

**EFFECT OF BREAST CANCER MULTIDISCIPLINARY TEAM MEETINGS (MDTM) ON
PATIENT-CARE AT KENYATTA NATIONAL HOSPITAL (KNH)**

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Master of Medicine in General Surgery

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DECLARATION

I declare that this proposal is the result of my original work and that it has not been submitted either wholly or in part in any other institution for an academic award.

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DEPARTMENTAL APPROVAL

The research proposal has been presented at the surgical departmental meeting held on 20th June, 2019 and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research Committee.

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LIST OF ABBREVIATIONS

AJCC	American Joint Committee on Cancer
EAGC	Expert Advisory Group on Cancer
KNH	Kenyatta National Hospital
KNCG	Kenya National Cancer Guidelines
IQR	Interquartile range
MDBCC	Multidisciplinary Breast Cancer Clinic
MDT	Multidisciplinary Team
MDTM	Multidisciplinary Team Meeting
MTRH	Moi Teaching And Referral Hospital
NHIF	National Hospital Insurance Fund
NCR	Nairobi Cancer Registry
RTC	Radiotherapy Clinic
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
TNM	Tumor size, Lymph Nodes affected, Metastases

ABSTRACT

Background: Many of the published studies in USA, Europe and Asia show that multidisciplinary team meetings (MDTM) are beneficial in management of cancer patients. There is paucity of study in our context.

Study objective: To study the effect of breast cancer MDTM on surgical patient-care at a local institution, Kenyatta National Hospital (KNH) in terms of patient flow and documentation of breast cancer evaluation in accordance to Kenya National Cancer Guidelines (KNCG).

Methodology: This was a retrospective cross sectional study carried out in the month of November, 2019. Data was extracted from files of all patients who had been discussed at breast cancer MDTM and were undergoing surgery for breast cancer at KNH over an eighteen month period. Data on patient demographics, flow and documentation of breast cancer evaluation was collected. These were compared with results of an audit carried out at KNH in 2017 before the installation of breast-MDTM. Data was analyzed for means and proportions.

Results: The mean age at diagnosis was 50.2 ± 11.8 years. Duration of time from referral to index breast clinic consultation was 8 days, down from 10.9 days in pre-MDT period. Duration of time from specialty consultation to surgery was 55 days, down from 64 days in pre-MDT period. From 89 files, the most prominent risk factors were reproductive history (89.9%) and hormonal use (82%) while the most frequent presentation is breast lump (95.5%); All the patient had their renal function test with very few having calcium (4.5%) test done. Mammogram (70.8%) is a very frequent test for diagnosis while chest CT scan (73.0%) for staging is the most common test. Majority of decisions were made from core biopsy (98.9%), immunohistochemistry was performed

in 84.3% of cases. In 77.5% there was documentation of TNM staging. Compared to pre-MDT study there was improvement in documentation of every aspect of breast cancer evaluation.

Conclusion: This study suggests that breast-MDTM have improved patient flow and documentation of breast cancer assessment in accordance to KNCG and thus patient-care at KNH.

INTRODUCTION

Before the introduction of multidisciplinary teams (MDT) cancer patients would be separately managed by one clinician/unit and then referred to another for subsequent management. The lack of integrated approach and thus poor coordination of patient care is an emotionally and physically draining experience for the patient, leading to low patient satisfaction rates with the services. The benefits of MDT are not limited to patients; involved healthcare professionals report greater job satisfaction and psychological wellbeing, better decision-making capacity and support for management of complex cases. MDT lays an educational framework through the active discussions, review of cases and collaborative research which helps to improve the understanding of the disease processes and ensure effective diagnostic and management options for the patients [1] [2].

Published data on multidisciplinary team meetings (MDTM) have shown them to benefit patients as well as healthcare providers in the developed world. In the United States a cohort study conducted on patients with newly diagnosed urological malignancies suggests that MDT approach affected and, in some cases, even changed the diagnostic and management plans [3]. Another study in the United Kingdom showed that after the introduction of MDT there was a significant rise in the number of colorectal cancer patients treated with adjuvant chemotherapy thus increasing the three-year survival rate of Duke stage C colorectal cancer patients [4]. *Gabel et al* in 1997 reported that Multidisciplinary Breast-Cancer Clinic (MDBCC) improved patient satisfaction and reduced the duration from diagnosis to the initiation of definitive treatment [5].

The treatment plan is decided by most MDTs without the patient actually being present and treatment decisions are made based on documentation in patients' files. Therefore, documentation on clinical assessment, laboratory tests, radiological assessments and AJCC-TNM staging is of utmost importance. From a 2017 audit by Miima et al on adherence to Kenya National Cancer Guidelines (KNCG) on diagnosis and staging of breast cancer at Kenyatta National Hospital (KNH), triple assessment for breast cancer was incomplete and inconsistent [6]. This could result in a negative impact on management of these patients.

There is paucity of data from African countries on the impact of MDTM in our local institutions. There may be cultural and medical practice differences in our local institutions that might have an influence on MDTM and their impact on patient-care [7].

This study's main objective is to research on the usefulness of the recently introduced MDT to the breast cancer patients undergoing surgery at KNH.

LITERATURE REVIEW

The Multi-disciplinary Team (MDT): A group of persons from different healthcare specialty units, regularly meeting together at a given time to discuss patients of interest. Each individual specialist then contributes his/her expert opinions to create a management plan in terms of diagnostic workup and treatment options for the patients [8].

The introduction of multidisciplinary teams in cancer management was stressed by the Expert Advisory Group on Cancer (EAGC) through the Calman-Hine report, 1995 in the United Kingdom (UK). Acknowledging the heavy burden of the disease on the community, the huge economic consequences and the variations in the recorded outcomes of treatment, the EAGC defined the policies for provision of cancer services. In the report they recommended a lead clinician be appointed to organize and coordinate all the clinical services in the cancer unit. The lead clinician should also involve surgical and nonsurgical colleagues in multidisciplinary consultations and this organization should standardize cancer treatment throughout the country [9].

Since the 1960s hypothesis that breast cancer was a systemic disease [10] a lot of research has led to development of complex breast cancer diagnostic, staging and treatment algorithms requiring a wider range of specialist expertise [11]. Optimal treatment strategies therefore require an effective communication between the cancer specialists, both surgical and non-surgical (oncological) [12]. Direct communication between the specialists led to the formation of MDTs which now play an important role in delivery of cancer care treatment globally. The structure and content of MDTs in different countries and regions may differ and most MDTs are tailored to their institutions.

Several studies published internationally emphasize on the benefits of MDTMs especially focused on care of patients with different types of cancer. It has been proved through the studies that follow that the benefits of cancer-care-MDTMs include

- greater adherence to evidence based guidelines [13]
- shorter duration from index consultation and diagnosis to treatment [5]
- better client satisfaction [5]
- change in diagnosis and treatment recommendations [14]
- better cancer survival rates [15]

One such study was conducted at the University of North Carolina at Chapel Hill in the United States in 2009. In their institution 269 patients, newly diagnosed with urological malignancies, were reviewed and discussed at a MDTM, following which, major changes in diagnosis were made in 17% of renal cancer cases and 23% of the bladder cancer cases. Also, major changes in treatment plans were made in 36% of renal cancer cases, 29% of testicular cancer cases and 44% of the bladder cancer cases [3]. This indicates that MDTMs helps clarify diagnosis and treatment plan therefore enhancing adherence to treatment guidelines thus would more likely lead to better outcomes.

Another study in the United Kingdom in 2008 followed a cohort of patients with colorectal cancer (Duke C) over 5 years after introduction of colorectal-MDT. More patients were enrolled in adjuvant chemotherapy in the cohort post-MDT as compared to the cohort pre-MDT; in the pre-MDT cohort the three year survival rate for Duke C colorectal cancer patients was 58%, compared to the post –MDT cohort in which it was 66% [4]. This shows that there was a significant rise in

the number of colorectal cancer patients treated with adjuvant chemotherapy thus increasing the three-year survival rate of Duke stage C colorectal cancer patients.

Gabel et al (1997) evaluated patient satisfaction in the newly diagnosed clients with breast cancer attending a multidisciplinary breast cancer clinic (MDBCC). They compared 177 clients seen in the first year after establishment of the MDBCC to a control group of 166 seen in the one year prior to introduction of MDBCC. Their results showed that MDBCC increased patient satisfaction by assisting patients to participate in their treatment decisions and by considering inputs of patients' families and friends. They also found that the duration between diagnosis and the initiation of definitive treatment was considerably reduced (42.2 days vs. 29.6 days; $P < 0.0008$).
[5]

Kesson et al in 2012 conducted a comparative study on the survival of 13,722 breast cancer patients following the establishment of MDT care at the Greater Glasgow Health Board (GGHB). Their control group in the West of Scotland continued to offer treatment in the conventional way at that time. In the pre-MDT-care cohort, breast cancer mortality was 11% higher in the GGHB than in the West of Scotland and the all-cause mortality rates were similar in both groups. At 5 years, the post-MDT-care cohort breast cancer mortality was 18% lower and all-cause mortality was 11% lower in the GGHB than in the West of Scotland [15].

The treatment plan is decided by most MDTs based on documentation in patients' files. Therefore, documentation on clinical assessment, laboratory tests, radiological assessments and AJCC-TNM staging is of utmost importance. S. Miima et al in 2017, evaluated adherence to KNCG in breast cancer diagnosis and staging at KNH [6]. Their study showed that the duration from the first consultation at breast clinic to surgical intervention was 64.0 ± 114.4 days; the inadequacies in

documentation of clinical, laboratory, radiological, pathological and metastatic workups are summarized in the table below:

Breast cancer assessment at KNH in 2017	% documentation
Clinical	24.8 - 86.4
Radiological	3.6 - 35.2
Metastatic evaluation	3.6 – 64.0
Laboratory	8.4 – 94.8
Pathological/ tumor biology	3.6 – 62.4
AJCC – TNM staging	16.0

With the recent introduction of breast-MDT at KNH in March 2018, studies are needed to evaluate the impact of MDT in patient care at this institution. International clinical practice guidelines recommend that breast cancer should be managed by MDT. However, few studies have looked at how these guidelines are followed by the medical community [16] [17].

STUDY JUSTIFICATION

As shown in the literature, MDTM are beneficial in the management of cancer patients by way of clarifying diagnosis and treatment plans and thus improving outcomes. In addition to the added advantage of navigating the patient, they do help improve patient flow and adherence to treatment guidelines. In KNH, breast cancer MDTM were introduced very recently; their impact on patient-care was yet to be studied. We did not know whether MDTM have improved patient flow and/or documentation of breast cancer evaluation in accordance to KNCG. There was paucity of data from African countries on the impact of MDTM in our local institutions. Given that breast-MDT is one of the first MDTs in KNH, its model could be extended to other cancer units, for example in colon cancer, hepatobiliary cancers, gynecological cancers etc.

STUDY OBJECTIVES

MAIN OBJECTIVE

To establish the effect of breast cancer MDTM on surgical care of breast cancer patients treated at KNH in the last eighteen months in terms of patient flow, treatment delays and documentation of breast cancer evaluation in accordance to KNCG.

SPECIFIC OBJECTIVES

- To determine duration of time from referral to index breast clinic consultation after introduction of breast cancer MDTM.
- To determine duration of time from index breast clinic consultation to surgery after introduction of breast cancer MDTM.
- Compare the time to index consultation and from index consultation to surgery with audit results of 2017

- To determine the documentation of breast cancer evaluation on clinical assessment, radiological assessment, pathologic diagnosis & tumor biology, laboratory investigations, metastatic assessment and AJCC-TNM staging, after introduction of breast cancer MDTM and compare this with audit results of 2017.

METHODOLOGY

STUDY DESIGN: A retrospective cross-sectional study

STUDY SETTING: KNH medical records. Patient files were derived from the medical records unit of KNH.

KNH, being a national referral hospital, boasts a capacity of 2000 beds and serves as a teaching hospital for the College of Health Sciences, University of Nairobi. It is the apex national referral institution that has the capacity in terms of specialized personnel in every area.

At KNH breast cancer MDTM are regularly held once weekly after the weekly breast clinic. The team is composed of specialists from different departments of the hospital namely, breast surgeons, surgery registrars, pathologists, oncologists and radio-oncologists. The files of all patients with breast cancer attended to at the preceding breast clinic are presented by the breast surgeons at the MDTM. This is followed by independent contributions from other attending surgeons/ surgery registrars, pathologists, oncologists and radio-oncologists. Decisions are thus made promptly on the next step in patient management. The aim of the MDTM is to improve patient care at KNH through a direct in-person face-to-face dialogue between the specialists.

STUDY POPULATION

Data was extracted from the files of all patients who had been discussed at breast cancer MDTM over duration of 18months (from March 2018 to November 2019) and were undergoing surgery for breast cancer at KNH;

INCLUSION CRITERIA: Medical records of all patients being operated on for breast cancer at KNH and discussed in the breast cancer MDTM, whose index breast clinic consultation was after installation of the MDTM.

EXCLUSION CRITERIA

- Patients who were being followed up at breast clinic for breast diseases other than breast cancer.
- Patients who had already been attended to at breast clinic before installation of breast cancer MDTM but were now being followed up and discussed in the MDTM.
- Patients who died before the planned surgery.
- Patients with incomplete medical records
- Patients undergoing other definitive management, for example, chemotherapy or radiotherapy

SAMPLING METHOD

Consecutive sampling was done for all patients who met the inclusion criteria

SAMPLE SIZE CALCULATION

The formula below was used to calculate the sample size:

$$\text{Unlimited population: } n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\epsilon^2}$$

$$\text{Finite population: } n' = \frac{n}{1 + \frac{z^2 \times \hat{p}(1-\hat{p})}{\epsilon^2 N}}$$

n = sample size for infinite population

n' = corrected sample size

P= prevalence; The estimated prevalence of 27.1% will be used (Globocan 2012 report)

e = confidence interval = 0.05

Z = 1.96 for level of confidence = 95%,

- $n = \frac{1.96^2 \times 0.271(1-0.271)}{0.05^2}$

- **n= 303**

LIMITATIONS

- No control over Data omission in patient files.
- This was a one hospital based study.
- No control over inherent delays from the time of decisions made by MDT to the time of execution of these decisions at KNH.

MITIGATION OF LIMITATION

KNH being the largest referral hospital in the country, it has a very large catchment area and this allows generalizations. We collected and analyzed data from complete records.

ETHICAL CONSIDERATIONS

This being a retrospective study, data was collected from patient files at the medical records unit of KNH without direct one-on-one patient interaction by the health care personnel. This being a low risk study we requested a waiver of consent from the ethics board of KNH.

Serial numbers were assigned to patient med records for patient confidentiality. Pretested structured questionnaire were coded to match the medical patients' files. The questionnaire was filled by research assistants who were trained on data collection, entry, confidentiality and ethical conduct during the study. All the collected data was stored in a secured locker accessible to the principal investigator (PI) whereas the soft copy was stored in a password protected file.

DATA COLLECTION AND ANALYSIS

Data was collected by employing a closed-ended questionnaire. The objectives of the study were attached with the questionnaire.

The PI and research assistants collected the data through filling in the questionnaires. The questionnaires were reviewed for completeness then were stored securely.

The data collected included patient demographics, duration to review at breast clinic (time of referral to breast clinic and first breast clinic visit), duration to surgery, documentations on: clinical presentation, laboratory investigations, radiological assessments, pathological assessments and AJCC-TNM staging. Data was entered into Statistical Package for Social Sciences (SPSS) version 21 and analyzed for means and proportions. Continuous data was analyzed and presented

as means and standard deviations; categorical data was analyzed and presented as frequencies and proportions.

Data was then displayed in tables.

RESULTS

From the date of installation of breast cancer MDT a total of 428 patients were discussed in the MDTMs over the eighteen month (18) period up-to the point of data collection. 10 were male patients and the rest were female. From the medical records only 89 medical records of patients met the eligibility criteria. 141 patients underwent neoadjuvant or palliative chemotherapy and radiotherapy, the rest were either lost to follow-up or died before receiving the definitive treatment. The mean age was 50.2 (SD=11.8). From the 89 files, the most prominent risk factors were reproductive history (89.9%) and hormonal use (82%) while the most frequent presentation is breast lump (95.5%) (Table 1).

Table 1: Distribution By Risk Factors And Signs

Variable	Frequency (%)
Risk factors	
Personal history of breast cancer	51 (57.30)
Reproductive history	80 (89.9)
Hormonal use	73 (82.02)
Family history of malignancy	68 (76.40)
History of ionizing radiation	9 (10.11)
Physical inactivity	3 (3.37)
Alcohol use	68 (76.40)

Cigarette smoking	69	(77.53)
Signs		
Jaundice	74	(83.15)
Breast lump	85	(95.51)
Nipple retraction	43	(48.31)
Skin darkening	64	(71.91)
Skin dimpling	46	(52.27)
Nipple discharge	74	(84.09)
Ulceration	27	(30.68)
Palpable nodes axilla	73	(82.02)
Palpable clavicular nodes	29	(32.95)
Breast enlargement	45	(50.56)
Cough	22	(24.72)
Bone pain	14	(15.73)
Pathological fractures	1	(1.12)
Breast pain	70	(78.65)

All the patient had their renal function test with very few having calcium (4.5%) test done (Table 2). Mammogram (70.8%) is a very frequent test for diagnosis while chest CT scan (73.0%) for staging is the most common test (Table2). Majority of decision were made from core biopsy (98.9%), immunohistochemistry was performed in 84.3% of cases (Table 2).

Table 2: Distribution Of Investigative Assessments

Variable	Frequency (%)
Laboratory investigation	
Full blood count	88 (98.88)
Urea electrolyte creatinine	89 (100.00)
Liver function test	43 (48.31)
Calcium	4 (4.49)
Urate	10 (11.24)
HIV	15 (16.85)
Radiological investigations	
Mammogram	63 (70.79)
Breast U/S	38 (42.70)
Axillary U/S	24 (27.27)
Breast MRI	3 (3.37)
Chest X-RAY	18 (20.22)
Abdominal U/S	27 (30.34)
Chest CT-Scan	65 (73.03)
Abdominal CT-Scan	58 (65.17)
Pathological investigations	
FNA biopsy	14 (21.88)
Core biopsy	88 (98.88)
Immunohistochemistry (IHC) / Hormonal status	75 (84.27)

In 77.5% there was documentation of TNM staging. The median duration from referral to index breast clinic consultation was 8 days (inter-quartile range (IQR) 2-16). The median duration from index breast clinic consultation to surgery was 55 days (IQR=25-121).

In comparing the flow and performance of investigation, the introduction of breast cancer MDT has improved the flow by few days, but the age seems to be increasing. The performance of investigation seems to also increase (Table 3)

Table 3: Comparison of results with a pre-Breast-MDT study (S. Miima et al in 2017)

Variable	Pre-MDT 2017	After-MDT - 2018
Age and patient flow		
Mean age in years (SD)	47.5 (15.5)	50.2 (11.8)
Duration from referral to index breast clinic consultation in days (IQR)	10.9	8
Duration from index breast clinic consultation to surgery in days (IQR)	64.0	55
Laboratory investigations documentation		
Variable	Frequency (%)	Frequency (%)
Full blood count	94.8	98.9
Urea electrolyte creatinine	94.8	100.0
Liver function test	44.4	48.3
Calcium	14.4	4.5
Radiological tests documentation		
Variable	Frequency (%)	Frequency (%)
Mammogram	35.2	70.8

Breast U/S	26.4	42.7
Axillary U/S	6.8	27.3
Breast MRI	3.6	3.4
Chest X-RAY	64.0	20.2
Abdominal U/S	46.0	30.3
Chest CT-Scan	12.8	73.0
Abdominal CT-Scan	9.6	65.2
Pathological diagnosis documentation	Frequency (%)	Frequency (%)
FNA biopsy	61.6	21.9
Core biopsy	62.4	98.9
Immunohistochemistry (Hormonal status)	37.7	84.2
AJCC-TNM staging documentation	Frequency (%)	Frequency (%)
TNM staged	16	77.5

DISCUSSION

Breast cancer is the most frequently diagnosed cancer in women and is associated with high morbidity and mortality worldwide. Early diagnosis and stage directed treatment are vital in reducing morbidity and mortality associated with breast cancer [16]. International clinical practice guidelines recommend that breast cancer should be managed by MDT. However, few studies have looked at how these guidelines are followed by the medical community [16] [17]. In KNH, breast cancer MDTM were introduced very recently; their impact on patient-care was yet to be studied. This study's main objective was to research on the usefulness of the recently introduced MDT to the breast cancer patients being treated at KNH in terms of patient flow and documentation of breast cancer evaluation in accordance to KNCG.

To establish this usefulness we determined the duration of time from referral to index breast clinic consultation, and duration of time from index breast clinic consultation to surgery after introduction of breast cancer MDTM, and also determined the documentation of breast cancer evaluation in accordance to KNCG of the following: clinical assessment, radiological assessment, pathologic diagnosis & tumor biology, laboratory investigations, metastatic assessment and AJCC-TNM staging, after introduction of breast cancer MDT.

From the date of installation of breast cancer MDT a total of 428 patients were discussed in the MDTMs over a period of eighteen (18) months. 10 were male patients and the rest were female. From the medical records only 89 medical records of patients met the eligibility criteria and were reviewed. 141 patients underwent neoadjuvant or palliative chemotherapy and radiotherapy; the rest either sought treatment in other facilities or were lost to follow-up for unknown reasons. Since the more widespread coverage of National Hospital Insurance Fund (NHIF) management of breast cancer is now being offered in many public and private hospitals across the country.

From the available records the mean age at diagnosis of breast cancer was 50.2 ± 11.8 years, the youngest being 26yrs and oldest 82yrs. This finding is consistent with several studies carried out on the African continent [18] [19] [20].

Duration of time from referral to index consultation at the breast clinic was 8 days, with IQR of 2 to 16 days. Duration of time from index breast clinic consultation to surgery was about 55 days with an IQR of 25-121 days. This was much shorter than in the pre-MDT period in which the time taken from first surgical consult to surgery was more than 2 months (64.4 ± 114.4 days). This long duration might be attributable to the fact that most patients present to the specialty clinic at a higher stage (III and IV) and grade at diagnosis [19] and are therefore sent for further investigations prior to surgery. Also, during this period the patients undergo laboratory, radiological and pathology assessments. The delays in awaiting NHIF approval to undergo these tests, patients' financial constraints to acquire the tests, and systematic delays within the different departments of the hospital may also contribute to the long duration. In the western world 77% of breast cancer patients undergo surgery within the first 30days [21] and time to surgery has been shown to have an effect on breast cancer survival [21].

History and physical examination.

From the 89 files, the most prominent risk factors were reproductive history (89.9%) and hormonal use (82%) while the most frequent presentation is breast lump (95.5%). Risk factor assessment was similar in the pre-MDT and post-MDT studies; however the least sought risk factors were still those of physical inactivity and ionizing radiation exposure at 3.4% and 10.1% respectively. It can be suggested that they be added to the standardized history and physical examination questionnaire used during the initial breast specialty clinic consultation. The history

of presenting illness and physical examination was not as comprehensive as that suggested by KNCG, and clinical evaluation for metastasis was inadequate and may even be worse than before-MDT (cough 24.7%, bone pain 15.7% and pathological fractures 1.1%). This may be due to omission of questions on metastasis evaluation on follow-up clinic visits.

Laboratory investigations.

All the patient had their renal function test with very few having calcium (4.5%) test done. Total blood count and urea-electrolytes-creatinine levels were the most frequently ordered investigations. This may be due to mandatory requirements of these investigations as preoperative work-ups. However, investigations assessing possible metastasis were not widely used despite being readily available in the laboratory (calcium and alkaline phosphatase). This may be due lack of emphasis of these additional investigations on already financially challenged patients who present to the public healthcare facilities. High serum uric acid concentration has been shown to predict poor survival in patients with breast cancer [22], uric acid report was documented in only 11% of the medical records.

Radiological evaluation.

Mammogram (70.8%) is a very frequent test for diagnosis while chest CT scan (73.0%) for staging is the most common test. Radiological breast assessment with mammography and ultrasonography was at 70.8% and 42.7% respectively which may suggest that more patients are undergoing diagnostic imaging studies now than before. Radiological metastasis assessment using computerized tomographic (CT) scan of the chest, abdomen and pelvis was complete in 73.0% and 65.2% respectively, assuming that the chest radiograph and abdominal ultrasound ordered in

the 20.2% and 30.3% was due to affordability of the investigations. These findings appear remarkably better in the post-MDT period than in the pre-MDT period.

Tissue diagnosis

Majority of decision were made from core biopsy (98.9%), immunohistochemistry was performed in 84.3% of cases. Some immunohistochemistry analysis is done in the post-surgery specimen and therefore the frequency is less than that of core needle biopsy. These findings appear remarkably better in the post-MDT period than in the pre-MDT period.

AJCC- TNM staging.

77.5% of the patients had documented AJCC- TNM staging of breast cancer. In the pre-MDT study only 16% had documented staging of breast cancer.

CONCLUSION

The mean age at diagnosis was 50.2 ± 11.8 years, duration of time from referral to index consultation at the breast clinic was 8 days, with IQR of 2 to 16 days, and duration of time from index breast clinic consultation to surgery was about 55 days with an IQR of 25-121. This study has established that breast-MDTM have improved patient flow and documentation of breast cancer evaluation in accordance to KNCG and thus patient-care at KNH. However, there is still room for much improvement in the triple assessment and AJCC-TNM staging documentation. There is need for training healthcare providers on KNCG and revision of the available standardized clinical assessment questionnaire.

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Appendix 1: STUDY TIME FRAME

ACTIVITY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
	2019	2019	2019	2019	2019	2019	2019
Proposal development							
Ethical approval							
Data collection							
Data analysis							
Dissertation submission							

Appendix 2: STUDY BUDGET

ITEM	COST (KShs)
Research fees	2,000
Stationery	10,000
Statistician	40,000
Research assistants	30,000
Printing and binding	20,000
Contingencies	20,000
TOTAL	122,000

Breast lump		
Nipple retraction		
Skin darkening		
Skin dimpling		
Nipple discharge		
ulceration		
Palpable nodes axilla		
Palpable clavicular nodes		
Breast enlargement		
Cough		
Bone pain		
Pathological fractures		
Breast pain		

Initial laboratory investigations (tick where applicable)

Investigation	Yes (has been documented)	No (has not been documented)
Full blood count		
Urea electrolytes creatinine		
Liver function test		
Calcium		
ALP		
Urate		
HIV		

Radiological tests (tick where applicable)

Investigation	Yes (has been documented)	No (has not been documented)
Mammogram		
Breast U/S		
Axillary U/S		
Breast MRI		
Chest X-RAY		
Abdominal U/S		
Chest CT-Scan		
Abdominal CT-Scan		

Pathological diagnosis (tick where applicable)

Investigation	Yes (has been documented)	No (has not been documented)
FNAC report		
Core biopsy report		
Immunohistochemistry report / hormonal status		

	Yes (has been documented)	No (has not been documented)
AJCC-TNM staging		

APPENDIX 4: KENYA NATIONAL CANCER GUIDELINES ON BREAST CANCER
NATIONAL GUIDELINES FOR CANCER MANAGEMENT KENYA

August, 2013

BREAST CANCER

Kalebi A, Abwao H, Chite FA, Othieno-Abinya NA, Muchiri L, Maina M, Adamali N ,

Sayed S, Bird P and Wasike R

Introduction

Breast cancer is the commonest cause of cancer related mortality in women, and a leading cancer in Kenya and globally. It is noted to have a more aggressive behavior in black African women. It also affects men, however majority of patients affected (>99%) are women.

Epidemiology

Breast cancer in Kenyan women occurs more commonly in younger women (age <50 years). It's the leading cancer in women in Kenya with the rate of 33.5/100,000 population according to the Nairobi Cancer Registry. The known risk factors include female sex, age, and a family history of breast cancer, prolonged exposure to estrogens, obesity, smoking and alcohol.

BRCA1 and 2 gene mutations are specific genetic abnormalities that are associated with high risk for breast and ovarian cancers that may be familial. Such candidates may be investigated using genetic tests for the BRCA1 & 2 gene mutation. If confirmed, affected

Subjects may be offered prophylactic mastectomy after child bearing and achieving desired family size.

Screening for early detection is recommended as lesions treated in the early stages have a high cure rate. Screening for breast cancer includes breast self-examination (BSE), clinical breast examination (CBE) and breast imaging (mammogram and/or ultrasound scanning).

BSE is recommended at day 10 of the menstrual cycle. For post-menopausal women, a monthly BSE schedule should be established. All patients with clinical suspicious lesions should have imaging as part of early detection. Mammogram is recommended for women over 40 years, while ultrasound is the imaging of choice for younger women. MRI may be used where possible for screening and early detection in patients at high risk of breast cancer such as those with BRCA1 & 2 gene mutations

Diagnosis

Clinical Features and Initial Presentations

During early stages the following symptoms and signs may be present:

- A painless lump in the breast (in majority of patients)
- Nipple retraction
- Skin changes such as darkening and dimpling (appearance like the skin of an orange)
- Nipple discharge that may be bloody

National Guidelines for Cancer Management Kenya

In late stages, common presentations include:

- Ulceration

- enlarged lymph nodes in the armpit and neck
- Uniform breast enlargement
- Symptoms and signs of distant metastases such as un-resolving cough, bone pains and pathological fractures

Pain is usually a late symptom.

Imaging

- Mammogram is recommended for women over 40 years, while ultrasound is the imaging of choice for younger women.
- MRI may be of value in select group of women who have had equivocal mammogram/ultrasound.

The imaging examination should include the axilla.

Pathology Diagnosis

- A core needle biopsy obtained manually, or preferably by ultrasound or stereotactic guidance is recommended

~ FNA should only be used as a screening test where core biopsy services are not possible / available. Any atypical/suspicious or malignant cytology on FNA must be confirmed on histopathological examination. Surgery should not be done on the basis of FNA results, except

where triple assessment (clinical, radiological and cytological findings) is definitive for malignancy.

* Preoperative or diagnostic open incision biopsy is not recommended.

- The histopathological reporting should be done according to WHO classification, specifying the histological type of breast cancer, grade, lymphovascular invasion, tumor dimensions, number of nodes sampled and number of nodes involved and presence of necrosis.

~ It is recommended that histopathology be reported by specialist pathologists, and if reported by a non-specialist pathologist that this is reviewed as referral before treatment is instituted at a specialist treatment centre.

- Immunohistochemistry (IHC) for estrogen receptor (ER) and progesterone receptor (PR) must be done.

- Fluorescence in situ hybridization (FISH)/chromogenic in situ hybridization (CISH) test is required for equivocal HER2 on IHC (HER2 2+) for confirmation of HER2 overexpression.

~ It is recommended that immunohistochemistry should be undertaken.

Staging and Risk Assessment

Preoperative related disease staging includes clinical, radiological and pathological information.

Clinical examination includes the size of tumor (T stage), axillary and supraclavicular node examination (N), symptoms and signs of metastases (M).

An attempt should be made to stage all breast cancers before any operative treatment. Tumour Node Metastases (TNM) staging system for cancer of the breast

Primary tumor (T)

TX Primary tumor cannot be assessed

T0 No evidence of primary tumor

Tis in-situ

T1 Tumor <20 mm in greatest dimension

T2 Tumor >20 mm but <50 mm in greatest dimension

T3 Tumor >50 mm in greatest dimension

T4 Tumor of any size with direct extension to the chest wall and/or to the skin (Ulceration or skin nodules)

Regional lymph nodes (N)

Clinical

NX Regional lymph nodes cannot be assessed (e.g. previously removed)

N0 No regional lymph node metastases

N1 Metastases to movable ipsilateral level I, II axillary lymph node(s)

N2 Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastases

N3 Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement; or in clinically detected ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node with or without axillary or internal mammary lymph node involvement

National Guidelines for Cancer Management Kenya

Pathological (pN)

pNX Regional lymph nodes cannot be assessed (e.g. previously removed, or not removed for pathological study)

pN0 No regional lymph node metastasis identified histologically

pN1 Micro metastases; or metastases in 1–3 axillary lymph nodes; and/or in internal mammary nodes with metastases detected by sentinel lymph node biopsy but not clinically detected

pN2 Metastases in 4–9 axillary lymph nodes; or in clinically detected internal mammary lymph nodes in the absence of axillary lymph node metastases

pN3 Metastases in >10 axillary lymph nodes; or in infraclavicular (level III axillary) lymph nodes; or in clinically detected ipsilateral internal mammary lymph nodes in the presence of one or more positive level I, II axillary lymph nodes; or in more than three axillary lymph nodes and in internal mammary lymph nodes with micrometastases or macro metastases detected by

sentinel lymph node biopsy but not clinically detected; or in ipsilateral supraclavicular lymph nodes

Distant metastasis (M)

M0 No clinical or radiographic evidence of distant metastases

M1 Distant detectable metastases as determined by classic clinical and radiographic means and/or histologically proven >0.2 mm

Radiology & Imaging for Staging

- In early disease (clinical T1 and T2 tumors), there is no need for further imaging.
- In locally advanced disease (clinical T3 and T4 tumors), chest x-ray and abdominal ultrasound are recommended. Further imaging such as bone scans is guided by clinical presentation.

Laboratory Investigations

- Full blood count (FBC)
- Biochemistry including liver and renal function tests, alkaline phosphatase (ALP), calcium and urate.
- Viral serology for HIV (recommended).
- Tumor markers have no role in diagnosis, treatment or prognostication of breast cancer.



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*To buy 1500/2
for access to patients
for records
code 4020
Bill*

Ref: KNH-ERC/A/422

7th November, 2019

Dr. Gurpreet Singh Roprai
Reg. No.H58/73825/2014
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Roprai

RESEARCH PROPOSAL: EFFECT OF BREAST CANCER MULTI-DISCIPLINARY TEAM MEETINGS (MDTM) ON PATIENT-CARE AT KENYATTA NATIONAL HOSPITAL(KNH) (P621/07/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 7th November 2019 – 6th November 2020.

This approval is subject to compliance with the following requirements:

- a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
- g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

Protect to discover



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Code = 0956015:

Ref: KNH/HOD/GEN-SURG/7/VOL.I

Date: 12th November, 2019

Dr. Gurpreet Singh Rooprai
Reg. No. H58/73825/2014
Dept. of Surgery
School of Medicine
College Of Health Sciences
University of Nairobi

Dear Dr. Gurpreet

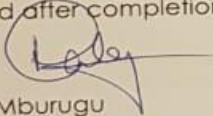
RE: APPROVAL TO COLLECT DATA FROM KNH BREAST SURGERY CLINIC

We acknowledge your request on the above, together with a study registration form and a KNH/UoN ERC approval letter on the study titled "**Effect of breast cancer multi-disciplinary team meetings (MDTM) on patient-care at Kenyatta National Hospital**".

Approval has been granted for you to collect data from the breast surgery clinic, Breast MDT meetings and records of patients who have earlier been seen at the clinic at Kenyatta National Hospital.

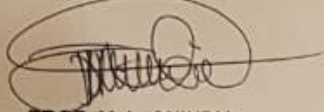
Kindly liaise with the ACN Incharge of the Surgical Out-patient Clinic No. 24 for facilitation. By a copy of this letter, the ACN is informed and requested to facilitate.

Note, we would like you to forward a copy of the study report to the undersigned after completion of the study.


Dr. Patrick Mburugu
HOD GENERAL SURGERY

Copy to: ACN Incharge
SOPC No. 24
KNH

Yours sincerely,



PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

- c.c. The Principal, College of Health Sciences, UoN
 The Director, CS, KNH
 The Chairperson, KNH- UoN ERC
 The Assistant Director, Health Information, KNH
 The Dean, School of Medicine, UoN
 The Chair, Dept. of Surgery, UoN
 Supervisors: Dr. Dan Kiptoon, Dept. of Surgery, UoN
 Dr. Eric Hungu, Dept. of Surgery, KNH

