

**QUALITY OF CARE AND SURGICAL OUTCOMES IN BREAST
CANCER MANAGEMENT, AT MUHIMBILI NATIONAL HOSPITAL**

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MANAGEMENT, AT MUHIMBILI NATIONAL HOSPITAL**

By

Franklyn Charles Bagenda

**A Dissertation Submitted in Fulfilment of the requirement for the
Degree of Master of Medicine (General Surgery) of
Muhimbili University of Health and Allied Sciences
October 2019**

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitle, “*Quality of care and Surgical Outcomes of breast cancer Management at Muhimbili National Hospital*” in (partial) fulfillment of the requirements for the degree of Master of Medicine (General Surgery) of Muhimbili University of Health and Allied Sciences

Dr. Larry Akoko
Senior Lecturer Department of Surgery
(Supervisor)

Date

DECLARATION AND COPYRIGHT

I, **Franklyn Charles Bagenda**, declare that this is my original work and that it has neither been presented nor will it be presented to any other University or learning Institutes for a similar or any other degree award.

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DEDICATION

This work is dedicated to my loving parents, Lydia and Charles Bagenda, my better half

Dr Maria Bulimba

And my sisters Beatrice and Lillian Bagenda.

TABLE OF CONTENTS

CERTIFICATION.....	i
DECLARATION AND COPYRIGHT	ii
ACKNOWLEDGEMENTS	iii
DEDICATION	iv
LIST OF TABLES	vii
LIST OF FIGURES.....	vii
LIST OF ABBREVIATIONS	viii
ABSTRACT	ix
1 INTRODUCTION.....	1
1.1 Background	1
1.2 Literature review	2
1.3 Problem statement	4
1.4 Rationale	5
1.5 Research questions	5
2 OBJECTIVES	6
3 METHODOLOGY	7
3.1 Study design	7
3.2 Study area.....	7
3.3 Study population	7
3.4 Study sample	7
3.5 Inclusion and Exclusion Criteria	7
3.5.1 Inclusion criteria.....	7
3.5.2 Exclusion criteria.....	8
3.6 Outcome measures	8
3.6.1 Number of Breast cancer patients with appropriate staging investigations.....	8
3.6.2 Number of Breast Cancer patients who received Neo-adjuvant Chemo-radiotherapy.....	8
3.6.3 30-day major complication rate.....	8
3.6.3 30-day mortality rate	8
3.7 Sample size.....	8

3.8	Recruitment	9
3.9	Data collection procedure.....	10
3.10	Research tool	10
3.11	Data management	10
3.12	Analysis plan.....	11
3.13	Ethical consideration	11
3.14	Study limitation	11
4	RESULTS	12
5	DISCUSSION	17
6	CONCLUSION & RECCOMENDATION.....	20
6.1	Conclusion.....	20
6.2	Recommendation.....	20
	REFERENCES.....	21
	APPENDIX I: INFORMED CONSENT (ENGLISH VERSION)	25
	APPENDIX II: FOMU YA MGONJWA.....	27
	APPENDIX III: QUESTIONNAIRE/CHEAK LIST	29
	APPENDIX IV: CDC Definition of Surgical Site Infection	37

LIST OF TABLES

Table 1: Base line characteristics of 66 breast cancer patients at MNH who underwent MRM.....	12
Table 2: Risk factors for the development of SSI among post MRM patients.....	16
Table 3: Risk factors for seroma development among post MRM patients	16

LIST OF FIGURES

Figure 1: Proportion of patients with metastatic work up done for each type of investigation, n= 66 ..	13
Figure 2: Proportion of patients who received NACT, yes had received while No had not received....	14
Figure 3: Proportion of complications occurring among the breast cancer patients post MRM.....	15

LIST OF ABBREVIATIONS

CT	Contrast Tomography
CXR	Chest x ray
FNAC	Fine Needle Aspiration and Cytology
FU	Flourouracil
LMIC	Low and/or Middle-Income Countries
MAMC	MUHAS Academic Medical Centre
MMed	Master of Medicine
MNH	Muhimbili National Hospital
MRI	Magnetic Resonance Imaging
MUHAS	Muhimbili University of Health and Allied Sciences
NCCN	National Comprehensive Cancer Network
SLNB	Sentinel Lymph-node Biopsy
SSI	Surgical Site Infection
TNM	Tumor Node Metastasis

ABSTRACT

Background: Breast cancer is ranked 2nd in number of new cases worldwide while is 4th in cancer mortality globally, while in Tanzania it is ranked fourth overall and second to cervical cancer among female patients with cancer. The use of breast self-examination with screening mammography has resulted in early diagnosis and standardized care with improved outcome. While algorithm for work up of breast cancer patients has been proposed, how this is implemented and its outcomes in Tanzania has been poorly investigated. Even though the infrastructure to improve breast cancer services from investigations to treatment are available, uniformity in patients' pathways might differ hence the difficulty in measuring survival and outcome. Standardizing such pathways will ensure each patient receives stage specific care with expected improved outcome and ease of measuring efficiency of interventions offered.

Objective: To assess the quality of implementation of evidence-based management of Breast cancer patients and outcomes of Modified Radical Mastectomy at Muhimbili National Hospital.

Methodology: A prospective cohort study of MRM patients was carried out at MNH in 2019. Patients who had received an MRM for confirmed breast cancer were recruited over a six months period. Information gathered includes investigations ordered, Provision of NACT, surgery type and complications post-surgery. A multi-center data collection tool adopted from Global Surgery Collaborative was used to gather information and variables entered in to SPSS version 24 where cleansing and coding was done. Descriptive statistics were summarized into proportions and continuous variables into means with association between variables determined by using Chi-squared test or Fisher's exact test. An association with P-value less than 0.05 will be considered significant. The study was conducted after being approved by MUHAS IRB.

Results: 66 breast cancer patients who had MRM were recruited. The mean age was 48.17±13.15 with only 3 (4.5%) being male. Invasive Ductal carcinoma was the most predominant seen in 59 (89.4%). Most of the patient at the time of surgery were Stage 3 by 95.5% while the rest were Stage 2. Chest x-rays and abdominal ultra sound was done in all

patients, while only 14(21.2%) had a mammography performed. Seroma and SSI were the reported complications affecting 40.9% and 18.2% respectively. Overweight was found to significantly relate with the development of SSI, p-value 0.011 while previous history of smoking related with seroma development, p-value 0.029. Surgical mortality was reported in 3(4.5%) of the patients.

Conclusion:Breast cancer patients undergoing MRM at MNH are under investigated, which might result in under treatment when immunohistochemistry for hormonal status and Her2/Neo expression are not part of the treatment plan. Similarly, with majority being stage 3 cancers, it could result in over-treating stage four patients that could have been picked by CT and MRI.

Recommendation: Introduction of Breast Cancer clinical pathway that eliminates and variability in the preoperative workup of a patient,also keeps track of the patient postoperative outcome. This is also improves record keeping with and offers easier institutional sharing of information to further improve on the outcome of patients.Finally, a clinical pathway set will ensure equitable utilization of available resources to all patients in different treatment institutions beyond Muhimbili National Hospital.

1 INTRODUCTION

1.1 Background

Worldwide, there will be about 2.1 million newly diagnosed female breast cancer cases in 2018, accounting for almost 1 in 4 cancer cases among women.(1)The disease is the most frequently diagnosed cancer in the majority of countries (154 of 185) and is also the leading cause of cancer death in over 100 countries. The treatment requires a highly complex approach, and quality care is dependent on coordinated multidisciplinary input. Increased Survival is due to the dramatic advances in the screening methods and early diagnosis.(2,3)Improving on Clinical Breast examination and imaging plays a major role in the diagnosis, treatment, and follow-up of breast cancers.

The currently used modalities include mammography, breast ultrasound, magnetic resonance imaging (MRI)and computed tomography (CT).Adding a single screening ultrasound to mammography will yield an additional 1.1 to 7.2 cancers per 1000 high-risk women.(4)CT scan staging of the thorax, abdomen and pelvis (CT-TAP) in patients with newly diagnosed breast cancer is a satisfactory stand-alone investigation for systemic staging.(5)Yet despite the clear evidence on the advantages of use of Diagnostic imaging Studies and the NCCN recommendation on use of diagnostic imaging there is no documentation on adherence of use of these imaging studies on day to day care of breast. Breast cancer patient at Muhimbili National hospital are offered the minimal radiological imaging which falls short of the NCCN recommendation despite the availability of the Imaging techniques.

The breast is relatively clean peripheral soft tissue organ thus many wound complications related to Modified Radical Mastectomy are relatively minor and frequently are managed on an outpatient basis. Complications such as Incisional dog ears, surgical site infection, seroma, hematoma, lymphedema, chronic pain, venous thromboembolism occur at varying incidence rates differing amongst institutes and studies. The quality of care Breast cancer patients can not only be assessed through the usage of Diagnostic modalities to improve Breast Staging but also the Surgical outcome looking at the incidence rates of complications that may affect the cancer related morbidity and mortality.

At Muhimbili National hospital there are no studies trying to show the incidence rates of Surgical Site Infection (SSI), seroma, chronic pain and the others. The Institute of Medicine (IOM) has defined quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”. (1,2). This study will thus attempt to assess selected components of both processes and outcome components of quality in service delivery to Breast cancer patients as its indicators.

1.2 Literature review

The UN has forecast that the global population will reach 7 billion by 2012 and 8.3 billion by 2030. These changes translated to a predicted global burden of 20.3 million new cancer, and a predicted 13.2 million cancer-related deaths worldwide by 2030.(6,7).57% of these new cancer cases and 65% of cancer deaths will have occurred in LMICs. Projections for new cancer cases in 2030 are estimated to be 21.6 million, and case fatality rates due to cancer are estimated to be highest in LMICs (75%) compared with in HICs (46%).(8)This clearly showed a demographic transition into non communicable diseases particularly cancers of all types being the 2nd cause of mortality. In LMICs, three-quarters of the surgical burden will be from cancers of the breast, stomach and colorectal(8)(9).

The Institute of Medicine (IOM) in America defined quality as “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (10). The challenge of ensuring quality of health care in regard to cancer care has remained high on the LMIC. The outcomes assessed in quality of care are focused in 6 domains Safety, Effective, Patient personalized, timely, Equitable and Efficient. In Tanzania, breast cancer represents 14.4% of new cancer cases among women. The age standardized breast cancer incidence in Tanzania is 19.4/100000 women and the age standardized breast cancer mortality rate is 9.7/100000. The overall incidence of cancer in Tanzania has similarly been on the rise and the ministry of health estimates that 25% of the country’s population is at risk of developing cancer.(11)

At Muhimbili the routine diagnostic workup offered to patients diagnosed to have breast cancer include, Fine Needle aspiration Cytology, Core needle biopsy for Histology, Sentinel lymph node biopsy, Chest X-ray and Abdominal pelvic ultrasound. Not all patients are offered Mammograms or CT scan or MRI during the pre-operative workup. One of the important diagnostic workup needed is a Diagnostic Mammography. A diagnostic Mammogram can reveal an abnormal area such as micro-calcifications which on screening was actually normal, or further evaluates the abnormalities seen in Breast ultrasound. The sensitivity and specificity of mammography in breast cancer diagnosis was variable and depended primarily on the age of the patient and breast density(12).

In studies evaluating sensitivity and specificity of Breast ultrasound and mammography in diagnosing Breast cancer showed, The specificity of ultrasound was 12.5% higher than mammographic but the difference in the specificities of the two imaging tests was not statistically significant and also combining the two methods, high sensitivity of 90.5% was achieved, which was 4.8% higher compared to the sensitivity of ultrasound alone. A 2008 study found a significant increase in diagnostic accuracy when using breast ultrasonography in addition to mammography , accuracy of 0.78 compared to with 0.91 (13)

Another important diagnostic tool during the workup for patient diagnosed with Breast cancer was Breast – Axilla MRI. Contrast-enhanced MRI captures 3-dimensional images and detects lesions hidden in dense tissue, making it suitable for finding tumors that mammography misses. Mammography alone was believed to miss between 10% and 30% of all breast cancers.(14). The American Society of Breast Surgeons had identified 5 indications for Breast MRI (15) but the most important being to determine the extent of tumor involvement in the ipsilateral breast and evaluate the contralateral breast in patients with proven cancer and to monitor the response to neoadjuvant chemotherapy. The sensitivity of MRI in detecting multicentric disease ranges from approximately 89% to 100% with bilateral imaging to 95% to 100% with unilateral imaging. The specificity of excluding multicentric disease ranges from 82% to 97%.(16) Mumtaz et al. [11] demonstrated that MRI was more accurate than mammography in determining tumor size in 85 invasive tumors ($r^2 = 0.93$ for MRI and 0.59

for mammography). Because MRI gives the most accurate measurement of tumor size of invasive tumors, this imaging modality has the potential for supplanting clinical and/or mammographic tumor size assessment in the preoperative TNM Breast cancer staging system.(17,18)

Together with MRI, a precise axilla investigation in terms of Sentinel Lymph node Biopsy(SLNB) was of utmost importance for clinically negative axillary node examination. It was essential that patients receive adequate evaluation of the axilla prior to surgery. Patients who have been sub-optimally examined for clinically involved nodes before surgery were at a greater risk for recurrence.(19)SLNB was indicated for staging patients with early T1-2 invasive breast cancer and clinically negative axillary nodes. SLNB was less invasive and was associated with a lower morbidity.(20)The SENTINA (SENTinelNeoAdjuvant) study, of 1737 patients who received treatment, 1022 women underwent sentinel-lymph-node biopsy before neoadjuvant chemotherapy (arms A and B), with a detection rate of 99.1%. Notable results of this study were that of the 592 women who converted from clinical node-positive to node-negative status, the SLN detection rate was 80 %.(21)

Some of the few studies have revealed the importance of quality health care services in improvement of outcomes.in a recent study done btKristel Lobo Prabhu et all looking at the relationship between surgical outcomes and patient satisfaction showed a significant association between patient satisfaction and the occurrence of postoperative surgical complications.(22)

1.3 Problem statement

Adherence to guidelines is a prerequisite to good outcomes in cancer surgery as they have been tested and found to work in other settings. Even in the absence of a national guideline, clinicians need to adopt best practices at all times. It is assumed that all clinicians understand these best practices with regards to breast cancer care. But how clinicians in Tanzania, a prototype of LMICs with no clinical guidelines in place, adhere to any known best practice has never been critically evaluated. In order to have quality of care particularly in breast cancer management, issues such as documentation that help track patient safety through management

process, terms of planned cure or palliation tailored to every individual patient .Furthermore protocols set to avoid delays in surgery or provision of neoadjuvant therapy. In the absence of standardized care, comparison and measurement of effectiveness of any intervention will not be possible. Similarly, the treatment outcomes for breast cancer at MUHAS teaching hospitals are not known. There is no defined clinical pathway that assures similar management pathway for all patients. All of this is in spite of the significance of Breast Cancer, being in top ten cancers in the country and Breast Cancer being potentially curable if appropriate treatment is offered.

1.4 Rationale

Offering high quality surgery is the aim of any cancer treating center. But similarly, being able to compare best practices from others provides motivation to further work towards improvement in quality of services with resultant improvement in survival among our cancer patients. Breast cancer is a potentially curable disease where screening tools are readily available and easy to use. Bearing in mind that financial, technical and humanitarian restraints present which makes it hard to catch up with rising health care costs and rising demands set by the public efficiency is paramount to guarantee equitability. Also, Muhimbili is facing increasingly stronger competition with private sector Institutes in terms quality of patient personalized care. Therefore, findings from this study will work as a catalyst for improving service delivery to this population of patients. Also, this is a study looking into the standard of care for diagnosis and management of patients with Breast Cancer.

1.5 Research questions

Do Breast cancer patients in Tanzania receive quality services that adhere to evidence based standards? What is the outcome of surgery for patients with Breast cancer surgery at MUHAS teaching hospital?

2 OBJECTIVES

2.1.1 Broad objective

To describe the patient's characteristics, quality and outcome of Breast cancer surgery at MUHAS teaching hospital.

2.1.2 Specific objective

- i. To determine proportion of patients with appropriate staging investigations performed for the diagnosis of Breast cancer.
- ii. To describe proportion of breast cancer patients in need of neoadjuvant therapy who actually received it.
- iii. To document the occurrence of complications following breast cancer surgery
- iv. To determine 30 – day operative mortality for Breast cancer surgery.

3 METHODOLOGY

3.1 Study design

This is a Prospective study with four months of data collection. The study recruited patients are newly diagnosed with Breast Cancer listed for Therapeutic or Palliative surgery at Muhimbili National Hospital.

3.2 Study area

The study is conducted at Muhimbili National Hospital which is the teaching tertiary hospital with capacity to investigate stage and offer surgery for cancer patients. With over 9800 surgical admissions annually, it will provide an easy single center for data collection given the short study time. In the past year of 2017 there were 1600 patients operated on by the main General surgical firms, Firm 1 and Firm 2. 10.7% of patients underwent Modified Radical Mastectomy due to Breast cancer.

3.3 Study population

All patients admitted to the general surgical firms scheduled to undergo Modified Radical Mastectomy were involved in this study.

3.4 Study sample

All patients with histological confirmed diagnosis of Breast cancer were included in the study for the time period of 4 months during the study period.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion criteria

- i. Adult patients 18 years and above
- ii. Provided informed consent/assent to participate.
- iii. Has undergone successful surgery for treatment purposes
- iv. Any patient handled with intention to treat protocol: turned benign, or surgery abandoned.

3.5.2 Exclusion criteria

- i. Operations where breast, cancer is not suspected to be the primary pathology should be excluded.
- ii. Breast cancer patients not listed for Modified radical Mastectomy
- iii. Patients whose surgery is for recurrence of breast cancer.

3.6 Outcome measures

3.6.1 Number of Breast cancer patients with appropriate staging investigations

- i. Breast ultrasound
- ii. Mammogram
- iii. Thoraco-Abdominal CT-scan
- iv. MRI

3.6.2 Number of Breast Cancer patients who received Neo-adjuvant Chemo-radiotherapy

3.6.3 30-day major complication rate: Defined as the occurrence of a Clavien-Dindo grade III or IV complication within 30-days of index operation. [Appendix V]

- i. **Seroma:** Seroma after breast surgery is defined as a serous fluid collection that develops under the skin flaps or in the axillary dead space following mastectomy and/or axillary dissection.
- ii. **Surgical Site Infection:** Surgical site infection will be defined according to the Centers for Disease Prevention and Control (CDC) [Appendix IV]

3.6.3 30-day mortality rate: Defined as death within 30-days of index operation, where day of operation is day 0.

3.7 Sample size

All consecutive patients having Breast Cancer Surgery, MRM were included. Using Cochran formula for determining sample size,

$$n_0 = \frac{Z^2 pq}{e^2}$$

where prevalence of surgical site infection is 14.2% (23), 95% confidence interval set at 1.96, and the margin of acceptable error kept to with 7%, patient undergoing MRM needed were 86, we managed to get 66 patients.

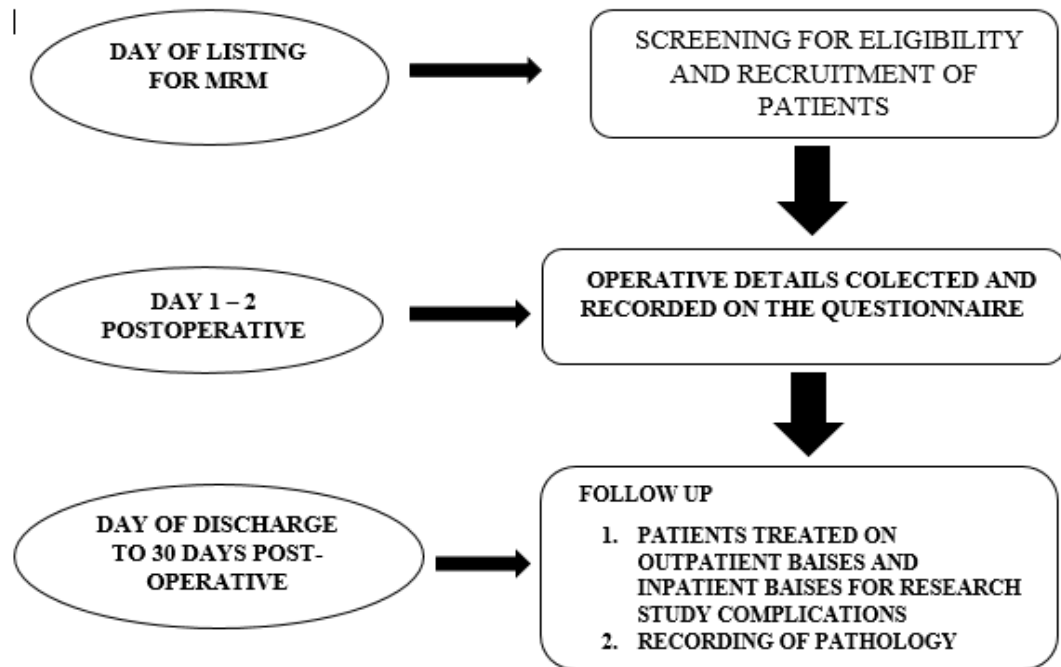
3.8 Recruitment

Patients with Breast cancer were identified in the operation list on daily basis for planned surgery and review of performed surgeries for emergency surgeries. Once a patient with histological proven Breast cancer was listed in the Elective operation list the patient was approached the day before operation and consent was sought to participate in the study which would include follow up for one month through clinic visits or phone calls.

Follow up would commence on the second day post-operative, for the Breast cancer patients and complications Surgical site infection will be assessed during the post-operative hospital stay period which is determined by the operating surgeon. Follow up visits were scheduled as per Muhimbilli protocol once a patient was discharged, to be seen after 2 weeks from discharge at the clinic. During clinic visits the pathology report of the resected specimen was traced and results recorded in the questionnaire.

The Breast cancer patients' post-operative complication of Seroma was assessed during clinic visits which are set on 10th to 14th day which was in line with time to remove the drain and sutures. Then the patient was followed up through weekly phone calls to enquire on features Seroma formation. For patients that acquired any of the complications after discharge during follow up they were readmitted for intervention of the particular complication. Only Deep surgical site infection, Organ space surgical infection were readmitted for intervention. For complication such as uninfected Seroma, or superficial surgical site infection intervention was addressed at the clinic on Outpatient bases.

3.9 Data collection procedure



3.10 Research tool

Information was gathered using a pre-tested and validated multicentre data collection tools adopted from Global Surg 3 “Quality and outcomes in global cancer surgery”(24)[Appendix III]. Patient’s demography and disease specific checklist for completeness of investigations, Neo-adjuvant therapy, complications, and death both within 30 days was used. The research tool was individualised for Breast Cancer patients recruited into the study.

3.11 Data management

Collected data was coded, checked for completeness, entered into excel spread sheet daily. In the end it was transferred to SPSS for analysis. Two sets of raw data have been stored: one in hard copy and the second in excel data base. At the end of the study, all patient data was handed to the supervisor for safe storage.

3.12 Analysis plan

Continuous variables were summarized into descriptive statistics while categorical variables into proportions. Quality measures in terms of completeness of investigations and treatment modalities were also be measured as a proportion. Data was analyzed according to the Outcome measures for specific objectives. Overall mortality was calculated followed by disease specific mortality taken as a proportion of those who underwent surgery and died. Surgical site infection rate was reported for all conditions while seroma rate for breast cancer patients.

3.13 Ethical consideration

Ethical clearance was sought from MUHAS IRB, Ref.No.DA.287/298/01A and separate permission to conduct the study was obtained from MNH authority, MNH/TRC/Permission/2019/128. All participants provided a written informed consent after receiving full information about the study. Direct identifiers of the cases were removed at analysis phase to maintain confidentiality as there was no need for follow up. Patient questionnaires and signed consent forms have been bound into a book and handed over to department for storage, and subsequent safe disposal would not disclose the file number of the patient's records.

3.14 Study limitation

This study served as a pilot into the bigger problem with breast cancer management in one National Hospital in Tanzania hence findings cannot be generalized neither to the whole country nor to the region.

4 RESULTS

During the four months study period, 66 patients with breast cancer underwent a Modified Radical Mastectomy. The mean age of the patients was 48.17 ± 13.15 (20 – 72) years of which only 3 (4.5%) were male. Most of the follow-up information 62 (92.1%) was retrieved through telephone interview done twice during the 30-day period. Breast cancer was diagnosed more on the Right breast by 46 (69.7%) as compared to the Left breast 20 (30.3%). Most of the patients, 44 (66.7%) were obese as according to the BMI. The Clinical TNM staging of Breast cancer revealed that 63 (95.5%) of patients operated at the hospital during the study period were Stage 3 patients and the rest were Stage 2 patients. The most prevalent Histological diagnosis for Breast cancer among the Patients was Invasive Ductal carcinoma by 59 (89.4%) the remaining all being Invasive Lobular Carcinoma.

Table 1: Base line characteristics of 66 breast cancer patients at MNH who underwent MRM.

<i>Characteristics</i>	<i>Frequency</i>
Age groups in years	
≤ 29	11 (3%)
30 – 59	32 (47%)
>60	23 (16%)
Gender	
Male	3 (4.5%)
Female	63 (95.5%)
Location	
Right breast	46 (69.7%)
Left breast	20 (30.3%)
Histology	
Invasive ductal carcinoma	59 (89.4%)
Invasive Lobular Carcinoma	7 (10.6%)
BMI	
Underweight	12 (18.2%)
Normal weight	10 (15.2%)
Overweight	44 (66.7%)
Smoking status	
Never	53 (80.3%)
Smoked before but currently stopped	10 (15.2%)
Currently smoke	3 (4.5%)
Performance status	
1	47 (71.2%)
2	16 (24.2%)
3	3 (4.5%)
Breast Cancer Stage	
Stage 2	3 (4.5%)
Stage 3	63 (95.5%)

OBJECTIVE 1: To document investigations done for metastatic work up in breast cancer patients.

Fig1 looks at metastatic investigations as was done among the 66 breast cancer patients at MNH. It can be noted that there was complete absence of any CT scan, MRI and Bone scan among these group of patients. Only Chest x-ray and Abdominal Ultrasonography were performed in all the patients. Breast, contralateral, assessment using either mammography or ultrasound was only done in 21.20% of the patients.

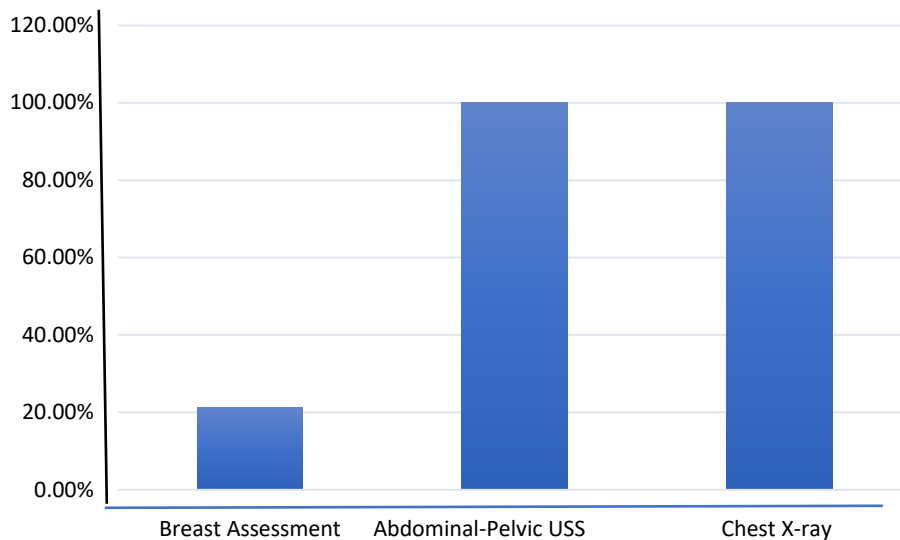


Figure 1: Proportion of patients with metastatic work up done for each type of investigation, n= 66

OBJECTIVE 2:To describe proportion of breast cancer patients in need of neoadjuvant therapy who actually received it.

While 63(95.5%) of all the patients had stage three disease based on the clinician assignment were in need of Neoadjuvant therapy according to the multidisciplinary Tumor board discussion, only 38 (57.6%) as can be seen from fig 2 below received it.

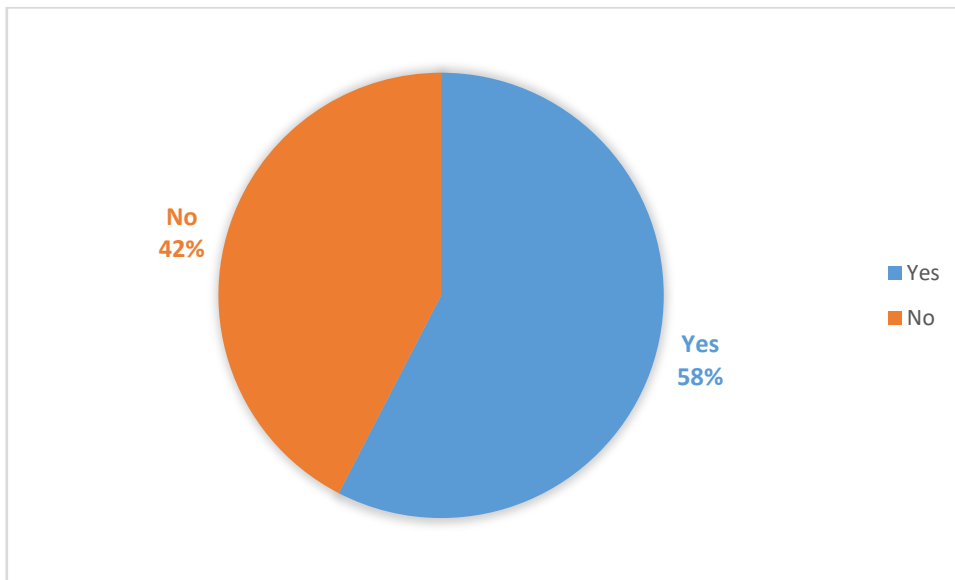


Figure 2: Proportion of patients who received NACT, yes had received while No had not received

OBJECTIVE 3:To describe the occurrence of complications following surgery as a treatment modality for Breast cancer.

Surgical outcomes were also assessed as can be seen in figure 3 below, seroma was the most frequent complication reported from 40.9% of the 66 patients post MRM while SSI affected only 18.2% of them. Mortality which is the most serious complication was reported in 3(4.5%) of all the patients.

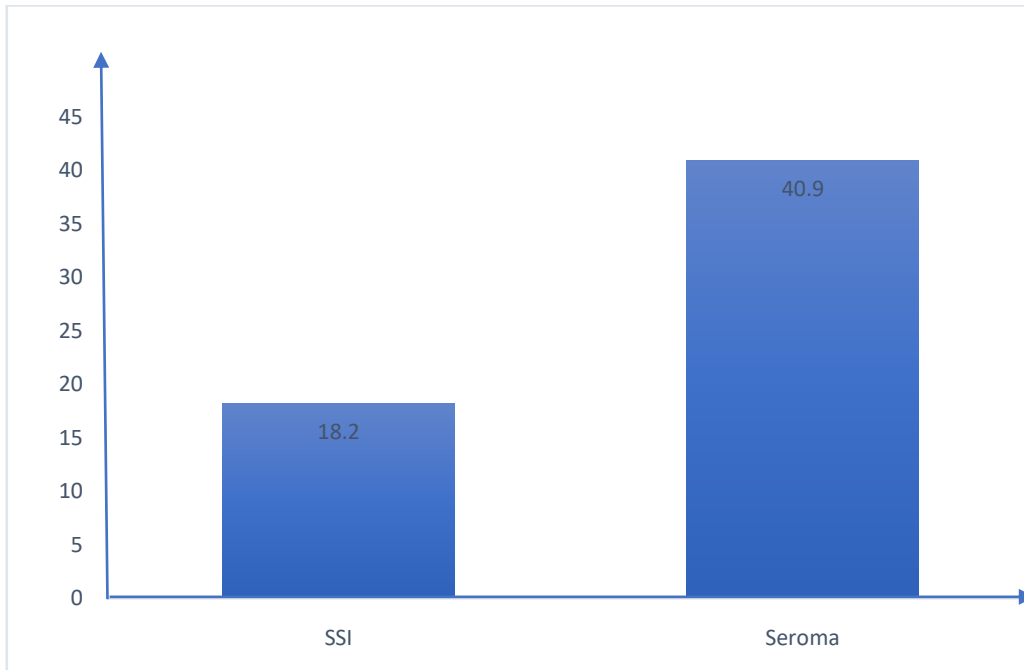


Figure 3: Proportion of complications occurring among the breast cancer patients post MRM

Risk factors for the occurrence of SSI and seroma among breast cancer patients was assessed against expected parameters as shown in table 4 and 5 below respectively. In assessing risk for SSI occurrence, the following factors were evaluated for any association: BMI, smoking history, Neo-adjuvant therapy and pre-operative Zubrod Performance Status. All patients with normal weight did not have any SSI hence were removed from association testing: when comparing the occurrence in SSI development between the overweight and the underweight patients, the latter were 2.6 times more at risk of SSI development than the former but failed to reach significant levels, $p=0.053$. Similarly, proportionately bigger majority of patients with poor performance status had SSI compared to the rest but also failed to reach significant levels, $p=0.090$. on risk for seroma development, smoking was shown to have significant association whereby proportionately it was twofold compared to non-smokers, $p=0.029$.

Table 2: Risk factors for the development of SSI among post MRM patients

<i>Risk factor</i>	<i>SSI</i>	<i>No SSI</i>	<i>P value</i>
Mean Age (years)	51.58	46.37	0.195
BMI			
Over weight	7 (15.9%)	37 (84.09%)	0.011
Normal	0 (0%)	10 (100%)	
Underweight	5 (41.7%)	7 (58.3%)	
History of smoking			1.000
Yes	2 (15.4%)	11 (84.6%)	
No	10 (18.9%)	43 (81.1%)	
Neoadjuvant therapy			0.953
Yes	5 (17.9%)	23 (82.4%)	
No	7 (18.4%)	31 (81.6%)	
Zubrod Performance Status			
0	7 (14.9%)	40 (85.1%)	0.090
1	3 (18.8%)	13 (81.3%)	
2	2 (66.7%)	1 (33.3%)	

Table 3: Risk factors for seroma development among post MRM patients

<i>Risk factor</i>	<i>Seroma Yes</i>	<i>Seroma No</i>	<i>P value</i>
Mean age (years)	49.41	45.87	0.264
BMI			
Overweight	19 (43.2%)	25 (56.8%)	0.611
Normal weight	3 (30%)	7 (70%)	
Under weight	5 (41.7%)	7 (58.3%)	
History of smoking			0.029
Yes	9 (69.2%)	4 (30.8.2%)	
No	18 (35.3%)	35 (64.7%)	
Neoadjuvant therapy			
Yes	11 (39.3%)	17 (60.7%)	0.818
No	16 (42.1%)	22 (57.9%)	
Zubrod Performance Status			
0	20(42.5%)	27 (57.5%)	0.657
1	6 (37.5%)	10 (62.5%)	
2	1 (33.3%)	2 (66.7%)	

5 DISCUSSION

Breast cancer, is an important health problem in the United Republic of Tanzania. Modified Radical Mastectomy is one amongst the most common surgical procedures done at Muhimbili National Hospital, a tertiary level hospital in Tanzania. The lack of sophisticated Diagnostic Imaging studies available for Breast cancer patients at the peripheral hospitals necessitates referral to the tertiary level Hospitals. No Muhimbili Hospital based study has tried to look at the actual utilization the full Diagnostic capacity of the existing health facilities in Tanzania. This is in recognition that appropriate work up does not only improve the clinical TNM staging, but also helps in providing evidence based guidance to patients when choosing a line of care (25).

Women who present with breast symptoms or who have palpable findings on clinical examination are usually investigated with breast imaging, which generally consists of mammography or breast ultrasound or both: breast Ultrasonography findings of suspicious Breast lesions must be Further examined using Mammography. This study showed that even well-resourced setting such as Muhimbili National hospital, Breast Mammography and Breast Ultrasonography is underutilized to further stem the diagnosis of Breast cancer. By missing out on Mammography especially in our study group of patients with mean average age 48 years increases the likelihood of missing a second primary tumor on the contralateral breast.

According to the 2017 National Comprehensive Cancer Network (NCCN) guidelines on Breast Cancer it recommends patients with T3 , N1 or M1 disease need CT scan Abdominal Pelvic (CTAP).(26). Unfortunately, the study has showed that despite the presence of CT scan facilities at the Study hospital none of the patients were offered this diagnostic imaging which may have identified patients with occult Metastatic disease that was yet to present clinically. But the study could not pick up missed patients with metastatic stage 4 disease that could have been diagnosed by CTAP and would have benefitted from readmission for terminal disease care after Modified Radical Mastectomy. Perhaps another study may be proposed to have a detailed look at such missed patients and where do they end up.

Again, as per the National Comprehensive Cancer Network (NCCN) recommendations Neoadjuvant therapy should be offered to Stage 2B patients and Stage 3 patients to downstage and improve treatment response after Modified Radical Mastectomy. *ETM Neyagawa et al* at Muhimbili National Hospital in 2011 concluded that the use of Neoadjuvant Chemotherapy is associated with high response rate in down staging of locally advanced breast cancer and hence improving patient management from palliative surgery to more definitive surgical management.(23) However this study has shown the number of patients who underwent Neoadjuvant therapy before surgery is less than a half. This is a significant number of missed opportunities for those patients that did not receive the therapy. It sheds the light that more research is needed to find out why more than 57% of the eligible patients for Neoadjuvant therapy miss out and whether there is lack of information given to patients on the continuum of care with our fellow counterpart Ocean Road Cancer Institute or do patients refuse this neoadjuvant treatment.

Surgical site infection SSI related to Breast cancer surgery is one of the main causes of prolonged Morbidity during the post-operative period. Based on different conducted surveys among published studies, SSI has a wide Incidence rate ranging between 0.8-26%.(27,28) The rate of Surgical site infection ranges depending on the individual patient comorbidities, preoperative therapy and reporting institution. Nyaoncha A et al from Aga Khan University hospital in 2016 showed an SSI rate of 6% amongst their Breast cancer surgery patients.(29) This study shows that Muhimbili National Hospital has Breast Cancer SSI rate within the published range. It should be the goal of the Institution to bring down this rate so as to decrease patient Morbidity.

One such captured risk factor seen in multiple studies is elevated BMI, where BMI >25 kg/m² was associated with an increased SSI rate (OR: 1.08.(30)(30)(31). This agrees with my study that showed 58.3% SSI patients were overweight. A statistically significant incidence of surgical site infection in obese patient as compared to non-obese patients. This suggests 1 in every 2 patients that are obese are bound to have SSI post-operatively, such numbers are unacceptable when it comes to assessment of quality of health care that aims to minimize any adverse or

undesirable outcomes such as SSI. Seroma formation is another frequently encountered complications following mastectomy. Xiao Feng Pan et al at Shangia Hospital in China demonstrate in a 5 year study the incidence rate of breast cancer surgery seroma formation to be 22.5%. (32) . There are many risk factors associated with Seroma formation including Breast size, Hypertension, presence of malignant nodes, previous surgical biopsy and use of heparin. (33,34) Marcos Sforza et al in UK showed in Smoking increases the odds of developing seroma by 19.8 times compared to non-smokers when follow up was done for 1 year. (35) . As shown in this study there is a statistically significant incidence of Seroma formation in patient with history of smoking.

Multiple studies looking at the 30 day Mortality rate for breast cancer surgery revealed rate less than 1 percent considering it to be a Clean surgery and done as mostly Elective procedures. (36,37). Unfortunately, this study shows rate 4.5% relatively as compared to Global trends. Due to this low incidence rate it is difficult to draw conclusion of association of any factors that may affect this mortality rate. Due to flow up being mostly done through telephone calls it was difficult to confirm death of the participants were attributed to disease or other complications from the operation

6 CONCLUSION & RECCOMENDATION

6.1 Conclusion

This study has highlighted the poor quality of breast cancer services attained by our patients. InLMICs where a majority of patients with breast cancer present with advanced stage disease,investigational imaging modalities such as MMG, CTAP and MRI scans were not done to trulycapture the severity of the disease which would have a knock over effect on the plan on Breastcancer management.Again the relatively high incidence of SSI amongst the operated patients particularly the obese patient's further wanes on the poor quality of health services experience by breasts cancer patients.Similarly, there was a lack in uniformity of care as shown in the fraction ofthe patients of patients in need of NACT receiving it.

6.2 Recommendation

- I. A pilot study looking at the use of a common Clinical Pathway for Breast cancer patients that may asses any improved efficiency management and tracking of the treatment course. The same Clinical Pathway will be shared by Muhimbilli National Hospital , Ocean road Cancer Institute and any other third party Health providing service during the treatment of the patient .
- II. Breast cancer patients should be first seen by surgical unit for clerkship and initial work up but subsequently seen by Multidisciplinary Team that must also involve Pre-operative rehabilitation visits so as to try to reduce incidence of obesity or cigarette smoking that have been shown to factor in on poor surgical outcomes.
- III. Standardize patients care by utilizing all available resources to improve patient's outcome and care such as access to standard medications deemed essential for optimal breast cancer care such NACT must be deemed as a mandate for every patient prior to surgery.
- IV. To put more emphasis on regular outcome studies are needed to measure efficiency of services and reduce disparities in the outcome goals

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APPENDICES

APPENDIX I: INFORMED CONSENT (ENGLISH VERSION)

FORM FOR PATIENTS WITH BREAST CANCER LISTED FOR OPERATION

INTRODUCTION

My name is **Bagenda Franklyn** I am doing research on the immediate outcomes of patients with Breast cancer at MNH from August 2018 to October 2019. I am going to give you some information and invite you to be part of this research, I will conduct an interview session with you and fill up my questionnaire and also do a follow up on you for a minimum of 30 days even after being discharged.

Purpose of the research; the aim of this research is to identify the outcomes of surgical treatment for those patients with breast cancer in our setting, identification of diagnostic variability encountered during preparation for major surgery. Lastly is the identification of patients that need further therapy.

What participation involves; this research involves all patients with breast cancer who have been listed for operative intervention at MNH during period of study from August 2018 to October 2018.

Voluntary participation; your participation is entirely voluntary and if you agree to join the study, you will be interviewed to answer questions from the questionnaires and some of your information will be extracted from the hospital file and computer system of the hospital, whether you choose to join the study or not you will be given standard care of treatment offered by hospital without any change.

Confidentiality; Confidentiality will be observed and unauthorized persons will have no access to the data collected.

Costs: No payment will be requested from you as a fee to participate in the study

Benefits; The information you provide will enable us to explore the system factors that contributing to the diagnostic modalities standardization for patients to be listed for surgical treatment for Breast cancer. The results of this study will enable hospital and health system to put measures in ensuring timely diagnosis and timely treatment to patients with above mentioned cancer

Risks; we do not expect that any harm will happen to you because of participating in this study.

Right to withdraw: You can stop participating in this study at any time, even if you have already given your consent and refusal to participate or withdrawal from the study will involve no penalty.

Who to Contact if you have questions about this study?

In case of any information about your rights as a participant in this study, please contact:

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P. O. BOX 65001, Dar es Salaam.

Supervisor

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Signature; I have read and understood the contents in this form and my questions have been answered.

I agree /do not agree to participate in this research.

Signature/thumb print of the participant.....

Signature/thumb of the witness

Signature of the Investigator

Date of signed Consent

APPENDIX II: FOMU YA MGONJWA

FOMU YA MGONJWA.

UTANGULIZI

Mimi **Bagenda Franklyn** nafanya utafiti wamotokeo namaendeleo ya matibabu ya wagonjwawasaratani ya matitinatumbo, waliohudumiwa hospitalikuu ya Muhimbili kuanzia mwezi wa Agosti, 2018 hadi Oktoba, 2018. Katika uchunguzi huu, nitafanyama hojiano ya anakwaana, nakujaza fomua alumiyenye maswali kadhaa. Mbalinahayana ombi akiufatilia mwenendowahali ya afyayako kwasiku 30 baada ya kuruhusiwa kutoka hospitali.

Madhumuni ya utafiti: Madhumuni ya utafiti huunika bainimatokeo ya matibabu ya upasuaji kwa wagonjwawasaratani ya matitinatumbo. Pia, kubainimama ya nambinuzi uchunguzi uliotumika kutambua uwepo wa gonjwa, nahatu azilizi chukuliwa hadi kufikia kupendekeza upasuaji kamanjia ya matibabu. Na pia kutambua kamagonjwa ata hitaji matibabu zaidi baada ya kuruhusiwa kutoka hospitalini.

Walengwa: Utafiti huu unalengwa gonjwa wote wenyesaratani ya matiti au saratani ya tumboni waliopendekeza wakufanyiwa upasuaji katika hospitalikuu ya Muhimbili kati ya miezi ya Agosti 2018 na Oktoba 2018

Ushiriki wa hiari: Ushiriki wa kowatafiti hiini wa hiari, na endapo utakubali kushiriki utahusi shama hojiano nakujaza fomua ya maswali. Pia, baadhi ya taarifa zitachukuliwa toka rekodi za hospitali.

Tafiti hii haihusianina huduma matibabu unayopewa hospitalini, endapo hutapenda kushiriki tafiti hii, utapata huduma kamakawaida.

Faragha:

Taarifa za kuzitatu kwa wasirina juhi kubwa itatumika kuhakikisha taarifa za koha zimfikiina walakutumika amtubaki.

Garama: Hakuna garama zote zile kwako kushiriki kwa utafiti huu.

Manufaa ya tafiti: Taarifa nitakazokusanyazitatumika kuchunguzana kubainimifumo bora ya kupimana kutumia upasuaji kamanjia ya matibabu ya saratani ya matitinatumbo.

Matokeo ya utafitihuupiautasaidiahospitalikubainimifumo ya kufanyavipimovyaharakanakuanzishamatibabu.

Athari: Hakunaathariyoyoteilekwamshiriki

Kusitishaushiriki: Unaruhusa ya kusitishaushirikiwako katika utafitihu mudawowoteule, nahakutakuwanalawamawalamalamiko.

Mawasiliano: Endapoutakuwana maswali kuhusu utafitihuu, uhalali wake au sawalalolotelilekuhusiananatafitihii, tafadhaliwasilianana.

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Sahihi;

Mimi nimesomanakuelewafomuhiina maswali yanguyamejibiwakifasaha.

Nakubali /Nakataa kushiriki utafitihuu.

Sahihi/Dole gumba – Mshiriki

Sahihi/Dole gumba - Shahidi.....

Sahihi/Dole gumba – Mtafiti

Tarehe

APPENDIX III: QUESTIONNAIRE/CHEAK LIST

Patient characteristics		
Patient ID	Local hospital field	
Primary method of patient identification	Multidisciplinary team meeting	
	theatre logbook,	
	tumour board list,	
	outpatient clinic list,	
	planned operating list,	
	ward/handover list, staff memory	
Age	Completed year	
Gender	Male, Female, Unknown	
Body mass index (weight (kg) / height ² (metres))	Underweight (BMI <18.5)	
	Normal weight (BMI 18.5 to 24.9)	
	Overweight (BMI 25 to 30)	
	Obese (BMI >30)	
Unintentional weight loss ($\geq 10\%$ over 6 months, include clothes size ref in key)	Yes, No, Unknown	
Performance status	0, 1, 2, 3, 4, Unknown	
ASA score	I, II, III, IV, V, Unknown	
Smoking status	No-never	
	Yes-but stopped now	
	Yes-current smoker	
	Unknown	
Pathway		

Presentation	Symptomatic	
	screening	
	detected incidentally	
	unknown	
Date of first consult for cancer symptoms (may be estimated)	DD/MM/YYYY	
Who did the patient first consult for cancer symptoms?	Local clinic: family doctor / general practitioner	
	Local clinic: nurse	
	Local clinic: specialist doctor	
	Hospital: out-patient clinic	
	Hospital: in-patient	
	Other/non-medical/traditional healer	
	Unknown	
Distance from home to hospital	< 10 km	
	10-20 km	
	20-50 km	
	50-100 km	
	>100 km	
	Unknown	
Disease characteristics		
Location	Right Breast	
	Left Breast	
Cancer specific information	Fixed fields for each cancer (see specific cancer variables)	
Diagnosis (what tests were performed pre-operatively, please tick all that apply)	Fixed fields for each cancer (see specific cancer variables)	
Clinical stage	TNM classification / Essential TNM	

	Classification	
Neoadjuvant therapy	Fixed fields for each cancer (see specific cancer variables)	
Operative characteristics		
Date of admission	DD/MM/YY	
Date and time of operation	DD/MM/YY	
Urgency of operation	Elective	
	Emergency	
Surgical intent (at completion of procedure)	Palliative	
	Curative	
Was a surgical safety checklist used?	No-but available in this hospital	
	No-but available in this hospital,	
	Yes,	
	Unknown	
Primary operation performed	Fixed fields for each cancer (see specific cancer variables)	
Pathology		
Most valid basis for cancer diagnosis	Clinical only	
	Imaging	
	Exploratory surgery/endoscopy without histology	
	Tumor specific markers	
	Cytology	
	Histology of metastasis (secondary deposit)	
	Histology of primary	
Histology	Fixed fields for each cancer (see specific cancer	

TNM (pathology)		
Total number of lymph nodes in specimen		
Histological grade	1, 2, 3, (4)	
Lymph vascular invasion	No	
	Yes	
	Unknown	
Resection margins	Fixed fields for each cancer (see specific cancer variables)	
Outcomes and adjuvant treatment		
How was 30-day follow-up status achieved?	Still an inpatient	
	Clinic review	
	Telephone review	
	Community/home review	
	Discharged before 30 days and not contacted again	
30-day mortality (if alive at the point of discharge and no follow-up information available, indicate Alive)	Alive	
	Dead (date of death	
	Unknown	
30-day cancer-specific complications	Fixed fields for each cancer (see specific cancer variables)	
Length of postoperative stay	Continuous number of days	

Surgical site infection	No,	
	Yes,	
	Unknown	
Post-operative hemorrhage	No	
	Yes-no intervention required	
	Yes-intervention required	
	Yes-critical care admission +/- intervention required	
	Unknown	
Planned adjuvant treatment	Fixed fields for each cancer (see specific cancer variables)	

BREAST CANCER SPECIFIC VARIABLES

Diagnosis (what tests were performed pre-operatively, please tick all that apply)	> USS (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> Mammogram (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> Biopsy: Fine needle aspiration (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> Biopsy: Core biopsy (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> Biopsy: Open/excision biopsy (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> CT (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> MRI (No-not indicated, No-indicated but not available, No-indicated and facilities available, but patient not able to pay, Yes, Unknown)	
	> ER, PR, HER2 status assessed (No-not available at this hospital, No-but available at this hospital, Yes-NEGATIVE, Yes-POSITIVE, Unknown)	
	Stage (dropdown box)	TNM classification / Essential TNM classification
Unknown		
Neoadjuvant chemotherapy	No, patient does not need it	
	No, patient needs it, but not available	

	No, patient needs it, facilities available, but patient not able to pay	
	No, planned but not given	
	Yes, NO anthracycline, NO taxane	
	Yes, anthracycline, NO taxane	
	Yes, anthracycline AND taxane	
	Yes, regimen unknown	
	Unknown	
Neoadjuvant radiotherapy	No, patient does not need it	
	No, patient needs it, but not available	
	No, patient needs it, facilities available, but patient not able to pay	
	No, planned but not given	
	Yes (Cobalt)	
	Yes (Linear accelerator)	
	Yes (type unknown)	
	Unknown	
Other neoadjuvant treatment (tick all that apply)	Hormone therapy	
	Biological therapy (HER2 inhibitor)	
	Oophorectomy	
	Other (free text)	
Operation		
Primary operation	Mastectomy	
	Partial mastectomy / wide local excision / lumpectomy	
	Open biopsy of breast	
	Other operations on breast	
Sentinel lymph node biopsy	No, not available in this hospital	
	No, but available in this hospital	
	Yes, single technique	
	Yes, dual technique	
	Unknown	
Axillary lymph node biopsy	No,	
	Yes,	
	Unknown	
Resection margins checked at time of	No,	
	not available in this hospital	

surgery		
Reconstruction	No, not available in this hospital	
	No, but available in this hospital	
	Yes, immediate – prosthesis	
	Yes, immediate – flap	
	Yes, planned at later stage	
Pathology		
Histology	Invasive ductal carcinoma	
	Invasive lobular carcinoma	
	Ductal carcinoma in-situ (DCIS)	
	Other CANCER (specify)	
	Other BENIGN (specify)	
	Unknown, not available in this hospital	
	Unknown, but available in this hospital	
Receptor status	ER, PR, HER2, Ki67	
	No-not available in this hospital	
	No-but available in this hospital	
	Yes-NEGATIVE	
	Yes-POSITIVE	
Resection margins	< 1 mm / tumor on inked margin	
	1-5 mm (NO tumor on inked margin)	
	>5 mm	
	Margins confirmed clear, but no distance given	
	Unknown, not available in this hospital	
	Unknown, but available in this hospital	
Outcomes and Adjuvant treatment		
Post-operative seroma	No	
	Yes, no intervention required	
	Yes, intervention required	
	Yes, critical care admission +/- intervention required	
	Unknown	
Planned adjuvant treatment (tick all that apply)	No, patient does not need it	
	No, patient needs it, but not available	
	No, patient needs it, facilities available, patient unable to pay	
	Radiotherapy	
	Biological therapy (anti-HER2)	
	Hormone therapy	
	Re-excision of margins	

APPENDIX IV: CDC Definition of Surgical Site Infection

SUPERFICIAL INCISIONAL SURGICAL SITE INFECTION

Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI made by a surgeon or attending physician.

DEEP INCISIONAL SURGICAL SITE INFECTION

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g. fascia, muscle) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the Surgical site
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever ($>38^{\circ}\text{C}$), localized pain or tenderness, unless incision is culture-negative
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
4. Diagnosis of deep incisional SSI made by a surgeon or attending physician

ORGAN/SPACE SURGICAL SITE INFECTION

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs and spaces) other than the incision which was opened or

manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in thorgan/space
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
4. Diagnosis of organ/space SSI made by a surgeon or attending physician.

APPENDIX V

Clavien–Dindo classification of surgical complications.2

Grade Definition

- I Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or radiological interventions
Permitted therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. The grade also includes wound infections opened at the bedside
- II Requiring pharmacological treatment with drugs other than those permitted for grade I complications
Blood transfusions and total parental nutrition are also included
- III Requiring surgical, endoscopic, or radiological intervention
 - IIIa Intervention not under general anaesthesia
 - IIIb Intervention under general anaesthesia
- IV Life-threatening complication (including complications of the central nervous system)a that requires management in a high dependency, or intensive therapy unit
 - IVa Single organ dysfunction (including dialysis)
 - IVb Multiorgan dysfunction
- V Death

Suffix “d” If the patient suffers from a complication at the time of discharge the suffix “d” (for “disability”) is added to the respective grade of complication.

It indicates the need for follow-up to fully evaluate the complication

“a” Brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks

