

Tanzanian Colorectal Cancer Cohort Study

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Research Plan

A. Specific Aims

Globally, 4 billion people are estimated to lack access to safe surgery with a majority of those people living in Sub Saharan African (1). This inequality has led to multiple initiatives to improve the access and quality of surgery provided in several countries within Sub Saharan Africa. Tanzania specifically has created a National Surgery Obstetrics and Anesthesia Plan (NSOAP) to address this need in the country. One of the pillars of the NSOAP is to collect data on the incidence of surgical disease and the peri-operative outcomes, but no data is currently collected prospectively on all patients undergoing colorectal surgery in the country. **The overall objective of this proposal** is to describe the clinical, financial, and functional outcomes of patients with colorectal disease who undergo laparotomy at Muhimbili National Hospital (MNH). We propose to conduct a **hypothesis generating preliminary mixed methods study** to accomplish our objective, as described in the following **specific aims**:

Problem 1: Little is known about the spectrum of surgical disease, or operative outcomes of patients undergoing colorectal surgery at MNH.

Aim 1: To describe the burden of surgical colorectal disease, proportion of curative versus palliative operations, and inpatient outcomes of participants undergoing laparotomy surgery at MNH.

Problem 2: The financial burden of receiving colorectal surgery and the effect of surgical interventions on patient quality of life in Tanzania is unknown.

Aim 2: To describe patients' post-operative functional status and rates of catastrophic medical expenditure among patients undergoing colorectal surgery at MNH.

Access to safe surgery is a public health priority for Tanzania. To improve the country's system of surgical care it is imperative to understand the burden of surgical disease, outcomes from surgical interventions, and the financial and social ramifications of colorectal surgery. This study will fill a needed data gap for the country by providing information on patients undergoing colorectal surgery *at the only national referral hospital* in the country. This information can be used by policymakers, researchers, hospital administrators, and Tanzanian clinicians as they work towards improving surgical care.

B. Significance

Globally, colorectal cancer (CRC) is the third most common malignancy and the second most common cause of cancer death. Incidence is increasing dramatically and it is estimated that there will be 2.2 million cases and 1.1 million deaths by 2030 (2,3). Currently, a majority of these patients live in countries with high human development indices (HDI) in Europe and North America, but an aging population and improvement in HDI is projected to lead to a rise in incidence in low- and middle-income countries (LMIC) in South America, Africa and Asia.

In Sub-Saharan Africa specifically, population-based cancer incidence data is lacking because only 2% of the population is covered by high-quality population-based registries (4). However, all the data that is available suggests the incidence of colorectal cancer is increasing in the region. For example, according to the population-based cancer registry in Harare, Zimbabwe, CRC incidence has increased 4% per year from 1991-2010 (4). Anecdotally, clinicians working in Tanzania have also noted increased rates of CRC. A review of CRC cases at Muhimbili National Hospital (MNH) and Ocean Road Cancer Institute, the two large cancer hospitals in Dar es Salaam, Tanzania, found a steady rise in frequency from 23 cases a year in 2005 to 146 cases per year in 2015 (5). Similarly, at a referral hospital in Northern Tanzania, case volume increased from 15-20 a year in 1998 to close to 50 cases a year in 2018. Moreover, 63% of those patients presented with advanced disease and diverting colostomy was performed in 60%, suggesting patients had significant delays in diagnosis and treatment of their disease (6). Lack of data also applies to understanding the overall survival of patients with CRC in Sub-Saharan Africa. A recent study in which patients captured in regional population-based registries were contacted found 5-year overall survival in Kenya to be 54%, in stark contrast to just 4.5% in Uganda (7). For Tanzania, there is no published survival data for patients with CRC. *The available data to date, problematic as it is, underscores concerning trends that require further investigation to better ascertain the burden of colorectal cancer in Tanzania.*

In Tanzania and East Africa as a whole, there is also little published on the incidence and outcomes of patients undergoing surgery for *benign* colorectal diseases. In Rwanda, sigmoid volvulus accounted for over 80% of all non-emergent laparotomies done for colorectal pathology (8). In a single center in Northern Tanzania, a recent study found that sigmoid volvulus accounted for 14.2% of all cases of bowel obstruction with an associated mortality rate of 17.1% (9). However, because this study did not follow patients after discharge, *long term survival and the impact of colorectal surgery for benign disease on quality of life is unknown.*

Finally, the impact of colorectal surgery on financial stability and quality of life in Tanzania is a priority for the NSOAP. An estimated 65-85% of all patients who seek surgical care in Tanzania are at risk of catastrophic expenditures (10). Studies to further understand and address this problem are lacking in Tanzania, but in neighboring Uganda, one study found that 31% of patients who received surgical care encountered a catastrophic medical bill and 53% had to borrow money to pay for their care (11). Both the financial implications and social effects of seeking surgical intervention are important factors in whether patients are willing to present to

the hospital for care. Stoma creation has a significant impact on body image and quality of life. This important surgical intervention has not been studied in Tanzania, but a cross-sectional study in Uganda among 51 patients with a stoma found that 100% suffered anxiety, 96% reported a negative body image associated with the stoma, and 84% reported symptoms of depression (12). *Understanding the financial and social impacts within the local Tanzanian context is imperative to guide policymakers and clinicians as they work towards providing surgical care in an affordable and culturally acceptable manner.*

The proposed study is significant because it will begin to address the critical data gaps in Tanzania by creating the first prospective observational cohort of patients with surgical colorectal disease at MNH, the only national referral hospital. This project will make it possible to determine the in-hospital and 6-month mortality rates of patients with colorectal disease treated at MNH and to provide insight into the financial and social ramifications of receiving colorectal surgery in Tanzania. Robust data on the burden of disease, surgical treatment, and outcomes for CRC and benign colorectal disease would be a cornerstone for policy decisions about allocating resources and addressing barriers to timely diagnosis and treatment, and would also aid clinicians in understanding the impact of colorectal disease in their community.

C. Preliminary Studies

Since the focus of the proposed project is on data collection itself, there is no preliminary data available. To ensure feasibility, our Tanzanian Colorectal Cohort Study (TCCS) is a planned sub-study within a larger surgical outcomes research project entitled EXPLoring LAParotomy Outcomes for Surgical Quality Improvement at a Tertiary Care Facility in Tanzania (EX LAP) that is currently being reviewed by the institutional review board at MUHAS. This study is funded by the UCSF Center for Health Equity in Surgery and Anesthesia. The goals of EX LAP are to determine the surgical complication rate in patients undergoing laparotomy at MNH and to assess the financial effect surgical intervention has on patients and their families 30 days after discharge. EX LAP will enroll all patients undergoing laparotomy surgery at MNH from November 1 2021 to October 31 2022.

D. Design and Methods

Study Design: This will be a prospective cohort study which will enroll eligible patients who undergo laparotomy at MNH for colorectal disease.

Study Site: The study will take place at MNH, which is the only National Referral Hospital in Tanzania and is the public teaching hospital affiliated with Muhimbili University of Health and Allied Sciences (MUHAS). The hospital has a 1500 bed capacity, admits 1,000 – 1,200 patients per day and provides outpatient care to more than 1,000 patients per week. The hospital functions as the safety net facility and provides care at a sliding scale for all Tanzanian citizens.

Study Participants: A review of two months of the operative log at MNH suggests that surgeons at MNH complete 15 laparotomies for colorectal pathology a month. This would suggest a

recruitment of 180 for the entire study. A recent review of the operative case log suggests that of these cases, 70% are for emergent indications and 30% are elective. As a public sector hospital, the patients treated at MNH represent all levels of socioeconomic status in Tanzania.

The *inclusion criteria* for this study will be any patient undergoing colorectal surgery at MNH for a non-traumatic indication. *Exclusion criteria* will be any patient < 18 years of age, with blunt or penetrating trauma as the primary indication for laparotomy, or any patient who does not consent to participation in the study.

Recruitment and Enrollment: The study coordinator will review the surgical case log at MNH daily to identify any patient who received an exploratory laparotomy, colectomy, diverting colostomy, abdominal perineal resection, or low anterior resection for inclusion in the study. Postoperatively, the study coordinator will review the brief op note of all patients and approach eligible patients about study participation and obtain written consent in either English or Swahili. All questions will be answered and if additional information is needed that can only be provided by an MD, Dr. Akoko, a surgical oncologist at MNH and mentor for the TCCS will be available to assist.

Data Collection: All information collected for the EX LAP study will be available to us. In addition, the study coordinator will collect pathology reports on all patients enrolled in the TCCS. No specimens will be collected for this study. Sources of information will be as follows: 1) brief op note to be completed by the surgical resident immediately postoperatively, 2) in-patient study form to be completed by the research coordinator using information from the medical chart and the patient, 3) pathology report to be completed by the study coordinator using information available in the medical chart, 4) 30-day and 6-month follow-up survey to be completed by the study coordinator using information gathered during structured telephone interviews with the patient. These phone surveys will collect information on 3-month and 6-month survival, rates of catastrophic medical expense and the impact of having a colostomy on quality of life. Catastrophic medical expense will be defined as spending greater than 10% of annual household expenditure on out of pocket medical and non-medical expenses (13). The impact of a colostomy on quality of life will be determined by using the colostomy impact score which has been validated in both benign and malignant colorectal disease (14,15).

Data Storage and Analysis: Data will be entered directly into REDCAP, a password-protected and encrypted browser-based database system. Surgical residents will use the REDCAP mobile app on their cell phones to upload the brief op note, and the research coordinator will collect all other data and enter it directly into REDCAP using a tablet computer. Quantitative data analysis will consist of descriptive statistics of burden of disease, operation performed, in hospital mortality and surgical complication rate. The ratio of diversion to resection will be calculated for colon cancer, rectal cancer and colorectal cancer as a whole and will be compared to published rates in high-income countries such as the US. The prevalence of catastrophic financial expenditure will be calculated using the same methodology used for this

calculation in Rwanda (13), and the impact of colostomy on quality of life will use the colostomy impact score (14,15).

Potential Problems and Alternative Approaches:

This study is vulnerable to delays due to IRB approval, difficulty with recruitment, and loss to follow up of enrolled participants. To address these potential problems, we have created a robust research team with a proven track record of completing research at MNH. Dr. Akoko and Godfrey Sama are both currently working at MNH and have shepherded multiple studies through the IRB approval process at MNH. Dr. Akoko is also very involved with surgical training at MHN and will be able to ensure trainee buy-in and guarantee eligible patients are identified by the residents and are approached for study enrollment. Finally, we will mitigate the risk of lost to follow-up by asking for the cell phone numbers of patients and their families in order to contact them after discharge. It is estimated that over 90% of Tanzanians have access to mobile phones, and therefore we are optimistic that our follow-up strategy will be successful in reaching all our participants even though many will be economically disadvantaged.

E. Human Subjects

Section D above describes the characteristics of the subject population, the criteria for inclusion or exclusion, the sources of research material in the form of records or data, plans for recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of information to be provided to prospective subjects and the method of documenting consent.

The primary potential risk to being enrolled in the study is the possibility of a data breach of protected health information. By utilizing the REDCAP data system for data storage, we will mitigate this risk to the best of our abilities. While there is no potential benefit to the participants directly enrolled in the study, the benefit to future CRC patients in Tanzania who outweighs the potential risks shouldered by the participants in this study.

F. Vertebrate Animals:

None

G. Literature Cited

1. Alkire BC, Raykar NP, Shrima MG, Weiser TG, Bickler SW, Rose JA, et al. Global access to surgical care: a modelling study. *Lancet Glob Heal* [Internet]. 2015 Jun 1 [cited 2021 Aug 24];3(6):e316–23. Available from: <http://www.thelancet.com/article/S2214109X15701154/fulltext>
2. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer

- Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin* [Internet]. 2021 May 1 [cited 2021 Aug 13];71(3):209–49. Available from: <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21660>
3. Arnold M, Sierra MS, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global patterns and trends in colorectal cancer incidence and mortality. *Gut* [Internet]. 2017 Apr 1 [cited 2021 Aug 8];66(4):683–91. Available from: <https://gut-bmj-com.ucsf.idm.oclc.org/content/66/4/683>
 4. Katsidzira L, Gangaidzo I, Thomson S, Rusakaniko S, Matenga J, Ramesar R. The shifting epidemiology of colorectal cancer in sub-Saharan Africa. *Lancet Gastroenterol Hepatol*. 2017 May 1;2(5):377–83.
 5. Katalambula LK, Ntwenya JE, Ngoma T, Buza J, Mpolya E, Mtumwa AH, et al. Pattern and Distribution of Colorectal Cancer in Tanzania: A Retrospective Chart Audit at Two National Hospitals. *J Cancer Epidemiol*. 2016;2016.
 6. Herman AM, Hawkins AT, Misso K, Issangya C, Tarmohamed M, Mremi A, et al. Colorectal Cancer in Northern Tanzania: Increasing Trends and Late Presentation Present Major Challenges. <https://doi-org.ucsf.idm.oclc.org/101200/JGO1900301>. 2020 Mar 3;6:375–81.
 7. Gullickson C, Goodman M, Joko-Fru YW, Gnangnon FHR, N'Da G, Woldegeorgis MA, et al. Colorectal cancer survival in sub-Saharan Africa by age, stage at diagnosis and Human Development Index: A population-based registry study. *Int J Cancer* [Internet]. 2021 [cited 2021 Aug 14];19:20. Available from: <https://onlinelibrary-wiley-com.ucsf.idm.oclc.org/doi/full/10.1002/ijc.33715>
 8. J R, L P, E A, N K, S E, C K, et al. Indications and Outcomes for Non-Trauma Emergency Laparotomy: A Comparison of Rwanda, South Africa, and the USA. *World J Surg* [Internet]. 2021 [cited 2021 Aug 23];45(3). Available from: <https://pubmed.ncbi.nlm.nih.gov/33225391/>
 9. PL C, JB M. Sigmoid volvulus and ileo-sigmoid knotting: a five-year experience at a tertiary care hospital in Tanzania. *World J Emerg Surg* [Internet]. 2015 Mar 8 [cited 2021 Aug 23];10(1). Available from: <https://pubmed.ncbi.nlm.nih.gov/25774209/>
 10. NATIONAL SURGICAL, OBSTETRIC AND ANAESTHESIA PLAN (NSOAP) 2018-2025 THE UNITED REPUBLIC OF TANZANIA.
 11. Anderson GA, Ilcisin L, Kayima P, Abesiga L, Portal Benitez N, Ngonzi J, et al. Out-of-pocket payment for surgery in Uganda: The rate of impoverishing and catastrophic expenditure at a government hospital. Staton CA, editor. *PLoS One* [Internet]. 2017 Oct 31 [cited 2021 Mar 28];12(10):e0187293. Available from: <https://dx.plos.org/10.1371/journal.pone.0187293>
 12. Ssewanyana Y, Ssekitooleko B, Suuna B, Bua E, Wadeya J, Makumbi TK, et al. Quality of

life of adult individuals with intestinal stomas in Uganda: a cross sectional study. Afr Health Sci [Internet]. 2021 Mar 1 [cited 2021 Aug 24];21(1):427. Available from: /pmc/articles/PMC8356576/

13. Rickard JL, Ngarambe C, Ndayizeye L, Smart B, Majyambere JP, Riviello R. Risk of Catastrophic Health Expenditure in Rwandan Surgical Patients with Peritonitis. World J Surg [Internet]. 2018 Jun 1 [cited 2020 Nov 28];42(6):1603–9. Available from: <https://link-springer-com.ucsf.idm.oclc.org/article/10.1007/s00268-017-4368-x>
14. HØ K, M K, P C, T T. Validation of the colostomy impact score in patients ostomized for a benign condition. Colorectal Dis [Internet]. 2020 Dec 1 [cited 2021 Aug 18];22(12):2270–7. Available from: <https://pubmed-ncbi-nlm-nih-gov.ucsf.idm.oclc.org/32741098/>
15. A T, KJ E, TD P, P C, S L. The colostomy impact score: development and validation of a patient reported outcome measure for rectal cancer patients with a permanent colostomy. A population-based study. Colorectal Dis [Internet]. 2017 Jan 1 [cited 2021 Aug 25];19(1):O25–33. Available from: <https://pubmed.ncbi.nlm.nih.gov/27883253/>

H. Consortium/contractual arrangements

None

I. Consultants

None

J. Appendix:

EX LAP Data Collection forms:

Ex Lap: *Initial operative questionnaire*

Instructions: Please fill out questionnaire within 24 hours of completing the operation. Questionnaires can be submitted to the study coordinator of the EX-LAP project.

Patient General Information:

1. Hospital Registration Number:
2. Patient's full name: (First Name, Last Name):
3. Age:
4. Sex: ☐ Male ☐ Female

Pre-op clinical assessment:

5. Pre-operative diagnosis: Please select all that applies.

- | | | |
|---|--|---|
| ☐ gastric ulcer | ☐ pancreatic carcinoma | ☐ appendicitis |
| ☐ gastric cancer | ☐ malignant obstruction | ☐ colon cancer |
| ☐ cholecystitis | ☐ small bowel obstruction | ☐ sigmoid volvulus |
| ☐ liver cancer | ☐ cholecystitis | ☐ cancer of unknown source |
| ☐ pancreatitis | ☐ traumatic injury | ☐ other (specify)_____ |

Vitals: (Please select all that is applicable)

6. (a) Tachycardia present (HR>100)? ☐ Yes ☐ No
- (b) Hypotension present (systolic BP <100) ☐ Yes ☐ No
- (c) Tachypnea present (respiratory rate>22) ☐ Yes ☐ No
- (d) Altered mental status present? ☐ Yes ☐ No

Operative Information:

7. Date of operation (DD/MM/YYYY): / /

8. Type of operation performed (please check all applicable procedure/s):

- | | | |
|---|--|---|
| ☐ exploratory laparotomy | ☐ hepatectomy | ☐ nephrectomy |
| ☐ gastrectomy | ☐ pancreatectomy | ☐ colectomy |
| ☐ gastric bypass | ☐ whipple procedure | ☐ abdominoperineal resection |
| ☐ graham patch | ☐ small bowel resection | ☐ hartmann's procedure |
| ☐ cholecystectomy | ☐ appendectomy | ☐ lysis of adhesions |
| ☐ common bile duct exploration | ☐ splenectomy | ☐ other (specify):_____ |

9. Post-operative diagnosis (please check procedures all that applies):

- | | | |
|---|--|---|
| ☐ gastric ulcer | ☐ pancreatic carcinoma | ☐ appendicitis |
| ☐ gastric cancer | ☐ malignant obstruction | ☐ colon cancer |
| ☐ cholecystitis | ☐ small bowel obstruction | ☐ sigmoid volvulus |
| ☐ liver cancer | ☐ cholecystitis | ☐ cancer of unknown source |
| ☐ pancreatitis | ☐ traumatic injury | ☐ other (specify)_____ |

10. Indications for the procedure

Emergency case? ☐ Yes ☐ No

11. Antibiotics given: ☐ Yes ☐ No

a) pre-incision? ☐ Yes ☐ No

12. Type of anesthesia given/administered:

☐ General

- ☐ Spinal
- ☐ Monitored anesthesia care
- ☐ Local

13. Total volume of IV fluids administered:

14. Blood products:

- ☐ Whole blood #units_____ ☐ packed cells #units_____ ☐ plasma #units_____
- ☐ Others (specify)..... #units_____

15. Urine output:

16. Estimated blood loss:

- ☐ Mild – 0-100 ml ☐ moderate – 010-500 mls ☐ severe – 500+ mls

17. Collected specimens: (please check all that applies)

- ☐ stomach ☐ pancreas ☐ spleen
- ☐ small bowel ☐ colon ☐ kidney
- ☐ gallbladder ☐ appendix ☐ liver
- ☐ other (specify)

18. Wound classification: (Please check that applies)

- ☐ Clean: Uninfected, no inflammation is present, and are primarily closed. If draining of these wounds is necessary, a closed draining method is necessary. Additionally, these wounds do not enter respiratory, alimentary, genital, or urinary tracts.
- ☐ Clean contaminated: Surgery enters the respiratory, alimentary, genital, or urinary tracts. However, these wounds have entered these tracts under controlled conditions.
- ☐ Contaminated: Fresh, open wounds that can result from insult to sterile techniques or leakage from the gastrointestinal tract into the wound.
- ☐ Dirty/Infected: Old traumatic wounds with devitalized tissue, clinical infection, and possible perforated viscera.

19. Anastomosis done? ☐Yes ☐No

20. Ostomy done? ☐Yes ☐No

21. Type of ostomy:

- ☐ End (Bowel is in discontinuity)
- ☐ Diverting (Bowel is continuous, ostomy made to temporarily divert fecal material to protect new anastomosis)

22. Patient's condition:

- ☐ Stable
- ☐ Unstable
- ☐ Deceased

23. Disposition of patient:

- ☐ Post-operative care unit
- ☐ Surgical Ward

- ☐ Intensive care unit
☐ Morgue

Name of person who completed questionnaire _____

Ex Lap: *Inpatient assessment*

Instructions: The study coordinator of the EX LAP project will obtain all information while the patient is still admitted to the hospital. Sources for the information will be structured interviews of the patient and the medical chart.

Patient General Information:

1. Date consent obtained (DD/MM/YYYY): / /
2. Hospital Registration Number:
3. Patient's full name: (First Name, Last Name):
4. Age:
5. Sex ☐ Male ☐ Female
6. (a) Country of residence:
☐ Tanzania ☐ Other, specify: [.....]
- (b) Region: [.....]
- (c) Village/District: [.....]
7. (a) Ethnicity
☐ African ☐ Arab ☐ Asian ☐ Caucasian ☐ Other:
- (b) If African, tribe?.....
8. Telephone number of patient: +255-
9. Name of closest relative and relation: [.....]
10. Telephone number of closest relative: +255-

Comorbidities:

ASA Classification (I/II/III/IV)

- *ASA I: A normal healthy patient*
- *ASA II: A patient with mild systemic disease*
- *ASA III: A patient with severe systemic disease*
- *ASA IV: A patient with severe systemic disease that is a constant threat to life)*

11. Patient's pre-operative functional status (check the **ONE** best option):
☐ Independent

- ☐ Partially dependent
- ☐ Totally dependent

12. Steroid use for chronic condition: ☐Yes ☐No

13. Smoking status:

- ☐ Never
- ☐ Past, not currently
- ☐ Current (within 1 year)



If current or past;

- a) how many cigarettes per day? _____
- b) For how many years? _____

14. Comorbidities (select all that apply):

- | | | |
|--|---|--|
| ☐ coronary artery disease | ☐ prior stroke | ☐ HIV/AIDS |
| ☐ heart failure | ☐ diabetes mellitus (oral or insulin dependent or untreated) | ☐ kidney disease |
| ☐ chronic obstructive pulmonary disease | ☐ cirrhosis/liver failure | ☐ Other (specify) _____ |
| ☐ hypertension | | |

15. Ascites present 30 days prior to surgery? ☐Yes ☐No

16. Systemic sepsis present 48 hours prior to surgery

- ☐ None
- ☐ SIRS (See definition below)
- ☐ Sepsis (SIRS in addition to a documented source of infection)
- ☐ Septic shock (Sepsis in addition to hypotension (MAP <65), or venous lactate > 2mmol/L)

SIRS is defined as any two of the following conditions: Body temperature >38C or <36C, heart rate >90 beats per minute, respiratory rate >20 breaths per minute, white blood cell count >12,000 or <4,000.

17. Ventilator dependent? ☐Yes ☐No

18. Dialysis prior to surgery? ☐Yes ☐No

19. Acute renal failure? ☐Yes ☐No

20. Disseminated cancer? ☐Yes ☐No

21. Dyspnea:

- ☐ None
- ☐ With moderate exertion
- ☐ At rest

22. Height.....cm, Weight.....kg

23. Home Medications: ☐Yes ☐No



if Yes please list home meds: _____

Social Economic History

24. Marital status

- ☐ Married
- ☐ Cohabiting
- ☐ Single
- ☐ Divorced
- ☐ Widowed

25. Housing status

- ☐ Own
- ☐ Rent
- ☐ Lacks stable housing

26. What type of insurance does the patient have (check corresponding box below)?

- | | |
|---------------------------------------|---|
| ☐ No insurance | ☐ Strategies |
| ☐ NHIF | ☐ Jubilee |
| ☐ NSSF | ☐ Resolution |
| ☐ AAR | ☐ Diamond |
| ☐ TRA | ☐ Other (specify)..... |
| ☐ JWTZ/JKT | |

27. Which of the following best describes patient's employment status?

- | | |
|---|---|
| ☐ Full time work | ☐ Homemaker |
| ☐ Part time work | ☐ Other (specify)..... |
| ☐ Unemployed | |
| ☐ Retired | |

28. Average monthly salary (Tanzanian Shillings):

29. Highest level of education completed?

- | | |
|---|---|
| ☐ None | ☐ Advanced Secondary |
| ☐ Some primary | ☐ Technical College |
| ☐ Primary | ☐ University |
| ☐ Some Secondary | ☐ Other (specify)..... |
| ☐ Ordinary Secondary | |

30. Are you able to pay for food, housing, and medical care for your entire household?

☐Yes ☐No

If no, please explain _____

31. Within the past 12 months, are you worried that your food would run out before you get money to buy more?

☐Yes ☐No

If yes, please explain _____

32. In the past 12 months, has lack of transportation or money kept you from medical appointments or from getting medications?

☐Yes ☐No

If yes, please explain _____

33. Number of people in the household? _____

34. How many are employed? _____ (specify their employment) _____

Pre-operative course:

35. How many days did you have symptoms prior to presenting to the clinic/hospital?

36. Where was the first place you presented?

☐Clinic ☐District Hospital ☐Regional Hospital ☐MTRH

37. How many days after you were first evaluated by a clinician did you have surgery?

Postoperative course:

38. Post operatively admitted to (check one):

☐Surgical Ward

☐Intensive Care Unit

39. Post-operative Antibiotics given? ☐Yes ☐No



If Yes, duration (days): _____

40. Postoperative complication? *(Make sure we're capturing most frequent complications – select all that apply)*

☐Infection

- ☐ Surgical site/wound infection
- ☐ Intra-abdominal infection/abscess
- ☐ Pneumonia
- ☐ Urinary tract infection
- ☐ Blood stream infection/septicemia/bacteremia
- ☐ Clostridium difficile infection
- ☐ Malaria

☐Respiratory failure/intubation

☐Cardiovascular complication

- ☐ Myocardial infarction
- ☐ Pulmonary embolism
- ☐ Venous thromboembolism
- ☐ Stroke
- ☐ Cardiac arrest

☐Post-operative bleeding

- Required a blood transfusion? ☐Yes ☐No
- ☐Gastrointestinal
 - Anastomotic leak
 - Pancreatic fistula
 - Prolonged ileus
 - Intestinal obstruction
 - Dehiscence/evisceration/burst abdomen
 - Enterocutaneous fistula
- ☐ Return to OR
- ☐Unplanned transfer to ICU
- ☐Foreign body retention
- ☐Wrong procedure/side/site/patient
- ☐Renal failure
- ☐Other (specify)

In Hospital Survival

41. Patient's status at last contact/review

- ☐Deceased: Date of death: (DD/MM/YYYY): / /
- ☐ Transferred to MNH Morgue
- ☐ Transferred to another hospital Morgue
- ☐Alive: (Please check that applies)
 - In the ward
 - Patient was discharged to,
 - a) Home,
 - b) Rehabilitation Center
 - c) Date: (DD/MM/YYYY): / /

42. Which of the following best describes patient's functional status at discharge?

- ☐ independent
- ☐partially dependent
- ☐totally dependent

ExLap: Follow up phone survey

Instructions: To be filled out by the EXLAP study coordinator through structured phone interviews with study subjects 30 days after discharge.

30 Phone Follow up Survey:

43. Current Health status:

☐ Since discharge:

- ☐ Has your pain been controlled? ☐ Yes ☐ No
- ☐ Have you needed to seek medical care? ☐ Yes ☐ No



If Yes, where did you go?

- ☐ Have you needed to be readmitted to the hospital? ☐ Yes ☐ No



If Yes,

a) what was the reason for admission?.....

b) How long were you admitted for (days)?.....

- ☐ Do you require assistance with basic activities, i.e dressing, bathing, cooking ect?

☐ Yes

☐ No



If yes, do you need help with all activities, or just some?

- ☐ Are you able to resume work as you were before your operation? ☐ Yes ☐ No



If No, why not?.....

Financial Implication:

44. Since your operation have you been able to have a steady income?

☐ Yes

☐ No



If yes

a) Full time

b) Part time

45. Did insurance cover some of your medical care costs? ☐ Yes ☐ No

46. In total, how much out of pocket expenses (your own money) did you have to incur for your medical care? _____

47. If your own money was spent to pay for your medical care, did you have to (select all that apply):

☐ Borrow money

☐ Sell an asset

☐ Spend money in savings

☐ Stop sending any children to school

48. Since discharge from the hospital have you been unable to pay for food, housing, or medical care for yourself or your entire household?

☐Yes ☐No

If Yes, please explain _____

49. Since discharge from the hospital have you been worried that your food would run out before you get money to buy more?

☐Yes ☐Sometimes

If yes, please explain _____

50. Since discharge from the hospital has lack of transportation or money kept you from medical appointments or from getting medications?

☐Yes ☐No

If yes, please explain _____