TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF THE SINO-NASAL OUTCOME TEST (SNOT-22)

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A dissertation submitted in partial fulfilment of the requirements for the award of the degree of Masters of Medicine in Otorhinolaryngology Head and Neck Surgery of the University of Nairobi

DECLARATION

I certify that this dissertation is my primary work and hasn't been submitted for any degree at any other university.

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Abbreviations:

ANOVA-	Analysis of Variance
CRS-	Chronic Rhinosinusitis
CT-	Computed Tomography
EPOS 2012 -	European Positional Paper on Rhinosinusitis 2012
ESS-	Endoscopic Sinus Surgery
HRQOL-	Health Related Quality Of Life
IQR-	Interquartile range
SF 36-	36 Item Short Form Survey
SIN-	Subject Identification Number
SNOT 22-	Sinonasal Outcome Test 22
WHO-	World Health Organisation

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ABSTRACT:

Background:

Chronic rhinosinusitis (CRS) affects millions worldwide. Sinonasal Outcome Test (SNOT-22) is the most suitable outcome measure in evaluating CRS patients. It was developed in English. Administering it in English would exclude our population who communicate in Swahili. It is therefore important to develop a Swahili questionnaire.

Objective:

To translate and validate a Swahili version of the Sinonasal Outcome Test (SNOT) -22 questionnaire.

Study Design:

This was a prospective cohort study.

Study setting:

The study was conducted in the Ear, Nose and Throat (ENT) department of Kenyatta National Hospital.

Study duration:

This study was carried out from July 2019 to February 2020.

Study population:

There were two cohorts of adult patients with CRS. One of 69 patients on scheduled clinic and another of 35 patients scheduled for sinonasal surgery.

Methodology:

The SNOT-22 was translated into Swahili using World Health Organisation (WHO) method, followed by testing on day 1 and retesting on day 14 to 69 cases to determine its consistency and validity.

The validated SNOT-22 was administered to 35 patients undergoing endoscopic sinus surgery (ESS) before surgery, then three months post-surgery to determine its reliability and magnitude of treatment effect.

Results:

In the test retest arm, females constituted 45(62.5%), and males 24(34.8%). In the operative arm, females made up 60% (21). Mean age in test retest group was 37yrs±13.61 and 33.4±8.26 in operative arm. Cronbach's alpha was 0.799. Intraclass correlation coefficient was 0.799(CI: 0.72-0.86, P<0.001). Comparing scores in preoperative and postoperative groups showed

statistical significance, 55.65±26.92 vs 19.41±10.35, P<0.001.Magnitude of treatment effect Cohen's *d* value was 1.77.

Conclusion and recommendations:

The Swahili version of the SNOT 22 from this study has good internal consistency, reliability and validity. It is a valid instrument in assessing HRQoL in Swahili speaking patients. It can be used for patient care and clinical research.

CHAPTER 1: INTRODUCTION:

Chronic rhinosinusitis (CRS) affects millions of people worldwide with its prevalence being estimated at 16% of the United States population.(1) The socio-economic consequence is huge considering family and overall healthcare expenditure, time and output lost at work, academic loss and absenteeism. Patients have difficulties performing activities of daily living and have an overall poor health related quality of life. CRS produces large direct and indirect costs. These costs are proportional to the severity of the patients CRS-specific Health Related Quality of Life (HRQoL) impairment(2).

Chronic Rhinosinusitis in adults according to EPOS 2012 is; two or more symptoms such as, facial pain, a facial pressure sensation, hyposmia or anosmia, nasal blockage or nasal discharge.(3) There should also be either a mucopurulent discharge from middle nasal meatus, nasal polyps, or mucosal obstruction in osteomeatal complex on endoscopy or computed tomographic (CT) scan changes affecting the osteomeatal complex with or without affecting paranasal sinuses.

Chronic rhinosinusitis is classified as CRS with nasal polyposis or CRS without nasal polyposis as determined by nasal endoscopy.(3)

Patient-reported outcome measures are considered more appropriate as a guide to treatment and also measuring patient outcome as opposed to medical criteria alone, since CRS predominantly characterised by patient symptoms.(4) Applying quality of life studies, researchers have shown significantly greater impact of CRS on pain scores and socioeconomic functioning than cardiac patients and some respiratory patient's e.g. chronic obstructive pulmonary disease.(5)

Locally, little has been studied on its effect or that of its treatment on health related outcomes and on quality of life. In the USA, in studies utilizing both disease-specific and general health instruments, patients with chronic rhinosinusitis were observed to have decrease in several subscales of general health, compared with the general population. Surgical intervention demonstrated a notable decline in symptoms and drug use/requirements ($P<.05$). Instruments

which measure outcomes can be used by clinicians to record clinical outcomes in patients with chronic rhinosinusitis. (7)

There are various HRQOL assessment questionnaires in CRS patients. However, the SNOT-22 is one of the most studied.(9,10) It scores highly in internal consistency, has a great test-retest reliability, is able to pick out validity (content,convergent,discriminant) , is responsive to patient specific symptoms , and can be applied to calculate the minimally important difference.(3) SNOT-22 was developed by National Comparative Audit of Surgery for Nasal Polyposis and Rhinosinusitis, Royal College of Surgeons of England as an improvement of SNOT-20(initially developed by Jay F. Piccirillo, M.D.)(6) It was subsequently validated by Hopkins et al.(7)

Comparing 15 sinonasal outcome tools already in use, Morley and Sharp considered SNOT-22 as the most suitable outcome measure tool for evaluating patients with chronic rhinosinusitis including post endoscopic sinus surgery.(8)

The SNOT-22 has 22 questions. It is scored as a total of the individual question scores. Each question score ranges between 0 and 5, with 5 being the worst symptom score.

In the SNOT-22, two questions have been added to the SNOT-20: one each on nasal blockage and on taste and smell. Most patients with CRS visit the otorhinolaryngologist due to nasal obstruction. Hypo/anosmia has the least improvement after sinus surgery, underscoring the importance of this two extra questions.

The SNOT-22 questions can be classified into 2 groups, 12 questions under the Physical symptoms domain which consider rhinologic, aural and facial symptoms and 10 questions under the Health related QoL domain which takes into account sleep pattern / disturbance and psychological function.

The SNOT-22 is originally in English but has many translations into several languages including; French, Hebrew, Italian, Spanish, Moroccan, Thai, Portuguese, Czech, Greek, Persian and Lithuanian.(4, 9–17). The purpose of these translations was to enhance utilization of standardised assessment tools for patients and also to enable recruitment into multicentre studies of CRS.

1.1 TRANSLATION, CROSS CULTURAL ADAPTATION AND VALIDATION OF RESEARCH INSTRUMENTS

Translation of documents and tools helps in increasing access to resources for knowledge, research, teaching and social purposes. In healthcare, it provides a basis for the inclusion of more people both in research and interventions, taking into account the different socio-cultural backgrounds, therefore eliminating selection bias in multicentre studies. (23)

Cross-cultural translation and adaptation of research instruments and questionnaires has two components, the translation of the HRQoL tool and adaptation with regard to idiom, cultural context and lifestyle.(18)

If the translation of a tool from its original language and cultural context is performed by simple translation the meaning is likely to be lost in translation because of language and cultural differences.(18) Majority of research tools are developed in English and are intended to be used in English only populations. However, with growing need for multicentre trials, studies and projects, having a tool in only a single language introduces the aspect of selection bias.(19)

The perception of HRQoL, health seeking behaviours and disease patterns varies from culture to culture. For a uniformly acceptable translation of a research tool, a systematic approach has to be adopted. Various authors have proposed different approaches to translation and adaptation of research tools.

The commonly used are the Brislin's method and WHO guidelines. (20, 21)

Brislin's method entails back translation and decentering. During translation, a bilingual speaker translates from the original to the new language, then another bilingual translates it back to the original language. This process should be repeated severally, using two or more bilinguals, who work on the preceding works. This back and forth translation between the two languages develops the concept of decentering. It ensures none of the languages is the center of attention, meaning, none has undue advantage over the other.

If it survives this decentering process, it is assumed that there must be available words with similar meaning in both languages. If it fails, i.e. it's not in the final version, it is considered to only be expressible in one language. The final draft should be pilot tested on respondents similar to those in the proposed sample group.(20)

The WHO guidelines entails four steps for cross cultural translation and adaptation of research instruments. These steps are, forward translation from original language, then, back-translation by an expert panel, followed by pilot testing and cognitive interviewing and finally development of the final new version. The WHO method has been reviewed, studied and refined by the WHO in association with several scholars to achieve the guidelines stipulated above. (23) Due to this, the WHO method is considered superior.

If a tool widely used in one language/culture with good reliability and validity with strong results becomes unreliable and/ or invalid in another culture, it possibly has variations in construct, semantic and normative measurement between the two languages/cultures. Experienced researchers, native speakers of a language, may use unfamiliar phrases because of the long duration they have pursued formal education, therefore being out of touch with normal language(22)

CHAPTER 2: LITERATURE REVIEW

A review, by Morley et al. of 15 CRS specific questionnaires/tools observed that the SNOT-22 was the best tool in evaluating HRQoL for CRS patients considering its ease of use, reliability, responsiveness and its validity.(8)

Hopkins et al, in England and Wales, studied "Psychometric validity of the 22-item Sinonasal Outcome Test", which was the original validation study in English. It was a prospective multicentre cohort study. They enrolled 3128 subjects undergoing surgery, 2803 filled pre-operative questionnaires, and 2284 filled post-operative questionnaires. For the test retest group, they sent out 117 forms, 78 filled the first questionnaire, 52 filled both copies (the first and the second after 2 weeks). They enrolled 116 controls. The Cronbach's alpha revealed high internal consistency at 0.91. Its high test–retest reliability (0.93) indicated good reliability when assessing repeated measures over time. It could differentiate between affected patients and healthy controls. They established the percentage by which SNOT-22 scores changed post surgery and the percentage of patients achieving a SNOT-22 minimal clinically important difference (MCID) of 8.9. They noted 40% decrease in SNOT-22 scores post operatively, whereas 66% of patients achieved the target MCID. Subjects with a SNOT 22 preoperative score of <20 did not achieve improvement greater than the target MCID. Subjects who scored >30 had a 70% probability of achieving the MCID. Subjects with polyps significantly improved in comparison to subjects without polyps.(23)

In Israel, Yael SG et al's study titled "Sino-Nasal Outcome Test–22- Hebrew translation and cross cultural adaptation" was done as a prospective cross-sectional study. They enrolled 73 subjects, 73controls, 51 pre ESS and 28 post ESS. The study revealed excellent reliability, with a high internal consistency and test-retest reproducibility (Cronbach's alpha coefficient, 0.91-0.936; Spearman's coefficient of 0.962 respectively). The mean of SNOT 22 scores for the preoperative group was 50.44, for the postoperative group 29.64, and in the control group 13.15. (P \.0001 for CRS vs healthy controls and P \.001 for pre-surgical compared to postsurgical groups). This values demonstrate that of the Hebrew questionnaire is valid and responsive.(10)

Francesco et al in Milan, Italy, studied "Cross-cultural adaptation and validation of the SNOT-22 into Italian" They enrolled 222 subjects, 119 controls, 60 for test retest reliability and 59 for pre and post ESS. They compared SNOT 22 scores against both the Lund-Mackay scores and Visual analogue scales. All subjects completed the Italian SNOT-22 without needing any assistance. Internal consistency and test–retest reliability were satisfactory. The Italian SNOT-22 was observed to demonstrate differences between the CRS patients and the asymptomatic subjects (p\0.008). The Italian SNOT-22 and VAS scores could be correlated, while it couldn't be correlated to the Lund–Mackay scores. Italian SNOT-22 scores in the pre-surgical group were much higher than in the post surgical group.(11)

In Kaunas, Lithuania, Vaitkus et al titled their study "Translation, cross-cultural adaptation, and validation of the sino-nasal outcome test (SNOT)-22 for Lithuanian patients". It was a prospective case–control study. They enrolled 34 subjects for the pilot phase, 34 in the test retest group, 115 controls, 36 pre and post ESS. The study setting was the university clinic during initial visit and follow-up either by mail or during second visit. Cronbach's alpha was 0.89 in the initial test. A score of 0.93 for the retest group depicts good internal consistency within the Lithuanian SNOT-22. It demonstrated ability to differentiate between CRS patients and the controls. The instrument had statistically significant reduction in the post-operative scores in comparison to pre-operative scores therefore demonstrating the instrument as responsive.(4)

In Porto, Portugal, de Vilhena et al studied "Sino-Nasal Outcome Test-22: translation, cultural adaptation and validation in Portugal". They enrolled 50 subjects and used the same for test retest validity, 15 controls from members of staff, they had no surgical group. The study demonstrated a good Cronbach's alpha (0.935), good test–retest reproducibility ($P < 0.001$), good internal consistency, and a good discriminant validity.(15)

In Larissa, Greece, Lachanas et al studied "The sino-nasal outcome test (SNOT) -22: validation for Greek patients". It was a prospective cross sectional study. They had 76 patients recruited, of whom 64 filled both questionnaires for the test-retest group and were accepted. They had 120 controls and the surgical group recruited 32 subjects. For the test group, Cronbach's alpha was

0.84. Upon retest, Cronbach's alpha was 0.89.This values demonstrate good internal consistency. Mann–Whitney test revealed a statistically significant score decline for the control group. Postsurgical scores were statistically, significantly lower than the preoperative scores while the surgery effect's magnitude, elsewhere referred to as the MCID was considered high.(16)

In Africa, Adnane et al, in Casablanca, Morocco, studied "Psychometric Validation of a Moroccan Version of the 22-Item Sino-Nasal Outcome Test". It was a prospective cohort study. They recruited 88 subjects pre-operatively, 74 post operatively and 51 controls. They studied the six months post operative scores. Cronbach's alpha coefficient was 0.968.The test-retest reliability Cronbach's alpha coefficient was 0.993. This indicates high reliability as well as high internal consistency on repeated administration. It has the ability to differentiate between healthy individuals and patients with CRS.(13)

Swahili, being the most commonly used language in Kenya and the great lakes region, serves a significant population. Translating and validating a Swahili version will serve this population with a tool for assessment and monitoring treatment to CRS. It will also offer local researchers a standardised tool for their use.

Concepts used in validation of research instruments:

Reliability: This is the extent to which a tool produces stable, and consistent results. It has two main components, namely internal consistency and test retest reliability.
Internal consistency measures that a test is free from random error. It reflects the way individual items in a scale relate to each other. It also tests the homogeneity of the test items. This is measured using Cronbach's Alpha. Cronbach's Alpha is interpreted as follows:(24)

- 0.00 to 69% = Poor
- 70 to 79 % = Fair
- 80 to 89% = Good
- 90 to 99% = Excellent

Test–retest reliability evaluates the stability and reproducibility of a tool over time. It is assessed by repeated administration of a tool over time. The time period should not be too short such that respondents remember the questions and their answers, neither too long such that symptomatology could have changed over time. Most authors use two weeks to one month as a guide.

Equivalence: If a phrase in one language carries the same intended meaning / message in another language, then these two phrases are considered equivalent. It could be semantic equivalence, where the word meanings are similar in two cultures/languages after translation or content/conceptual/cultural equivalence, the extent to which a construct derives similar meanings (not necessarily similar wording) and relevance in two different cultures/ languages. It requires that translated version adequately reflects the cultural assumptions, norms, values of the target population and culture.(25)

In the Kenyan setup, spoken Swahili might have different semantic versus content equivalence due to variances in spoken and written language. There are also some words and phrases that have no absolute/ straightforward translation in Swahili as observed by Kumar et.al (22)

Validity: The degree to which a tool measures its intended measure is defined as its validity. Several types of validity are described. Criterion validity compares how a tool/score performs in comparison to a gold standard. Construct validity refers to the extent to which a tool/instrument measures the hypothetical construct that it is designed to measure. It has two components, namely; convergent validity and discriminant or divergent validity.
Convergent validity compares two tools that measure the same subject content and shows that they are indeed related. e.g., comparing SNOT 22 with another sinonasal outcome questionnaire.
Discriminant /divergent validity- demonstrates that two constructs/measures that are deemed unrelated are actually, unrelated.(26)

Study justification:

CRS is a common condition diagnosed by the otolaryngologist. The symptoms of CRS significantly alter the HRQoL of affected patients. Various tools have been used to assess the HRQoL in CRS. The SNOT-22 is universally accepted as the most responsive to patient's needs. It has been translated into other languages e.g. Thai, Portuguese, Lithuanian, French etc.

Kiswahili is widely used in the great lakes region, with the World Bank report (2015) estimating Kiswahili speakers at between 120-150 million. In Kenya, it is one of two official languages and is the only official language in Tanzania.

No validated SNOT-22 questionnaire in Swahili has been developed for this population. This study aimed at translating and validating a Swahili version of SNOT -22 questionnaire and then using it to assess HRQoL before and after ESS. This might then be useful both in clinical settings and as a tool for research on CRS.

CHAPTER 3: METHODOLOGY

3.1 Research question:

How reliable and valid is a Swahili version of the SNOT-22 questionnaire in assessing HRQoL in patients with CRS?

3.2 Study objectives:

3.2.1 Broad objective

To translate and validate a Swahili version of SNOT-22 HRQoL questionnaire.

3.2.2 Specific objectives:

i. To translate the SNOT-22 HRQoL questionnaire into Swahili.
ii. To test the Swahili SNOT-22 HRQoL questionnaire for consistency, reliability and validity in patients with CRS.
iii. To assess the Health related quality of life before and after sinonasal surgery using the Swahili SNOT-22 HRQoL questionnaire.

3.3 Study design:

This was a prospective cohort study.

3.4 Study setting:

This study was carried out in the ENT department at Kenyatta National Hospital, a large and the pioneer teaching and referral hospital in Kenya. It serves as the main ENT referral centre for the entire country and the region. It serves an average of 100 patients daily with various ear, nose, throat, head and neck diseases. It has fifteen consultant ENT specialists with varied years of experience, twenty seven registrars at different levels of training, 10 clinical officers, 34 nurses, 4 audiologists, 8 trainee clinical officers, 5 trainee audiologists, 3 speech therapists and 3 support staff. The department consists of a clinic block containing outpatient clinics, filter clinics, satellite theatre, audio-vestibular unit and offices. It also has a ward with a bed capacity of 52 and a fully fledged, daily main theatre space with state of the art endoscopic and general ENT equipment.

3.5 Study Population:

The study included adult patients presenting to the ENT department with a diagnosis of CRS as per the EPOS 2012 criteria

There were two cohorts. The first included 69 patients on medical management and follow up at clinic. This were used for clinical validity and reliability analysis. The second included 35 patients who underwent ESS. Thirteen of the 69 patients were scheduled for surgery and were therefore included in the surgical group. These were used to assess the responsiveness of the Swahili SNOT-22 in picking up clinical changes after surgical intervention and changes of HRQoL.

3.6 Inclusion criteria:

The study included:

i. Adults 18 years and above with CRS as per EPOS criteria
ii. Those who understood Swahili
iii. Those who consented to participate in the study.
iv. Patients who were on follow-up at the clinic for CRS were enrolled for the clinical validity cohort.
v. Patients who were on follow-up at the clinic for CRS who met criteria for endoscopic sinus surgery were also recruited for the surgical cohort.
vi. Patients who underwent ESS were enrolled for the surgical cohort.

3.7 Exclusion criteria:

The study excluded patients with:

i. Sinonasal or respiratory malignancies
ii. Nasal trauma
iii. Previous sinonasal surgery
iv. Uncontrolled asthma.

These conditions can alter the normal sinus and nasal anatomy and physiology therefore giving a wrong assessment of CRS status, physiologic function and quality of life.

Patients with cognitive impairment were excluded since it impairs their ability to objectively and effectively fill in a questionnaire.

3.8 Sample size:

The sample size for this study was estimated using the formula below for comparing means(27)

$$n_1 = \frac{r+1}{r} * \frac{(Z_{\alpha/2} + Z_{\beta})^2 * \sigma^2}{(\mu_1 - \mu_2)^2}$$

Where r is the ratio of the two comparison groups (here r=1),

$Z_{\alpha/2}$ is the critical value of the Normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96),

Z_{β} is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84),

σ^2 is the population variance (here 10%),

μ_1 is the estimated percentage of patients positively identified by the Swahili SNOT-22 tool (here 80%)

μ_2 is the estimated percentage of healthy individuals correctly identified by the Swahili SNOT-22 questionnaire (here 85%),

n_1 is the estimated sample size of the smaller group (here 68).

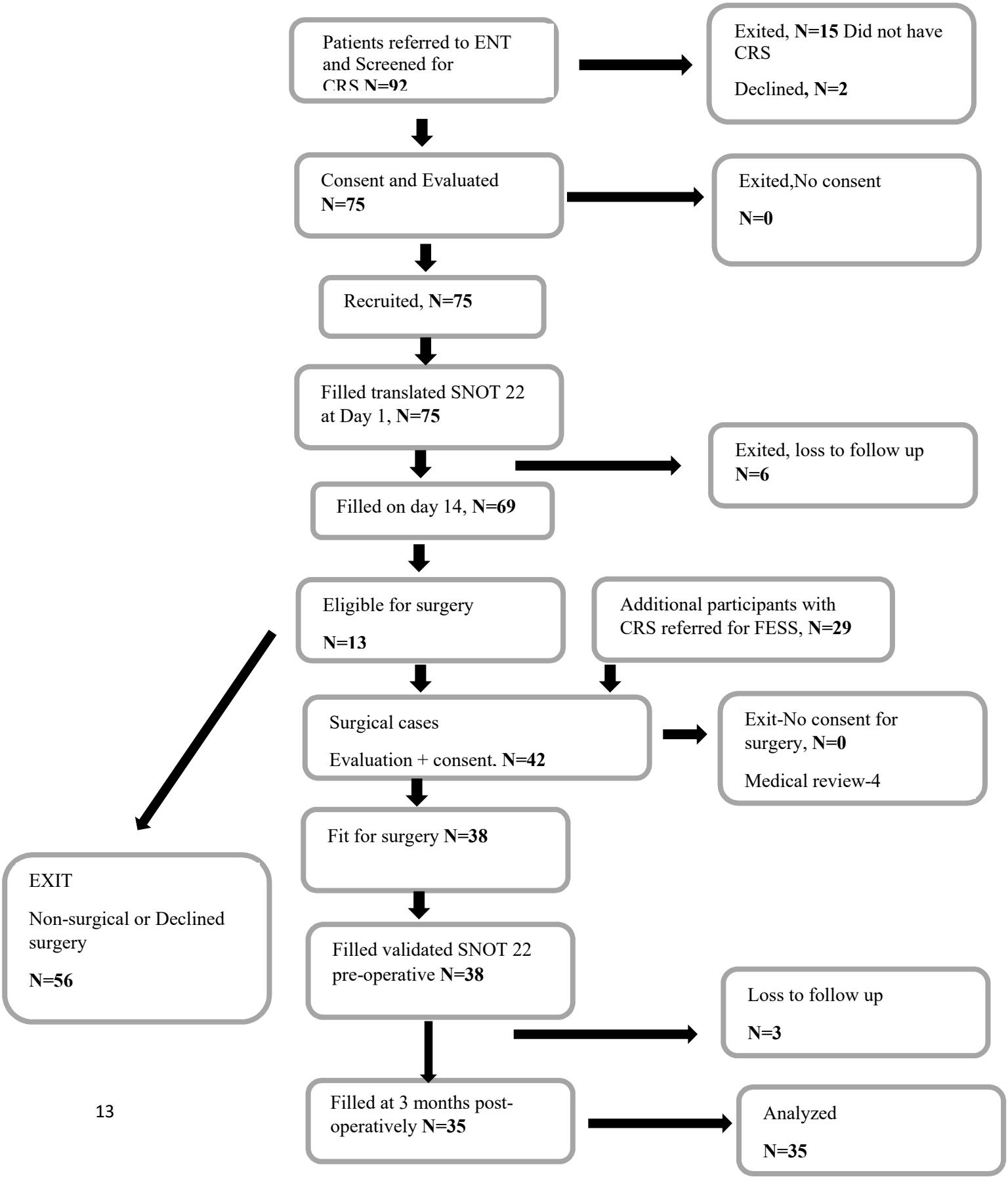
Taking into consideration a 10% drop off rate, we enrolled 75 subjects in the clinical validity cohort

We enrolled 38 patients for the pre and post-surgical intervention cohort, being half of the clinical validity cohort.

3.9 Sampling method:

Convenient consecutive sampling was used. All patients who fit the criteria were recruited. Figure 1 below illustrates the sampling procedure during the study.

Figure 1: Sampling procedure during the study:



3.10 Study procedure:

The study was executed in three phases:

1. Translation of the English SNOT-22 to Swahili.
2. Administration of the SNOT -22 Swahili questionnaire to the clinical validity cohort on day 1 and repeat administration to same cohort on day 14.
3. Pre and post-surgical intervention (ESS) cohort administration of the Swahili SNOT-22 questionnaire before surgery then three months after surgery.

Phase 1: Translation of SNOT-22 to Swahili:

The WHO procedure of translation and adaptation of instruments was used. This entails four entities:

1. Forward translation from English to Swahili.
2. Back-translation to English by an expert panel
3. Pilot testing and cognitive interviewing
4. Development of the final Swahili version

i) Forward translation from English

Translation of the original document by two multilingual residents from the department of ENT, (majority of our residents speak at least three languages, English, Swahili and mother tongue) who are familiar with the area covered by the instrument. They individually translated the instrument to Swahili then had a review amongst themselves and came up with a consensus version of the Swahili SNOT- 22 (version 1).

ii) Expert panel back translation:

This involved translating the Swahili SNOT 22 version 1 back to English (Version 2). WHO recommends use of individuals who are primarily experts in the technical area as opposed to linguistic experts therefore, in this case, we engaged two multilingual otolaryngologists. Through this, material lost in translation and syntax was captured. In both forward and back translation, emphasis was placed on conceptual and cultural equivalence and not linguistic equivalence. After this phase, a consensus Swahili SNOT -

22 (Version 3) was agreed on by the principal researcher in consultation with the forward and backward translators.

Iii) Pre-testing and cognitive interviewing:

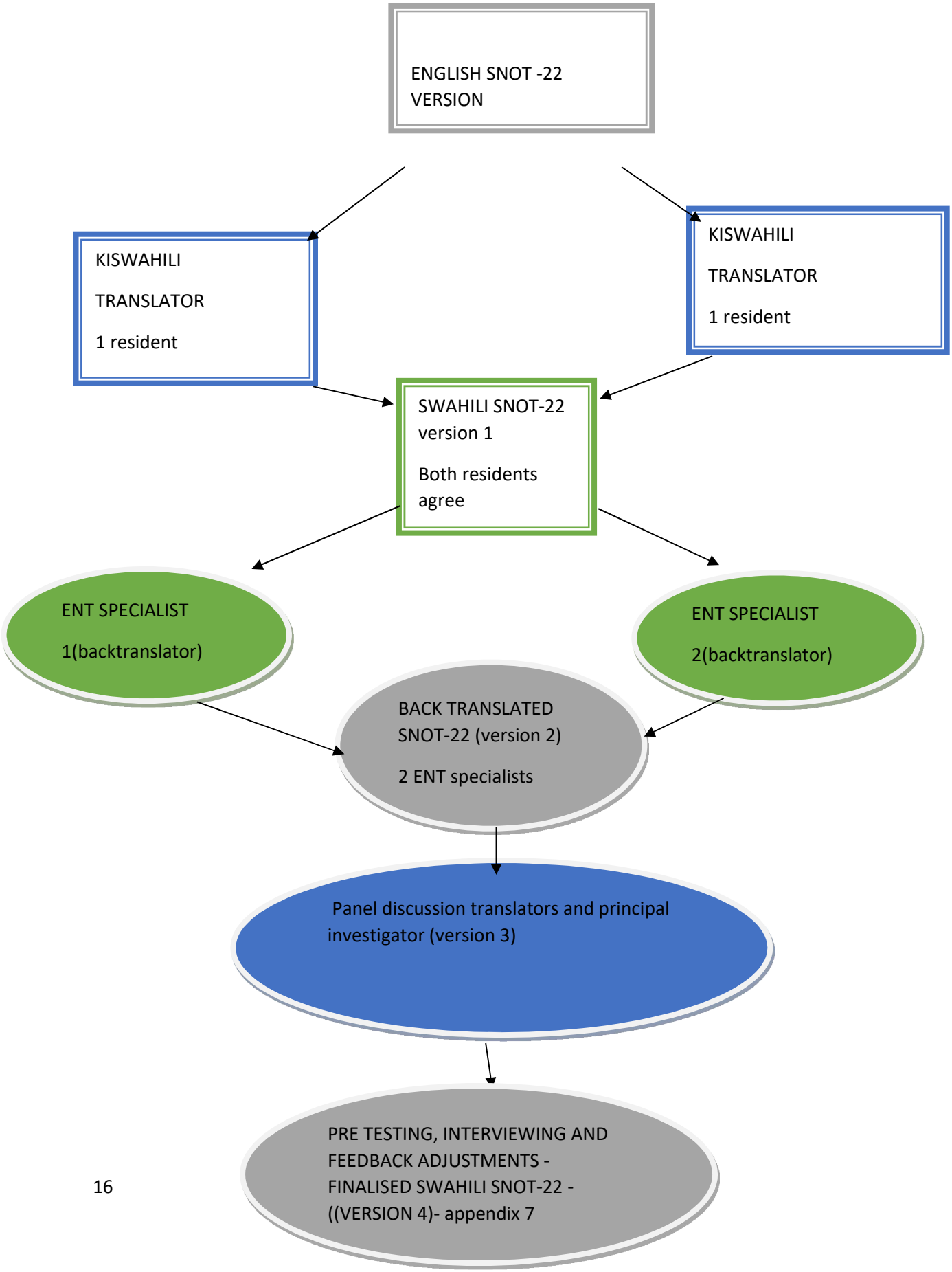
This was carried out by the principal researcher. He administered the instrument to 15 (fifteen) patients with CRS in the ENT department. The respondents were given the questionnaire and were subsequently debriefed. During debriefing, respondents were asked the meaning of the question. Then they rephrased the question using their own words or phrases. They were also asked what they thought phrase or term meant. They were whether they found any item unacceptable, offensive or inappropriate. Respondents were asked to choose the most appropriate alternative words or phrases where such exist. Their responses were captured in a pretest questionnaire.

IV) Final version:

The final version (Version 4) was a product of the input and feedback given during the Pre testing and cognitive interviewing phase. All the above cultural adaptation procedures were documented and availed at each phase of item development.

The translation process is captured in figure 2 below.

Figure2: Flowchart showing the translation process from English to Swahili SNOT-22



Phase 2: Administration of the SNOT -22 Swahili questionnaire to the clinical validity cohort on day 1 and repeat administration to same group on day 14.

The principal investigator took a history and performed a physical examination (including nasal endoscopy in patients with equivocal imaging findings) and review of the patient's imaging to determine if the respondent fits the EPOS 2012 criteria. Patients with CRS filled in the Swahili SNOT-22 (Appendix 7) during a clinic visit. The patient filled it again on the 14^{th} day during a routine clinic follow up (Figure 1).This duration has been used by various authors as a guide since it is postulated that in two weeks, the symptomatology doesn't change much neither does the patient's recall ability. (4, 11, 15). This reduces recall bias.

When filling in the second Swahili SNOT-22, the respondents had no access to the previously answered one to cross check their answers.

Phase 3: Pre and post-surgical intervention (ESS) cohort administration of the Swahili SNOT-22 questionnaire

Patients who had CRS and underwent endoscopic surgical management as per the EPOS 2012 guidelines were recruited in this phase. The principal investigator took a history and examined the patients. 13 patients from phase two of the study were candidates for surgical intervention and were therefore recruited into the surgical cohort after consenting for both surgery and the study as per the hospital requirements. Each patient completed the Swahili SNOT-22 before surgery (during the preoperative review) and at three months post-surgery review (during routine clinic follow up) as illustrated in figure 1. Intraoperative endoscopic findings were also documented. The Swahili SNOT-22 scores obtained pre surgery were analysed alongside those post-surgical intervention. These indicated the responsiveness of the tool and the ability of the tool to detect clinical changes over time.

3.11 Study duration:

The study took place from July 2019 to February 2020.

3.12 Data management and analysis:

Completeness of the questionnaires was analysed before start of data entry. The questionnaires were stored by the principal investigator in a safe and secure cabinet. Only the Statistician and the Principal Investigator had access to a password protected database holding the data. All questionnaires were used for comparison between hard and soft copies to ensure accuracy of entry. If discrepancies were noticed, the data entry was repeated.

In order to determine factors associated with accuracy of the SNOT-22 tool in correctly assigning individuals as either healthy or otherwise, chi-squared tests were applied where the predictor was variable and analysis of variance (ANOVA) tests where the predictor was continuous. This was followed by logistic regression to determine independent factors associated with this accuracy.

3.13Ethical requirements:

1. Approval for this study was obtained from the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee. An approval letter was obtained before starting the study and was availed to interested parties on demand.
2. Informed consent was obtained from the respondents after understanding the objective of the study and their role in the study and any implications. The consent process included the goal of the study and the study procedure. The principal investigator or assistant executed the consent process and answered questions or concerns about the study. Consent was obtained on voluntary basis.
3. Only standard treatment was used during this study.
4. Participating patients continued receiving treatment throughout the course of the study.
5. Participating patients had no extra costs.
6. No children were enrolled for the study

3.14 Confidentiality:

The investigator ensured the highest standard of confidentiality was maintained. All study material, processes and procedures were strictly confidential. No unauthorized person/ party accessed any study data or information. A Subject Identification Number (SIN) was applied to maintain subject confidentiality of participants. Data collection items will be destroyed at the end of the study by shredding. Clinical information was not released to third party entities. The study and its results will be presented in scientific conferences and published in a medical journal of good standing.

Chapter 4: RESULTS

Phase 1: The translation

The SNOT-22 questionnaire was translated to Swahili by two otorhinolaryngology residents after which a consensus version of the Swahili back translation was developed. This process is summarized in a questionnaire which captured the initial translations as well as the consensus versions. Any contentious issues were captured in the footnotes of the original translation which are attached as appendices.

Table 1: Forward translation of Swahili SNOT-22

Question number	English version	Translator 1	Translator 2	Consensus Swahili draft
1	Need to blow nose	Kuhisi kupuliza pua	Hisia ya kupuliza mapua	Haja ya kupuliza pua
2	Sneezing	Kuchemua		Kuchemua
3	Runny nose	Kamasi kwenye pua	Makamasi kutiririka kwa mapua	Kamasi kutiririka kwa pua
4	Nasal obstruction	Kufungana pua	Mapua kufungamana	Kufungana pua
5	Loss of smell or taste	Kutohisi harufu au ladha	Kupotea kwa harufu ama ladha	Kupotea kwa harufu au ladha
6	Cough	Kukohoa	Kikohozi	Kukohoa
7	Post-nasal discharge	Kamasi kutiririka nyuma ya pua	Mtiririko wa makamasi	Kamasi kutiririka nyuma ya pua

			kinywani	
8	Thick nasal discharge	Kamasi nzito/ makamasi mazito	Makamazi mazito kutiririka kwa mapua	Makamasi mazito
9	Ear fullness	Uzito sikioni/ kuhisi kujaa sikioni	Kufungamana kwa maskio	Kuhisi kujaa sikioni
10	Dizziness	Kizunguzungu	Hali ya kizunguzungu	Kizunguzungu
11	Ear pain	Uchungu sikioni	Uchungu wa masikio	Uchungu sikioni
12	Facial pain/pressure	Uchungu usoni	Kukazana kwa uso	Uchungu usoni
13	Difficulty falling asleep	Ugumu wa kupata usingizi	Ugumu wa kupata usingizi	Ugumu wa kupata usingizi
14	Waking up at night	Kuamkaamka usiku	Kuamka mara kwa mara usiku	Kuamka mara kwa mara usiku
15	Lack of a good night's sleep	Ukosefu wa usingizi nzuri usiku	Kukosa usingizi mwanana wakati wa usiku	Kukosa usingizi nzuri usiku
16	Waking up tired	Uchovu unapoamka	Kuamka asubuhi na uchovu mwilini	Uchovu unapoamka

17	Fatigue	Uchovu	Uchovu kupindukia	Uchovu
18	Reduced productivity	Kupunguka kwa utenzi/ tija	Ukosefu wa motisha	Kupunguka kwa tija
19	Reduced concentration	Umakini kupungua	Ukosefu wa kumakinika	Umakini kupungua
20	Frustrated/restless/irritable	Kutatanishwa/kutotulia/kuudhishwa upesi	Kukosa utulivu	Kutatanishwa/kukosa utulivu/kuudhishwa upesi
21	Sad	Huzuni	Kuwa na majonzi	Huzuni
22	Embarrassed	Kuaibika	Kuwa na fedheha	Aibu

The consensus Swahili version was then presented to two qualified otolaryngologists who backtranslated it to English to check for semantic equivalence.

Table 2: Backtranslation of consensus Swahili version to English

CONSENSUS TRANSLATED SWAHILI SNOT-22	English back translation 1	English back translation 2
1. Haja ya kupuliza pua	Need to blow my nose	Need/urge to blow nose
2. Kuchemua	To sneeze	Sneeze
3. Kamasi kutiririka kwa pua	Snot dripping from nose	Running nose/rhinorrhea
4. Kufungana pua	Nose blocking	Blocked nose
5. Kupotea kwa harufu au ladha	Loss of smell or flavour sensation	Loss of sense of taste or smell
6. Kukohoa	Cough	Coughing
7. Kamasi kutiririka nyuma ya pua	Mucus dripping at the back of the nose	Post nasal drip
8. Makamasi mazito	Thick mucus	Thick/heavy mucus
9. Kuhisi kujaa sikioni	Feeling of ear blockage	Fullness in the ear/ aural fullness
10. Kizunguzungu	Dizziness	Dizziness/vertigo
11. Uchungu sikioni	Ear pain	Ear pain/ otalgia
12. Uchungu usoni	Facial pain	Facial pain
13. Ugumu wa kupata usingizi	Difficulty falling asleep	Difficulty falling asleep
14. Kuamka mara kwa mara usiku	Waking from time to time at night	Recurrent insomnia/ waking up at night
15. Kukosa usingizi nzuri usiku	Inability to sleep well at night	Poor quality sleep/ disturbed sleep
16. Uchovu unapoamka	Tiredness on waking up	Fatigue on waking up
17. uchovu	Tiredness	Malaise/ fatigue
18. Kupungua kwa tija	Decreased??	Loss of??
19. Umakini kupungua	Decreased attentiveness	Difficulty

		concentrating
20. Kutananishwa/ kukosa utulivu/kuudhishwa upesi	???/ loss of calmness?/ easy irritability	Easily angered/ confusion/ restless
21. Huzuni	Sadness or sorrow	Sorrow
22. Aibu	Embarrassment	Shame

From the back translation, the term"Tija", which implies productivity was challenging to both the backtranslators. The phrase was therefore changed to "kupungua uwezo wa kutenda kazi" and the backtranslator responses were semantically equivalent. One was "decreased ability to perform work", the other was "loss of productivity at work" which have similar meaning.

After the back translation, taking into consideration the concerns of the translators, an improved Swahili version was developed. The term "tija" was changed to a phrase"kupungua uwezo wa kutenda kazi".

The improved Swahili version was then administered to 15 patients with CRS in the pilot testing phase. They were asked to say in their own words what they thought the question was asking and if there were any unclear phrases. In question 5, there was a concern that the phrase"kupotea kwa harufu" was time specific and implied that the patient had a sense of smell whereas for longstanding cases they couldn't perceive smell for a long duration. This was therefore changed to "Kutohisi".

In question 12, the term "uchungu" referred to only pain and not pressure, therefore, the term "kukazwa" which means tightness was added.

The rest of the questionnaire was reported as easy to understand and reflective of patients complaints. The final Swahili version was developed after the pilot testing phase.

Table 3: Final Swahili Snot-22 questionnaire after pilot testing.

Katika mda wa wiki mbili zilizopita, yafuatayo yalikuathiri vipi?	0-Hamna tatizo, 1- Tatizo kidogo sana, 2- tatizo kidogo 3- Tatizo wastani, 4- Tatizo nyingi, 5-Tatizo mbaya kupita kiasi.					
1. Haja ya kupuliza pua	0	1	2	3	4	5
2. Kuchemua	0	1	2	3	4	5
3. Kamasi kutiririka kwa pua	0	1	2	3	4	5
4. Kufungana pua	0	1	2	3	4	5
5. Kutohisi harufu au ladha	0	1	2	3	4	5
6. Kukohoa	0	1	2	3	4	5
7. Kamasi kutiririka nyuma ya pua	0	1	2	3	4	5
8. Makamasi mazito	0	1	2	3	4	5
9. Kuhisi kujaa sikioni	0	1	2	3	4	5
10. Kizunguzungu	0	1	2	3	4	5
11. Uchungu sikioni	0	1	2	3	4	5
12. Uchungu/Kukazwa usoni	0	1	2	3	4	5
13. Ugumu wa kupata usingizi	0	1	2	3	4	5
14. Kuamka mara kwa mara usiku	0	1	2	3	4	5
15. Kukosa usingizi nzuri usiku	0	1	2	3	4	5
16. Uchovu unapoamka	0	1	2	3	4	5
17. Uchovu	0	1	2	3	4	5
18. Kupungua uwezo wa kutenda kazi	0	1	2	3	4	5
19. Umakini kupungua	0	1	2	3	4	5
20. Kutananishwa/ kukosa utulivu/kuudhishwa upesi	0	1	2	3	4	5
21. Huzuni	0	1	2	3	4	5
22. Aibu	0	1	2	3	4	5

Phase 2: The clinical reliability and validity testing

A total of 75 CRS patients were recruited into the test retest arm of the study. We lost six patients to follow-up and therefore analysed data from 69 patients. Females constituted 45(62.5%) and the rest 24(34.8%) were males. Mean age of respondent in test retest group was 37yrs±13.61. Male: Female ratio was 1:2 for test retest arm.

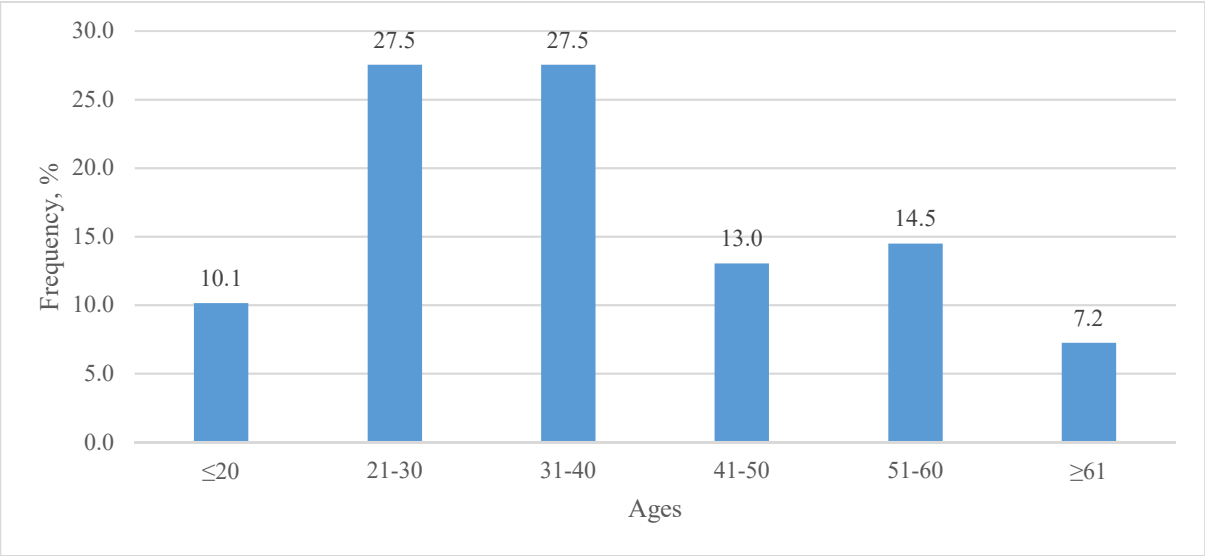


Figure 3: Age distribution for test retest arm

		GENDER		Total
		FEMALE	**MALE**	
AGE GROUPS	<20	6	1	7
	21-30	12	7	19
	31-40	13	6	19
	41-50	5	4	9
	51-60	6	4	10
	>61	3	2	5
Total		45	24	69

Table 4: Age group vs gender distribution for test retest arm.

Internal consistency and test retest reliability of the questionnaire were calculated by calculating Cronbach's alpha and Intraclass correlation coefficient respectively. Paired sample t-test was used to establish mean SNOT scores in test and retest arms thereby establishing validity of the questionnaire.

Reliability and internal consistency:

All 22 items had excellent test-retest reliability, indicating good stability. The consistency coefficient (Cronbach's alpha) ranged from 0.768 to 0.819 thus >0.70, indicating acceptable internal consistency (Table 4). However, questions 10, 12 and 21 in the Swahili version scored poorly on the corrected item total correlation indicating some inconsistencies and ambiguities in these responses.

Table 5: Total item correlation scores and their Cronbach's alpha

Questions	**Corrected item total correlation**	**Cronbach's Alpha**
RQ1 Haja ya kupuliza pua	0.015	0.806
RQ2 Kuchemua	0.355	0.791
RQ3 Kamasi kutiririka kwa pua	0.664	0.771
RQ4 Kufungana pua	0.530	0.792
RQ5 Kutohisi harufu au ladha	0.661	0.771
RQ6 Kukohoa	0.519	0.782
RQ7 Kamasi kutiririka nyuma ya pua	0.698	0.768
RQ8 Makamasi mazito	0.085	0.804
RQ9 Kuhisi kujaa sikioni	0.147	0.804
RQ10 Kizunguzungu	-0.015	0.812
RQ11 Uchungu sikioni	0.154	0.800
RQ12 Uchungu/Kukazwa usoni	-0.020	0.804
RQ13 Ugumu wa kupata usingizi	0.620	0.774
RQ14 Kuamka mara kwa mara usiku	0.507	0.784
RQ15 Kukosa usingizi nzuri usiku	0.561	0.779
RQ16 Uchovu unapoamka	0.424	0.788

RQ17 Uchovu	0.101	0.805
RQ18 Kupungua uwezo wa kutenda kazi	0.452	0.786
RQ19 Umakini kupungua	0.392	0.789
RQ20 Kutananishwa/ kukosa utulivu/kuudhishwa upesi	0.679	0.770
RQ21 Huzuni	-0.056	0.819
RQ22 Aibu	0.251	0.796

Cronbach's alpha for the Swahili questionnaire was **0.799**

Validity:

Swahili Snot-22 overall scores in test and retest arms were 58.44±10.23 and 58.91±11.27, P=0.79. This implies there was no significant difference in scores for test and retest arms. When analysed using the paired sample t test, the various domains of the SNOT-22 demonstrated stability with no statistically significant change between the test and the retest as demonstrated in the table below.

Table 6: Test and retest Swahili SNOT-22 domain scores

Snot 22 domains	**Test**	**Retest**	**P-value**
Rhinologic	15.6±2.7	15.8±3.4	0.71
External nasal	12.1±2.3	12.2±2.6	0.61
Facial	12.0±3.4	12.1±3.6	0.78
Psychological	20.4±5.9	20.0±6.3	0.67
Sleep dysfunction	10.7±3.4	10.7±3.3	0.91

Phase 3: Responsiveness and sensitivity to change

There were 38 CRS patients recruited into the operative arm of the study. However, three got lost to follow up in the post-operative period. Therefore, the data analysed was from 35 patients. Females made up 60% (21) whereas there were 14 males (40%). Male: Female ratio was 2:3 in the operative arm.Mean age of respondents in the operative arm was 33.4 yrs±8.26.

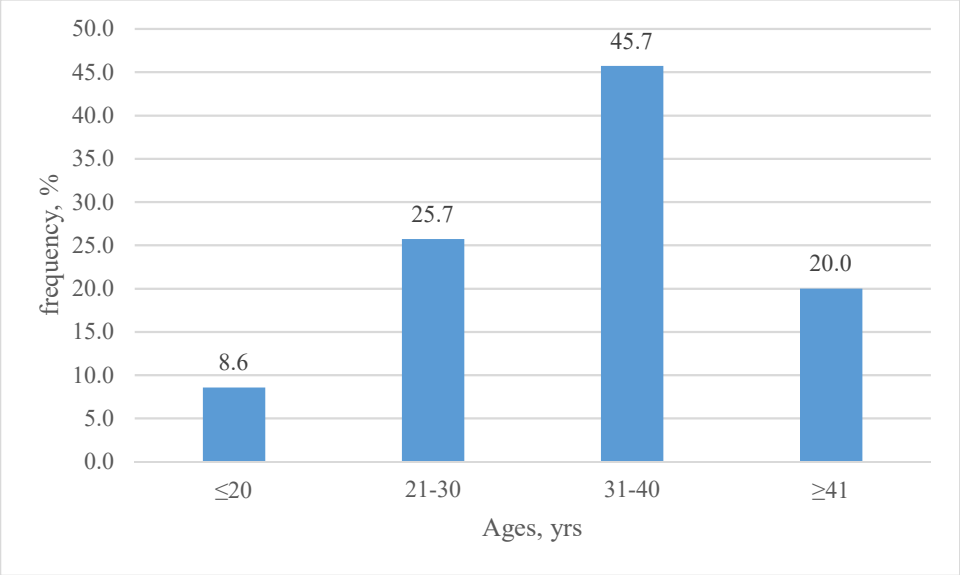


Figure.4 Age distribution for operative arm

Table 7: Age group vs gender distribution for operative arm.

		GENDER		Total
		FEMALE	**MALE**	
AGE GROUPS	<20	2	1	3
	21-30	6	3	9
	31-40	10	6	16
	>41	3	4	7
Total		21	14	35

Comparing total scores in preoperative and postoperative groups using paired sample T-test showed statistical significance, 55.65±26.92 vs 19.41±10.35, P<0.001.

Table 8: Preoperative and post operative Swahili SNOT 22 domain scores

Snot 22 domains	**PREOPERATIVE**	**POSTOPERATIVE**	**P-value**
Rhinologic	15.1±1.3	4.1±0.4	**<0.001**
External nasal	9.2±4.1	3.5±2.1	**<0.001**
Facial	11.6±7.0	4.4±3.4	**<0.001**
Psychological	19.5±10.7	6.1±4.2	**<0.001**
Sleep dysfunction	10.6±5.3	4.8±3.1	**<0.001**

Magnitude of treatment effect was quantified using effect size which gave a Cohen's *d* value of 1.77. This means that the effect size is very large which demonstrates a large impact of surgical intervention in the population.

Chapter 5: DISCUSSION

The Snot-22 is a HRQoL tool developed from the Rhinosinusitis Outcomes Measure-31 (RSOM-31), by Piccirillo et. al (28) in 2003 and validated by Hopkins et al in 2009.(7)
Measuring the HRQoL from disease and the effect of treatment from the patient's perspective is gaining traction compared to evaluation done only by the doctor. The objective of this study was to translate and validate a Swahili version of SNOT-22. The tool has already been translated to Greek, Persian, Portuguese, Moroccan, Thai, Hebrew and Lithuanian amongst other languages.(4,10,13,14,16,17)
In developing the Swahili version of the SNOT-22, we applied the method described by the WHO on cross cultural translation and adaptation of research instruments(21). The Swahili SNOT-22 tool characteristics were thereafter evaluated in this prospective cohort study, to determine its internal consistency, reliability, validity and sensitivity to change.

In assessing the internal consistency of the Swahili SNOT-22, Cronbach's alpha was calculated and was 0.799. This is acceptable since as closer to 1 the number is, the higher the internal consistency(27). A value above 0.7 indicates that the tool is reliable. Our study results demonstrate good reliability as also seen in the Lithuanian(4), Hebrew(10), Persian(17), Greek(16), Spanish(12), Thai(14), Brazilian Portuguese(29)and Moroccan(13) which posted Cronbach's alpha of 0.89,0.93,0.89,0.89,0.91,0.94,0.93 and 0.968 respectively.

However, questions 10, 12 and 21 in the Swahili version scored poorly on the corrected item total correlation indicating some inconsistencies and ambiguities in their responses. This could be attributed to the variations in Swahili dialect amongst our population. In question 10, the English term dizziness was translated to the Swahili term "Kizunguzungu". This word can be construed to mean 'fainting', 'a spinning sensation', or even 'imbalance' by some Swahili speakers. We postulate that this difference in meaning may have led to the ambiguities in this question. In question 12, the term "facial pain/pressure" was translated to the Swahili terms "Uchungu / Kukazwa Usoni". The element of pressure has no clearly discernible Swahili equivalent as also discovered during the pilot phase. The closest term 'Kukazwa' may be interpreted by some people as tightness or congestion. This could have led to the ambiguities in this question. The term "huzuni" as interpreted from "sad" in question 21 also was noted to have

ambiguous responses. This term is linguistically equivalent to 'Sad', therefore, we postulate that the in ambiguity could be due to lack of full emotional disclosure by patients, possibly due to cultural norms in which emotional issues are shunned upon and not easy to disclose.
When these questions are excluded from the analysis, the Cronbach's alpha of the questionnaire improves to 0.83. However, for completeness of the Swahili SNOT 22, the questions have been included and therefore drop the Cronbach's alpha to 0.799 which is still within acceptable range.

In assessing the validity of the study, Swahili SNOT-22 scores in test and retest arms were 58.44±10.23 and 58.91±11.27. (P=0.79). This implies there was no significant difference in scores for test and retest arms. In the Lithuanian study, the mean SNOT-22 sum score was 44.52 for the initial test, and 46.44 in the retest. The total domain scores and their correlations show no statistically significant change between the tests and retest arms and therefore affirm the stability of the Swahili SNOT -22 tool. The absence of a statistically significant difference between the test and retest arms in our study implies that the tool is stable over time and is in keeping with most other validated versions of the SNOT-22.

In assessing the tool's responsiveness and sensitivity to change, total scores in preoperative and postoperative groups were compared using the paired sample T-test, the overall scores of the pre-operative and post operative groups were 55.65±26.92 vs 19.41±10.35, P<0.001 respectively. This demonstrated statistical significance. This is comparable to the Lithuanian study (43±20.2 vs 22.52±20.85, P<0.001), the Hebrew study (49.46±25.73 vs 29.64±19.96, P<0.001), Italian study (44.4±22.7 vs 20.1±23.8, P <0.001) and the Greek study (44.3±12.6 vs 11.2±11.4, P<0.001).

The Spanish(12) and Moroccan(13) studies used the Wilcoxon test, a non-parametric alternative to the paired t test and also found that the difference before and after treatment was statistically significant (p\0.0001).

This findings imply that the tool is capable of detecting changes in symptomatology and clinical improvement after surgery

Magnitude of treatment effect was quantified using effect size which gave a Cohen's *d* value of 1.77. This depicts a very large effect size and demonstrates that the tool is able to detect clinical change over time after surgical intervention in patients with CRS.

Study limitations:

Test-retest bias especially in newly diagnosed patients who improve within two weeks of medical treatment, in whom there was an improvement in scores due to medical intervention.

Variations in Swahili dialect and understanding amongst the various ethnic groups could give a different meaning or interpretation of the various words.

For patients who were recruited in phase 1 and two as opposed to either phase alone, they filled the questionnaire 4 times. This could have an element of recall bias in this patients due to filling the questionnaire multiple times.

Conclusion:

The Swahili version of the SNOT 22 developed in this study has demonstrated good internal consistency, reliability and validity. The Swahili SNOT-22 is a valid instrument in assessing HRQoL in Swahili speaking patients with rhinosinusitis.

Recommendation:

This tool can be used by institutions and clinicians both for patient care and clinical research in rhinosinusitis.

Timelines:

ACTIVITY	FROM	TO
Development of Research Proposal	August 2018	August 2018
Presentation to ENT Department	September 2018	September 2018
KNH/UON Ethics & Research Committee approval	January 2019	June 2019
Swahili SNOT-22 Questionnaire development	July 2019	July 2019
Data collection	August 2019	February 2020
Data Analysis	March 2020	March 2020
Defence and revisions	April 2020	April 2020
Submission for marking	May 2020	May 2020

Expenditure:

ITEM/ACTIVITY	COST(KENYA SHILLINGS)
STATIONERY	15,000
BIOSTATISTICIAN	30,000
RESEARCH ASSISTANT	15,000
TELEPHONE CHARGES	10,000
CONTINGENCY	20,000
ETHICS COMMITTEE FEE	2,000
PUBLISHING COST	20,000
TOTAL	112,000

REFERENCES

1. Anand VK. Epidemiology and economic impact of rhinosinusitis. Ann Otol Rhinol Laryngol Suppl. 2004 May;193:3–5.

2. Rudmik L. Economics of Chronic Rhinosinusitis. Curr Allergy Asthma Rep. 2017 Apr;17(4):20.

3. Fokkens WJ,Lund VJ, Mullol J et al. European Position Paper on Rhinosinusitis and Nasal Polyps.Rhinology 2012 Mar;50(23)1-298

4. Vaitkus S, Padervinskis E, Balsevicius T et al. Translation, cross-cultural adaptation, and validation of the sino-nasal outcome test (SNOT)-22 for Lithuanian patients. Eur Arch Oto-Rhino-Laryngol Head Neck Surg. 2013 May;270(6):1843–1848.

5. Metson RB, Gliklich RE. Clinical outcomes in patients with chronic sinusitis. The Laryngoscope. 2000 Mar;110(3 Pt 3):24–28.

6. SNOT - Sino-Nasal Outcome Test [Internet]. [cited 2018 Sep 16]. Available from: https://eprovide.mapi-trust.org/instruments/sino-nasal-outcome-test

7. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. Clin Otolaryngol 2009 Oct;34(5):447–454.

8. Morley AD, Sharp HR. A review of sinonasal outcome scoring systems - which is best? Clin Otolaryngol 2006 Apr;31(2):103–109.

9. de Dorlodot C, Horoi M, Lefebvre P, et al. French adaptation and validation of the sino-nasal outcome test-22: a prospective cohort study on quality of life among 422 subjects. Clin Otolaryngol 2015 Feb;40(1):29–35.

10. Shapira Galitz Y, Halperin D, Bavnik Y, et al. Sino-Nasal Outcome Test-22: Translation, Cross-cultural Adaptation, and Validation in Hebrew-Speaking Patients. Otolaryngol--Head Neck Surg. 2016;154(5):951–956.

11. Mozzanica F, Preti A, Gera R, et al. Cross-cultural adaptation and validation of the SNOT-22 into Italian. Eur Arch Oto-Rhino-Laryngol -Head Neck Surg. 2017 Feb;274(2):887–895.

12. de los Santos G, Reyes P, del Castillo R, et al. Cross-cultural adaptation and validation of the sino-nasal outcome test (SNOT-22) for Spanish-speaking patients. Eur Arch Oto-Rhino-Laryngol - Head Neck Surg. 2015 Nov;272(11):3335–3340.

13. Adnane C, Adouly T, Oubahmane T et al. Psychometric Validation of a Moroccan Version of the 22-Item Sino-Nasal Outcome Test. Otolaryngol--Head Neck Surg-Head Neck Surg. 2016;155(4):681–687.

14. Numthavaj P, Bhongmakapat T, Roongpuwabaht B et al. The validity and reliability of Thai Sinonasal Outcome Test-22. Eur Arch Oto-Rhino-Laryngol - Head Neck Surg. 2017 Jan;274(1):289–295.

15. de Vilhena D, Duarte D, Lopes G et al. Sino-Nasal Outcome Test-22: translation, cultural adaptation and validation in Portugal. Clin Otolaryngol. 2016 Feb;41(1):21–24.

16. Lachanas VA, Tsea M, Tsiouvaka S,et al. The sino-nasal outcome test (SNOT)-22: validation for Greek patients. Eur Arch Oto-Rhino-Laryngol - Head Neck Surg. 2014 Oct;271(10):2723–2728.

17. Jalessi M, Farhadi M, Kamrava SK et al. The Reliability and Validity of the Persian Version of Sinonasal Outcome Test 22 (Snot 22) Questionnaires. Iran Red Crescent Med J. 2013 May;15(5):404–408.

18. Regmi K, Naidoo J, Pilkington P. Understanding the Processes of Translation and Transliteration in Qualitative Research. Int J Qual Methods. 2010 Mar 1;9(1):16–26.

19. Guillemin F, Bombardier C, Beaton D et al.Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. J Clin Epidemiol. 1993 Dec;46(12):1417–1432. 20. W. Brislin R. The Wording and Translation of Research Instrument. Field Methods Cross-Cult Res. 1986 Jan 1;8.

20. W. Brislin R. Back translation for cross cultural research .J of cross cultural,psychology.1970 Sep;1(3) 185-216

21. WHO | Process of translation and adaptation of instruments [Internet]. WHO. [cited 2018 Jul 15]. Available from: http://www.who.int/substance_abuse/research_tools/translation/en/

22. Kumar M, Ongeri L, Mathai M, et al. Translation of EPDS Questionnaire into Kiswahili: Understanding the Cross-Cultural and Translation Issues in Mental Health Research. J Pregnancy Child Health 2015 Jan; 15;2(1)134

23. Confusing Stats Terms Explained: Internal Consistency [Internet]. Stats Make Me Cry Consulting. [cited 2018 Jul 23]. Available from: http://www.statsmakemecry.com/smmctheblog/confusing-stats-terms-explained-internal-consistency.html

24. Warui SW. Translation and validation of a Swahili version of obstructive sleep apnea 18 (OSA 18) quality of life instrument in children with sleep disordered breathing due to adenoid and tonsillar hypertrophy.Thesis; University of Nairobi; 2017 [cited 2018 Jul 23]. Available from: http://erepository.uonbi.ac.ke:8080/xmlui/handle/11295/101678

25. Stephanie. Convergent Validity and Discriminant Validity: Definition, Examples [Internet]. Statistics How To. [cited 2018 Jul 23]. Available from: http://www.statisticshowto.com/convergent-validity/

27. Hulley SB, editor. Designing clinical research. 4th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins; 2013.

28. Piccirillo JF, Edwards D, Haiduk A,et. al. Psychometric and Clinimetric Validity of the 31-Item Rhinosinusitis Outcome Measure (RSOM-31). Am J Rhinol. 1995 Nov 1;9(6):297–306.

29. Kosugi EM, Chen VG, Fonseca VMG et al. Translation, cross-cultural adaptation and validation of SinoNasal Outcome Test (SNOT): 22 to Brazilian Portuguese. Braz J Otorhinolaryngol. 2011 Oct;77(5):663–669.

APPENDIXES:

APPENDIX 1: CONSENT EXPLANATION:

My name is Dr Michael Sitima. I am the principal researcher in this study. The study has been approved by the KNH/UON Ethics and Research Committee.

I am conducting a study amongst patients with chronic rhinosinusitis to determine their quality of life using a Kiswahili version of SNOT 22. This is a validated questionnaire used to assess the quality of life of patients who have chronic rhinosinusitis.

SNOT 22 is used to assess quality of life in patients with Chronis Rhinosinusitis and to determine improvements in quality of life following various intervention measures.

The SNOT 22 questionnaire is currently in use in the English version and has been validated in English. Kiswahili is our national language and understood by a majority of the population.

The aim of this study is to develop a Kiswahili version for the same and validate its usefulness in determining the Quality of Life in patients with nasal disorders due to Chronic Rhinosinusitis.

The Study will entail you, the patient responding to the Kiswahili version of OSA 18 questionnaire at the point of recruitment into the study, during your clinic visit. Your biodata and social data will be taken at the same sitting. The principal researcher will then do a physical examination.

You will then be requested to respond to the Kiswahili version again after two weeks. This will then be followed by your Sinus surgery if prescribed. You will again be required to respond to the Swahili SNOT 22 three months after surgery.

The first two sets of responses will then be analysed to determine the validity of the instrument. The third postoperative response will be used to assess and compare quality of life before and after sinus surgery.

Are there any risks involved?

There are no known risks anticipated in your participation in this study.

Is there any penalty for refusing to participate in the study?

No, there are no penalties and the patient will receive the same treatment expected for sinonasal disease.

What benefits will I get for participating in the study?

There will be no immediate direct benefits to you. The study will however help doctors monitor their patients and their response to treatment modalities in a more accessible manner and language. It will also offer a baseline for local guidelines in management of sinonasal disease.

What about confidentiality?

All the information that we obtain will be kept confidential.

Are there any extra costs involved?

There are no extra costs involved in the participation in this study. The patient will however be subject to any standard fees charged by the Kenyatta National Hospital as part of their management.

Are you satisfied with the information provided?

In case of any questions or inquiries, contact the following:

A. **Principal Investigator:**

Dr. Michael Sitima,

Department of Surgery,

College of Health Sciences,

University of Nairobi.

P.O. BOX 2134-00100 Nairobi.

Phone number: 0720322451

Email: sitimamike@gmail.com

B. Supervisors:

1. Professor Isaac Muthure Macharia

   Professor in ENT, Head and Neck Surgery,

   Department of Surgery,

   University of Nairobi, College of Health Sciences.

2. Dr M. Omutsani,

   Consultant ENT Surgeon, Head and Neck Surgeon.

   Kenyatta National Hospital, Nairobi.

3. The Chairman, KNH-UON Ethics and Research Committee,

   Kenyatta National Hospital, Nairobi

If you are satisfied with the explanation, kindly complete and sign the attached consent form.

APPENDIX 2: CONSENT FORM

I……..……..……IDNo…… ……of…… do hereby consent Mr./Mrs./Master/Miss/Self ……. to be included in this study on "TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF THE SINO-NASAL OUTCOME TEST (SNOT-22)". The nature of the study has been fully explained to me by Dr.……. I have not been promised any material gain to participate.

Signed (Patient/parent/guardian) …….

Date…….

Signed (Doctor) …….

Date ……...

For any further clarification, contact any of the following:

Principal Investigator:

Dr. Michael Sitima

Department of Surgery,
College of Health Sciences,
University of Nairobi.

P.O. BOX 2134-00100 Nairobi.

Tel: 0720322451
Email: sitimamike@gmail.com

Supervisors:

Professor Isaac Muthure Macharia

Professor in ENT, Head and Neck Surgery,

Department of Surgery,

University of Nairobi, College of Health Sciences.

2. Dr M. Omutsani,

   Consultant ENT Surgeon, Head and Neck Surgeon.

   Kenyatta National Hospital, Nairobi.

The Chairman,

KNH/UON Ethical and Research Committee,

Kenyatta National Hospital

Tel: 2726300 – 9 Ext. 44355

APPENDIX 3: KIAMBATISHO: MAELEZO YA UTAFITI NA KIBALI CHA KUSHIRIKI

MAELEZO YA UTAFITI:

Jina langu ni Dk Michael Sitima. Mimi ndiye mtafiti mkuu wa utafiti huu.Utafiti wenyewe umeithinishwa na hospitali kuu ya Kenyatta na kamati ya madili na utafiti katika chuo kikuu cha Nairobi.Ninaendesha utafiti miongoni mwa wagonjwa wa findo la kooni kubaini dhamana yao ya maisha kutumia toleo la Kiswahili la SNOT 22. Hili ni dodoso la maswali lililoidhinishwa kutumiwa katika kubaini dhamana ya maisha kwa wagonjwa walio na matatizo ya shida za kupumua na mapua kudhibitisha hali ya afya yao. Kigezo cha SNOT 22 kinatumiwa kubaini dhamana ya maisha kwa walio na matatizo ya mapua na koo ili kubaini jisni ya kuimarisha maisha yao kwa kutumia mbinu mbali mbali.Toleo la SNOT 22 la maswali kwa sasa linatumiwa kwenye lugha ya kingereza . Kiswahili ndio lugha yetu ya kitaiafa na inaeleweka na watu wengi miongoni mwetu.

Somo hili linalenga kukuza toleo la Kiswahili la SNOT 22 kwa minajili ya hilo na kuidhinisha matumizi yake katika kubaini kiwango cha hali ya maisha miongoni mwa wakenya walio na matatuzi ya maumivu yanayo wadhuru mwilini.

Utahitajika kujibu maswali yanayohusu toleo hilo la Kiswahili. Tena baada ya majuma mawili au siku moja kabla ya upasuaji wako wa pua.Utahitajika kulijaza toleo la SNOT 22 kwa mara ya tatu miezi tatu baada ya upasuaji.

Aina mbili za kwanza za majibu zitachunguzwa kubaini uhakika wa kifaa hicho.Majibu ya tatu yatatumika kubaini tofauti ya dhamana ya maisha kabla na baada ya upasuaji.

Je kuna hatari zinazohusiana na utafiti huo?

Hadi kufikia sasa hakuna hatari zozote ambazo huenda zikakukumba wewe ama mwanao unaposhiriki kwenye utafiti huu.

Je kuna hatua yoyote ya kinidhamu itakayo chukuliwa iwapo utakosa kushiriki?

La, hakuna adhabu yoyote na mgonjwa, atapokea matibabu yale yanayohitajika iwapo mmoja ana ugua ugonjwa wa findo na maumivu mengine.

Je ni faida ipi nitakayopata kwa kushiriki kwenye utafiti huu ?

Hakuna faida za haraka ama zile za moja kwa moja utakayopata ama mwanao.

Hata hivyo utafiti huu utasaidia madakitari kufuatilia wagonjwa wao na jinsi wanavyopokea matibabu katika njia na lugha wanayofahamu vyema zaidi.

Je, kuhusu usiri?

Maelezo yote yatakayopatikana yatawekwa kama siri .

Je kuna gharama zaidi zinazohitajika?

Hakuna gharama inayohusishwa katika kushiriki kwenye utafiti huu. Mgonjwa hata hivyo atahitajika kulipa ada zozote ambazo zinalipwa na wagonjwa katika hoospitali kuu ya Kenyatta kama sehemu ya kufuatilia kwao.

Je umeridhika na maelezo yaliyotolewa?

Iwapo una swali ama dukuduku wasiliana na wafuatao:

Mtafiti mkuu: Dr Sitima Michael Oruko; MBCHB,

Idara ya Upasuaji, Chuo cha Sayansi ya Afya,

Chuo kikuu cha Nairobi.

Anwani: 2134-00100 Nairobi.

Nambari ya simu: 0720322451

Baruapepe: sitimamike@gmail.com

Wasimamizi:

1. Professor Isaac Muthure Macharia

Professa na Mhadhiri mkuu, Idara ya upasuaji,

Chuo cha Sayansi ya Afya ,

Chuo kikuu cha Nairobi.

Anwani: 19676-00202 Nairobi

.

2: Dr M. Omutsani

Daktari wa Upasuaji wa shingo na Kichwa

Mhadhiri mkuu, Idara ya upasuaji,

Chuo cha Sayansi ya Afya,

Chuo kikuu cha Nairobi.

Anwani: 19676-00202 Nairobi

3: Mwenyekiti**:**

Kamati ya utafiti na maadili katika hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

Hospitali kuu ya Kenyatta,

Nairobi.

Simu: 020-2726300

Iwapo umeridhika na maelezo yaliyotolewa, tafadhili kamilisha na utie saini fomu ya kukubali hilo.

APPENDIX 4: KIBALI CHA UTAFITI

Mimi……..……..……..Kitambulisho

Nambari…….kutoka……nakubali mimi/mwanangu/ninayemsimamia…….

Kuhusishwa katika utafiti wa "kubaini dhamana ya maisha katika wakenya wenye shida za mafua ya koo la Kiswahili la SNOT 22" ambao nimeelezewa kwa makini na

Daktari…….. Mimi sijaahidiwa chochote cha kunifaidi kwa kushiriki.

Sahihi ya Mgonjwa/Mzazi/Msimamizi …….

Tarehe……..…….

Sahihi ya Daktari …….

Tarehe ……...

Ikiwa unahitaji maelezo zaidi kuhusu huu utafiti, unaweza kuwasiliana na wafuatao:

Mtafiti Mkuu:

Daktari Michael Sitima

Anwani: 2134-00100 Nairobi

Simu: 0720322451

Barua pepe: sitimamike@gmail.com

Wasimamizi:

1: Professa Isaac Muthure Macharia

Professa na Mhadhiri mkuu, Idara ya upasuaji,

Chuo cha Sayansi ya Afya,

Chuo kikuu cha Nairobi.

Anwani: 19676-00202 Nairobi

2: Dr M. Omutsani

Daktari wa Upasuaji wa shingo na Kichwa

Mhadhiri mkuu, Idara ya upasuaji,

Chuo cha Sayansi ya Afya,

Chuo kikuu cha Nairobi.

Anwani: 19676-00202 Nairobi

3: Mwenyekiti**:**

Kamati ya utafiti na maadili katika hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

Hospitali kuu ya Kenyatta,

Nairobi.

Simu: 020-2726300

APPENDIX 5: STUDY TOOLS

Questionnaire number: …… Date: ……..

SECTION A: Sociodemographic Characteristics

1. Age in years ……
2. Gender Male ☐ Female ☐
3. Level of education
    a. Not attended school ☐
    b. Primary education ☐
    c. Secondary education ☐
    d. Tertiary education ☐
4. History of Chronic sinusitis
    a. nasal blockage/obstruction ☐
    b. nasal congestion ☐
    c. nasal discharge (anterior/posterior nasal drip) ☐
    d. facial pain/pressure, ☐
    e. reduction or loss of smell for ≥12 weeks ☐
5. Physical exam findings
    a. Rhinorrhea ☐
    b. Polyps ☐
    c. Hypertrophied turbinates ☐
    d. Post nasal drip ☐
    e. Nasal inflammation ☐
    f. Facial tenderness ☐
    g. Other
6. CT scan findings:
    a. Normal ☐
    b. Opacification of sinuses ☐
    c. Obstructed osteomeatal complex ☐
    d. Hypertrophied inferior turbinates ☐
    ☐

e. Thick sinonasal mucosa

f. Other ……..

7. Endoscopic findings

a. Polyposis ☐

b. Nasal discharge ☐

c. Mucosal edema ☐

d. Obstructed osteomeatal complex ☐

e. Anatomical structural variation ☐

f. Other ……

8. Meets EPOS 2012 criteria for CRS

a. Yes ☐

b. No ☐

9. Medical treatment

a. Yes ☐

b. No ☐

10. Type of endoscopic sinus surgery

a. Turbinoplasty ☐

b. Ethmoidectomy ☐

c. Middle meatal antrostomy ☐

d. sphenoidotomy ☐

e. frontal pathway clearance/Draf dissection ☐

f. full house ESS ☐

Appendix 6: Sino-Nasal Outcome Test (SNOT-22) Questionnaire

(The English version which was translated to Swahili)

Below you will find a list of symptoms and social/emotional consequences of your nasal disorder. We would like to know more about these problems and would appreciate your answering the following questions to the best of your ability. There are no right or wrong answers, and only you can provide us with this information. Please rate your problems as they have been over the past two weeks. Thank you for your participation.

A. Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by circling the number that corresponds with how you feel using this scale below.

B. Please check off the most important items affecting your health in the last column (max of five items)

	No Problem	**Very Mild Problem**	**Mild or Slight Problem**	**Moderate Problem**	**Severe Problem**	**Problem as bad as it can be**	**Most important items**
1. Need to blow nose	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
2. Sneezing	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
3. Runny nose	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
4. Nasal obstruction	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
5. Loss of smell or taste	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**

6. Cough	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
7. Post-nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
8. Thick nasal discharge	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
9. Ear fullness	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
10. Dizziness	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
11. Ear pain	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
12. Facial pain/pressure	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
13. Difficulty falling asleep	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
14. Waking up at night	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
15. Lack of a good night's sleep	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
16. Waking up tired	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
17. Fatigue	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
18. Reduced productivity	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
19. Reduced concentration	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**

20. Frustrated/restless/irritable	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
21. Sad	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
22. Embarrassed	**0**	**1**	**2**	**3**	**4**	**5**	**[ ]**
TOTALS (each column):							

TOTAL SCORE (all columns):

Appendix 7: Swahili version of Sino nasal Outcome Test (SNOT-22)

Katika mda wa wiki mbili zilizopita, yafuatayo yalikuathiri vipi?	0-Hamna tatizo, 1- Tatizo kidogo sana, 2-tatizo kidogo 3- Tatizo wastani, 4- Tatizo nyingi, 5-Tatizo mbaya kupita kiasi.					
1. Haja ya kupuliza pua	0	1	2	3	4	5
2. Kuchemua	0	1	2	3	4	5
3. Kamasi kutiririka kwa pua	0	1	2	3	4	5
4. Kufungana pua	0	1	2	3	4	5
5. Kutohisi harufu au ladha	0	1	2	3	4	5
6. Kukohoa	0	1	2	3	4	5
7. Kamasi kutiririka nyuma ya pua	0	1	2	3	4	5
8. Makamasi mazito	0	1	2	3	4	5
9. Kuhisi kujaa sikioni	0	1	2	3	4	5
10. Kizunguzungu	0	1	2	3	4	5
11. Uchungu sikioni	0	1	2	3	4	5
12. Uchungu/Kukazwa usoni	0	1	2	3	4	5
13. Ugumu wa kupata usingizi	0	1	2	3	4	5
14. Kuamka mara kwa mara usiku	0	1	2	3	4	5
15. Kukosa usingizi nzuri usiku	0	1	2	3	4	5
16. Uchovu unapoamka	0	1	2	3	4	5
17. Uchovu	0	1	2	3	4	5
18. Kupungua uwezo wa kutenda kazi	0	1	2	3	4	5
19. Umakini kupungua	0	1	2	3	4	5
20. Kutananishwa/ kukosa utulivu/kuudhishwa upesi	0	1	2	3	4	5
21. Huzuni	0	1	2	3	4	5
22. Aibu	0	1	2	3	4	5