod_Pain	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
41	Pre-op: Severe pain	Pre-op_Sev_Pain	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
42	Pre-op: Nausea or vomiting	Pre-op_NV	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
43	Pre-op: Feeling worried or anxious	Pre-op_Worried	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
44	Pre-op: Feeling sad or depressed	Pre-op_Sad	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
45	Post-op: Able to breathe easily	Post_Breathe	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
46	Post-op: Been able to enjoy food	Post_Food	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous

47	Post-op: Feeling rested	Post_Rest	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
48	Post-op: Have had a good sleep	Post_Sleep	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
49	Post-op: Able to look after personal toilet and hygiene unaided	Post_toilet	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
50	Post-op: Able to communicate with family or friends	Post_Comm	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
51	Post-op: Getting support from hospital doctors and nurses	Post_Support	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
52	Post-op: Able to return to work or usual home activities	Post_Home	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
53	Post-op: Feeling comfortable and in control	Post_Comfort	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
54	Post-op: Having a feeling of general well-being	Post_Well	Score from 0 to 10 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
55	Post-op: Moderate pain	Post_Mod_Pain	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
56	Post-op: Severe pain	Post_Sev_Pain	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
56	Post-op: Nausea or vomiting	Post_NV	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
57	Post-op: Feeling worried or anxious	Post_Worried	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous
58	Post-op: Feeling sad or depressed	Post_Sad	Score from 10 to 0 as recorded by patient on data collection form.	Recorded from questionnaires	Numerical, continuous

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REPUBLIC OF SOUTH AFRICA

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To Dr U Mzinyathi
Department of Anaesthesiology
Sefako Makgatho University

Date :13 May 2025

PERMISSION TO CONDUCT RESEARCH

The Dr. George Mukhari Academic Hospital hereby grants you permission to conduct research on "Validation of the Setswana translated quality of recovery questionnaire in Questionnaire in Orthopaedics patients at a tertiary hospital in South Africa: a Cross - sectional observational study" at Dr George Mukhari Academic Hospital

This permission is granted subject to the following conditions:

- ☑ That you obtain Ethical Clearance from the Human Research Ethics Committee of the relevant University
- ☑ That the Hospital incurs no cost in the course of your research
- ☑ That access to the staff and patients at the Dr George Mukhari Hospital will not interrupt the daily provision of services.
- ☑ That prior to conducting the research you will liaise with the supervisors of the relevant sections to introduce yourself (with this letter) and to make arrangements with them in a manner that is convenient to the sections.
- ☑ Formal written feedback on research outcomes must be given to the Director: Clinical Services.
- ☑ Permission for publication of research must be obtained from the Chief Executive Officer

Yours sincerely

DR. K MATEA
ACTING DIRECTOR CLINICAL SERVICES
DATE: 13/05/2025

9.7

9.8 STROBE 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	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-11
Objectives	3	State specific objectives, including any prespecified hypotheses	11
Methods			
Study design	4	Present key elements of study design early in the paper	12
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	12
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	12
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	17-19
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	17-19
Bias	9	Describe any efforts to address potential sources of bias	20-21
Study size	10	Explain how the study size was arrived at	14
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
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	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—e.g. 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	

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.