



**Percutaneous Endoscopic Gastrostomy (PEG) tube placement:
indications, management, complications, outcomes, and care applied to endoscopy unit
patients in a tertiary care hospital.**

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Declaration

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

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Master Luke Muriithi Munene, as you grow, remember—sometimes in the wild goose chase of life, we miss the golden goose but instead stumble upon a nondescript goose that lays the golden egg. May you find your goose.

Dedication

The precarious balance between science and service lies in appreciating that knowledge is not an end in itself- It is a tool for compassion. In the face of great personal loss, I have come to the solemn understanding that scientific advancement does not require rejection of our humanity. Rather, it demands that we feel deeply, serve with humility and act decisively. This thesis stands at that confluence-where reason meets remembrance and where healing becomes both a discipline and devotion.

RIP. Tom Mathagu Munene & Tam Mathagu Munene (19th October 2023)

ABSTRACT - OPEN

Background: Enteral access is preferred as the most physiological and beneficial feeding route. Percutaneous endoscopic gastrostomy (PEG) is a widely used access route for enteral feeding in patients with a functional gastrointestinal system, but who are unable to maintain sufficient oral intake to meet daily nutritional and metabolic needs. PEG-related complications can be significant, but reported rates are variable.

Aim: To investigate the use, complications, and outcomes associated with PEG insertion in a South African tertiary-level centre.

Methods: This was a retrospective study including all patients who underwent PEG insertion at the Groote Schuur Hospital Gastroenterology Unit between March 2018 to June 2023. Variables obtained included patient demographics, comorbidities, PEG insertion details, and complications.

Results: A total of 149 patients undergoing 158 PEG-insertion procedures were included with a median age of 54 years (IQR: 38-64) with the majority being male (91; 61.1%). The most common indication for PEG insertion was cerebrovascular accident (CVA) at 25.5% (38). PEG-related complications were divided into insertion-related, early (within 30 days of insertion) and late (after 30 days of insertion) and observed in 64 patients (43.0%). The only factor found to be associated with an increased early complication rate was the size of the PEG, with 24Fr tubes having a higher complication rate compared to smaller tubes (25.5% vs 3.7%, $p < 0.001$).

Conclusions: Local indications and high complication rates of PEG placement are highlighted, advocating for the judicious placement of PEGs. Early complications are notably higher with increased diameter tubing, and we recommend that the use of 24Fr tubes be avoided if possible.

List of acronyms

BMI - Body mass index

CVA - Cerebrovascular accident

CXR - Chest x-ray

ECOG - Eastern Cooperative Oncology Group

EHRs - Electronic health records

GI - Gastrointestinal

Hb - Haemoglobin

HIV - Human immunodeficiency virus

IBM - International Business Machines Corporation

INR - International normalized ratio

NGT - Nasogastric tube

NSAIDs - Non-steroidal anti-inflammatory drugs

PEG - Percutaneous endoscopic gastrostomy

SPSS - Statistical Package for the Social Sciences

WCC - White cell count

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Introduction

Percutaneous endoscopic gastrostomy (PEG) placement was first described in 1980 by Ponsky and Gauderer, with this novel endoscopic technique developed as an alternative to the surgical approach that was considered standard of care at that time (1). PEG placement has now become a widely used treatment modality to provide enteral nutritional support in those patients who are unable to maintain sufficient oral intake to meet daily nutritional and metabolic needs but with a functional gastrointestinal system (2,3). Indications for PEG placement includes patients with dysfunctions of the neurological system, such as cerebrovascular accident (CVA), severe intellectual disability, dementia, bulbar palsy, cerebral palsy, neuromuscular disorders, head and neck trauma, head and neck cancers and patients undergoing upper aerodigestive tract surgery. In these examples, PEG tubes have emerged as a substitute for parenteral nutrition and feeding via other enteral routes, such as nasogastric tube (NGT) feeding. Enteral feeding is acknowledged as the most physiological and preferred feeding modality given the multitude of beneficial effects over parenteral feeding (2,3).

PEG placement is an endoscopic procedure allowing the formation of a permanent or temporary communicating channel between the stomach and anterior abdominal wall, thereby allowing for direct passage of food into the stomach (4). Other than feeding, PEG tubes can be used as a means to decompress the stomach (4). In those patients where the nutritional administration enterally is expected to exceed four weeks and the life expectancy of the patients exceeds two months, PEG insertion is favoured for its utility, safety profile, simplicity, low cost and relative ease of insertion (5).

PEG use is recognized as a minimally invasive procedure that eliminates the need for general anaesthesia and requires less instrumentation and is therefore a valued access route for enteral

feeding in hospitals, nursing homes and home environments (6). Two different PEG placement techniques are described, the “Pull” and “Push” techniques, with the “Pull” technique being more commonly utilized (1,4). The main absolute contraindications to PEG tube placement in hospitalized patients include severe uncorrectable coagulopathy, haemodynamic instability or distal enteral obstruction (6). While PEG insertion is generally a fairly safe procedure, complications can occur during insertion or after the procedure either in the short- or long term. These complications can generally be classified into three major categories: PEG procedure related complications, early procedure-related complications, and late complications linked to PEG tube maintenance and wound care. Complications can also be classified according to severity, either major or minor. Major complications may include, amongst others, haemorrhage, injury to solid or visceral organs, e.g. colon, small bowel or the liver and procedural aspiration, whereas minor complications include PEG-site infection and minor bleeding (6).

An appreciation of the possible complications, as well as an understanding of the regular maintenance of PEG tubes, can improve the quality of care for patients and allow for appropriate referral for PEG placement (4). There is a significant difference and variation in the incidence of adverse events with PEG placement reported in the literature. Given these reported variabilities in complication rates and the paucity of data from South Africa, it calls for more studies to gain a greater understanding of the use of PEGs in our context. The aim of this study was to investigate the use, complications and outcomes associated with PEG insertion in a South African tertiary-level referral centre.

Methodology

Study design

This was a retrospective descriptive cohort study including all adult patients who underwent PEG tube insertion by the Gastrointestinal (GI) Unit at Groote Schuur Hospital between 1st March 2018 and 30th June 2023. The objectives of the study were to determine the clinical indications, comorbidities and demographics of patients referred for PEG placement, and to investigate the immediate, early and late complications associated with PEG tubes.

Study population

All patients referred to the GI Unit at Groote Schuur Hospital for PEG insertion were evaluated for possible inclusion into the study. The inclusion criteria for our study were defined as follows: all adult patients (>18 years old), with an expected life expectancy of more than 3 months; patients with confirmed indication for PEG tube insertion, such as cerebrovascular disease, bulbar dysphagia, severe cognitive impairment, dementia and head or neck cancer, etc; and patients with no contraindication for enteral nutrition.

The exclusion criteria for our study were defined as: patients who required a change of gastrostomy without needing an upper gastrointestinal endoscopy; patients in whom no standard ‘pull-through’ technique with or without preceding Savary-Gilliard dilation (SG-dilation) was possible due to stenosis of the hypopharynx or oesophagus (7); and patients in whom PEG placement had to be terminated prematurely due to respiratory compromise or other complications.

PEG insertion procedure

The standard PEG insertion technique in our unit uses the modified pull-through technique as described by Gauderer (1). After informed consent is obtained the patient is placed supine after receiving topical pharyngeal lignocaine and conscious sedation (individualized combinations

of fentanyl and midazolam or propofol) with nasal prong oxygen, procedural blood pressure, pulse and oxygen saturation monitoring. A single prophylactic dose of intravenous co-amoxycylavulanic acid is routinely given (routine practice since January 2020 and adjusted if any known allergies). An appropriately sized PEG placement kit is chosen taking into account the individual patient's size and proposed PEG usage. A full diagnostic upper gastrointestinal endoscopy is first performed, after which maximal gastric distension is achieved by continuous insufflation to ensure direct contact of the stomach with the anterior abdominal wall. Simultaneously, the assistant prepares the abdomen in a sterile fashion and identifies an appropriate site for the PEG placement by using digital pressure to achieve simultaneously visible gastric distortion on endoscopy in an appropriate anatomical location in the stomach. Care is taken with any previous surgical sites in anticipation of intra-abdominal adhesions and a minimum 2cm gap is left from the rib margin to facilitate comfortable external flange/bumper positioning. The proposed PEG site is infiltrated with lignocaine; an appropriately sized skin incision is made through which a 14 French cannula is introduced percutaneously perpendicularly into the stomach until it is endoscopically visible.

The supplied guidewire is then fed through the cannula into the stomach, which is then grasped by endosnare and subsequently extracted orally on removal of the endoscope. The PEG tube is looped to the guidewire with the assistant then pulling the wire back again allowing the PEG tube to follow. Purposeful but controlled traction is required to pull the tapered PEG tubing tip through the abdominal wall. Once the tubing is visible, gentle traction continues until there is resistance felt as the internal flange/bumper offers resistance. At this point the endoscope is passed back into the stomach to assist with securing an appropriate height of the external flange/bumper. The tube is secured at skin level using the provided flange, ensuring the internal PEG bumper is snug against the gastric mucosa, but with the assistant still able to externally

rotate the tubing comfortably, so avoiding pressure necrosis of the abdominal wall with associated sepsis. The endoscope is extracted finally as the appropriate clamp and feeding port supplied within the kit are attached to the external PEG tubing with the site cleaned on completion. Once discharged from the recovery room, the attending dietician is informed such that enteral feeds may be started on the patient's return to the referral ward. The choice of feed and rate thereof is at the discretion of the dietician. The patient is reviewed by the PEG insertion team for 48 hours ensuring no early intra-abdominal complications have occurred.

Locally absolute and relative contraindications to PEG tube insertion included patients with pre-existing ventriculoperitoneal shunts (V-P shunt), advanced malignancy such as stomach or peritoneal metastatic cancers, previous subtotal or total gastrectomy, pregnancy at time of PEG insertion, tense ascites, gastroparesis or any obstruction of the stomach or distal thereof (7).

Definition of complications

Complications that occurred during hospitalization were graded according to severity using the Clavien-Dindo classification for surgical complications (8) as follows:

- Grade I: Any deviation from normal post-operative course without the need for pharmacological, surgical, endoscopic or radiologic treatment
- Grade II: Requiring pharmacological treatments other than those allowed in Grade I
- Grade III: Requiring surgical or endoscopic treatment
 - o IIIa: Intervention not under general anaesthesia
 - o IIIb: Intervention under general anaesthesia
- Grade IV: Life-threatening complication requiring specialist intensive care management
 - o IVa: Single-organ dysfunction
 - o IVb: Multiple-organ dysfunction
- Grade V: Patient mortality

Complications were also further divided into three different categories related to timing of the complication occurrence as follows:

1. Insertion-related: these were defined as adverse events occurring during or immediately following the placement of a PEG tube, primarily due to mechanical trauma, procedural missteps, or physiological responses to the intervention. These complications varied in severity, ranging from minor, self-limiting conditions to life-threatening events requiring urgent medical intervention.
2. Early complications (within 30 days): these referred to complications that occurred within 30 days post-insertion, resulting from procedural trauma, infection, or device-related issues.
3. Late complications (after 30 days): these were defined as complications that arose after discharge and usually relate to tubing issues.

Direct or indirect complications of PEG insertion such as procedural cardiac and/or respiratory arrest, aspiration, acute respiratory distress syndrome or intestinal perforation causing death were defined as PEG-related mortality (9). Progression of underlying disease resulting in death was not considered a PEG-related mortality.

Data collection and management

All patients requiring a PEG during the study period and meeting the inclusion criteria were identified from two prospective and ethically approved endoscopy registries at Groote Schuur Hospital the Upper Gastrointestinal Surgery Registry (HREC R013/2015) and the Medical Gastrointestinal Registry (HREC R043/2015). Data was retrospectively collected, with the data points collected being age, gender, body mass index (BMI), performance status, indication

for PEG insertion, comorbidities, smoking, white cell count (WCC), haemoglobin (Hb), international normalised ratio (INR), platelets, and complications. Data was retrieved and appropriately anonymised to ensure patient confidentiality.

Statistical analysis

Data exploration and analysis was done using Microsoft Excel and IBM SPSS Statistics (version 28.0.1.1). Patient demographics, comorbidities, PEG insertion and complication details were described using simple descriptive statistics. Parametric data were described using mean with standard deviation and non-parametric data were described using median with inter-quartile range. BMI was divided into three groups as underweight ($<18.5\text{kg/m}^2$), normal ($18.5\text{--}24.9\text{ kg/m}^2$) and overweight ($>24.9\text{kg/m}^2$). Bivariate analysis to assess for associations between early complications and multiple patient factors (including age, sex, BMI, performance status and comorbidities) and PEG-insertion factors (these included factors related to endoscopic factors such as need for oesophageal dilatation, presence of gastritis but also factors related to the PEG itself, such as indication for PEG insertion and the diameter of the tube) was performed using the Chi-squared test for categorical data and the Kruskal-Wallis test to allow for comparison of multiple groups with non-parametric data. Further post-hoc multiple comparison analyses using the Mann-Whitney U test were performed on any variables shown to be statistically significant. A p-value of <0.05 was considered statistically significant.

Results

Patient characteristics and PEG-insertion indications

A total of 149 patients were included, undergoing 158 PEG insertion procedures during the study period. The median age was 54 years (IQR: 38-64 years) with the majority being male (91; 61.1%). BMI was underweight in 42 patients (28.2%), normal in 68 patients (45.6%), overweight in 18 patients (12.1%) and unknown/not recorded in 21 patients (14.1%).

Indication for PEG insertion (Table 1) was categorised into five main groups: neurological, post-traumatic, malignancy, benign oesophageal and other causes. Neurological disorders comprised the largest group which included CVA (38; 25.5%), progressive neurological diseases (23; 15.4%), and cerebral palsy (5; 3.4%). Post traumatic causes included traumatic brain injury (12; 8.1%), and traumatic neck & facial injuries (11; 7.4%). Oncological conditions included resectable obstructive oesophageal malignancy for nutritional rehabilitation (7; 4.7%), benign oesophageal conditions (6; 4.0%) and other causes (6; 4.0%).

Table 1: Overview of indications for PEG insertion. ^aPEG = percutaneous endoscopic gastrostomy; ^bCVA = cerebrovascular accident

Indication for PEG^a (n = 149)	No	%
CVA ^b	38	25.5%
Head & Neck Malignancy	32	21.5%
Progressive Neurological Condition	23	15.4%
Traumatic Brain Injury	12	8.1%
Trauma - Neck/Facial	11	7.4%
Oesophageal Malignancy	7	4.7%
Benign Oesophageal	6	4.0%
Cerebral Palsy	5	3.4%
Pharyngeal & Oesophageal Fistula	5	3.4%
Optimisation for lung transplant	4	2.7%
Other	6	4.0%

The most common comorbidities were other chronic neurological conditions (30; 20.1%), with hypertension (35; 23.5%) as the leading non-neurological condition, while smoking (42; 28.2%) was the most prevalent substance use, and HIV (11; 7.4%), diabetes (10; 6.7%), and ethanol use (7; 4.7%) were less frequent. Table 2 demonstrates comorbidities and substance use.

Table 2: Patient comorbidity and substance use. ^bHIV = human immunodeficiency virus, ^cNSAIDs = non-steroidal anti-inflammatory drugs

Comorbidity (n = 149)	No.	%
Other Chronic Neurological Condition	30	20.1%
Hypertension	35	23.5%
Malignancy	24	16.1%
Chronic Lung Disease	15	10.1%
HIV ^b	11	7.4%
Diabetes	10	6.7%
Other	24	16.1%
Substance Use (n = 149)	No.	%
Smoker	42	28.2%
NSAIDs ^c	2	1.3%
Recreational Drugs	3	2.0%
Chronic Corticosteroid Use	1	0.7%
Regular Ethanol Use	7	4.7%

Complications (insertion-related, early and late)

Overall, 64 patients (43.0%) experienced a total of 76 separate complications (Table 3). The severity of the complications was low, with only two patients (2.6%) requiring general anaesthesia for management of the complication (Clavien-Dindo IIIb), while the rest required mainly endoscopic management without general anaesthesia (53 patients, 69.7%, Clavien-Dindo IIIa) or only pharmacological therapy (18 patients, 23.7%, Clavien-Dindo II). No patient developed organ dysfunction requiring intensive care. There were no mortalities linked to the PEG insertion in this cohort. Table 3 outlines the reported complication.

The insertion-related complication rate was 10.8% (17 cases), with the majority of attributed to sedation issues with 12 patients (7.6%) requiring sedation reversal. Significant laryngospasm occurred in 2 patients (1.3%).

The early complication rate (<30 days) was 17.7% (28 cases) with accidental PEG removal noted as the most common occurrence (15; 9.5%) Buried bumper syndrome featured in almost equal frequency as both an early complication, (4; 2.5%), and a late complication, 6 cases

(3.8%). PEG site sepsis was seen as an early complication in 6 cases (3.8%). All six of these cases had cellulitis managed with antibiotics and local wound management, with none requiring surgical debridement.

The late complications (>30 days) were most frequent at 19.6% (31) with the vast majority relating to accidental removal (20; 12.7%). Other late complications included leakage around the insertion site (8; 5.1%), buried bumper syndrome (6; 3.8%) and PEG tube blockage 2 cases (1.3%). Infrequent complications irrespective of timeline included insertion through the transverse colon, accidental tooth extraction, bite block dislodgement into the pharynx, bleeding and incisional hernia. The PEG-insertion through the colon was only diagnosed seven days post PEG insertion when faecal material was seen draining from the tract (the patient was clinically well with a soft, non-tender abdomen). The incisional hernia developed more than 3 years post the initial PEG insertion. Both were managed with surgery, and both had subsequent good outcomes without further complications.

Table 3: Insertion-related, early, and late complications of PEG placement, and Clavien-Dindo classification for all complications. ^aPEG = percutaneous endoscopic gastrostomy

Complications (n = 158)	No.	%
Insertion-related Complication Rate	17	10.8%
Early Complication Rate (≤30 days)	28	17.7%
Late Complication Rate (>30 days)	31	19.6%
Insertion-related Complication		
Sedation-related complication	12	7.6%
Laryngospasm	2	1.3%
Accidental tooth extraction	1	0.6%
Bite block dislodgement	1	0.6%
Bleeding	1	0.6%
Early Complications (≤30 days)		
Accidental Removal	15	9.5%
PEG ^a -site sepsis	6	3.8%
Buried Bumper	4	2.5%
Significant leaking around PEG-site	3	1.9%
Blocked PEG	1	0.6%
Insertion through transverse colon	1	0.6%
Late Complications (>30 days)		

Accidental removal	20	12.7%
Significant leaking around PEG-site	8	5.1%
Buried Bumper	6	3.8%
Necrosis of PEG tract	2	1.3%
Blocked PEG	2	1.3%
PEG-site Sepsis	1	0.6%
Incisional Hernia	1	0.6%
Clavien-Dindo Classification for All Complications (n=76)		
Grade I	3	3,9%
Grade II	18	23,7%
Grade IIIa	53	69,7%
Grade IIIb	2	2,6%
Grade Iva	0	0,0%
Grade IVb	0	0,0%
Grade V	0	0,0%

Factors associated with early complications

Bivariate analysis was performed to assess for factors associated with an increased risk of early complications. None of the factors analysed (including demographics, comorbidities, BMI, indication for PEG placement, presence of gastritis or need for oesophageal dilatation), other than the size of the PEG tube showed a positive association (*Table 4*). Overall, the 24Fr PEG was the commonest size utilized in 102 cases (68.9%) and was responsible for early complications in 26 cases (25.5%). Compared to smaller tubes, this rate of early complications was significantly higher and reached statistical significance (25.5% vs 3.7%, $p<0.001$).

Table 4: Bivariate analysis of associations between numerous patient and PEG insertion factors and early complication rate.

^aBMI = body mass index; ^bPEG = percutaneous endoscopic gastrostomy; ^cCVA = cerebrovascular accident;

^dECOG = Eastern Cooperative Oncology Group

Patient Factors (n=149)		Early Complication		p-value
Age	≥ 50 years	15	17.4%	0.623
	< 50 years	13	20.6%	
Gender	Female (n = 58)	11	19.0%	0.966
	Male (n = 91)	17	18.7%	
BMI ^a (n=128)	<18.5 (n = 42)	6	14.3%	0.241
	18.5-24.9 (n = 68)	13	19.1%	
	>24.9 (n=18)	5	27.8%	
Indication for PEG ^b Insertion	CVA ^c (n = 38)	7	18.4%	0.327

			Head/Neck Malignancy (n = 32)	9	28.1%	
			Progressive Neurological Condition (n = 23)	3	13.0%	
			Traumatic Brain Injury (n = 12)	3	25.0%	
			Trauma - Neck/Facial (n = 11)	3	27.3%	
			Oesophageal Malignancy (n = 7)	1	14.3%	
			Benign Oesophageal (n = 6)	0	0.0%	
			Cerebral Palsy (n = 5)	0	0.0%	
			Pharyngeal/Oesophageal Fistula (n = 5)	0	0.0%	
			Optimisation for lung transplant (n = 4)	0	0.0%	
			Other	2	33.3%	
Diabetes			Not Diabetic (n = 139)	28	20.1%	0.116
			Diabetic (n = 10)	0	0.0%	
Hypertension			Not Hypertensive (n = 114)	23	20.2%	0.437
			Hypertensive (n = 35)	5	14.3%	
Chronic Lung Disease			No Chronic Lung Disease (n = 134)	28	20.9%	0.05
			Chronic Lung Disease (n = 15)	0	0.0%	
CVA			No CVA (n = 117)	20	17.1%	0.312
			CVA (n = 32)	8	25.0%	
Other Neurological Condition			No Other Neurological Condition (n = 119)	24	20.2%	0.393
			Other Neurological Condition (n = 30)	4	13.3%	
Traumatic Brain Injury			No Traumatic Brain Injury (n = 139)	28	20.1%	0.116
			Traumatic Brain Injury (n = 10)	0	0.0%	
Malignancy			No Malignancy (n =125)	23	18.4%	0.781
			Malignancy (n =24)	5	20.8%	
Smoker			Not Smoker (n = 107)	21	19.6%	0.678
			Smoker (n = 42)	7	16.7%	
Ethanol			No Regular Alcohol Use (n = 142)	27	19.0%	0.755
			Regular Alcohol Use (n =7)	1	14.3%	
ECOG^d (n=127)	Performance	Status	PS 0 (n = 19)	7	36.8%	0.55
			PS 1 (n = 28)	4	14.3%	
			PS 2 (n = 29)	5	17.2%	
			PS 3 (n = 22)	7	31.8%	
			PS 4 (n = 29)	5	17.2%	
PEG Insertion Factors (n=158)				Early Complication		p-value
PEG Size (n=148)			Size 24Fr (n=102)	26	25.5%	<0.001
			Size 20Fr or smaller (n=54)	2	3.7%	
Presence of Gastritis			No gastritis (n=130)	23	17.7%	0.984
			Gastritis (n=28)	5	17.9%	
Requiring Oesophageal Dilatation			No oesophageal dilatation (n=145)	25	17.2%	0.599
			Oesophageal dilatation (n=13)	3	23.1%	

Discussion

PEG placement is considered a relatively safe procedure. However, life-threatening complications may occur and can arise at any stage of post-procedural care (3). Our study found that almost half (43.0%) of patients experienced complications following PEG tube placement. This surprisingly high percentage, however, includes the whole spectrum of insertion-related, early and late complications, highlighting the potential morbidity of the procedure.

Internationally, the complication rates vary greatly across settings, with overall rates in adult cohorts ranging from approximately 16 % (Lockett et al.) to 32-44.9 % (Afifi et al.; Alhasani et al.) and a paediatric study by Gang & Kim reporting short-term rates as high as 84.6 % (2,3,10–13). Insertion-related complications were often related to patient factors such as sedation and aspiration and ranged from minor issues to serious adverse events. Aspiration pneumonia, particularly in patients with neurological disorders, was a significant complication. The risk of aspiration was noted to be exacerbated by factors like the level of sedation, supine positioning during the procedure, and impaired protective airway reflexes (14). Nicholson et al. emphasized that patients with severe respiratory disease may be too frail for the sedation necessary for endoscopy, further elevating the risk of aspiration (15). According to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD), 9% of patients undergoing PEG required reversal of sedation, indicating potential oversedation and associated respiratory complications. Three percent of patients also experienced hypoxaemia ($\text{SpO}_2 \leq 90\%$) during the procedure, underscoring the need for careful sedation management (16).

Short-term complications, occurring within days to weeks after PEG insertion, were generally more frequent, and had the highest percentage of septic related issues such as local site infections, bleeding, and tube dislodgement. Blomberg et al. reported a 39% complication rate within one month, while a study done in the United Arab Emirates in 2012 reported a 39%

complication rate at two weeks (17,18). In contrast, long-term complications were dominated by tube issues such as buried bumper syndrome, tube blockage, or granulation tissue formation, were typically less common but still clinically relevant. Studies like that by Ermis et al. (18% at one year) and Alhasani et al. (44.9% within a year) highlight that adverse events can persist or emerge over time (3,19).

An earlier study of 36 patients by Watermeyer et al., from our institution, demonstrated comparable morbidity, mortality and long-term outcomes. However, a small number of patients were studied, where minor complications were reported in 36% of cases and which occurred commonly within the first week following the procedure (20). The wide range in complication rates is most likely due to differences in patient characteristics (e.g., age, health, healthcare access). Across these studies, the early post-procedural period (within 30 days of PEG placement) appears to carry the highest risk for complications, particularly minor ones, reinforcing the need for vigilant monitoring and standardised care protocols during this phase. We found that neurological disorders were the most common indication with CVA reported at 25.5%. This could be explained by the fact that neurological dysphagia is a common finding after stroke (9). These findings are similar to a study carried out by Abdel Azim Morsy Afifi et al., where stroke with bulbar symptoms was reported as the most common indication for PEG insertion at 45% (2). Accidental removal was noted as the most common complication seen both as an early complication at 9.5% and as a late complication at 12.7%. These numbers are much higher than those reported by Seamon et al., who reported a rate of 1.6% - 4.4% with this complication commonly reported in confused and/or combative patients (4).

Buried bumper syndrome is caused by excessive tension between the stomach wall and the skin leading to ulceration of the gastric wall at the site of the bumper (9). This syndrome is a potentially dangerous complication with an incidence of 0.5 - 2.4% (2,4). In our study, occurrence of buried bumper syndrome featured in almost equal frequency as both an early

complication (2.5%) and late complication (3.8%). These numbers are slightly higher than the standard reported rate of 0.3-2.4% of patients (2,7,9,17).

PEG site sepsis was seen commonly as an early complication at 3.8% in comparison to late complications at 0.06%. Thus, infection remains the less common complication associated with PEG tubes with the advent of routine prophylactic antibiotic use (3). The use of antibiotic prophylaxis is reported to reduce the occurrence of infection by 3% (4). In stroke patients and patients on cardiac supportive apparatuses, thrombocyte aggregation inhibitors (e.g., acetylsalicylic acid [Aspirin®, Bayer Schering Pharma, Germany] or clopidogrel [Plavix®, Bristol-Myers Sanofi Pharmaceuticals Partnership, USA]) were generally not discontinued before PEG insertion, and treatment with low molecular weight heparin (LMWH Enoxaparin; Clexane) did not prevent placement. (11,20,21)

Blockage of PEG tube featured in equal frequency as both an early complication at 0.6% and a late complication at 1.3%. This is lower than what Seamon et al., reported in their study where PEG tube blockage occurred in up to 45% of the cases (4). Abdel Azim Morsy Afifi et al., reported a 2.1% incidence of minor PEG tube blockage and 0.3% incidence of major blockage requiring tube exchange (2). Alhasani et al., reported a blockage rate of 2% (3). PEG tube leakage, on the other hand, has been reported more frequently in older patients possibly due to weaker immune systems, which can delay healing and increase infection risk. Similar findings were observed in a study conducted by Lee et al., where older age and diabetes were risk factors for complications (12). In our study age played no role in infective risk post-PEG placement. A poor nutritional status is expected to delay healing in malnourished patients and a high BMI potentially should have more infective issues due to the length of the tract through the abdominal adiposity, yet the extreme BMI ranges were not associated with any increased complications in our cohort.

Following bivariate analysis, the only positive association within this cohort for increased risk of early complications was the diameter of the tubing. A 24Fr PEG was the commonest size (68.9%) utilized and was responsible for higher early complications (25.5% vs 3.7%, $p < 0.001$). With an odds ratio of 1.26 for 1-Fr increments, a Korean study conducted by KASID research (Korean Association for the research of Intestinal Diseases) demonstrated a significant relationship between PEG tube diameters and the occurrence of adverse events (21). Conversely, a study conducted by Shangab M et al., showed a high correlation between PEG tube diameter and minor adverse events, with smaller PEG tube sizes being associated with PEG tube blockage and removal (18).

An increase in complication rates may be due to study duration. Other studies concentrated on shorter time periods, whereas our study included any late adverse event beyond 30 days occurring within the overall study period.

Limitations

This study faced several limitations due to its retrospective design. Firstly, reliance on existing medical records introduced challenges related to data completeness and accuracy. Some files lacked comprehensive documentation, particularly regarding complications and follow-up, potentially leading to underreporting. Additionally, several patients were referrals from external facilities and were subsequently lost to follow-up, further contributing to data gaps. Selection bias was another concern, as participants were not randomly selected but were included based on record availability, possibly skewing the data. Documentation bias also posed a challenge; minor or subjective complications may have gone unrecorded due to variability in clinician reporting practices. The observational nature of the study also limited our ability to draw definitive causal inferences.

Confounding variables, such as comorbidities, procedural differences, and disparities in post-PEG care, could not be fully controlled for, thus potentially influencing the frequency and type of complications observed. Furthermore, the absence of standardized definitions and classification criteria across records led to inconsistencies in how complications were reported. Finally, the lack of long-term follow-up data likely resulted in an underestimation of late-onset complications, and the absence of a prospective control group limited comparative analysis. These factors collectively impacted the generalizability and interpretability of our findings.

Recommendations for future research

Future advancements in retrospective studies on percutaneous endoscopic gastrostomy (PEG) complications can be realized through several avenues. Enhancing data quality via the integration of electronic health records (EHRs) with standardized data entry templates would significantly improve accuracy, completeness, and uniformity, thereby minimizing documentation gaps. Expanding research through multicentre collaboration presents an opportunity to increase sample sizes, improve population diversity, and enhance the external validity of findings by capturing a wider spectrum of clinical practices and patient profiles. Additionally, the application of advanced analytical tools, including machine learning algorithms and multivariate statistical models, could facilitate the identification of complication patterns, prediction of adverse outcomes, and adjustment for confounding factors. Establishing a universally accepted framework for defining and reporting PEG-related complications would also improve consistency and allow for more reliable cross-study comparisons.

Longitudinal data collection through national registries or institutional databases would enable tracking of long-term outcomes, offering insights into delayed complications and improve follow-up completeness. Subgroup analyses targeting vulnerable populations such as

paediatric, geriatric, or neurologically compromised patients could uncover population-specific risk factors and guide personalized interventions. Moreover, integrating patient or caregiver-reported outcomes may help capture subjective experiences such as discomfort or quality-of-life impacts. Comparative studies using retrospective data to compare PEG outcomes with alternative enteral feeding modalities such as nasogastric tubes or surgical gastrotomy, would further inform clinical decision-making.

Conclusion

PEG tube insertion remains a rapid, readily accessible, and vitally important feeding route for many patients in our setting. However, PEG placement is associated with a high complication rate, although most complications are mild and comparable with other international data. The most significant finding was that larger tube size seems to increase early complication rate in our setting. We advocate for appropriate patient selection, good patient follow-up and most practically the use of 20Fr sized tubes to reduce these complications.

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Appendices

Appendix 1: HREC Approval Letter



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



Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

11 May 2023

HREC REF: 289/2023

Prof M Setshedi
Division of Gastroenterology
E-23 NGSH
Email: mashiko.sethsedi@uct.ac.za

Dear Prof Setshedi

PROJECT TITLE: PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) TUBE PLACEMENT: INDICATIONS, MANAGEMENT, COMPLICATIONS, OUTCOMES AND CARE APPLIED TO ENDOSCOPY UNIT PATIENTS IN A TERTIARY CARE HOSPITAL-

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, subject to providing Form A.

Approval is granted for one year until the 30 May 2024.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF 289/2023 in all your correspondence.

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

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

Yours sincerely


PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical

HREC/ref 289.2023

Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.



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



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Website: www.health.uct.ac.za/home/human-research-ethics

04 November 2025

HREC REF: 289/2023

Dr Matthias Scriba
Surgical Gastroenterology
E-23 NGSH
Email: matthias.scriba@gmail.com
Student: munenedominic@gmail.com

Dear Dr Scriba

PROJECT TITLE: PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) TUBE PLACEMENT: INDICATIONS, MANAGEMENT, COMPLICATIONS, OUTCOMES AND CARE APPLIED TO ENDOSCOPY UNIT PATIENTS IN A TERTIARY CARE HOSPITAL-

Thank you for submitting the study staff amendment (FHS007) dated 20 October 2025 to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review and approval.

The HREC acknowledges that the Mphil Candidate Dr Dominic Munene Mutura is involved in the above-mentioned study.

The study is approved until **30 April 2026**.

Please quote the HREC REF 289/2023 in all your correspondence.

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

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

Appendix 2: Form FHS011 Study Deviation Letter



UNIVERSITY OF CAPE TOWN
UNIVERSITEIT VAN KAAPSTAD

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee



FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
☒ Approved	Annual progress report	Approved until/next renewal date	30.04.2026
☐ Not approved	See attached comments		
Signature Chairperson of the HREC/ Designee			Date Signed 16/4/2025

Note: Please email this form and supporting documents (if applicable) in a combined pdf file to hrec-enquiries@uct.ac.za.

Please use the latest form found on our website:
<http://www.health.uct.ac.za/fhs/research/humanethics/forms>

Comments to PI from the HREC



Thank you for your Study
Deviation

28/4/23

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	14 th April 2025		
HREC REF Number	289/2023	Current Ethics Approval was granted until	30 th May 2024
Protocol title	Percutaneous Endoscopic Gastrostomy (Peg) Tube Placement: Indications, Management, Complications, Outcomes and Care Applied to Endoscopic Unit Patients in A Tertiary Care Hospital		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?		☐ Yes	☒ No
If yes, could you please provide the HREC Reference number for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			

HREC Chair Signature

Date: 16/4/2025



Principal Investigator	Dr Matthias Scriba
Department and email address	E23 Gastrointestinal Unit, Groote Schuur Hospital Main Road, Observatory, Cape Town, 7925

1.1 Does this protocol receive US Federal funding?	☐ Yes	☒ No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☒ No
Note: Any annual approvals for Full Committee review MUST be submitted on the monthly HREC submission dates. (Please send electronic combined copy if for full committee review to hrec-submission@uct.ac.za)		

If yes in 1.2 please complete section 1.3 below for invoicing purposes

1.3 Ethics Renewal Fee

Please (tick ✓) appropriate box for billing purposes:

<u>Submission Type</u>	<u>Description</u>	<u>New fee (Vat Incl.)</u>	<u>tick ✓</u>
Research funded solely from UCT departmental/divisional/group budget/self-initiated research	Annual evaluation of research progress report for re-certification	R0,00	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Annual evaluation of research progress report for re-certification	R0,00	☒
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R7700,00	☐
Annual re-certification / Progress report (FHS016 Form)	Clinical Trial & International Grant Funded Research - Annual evaluation of research progress report for re-certification for Expedited review	R3800,00	☐
Annual re-certification / Progress report (FHS016 Form)	National grant funded research - Annual evaluation of research progress report for re-certification for Full Committee Approval	R5000,00	☐
Annual re-certification / Progress report (FHS016 Form)	National Grant funded research for Annual evaluation of research progress report for re-certification for Expedited review	R1650,00	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
----------------	--



Billing Address of Sponsor:	
Vat Number:	
Contact person	
Telephone number	
Email Address	
2. Internal Journal Billing:	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

2. List of documentation included to support this approval where applicable

--

3. Protocol status (tick ✓)

☐	Open Enrolment
☐	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
☒	Research-related activities are complete, data analysis only
☐	Main study is complete but sub-study research-related activities are ongoing
☐	Publication or thesis submitted and final completion?
☐	Study is closed → Please submit a Study Closure Form (FHS010)

4. Enrolment

Number of participants enrolled to date	149
Number of participants enrolled, since last HREC Progress report (continuing review)	149
Additional number of participants still required	None

5. Refusals

Total number of refusals (participants invited to join the study, but refused to take part)	None (retrospective data)
---	---------------------------

6. Cumulative summary of participants

Total number of participants who provided consent	149
Number of participants determined to be ineligible (i.e. after screening)	0
Number of participants currently active on the study	149
Number of participants completed study (without events leading to withdrawal)	149
Number of participants withdrawn at participants' request (i.e. changed their mind)	0
Number of participants withdrawn by PI due to toxicity or adverse events	0
Number of participants withdrawn by PI for other reasons (e.g. pregnancy, poor compliance)	0
Number of participants lost to follow-up. Please comment below on reasons for loss of follow-up.	0
Number of participants no longer taking part for reasons not listed above. Please provide reasons below:	

7. Progress of study

Please provide a brief summary of the research to date including the overall progress and the progress since the last annual report as well as any relevant comments/issues you would like to report to the HREC:
The retrospective research on the PEG study has concluded, with overall progress marked by successful data collection and analysis. Key outcomes have been documented, and all objectives of the study were met within the designated timeframe. No significant issues arose during the study. There are no additional comments or concerns to report to the HREC at this time. The study is currently being written up for the purposes of submission as a Masters in Philosophy (Subspeciality: Medical Gastroenterology) and for publication in a peer-reviewed journal

8. Protocol violations and exceptions (tick ✓ all that apply)

☒	No prior violations or exceptions have occurred since the original approval
☐	Prior violations or exceptions have been reported since the original approval and have already been acknowledged or approved If so, did these occur in the last review period
☐	Unreported minor violations that have occurred since the last review, as well as significant deviations not yet reported, are attached for review

9. Amendments (tick ✓ all that apply)

☐	No Prior amendments have been made since the original approval
☒	Prior amendments have been reported since the last review and have already been approved
☐	New protocol changes/ amendments are requested as part of this continuing review (See note below)

Note: If new protocol changes are being requested in this review, please complete an amendment form (FHS006).

Specific changes in the amended protocol and consent/assent forms must be **bolded**, *italicised* or tracked and all changes must include a rationale.

10. Adverse events

10.1 Please provide below or attach a narrative summary of serious adverse events and/ or unanticipated problems since the last progress report. Please indicate changes made to the protocol and informed consent document(s) as a result (if not already reported to the HREC). Please comment on whether causality to any study procedure or intervention could be established.

None

10.2 Have participants received appropriate treatment/ follow-up/ referral when indicated (e.g. in the case of abnormal or incidental clinical findings, distress or anxiety)?

☐ Yes ☐ No ☒ Not applicable

If yes, please describe:

11. Summary of Monitoring and Audit Activities (tick ✓)

11.1 Was this study monitored or audited by an external agency (e.g. SAHPRA, FDA)?

☐ Yes ☐ No ☒ Not applicable

11.2 Did a Data and Safety Monitoring Board publish a report?

☐ Yes ☐ No ☒ Not applicable

11.3 If yes, please identify the agency and attach a summary of the findings.

Agency Name		Report attached	☐ Yes	☐ No	☐ Not applicable
		DSMB report attached	☐ Yes	☐ No	☐ Not applicable

11.4 Has there been any agency, institutional or other inquiry into non-compliance in this study, or any finding of non-compliance concerning a member of the research team?

☐ Yes ☒ No

If yes, please explain:

--

12. Level of risk (tick ✓)

12.1 In light of your experience of this research, please indicate whether the level of risk to participants has:

☐ Increased

☐ Decreased

☒ Shown no change

If there has been a change, please explain:

--

12.2 Please provide a narrative summary of recent relevant literature that may have a bearing on the level of risk.

--



13. Insurance

Please confirm that valid no fault insurance is still in place? (tick ✓)			
☐ Yes		☐ No	
If yes, please complete the following:			
Insurer's name:			
Policy no.		*Coverage Period:	
For UCT sponsored studies please liaise the Insurance office via fhs.sponsorship@uct.ac.za regarding the required documentation and information required obtain a renewed UCT No-fault Insurance Certificate.			

14. Statement of conflict of interest

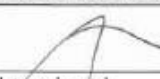
Has there been any change in the conflict of interest status of this protocol since the original approval? (tick ✓)	
☐ Yes	☒ No
If yes, please explain and if necessary, attach a revised conflict of interest statement (Section #7 in the New Protocol Application Form FHS013):	

15. Signature

My required signature certifies that the above is complete and correct.			
Signature of PI		Date	14 th April 2025



Form FHS011: Study deviation

HREC office use only (FWA00001637; IRB00001938)		
This serves as acknowledgement of a protocol deviation as described below.		
Chairperson of the HREC signature/ Designee		Date 16/4/2025

Note: Please note that incomplete submissions will not be reviewed.

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za. Our website address: <https://health.uct.ac.za/home/human-research-ethics>

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	14 th April 2025	HUMAN RESEARCH ETHICS COMMITTEE 16 APR 2025 HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN
HREC REF Number	289/2023	
Project Title	Percutaneous endoscopic gastrostomy (PEG) tube placement: indications, management, complications, outcomes, and care applied to Endoscopy Unit patients in a tertiary care hospital.	
Protocol number (if applicable)		
Principal Investigator	Dr Matthias Scriba	
Department and Email address	E23 Gastrointestinal Unit, Groote Schuur Hospital Main Road, Observatory, Cape Town, 7925	

2. Protocol deviation description

Please describe the deviation below, including the reason why the deviation has occurred.

This report addresses a deviation from the original study protocol due to an unanticipated delay in the study period. The delay occurred because of personal academic commitments, specifically the need to prepare for and complete final CMSA exams. Consequently, this led to an oversight in submitting the protocol update form within the designated timeframe. This deviation has been documented to ensure transparency and to outline the steps taken to mitigate any potential impact on the study's integrity. Future measures will be implemented to prevent similar issues, including better time management and scheduling for academic responsibilities alongside research activities.

3. Follow-up actions

3.1 Please describe any follow-up action(s) taken or planned as a result of this deviation e.g. DSMB reporting, report to sponsor, informing participants.



Advance Planning: Created a checklist of protocol updates and submission deadlines well in advance of academic obligations. This helped prioritize tasks and maintain compliance with study timelines.

Regular Check-ins: Scheduled regular meetings with principal investigator to discuss progress, challenges, and any required updates to analysis.

Setting Reminders: Use digital calendars to set reminders for important deadlines, such as submitting protocol update forms and conducting study assessments.

Communication with Ethics Board: Proactively communicate with the ethics review board about potential delays and ensuring they are informed and can provide guidance.

3.2 Please describe what action(s) have or will be taken to prevent similar deviations in future.

Actions as enumerated above.

Communication with Ethics Board: FHS016 form submission done

4. Principal Investigator's acknowledgement of responsibility

The required signature indicates the PI has reviewed the deviation, taken appropriate follow-up action and implemented or plans to implement preventative steps where possible.

Signature of PI		Date	14/04/2025
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Appendix 3: Hospital Approval Letter



GROOTE SCHUUR HOSPITAL

Enquiries: Mr Lionel Naidoo

e-mail: GSHResearch.Request@westerncape.gov.za

Prof Mashiko Setshedi / Dr Matthias Scriba
Division of Gastroenterology
mashiko.setshedi@uct.ac.za

Dear Prof Mashiko Setshedi / Dr Matthias Scriba

RESEARCH PROJECT: Percutaneous Endoscopic Gastrostomy (PEG) tube placement: Indications, management, complications, outcomes, and care applied to endoscopy unit patients in a tertiary care hospital.

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 April 2026**.

Please note the following:

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist with the research.
- c) **Confidentiality must always be maintained.**
- d) No additional costs to the hospital should be incurred as indicated in your Annexure 2 i.e. Lab, consumables or stationery. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form and approach Information Management to assist with data.**
- e) **No patient folders may be removed from the premises or be inaccessible.**
- f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
- g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
- h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
- i) Please discuss the study with the HOD before commencing.
- j) Please introduce yourself to the person in charge of an area before commencing.
- k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
- l) If the researcher is not GSH staff member, a supernumerary contract is required before commencement of the research.
- m) Please contact Michelle Riley (Patient Fees) at ext. 2276 to ascertain if there will be charges for conducting the Research and to obtain a quote or to discuss charges
- n) **Kindly submit a copy of the publication or report to this office on completion of the research.**
- o) **At no time should any posters encouraging patients to partake in research be displayed within a clinical area.**
- p) **All Clinical Trials to be registered on Clinicom with Michelle Riley. michelle.riley@westerncape.gov.za**
- q) **All clinical personnel viewing/using patient folders for research purposes must be carried out according to the following:**
Patient folders must be researched in the Medical Records Department (Medical Research Suite, A14, New Main Building).
No research patient folders may be removed from the Medical Records Department.
Patient folders required for research purposes may not be requested via clerical staff and the Clinicom system.
Non-compliant researchers could have their GSH institutional research approval revoked.

I would like to wish you every success with the project.

Yours sincerely

LIONEL NAIDOO
HEAD: ALLIED HEALTH
Date: 14 October 2025.
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Appendix 4: Author Guidelines of the SAJCN

Author Instructions

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Author instructions

All manuscripts and correspondence to be submitted electronically to: www.sajcn.co.za

Copyright

Material submitted for publication in the South African Journal of Clinical Nutrition (SAJCN) is accepted provided it has not been published elsewhere. Copyright forms will be sent with acknowledgement of receipt and the SAJCN reserves copyright of the material published. The SAJCN does not hold itself responsible for statements made by the authors.

Authorship

All named authors must give consent to publication. Authorship should be based only on substantial contribution to: (i) conception, design, analysis and interpretation of data; (ii) drafting the article or revising it critically for important intellectual content; (iii) final approval of the version to be published. All three of these conditions must be met (Uniform requirements for manuscripts submitted to biomedical journals: www.icmje.org/index.html).

Manuscripts

Short items are more likely to appeal to our readers and therefore to be accepted for publication. **Manuscript should not exceed 4000 words in total all contents inclusive.**

Original articles of 4 000 words or less, with up to 6 tables or illustrations, should normally report observations or research of relevance to the field of nutrition. References should preferably be limited to no more than 25.

Short reports or scientific letters, which include case reports, side effects of nutrient supplements/drugs and brief or negative research findings should be 1000 words or less, with 1 table or illustration and no more than 6 references.

Editorials, Opinions, Issues in the field of nutrition, should be about 1000 words and are welcome, but unless invited, will be subjected to the SAJCN peer review process.

Review articles are rarely accepted unless invited.

Letters to the editor, if intended for the correspondence column, should be marked 'for publication', signed by all authors and presented in triple spacing. Letters should be no longer than 400 words with only one illustration or table.

Obituaries should not exceed 400 words and may be accompanied by a photograph.

Manuscript preparation

- Please submit your manuscript electronically at www.sajcn.co.za. (Register as an author, log in and follow the 5 steps to upload your manuscript.)
- Please submit the manuscript as a MS Windows Word document.
- Please have your manuscript edited by a language expert or colleague proficient in English prior to submission. Articles must be in UK English.
- All manuscripts must include an abstract (50-250 words).
- Research articles should have a structured abstract not exceeding 250 words (50 for short reports) comprising: Objectives, Design, Setting, Subjects, Outcome measures, Results and Conclusions.
- Refer to articles in recent issues for guidance on the presentation of headings and subheadings.
- Abbreviations should be spelt out when first used in the text and thereafter used consistently.
- Scientific measurements should be expressed in SI units except: blood pressure should be given in mmHg and haemoglobin values in g/dl.

If in doubt, refer to www.icmje.org/index.html

Illustrations

1. All illustrations must be submitted electronically. High resolution (300dpi) .jpg or .tiff files are preferred.
2. Figures consist of all material that cannot be set in type, such as photographs and line drawings.
3. Tables and legends for illustrations should appear on separate sheets and should be clearly identified.

4. Line drawings should be arranged to conserve vertical space. Note that reduction to 80 mm for a single column or 170 mm for double columns should not render lettering illegible. Explanations should be included in the legend and not on the figure itself.

5. Figure numbers should be clearly marked on the back of prints and the top of illustrations should be indicated.

6. If any tables or illustrations submitted have been published elsewhere, written consent to republication should be obtained by the author from the copyright holder and the author(s).

7. A limited number of illustrations are free at the discretion of the editor. Colour illustrations are encouraged but are charged to the author.

References

References should be inserted in the text as superior numbers and should be listed at the end of the article in numerical and not in alphabetical order.

Authors are responsible for verification of references from the original sources.

References should be set out in the Vancouver style and approved abbreviations of journal titles used; consult the List of Journals in Index Medicus for these details.

Names and initials of all authors should be given unless there are more than six, in which case the first three names should be given followed by et al. First and last page numbers should be given.

Journal references should appear thus:

1. Price NC. Importance of asking about glaucoma. *BMJ* 1983; 286: 349-350. Book references should be set out as follows:

1. Jeffercoat N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975: 96-101.
2. Weinstein L, Swartz MN. Pathogenic properties of invading microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974: 457-472.

Manuscripts accepted but not yet published can be included as references followed by (in press).

Unpublished observations and personal communications may be cited in the text, but not in the reference list.

Manuscript revisions

In the event of a manuscript needing revision following the peer review process, all revision changes to the original manuscript should be made using the "track changes" function in Microsoft Word, or in any other such similar format so as to facilitate the speedy completion of the review process. In the event of an "author-reviewer" difference of opinion, the author(s) should state their opinion in writing in the text, which should be bracketed. Revised manuscripts which do not conform to this revision format will be returned to the authors for editing.

Revised manuscript should be resubmitted electronically within 3 weeks of receipt thereof.

Galley proofs

Galley proofs will be forwarded to the author before publication and if not returned, it will be regarded as approved. Please note that alterations to typeset articles are costly and will be charged to the authors.

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