

**IMPACT OF A CAPACITY BUILDING INITIATIVE TO IMPROVE CANCER
DIAGNOSIS USING BONE MARROW AND FINE NEEDLE ASPIRATION BIOPSY
TECHNIQUES IN TWO LEVEL- 5 HOSPITALS IN KENYA.**

BY

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DECLARATION

I hereby declare that this dissertation is my original work under the guidance of my supervisors and has not, to the best of my knowledge been submitted for a degree award in any other University.

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DEDICATION

To the memory of my father, for the extraordinary sacrifice he made to help me realize my potential, and to my mother, my wife and my dear sons Michael and Joel.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
AIDS- KS	AIDS-associated Kaposi Sarcoma
AKU	Aga Khan University
AKUH	Aga Khan University Hospital
ALL	Acute Lymphoblastic Leukemia
AML	Acute Myeloid Leukemia
ASLM	African Society of Laboratory Medicine
BMA	Bone Marrow Aspiration
BME	Bone Marrow Evaluation
CME	Continuous Medical Education
CML	Chronic Myeloid Leukemia
CPGH	Coast Provincial General Hospital
EQA	External Quality Assurance
ERC	Ethical Review Committee
FNA	Fine Needle Aspiration
FNAB	Fine Needle Aspiration Biopsy
FNAC	Fine Needle Aspiration Cytology
GLOBOCAN	Global Cancer Incidence, Mortality and Prevalence
H/E	Hematoxilin and Eosin
HCWs	Health Care Workers
HTC	HIV testing and counseling
IOP	International Outreach Programme
IPC	Infection Prevention and Control
ISO	International Organization for Standardization
ITP	Idiopathic Thrombocytopenic Purpura
JOOTRH	JaramogiOgingaOdinga Teaching and Referral Hospital
KNH	Kenyatta National Hospital
LD	Leishmania Donovanii
LMICs	Low and Middle- Income Countries

LSS-EOC-NC	Life Saving Skills-Essential Obstetric Care and Newborn Care
MCQ	Multiple Choice Questions
MDS	Myelodysplastic Syndrome
MPD	Myeloproliferative Disorders
NCCP	National Cancer Control Programs
NCD	Non communicable diseases
NCI	National Cancer Institute
OJT	On Job Trainings
PAS	Periodic Acid Schiff
PCR	Polymerase chain reaction
PGH	Provincial General Hospital
POC	Point of care
QA	Quality assurance
SAQ	Short Answer Questions
SIKO	Strategies to improve Kaposi sarcoma outcomes
SOP	Standard Operating Procedures
SPSS	Statistical Package for Social Sciences
TAT	Turn Around Time
THET	Tropical Health and Education Trust
UoN	University of Nairobi
WHO	World Health Organization
ZN	Ziehl Neelsen stain

DEFINITION OF TERMS

Competence: The quality of being capable of performing an allotted function/ task, exhibited by possession of required skill and knowledge.

Confidence rating: It is how confident the subject feels in performing a certain task. People are often aware of their limitations and this often correlates with their objective performance.

Impact: The consequence or effect of a particular project /program. In this study it defines the capacity building initiative's ability to increase quality diagnosis, and also positive effect on epidemiological or patient centered outcomes.

Non- pathologist: The different cadres of medical staff in a hospital who are not human pathology specialists for example, nursing and clinical officers, physicians and medical officers.

Outcomes: A final product or end result; consequence.

Performance: The manner in which or the efficiency with which something fulfills its intended purpose.

Post-test analysis: An evaluation to assess the level of understanding after a course/ program content delivery with a view to identify areas of clarification and emphasis.

Pre-test analysis: An evaluation to assess the level of understanding before a course content delivery with a view to identify knowledge gaps and to help assess progress.

Proficiency: It's a quality that manifests ability or skillfulness. In this study, its defined based on rates of unsatisfactory samples and monitoring the frequency of inadequate material leading to missed diagnosis.

Uptake: Making use of something that is available; for example adoption of the diagnostic procedures as part of laboratory test menus and supporting implementation for posterity.

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ABSTRACT

Background: GLOBOCAN (Global Cancer Incidence, Mortality and Prevalence) estimates project cancer burden to have shifted to low and middle income countries (LMICs), posing both social and economic challenges. Kenya is not a stranger to this trend and under diagnosis and late diagnosis has been identified as critical aspects associated with poor outcomes. Simple, relatively easy to perform tests used in cancer diagnosis such as fine needle aspiration (FNA) and bone marrow aspiration (BMA) are underutilized in Kenya. To tackle this limitation, University of Nairobi in conjunction with Aga Khan University in collaboration with the Ministry of Health and the National Cancer Institute (NCI, United States) initiated a capacity building program to increase the use of FNA, BMA and trephine biopsy for cancer diagnosis. The project intended to provide capacity building in performing the FNA, BMA and trephine biopsy techniques in the two hospitals through training, administrative support logistics, quality control and monitoring and evaluation.

Objective: The main aim of this study was to assess the impact of training clinicians and laboratory technologists on bone marrow and fine needle aspiration procedures in two level-5 hospitals in order to improve cancer diagnosis.

Study Design: This was an interventional study that assessed the impact of training non-pathologists in Nyeri Provincial General Hospital (NPGH) and the Coast Provincial General Hospital (CPGH).

Methodology: The study subjects included clinicians and laboratory technologists. The clinicians were trained on sample collection using two techniques of bone marrow and fine needle aspiration. The laboratory technologists were trained on quality aspects of sample preparation and processing. Necessary equipment and supplies were provided to get the institutions started as well as expertise support in terms of laboratory result generation was offered by the University of Nairobi (UoN) and the Aga Khan University Hospital (AKUH). Monitoring and evaluation sessions were organized periodically to assess progress. Ethical approval was sought from the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee, and permission to perform the study from the hospitals involved before carrying out the study.

Data Analysis: Data collected included qualitative and quantitative variables. Data was entered in the statistical software SPSS version 22 for analysis. Descriptive analysis using frequencies and proportions was computed. Association between dependent variables and independent variables was analyzed using binary logistic regression.

Results: Of the 23 participants that were trained in this capacity building initiative, 15 (65%) were medical officers from different departments. In total, 13 were certified proficient (due to drop-outs and staff attrition) in sample collection using bone marrow evaluation (BME) and FNAB techniques through practical steps including pre and post-testevaluations.

There was an increase in the number of fine needle aspiration biopsy (FNAB), BMA and trephine procedures performed in both CPGH and Nyeri PGH in the year 2016 when the study was carried out. A total of 588 cases were reported in CPGH compared to 225 in the previous year (2015); while 783 cases were reported in Nyeri Provincial General Hospital (NPGH) compared to 420 cases in the year 2015.

There was a marked improvement in the sample quality attributes of smear making, staining and overall specimen quality in terms of cellularity and diagnostic capability. Similarly, the unsatisfactory rates improved in both facilities as well as at individual operator level given by low (2.6%-25%) unsatisfactory rates registered.

Both study sites reported an increase in the number of new cancer cases diagnosed using BME and FNAB techniques compared to the previous year. A total of 50(8.5%) new cases were reported in CPGH compared to 27(6.0%) in the year 2015(p-value= 0.132); while 36 (4.6%) new cases were diagnosed in NPGH compared to 23 (2.7%) in the previous year (p-value=0.047).

Conclusions:

Prior the initiative, few diagnostic procedures were performed due to lack of supporting infrastructure. Training as an intervention helped improve on quality diagnosis through proper sample collection and processing therefore reducing the unsatisfactory rates in both facilities. An increase in the number and proficiency of those performing the diagnostic techniques led to an increase in the number of new cancer cases diagnosed.

Recommendations:

Training of non-pathologists in BME and FNAB should be maintained and the curriculum delivery up-scaled to include in-service training at the county and national hospitals. Review of facility infrastructure support and adoption of standard operating procedures (SOPs) for the diagnostic tests should be implemented in all level-4 and level-5 hospitals in Kenya.

1.0 INTRODUCTION

Cancer constitutes an enormous burden on society in the more and less economically developed countries alike (1). Based on GLOBOCAN estimates, about 14.1 million new cancer cases and 8.2 million deaths occurred in 2012 worldwide. The burden has shifted to less developed countries, which currently account for about 57% of cases and 65% of cancer deaths worldwide (2). The number of new cancer cases in Africa is predicted to increase to 1.28 million, with 970,000 deaths each year by 2030 (3). While the burden of cancer in Africa continues to rise, survival rates are adversely affected by late detection, delay in seeking diagnosis, the lack of availability of technical support for diagnosis and scarcity of resources for treatment (3).

In Kenya, cancer is the 3rd highest cause of morbidity (7% of deaths per year), after infectious diseases and cardiovascular diseases. Statistics show that 70-80% of cancer cases are diagnosed in late stages due to: lack of awareness; inadequate diagnostic facilities; lack of treatment facilities; high cost of treatment and high poverty index (4). Currently, diagnostic services are limited and are available mainly in the capital and large cities.

Cancer poses an economic burden not only on social welfare and health systems but also on national economies. The availability of reliable cancer surveillance data, including cancer incidence, stage at diagnosis and mortality, generated by population-based cancer registries is vital for developing targeted and effective National Cancer Control Programs (NCCPs) and for evaluating the impact of national programs. Yet, good-quality data are often unavailable. In low- and middle- income countries (LMICs), Kenya included, coverage of high- quality data from registries is well below 10% (5). There is therefore, an urgent need to build this capacity in these regions.

Bone marrow evaluation (BME) is an important diagnostic tool used to evaluate various disorder including both neoplastic and non-neoplastic hematological diseases. BME (BMA and BM trephine biopsy) may either confirm clinically suspected disease or may provide the previously unsuspected diagnosis (6). Despite being a highly informative test procedure in diagnostic evaluation of blood and blood related diseases, there is underutilization of the test (7).

Fine needle aspiration biopsy (FNAB) is widely used for evaluation and diagnosis of palpable superficial benign and malignant neoplasms as well as deep seated non palpable lesions under imaging guidance (8). FNAB is a simple, safe, cheap and minimally invasive procedure that can be used to screen, diagnose and follow-up both infectious and neoplastic diseases.

Currently in Kenya, BME and FNAB procedures are mostly performed by pathologists, and training resident doctors at the mainstream referral hospitals. This has contributed to the current state of under diagnosis of cancer due to limited access to these procedures (9); hence, deficit of information available for population based cancer registries. The correct use of these diagnostic procedures has the potential to improve diagnostic capabilities and provide access to timely and cheaper patient care.

This research study was part of a resident driven FNA/BMA/biopsy project, an initiative of the University of Nairobi (UoN) and the Aga Khan University (AKU) in collaboration with the MOH and National Cancer Institute (NCI). The program was a pathology strategic plan as part of the Kenya National Cancer Strategy on cancer diagnosis and surveillance by the Ministry of Health. Resident clinicians in the Department of Human Pathology, who perform BMA and FNAB more often, were best placed to champion the initiative hence, “resident driven”. The objective of this project was to have trained pathology residents from UoN and AKU train medical officers, clinical officers, physicians, pediatricians, surgeons and technologists in these techniques at two level 5 hospitals outside of Nairobi. The overall aim was to make the diagnostic procedures accessible to the public and provide practical short and long term solutions.

2.0 LITERATURE REVIEW

Several initiatives have been carried out both locally and internationally based on implementation research programs as well as efforts to improve service delivery in various aspects of health. Most of these study initiatives include outreach and sensitization programs aimed at improving quality care especially in oncology, human immunodeficiency virus (HIV) and maternal and neonatal health. As a result of epidemiological transition in LMICs and the surge of cancer and other non-communicable diseases (NCDs), governments agree on a set of commitments to tackle the global burden and threat of NCDs as a major obstacle for development. Other drivers creating awareness and world commitment to fight cancer in LMICs include the Global Action Plan for the Prevention and Control of NCDs. The Action Plan ensures cost effective and affordable interventions on NCDs, including cancer (10).

In one article by Ian Magrath and Simon Sutcliffe titled Building capacity for cancer treatment in low-income countries with particular reference to East Africa, various considerations are outlined to help tackle the increasing cancer rates (11). Of note is the emphasis on education of the public and medical community as single most important step to be taken if better survival rates are to be realized. The article points out among other considerations; i) re-focusing and re-balancing the mix of academic (degree-based), competency-based training and practical service delivery, ii) institution-to-institution collaborations (twinning) to strengthen service provision.

2.1 Role of bone marrow evaluation in diagnosis

Bone marrow evaluation is the mainstay of diagnosis, staging as well as measurement of treatment response for many hematologic malignancies like leukemia, MPD and MDS (12). Obtaining quality bone marrow specimens is essential in the assessment of overall bone marrow cellularity and is an indispensable tool for staging in lymphoma (12). Because of the relative ease in accessibility, aspiration, biopsy and culture of the bone marrow may also play a role in the evaluation of patients with pyrexia of undetermined origin as well as in diagnosis of various storage and infiltrative disorders. The decision to subject a patient to bone marrow examination must be made after careful assessment of patient history including the full blood count and examination of the peripheral blood film (13,14). A study by Ekwere TA et al in Nigeria identified the most common indications for BMA cytology in children in a descending order of frequency as anemia, diagnosis and management of leukemia and pancytopenia (15). In a similar study in children in Kenya, Githanga and Dave identified unexplained anaemia and suspected

leukemia as the two most frequent indications for BMA and trephine biopsy respectively (16). The bone marrow evaluation techniques (BMA and trephine biopsy) most often will be carried out as part of the same procedure (17).

Bone marrow trephine biopsy allows histologic evaluation of marrow architecture as well as quantification of different cell populations that cannot be accomplished by the aspiration smears alone (18). Entities like aplastic anaemia, myelofibrosis and myelophthitic lesions mostly result in a dry tap on several aspiration attempts and are best studied by marrow biopsy. Core biopsy samples are suitable for histopathology sections, touch preparations (imprints) and electron microscopy. A touch preparation is particularly important when marrow aspirate cannot be obtained as it is often better for evaluating cell morphology and assessing cellularity (18,17). Preparations of frozen sections of trephine biopsy specimens allow for use of wide range of immunological markers. In a study by Aljadayah et al in Jordan, BME was found to have good predictive value and reliability in hematological malignancies, immune thrombocytopenia and anaemias (19). It is recommended that the patient undergoing a bone marrow assessment procedure be given adequate information about the procedure, its indication and potential risks (7). Informed consent should be obtained- preferably written and documented. While premedication including anxiolytics or opiates, are not usually necessary (20), sedation is required for good outcomes in young children or those patients with increased anxiety. It cannot be overstated that the quality of the sample obtained may be largely superior in a cooperative and comfortable patient.

2.2 Diagnostic utility of fine needle aspiration (FNA).

Once the specimen is obtained from the patient, various undesirable events may occur, including poor fixation or preparation, improper staining, mislabeling, or loss of the sample. Thus, the success of an FNA will hugely depend on the technique employed in performing the procedure and preparation of the on-site smears (21,22).

FNA is widely associated with a higher diagnostic output and minimal complications compared to core biopsies. The establishment of a reliable diagnosis using FNA, put together with the localization and staging achieved through imaging provides vital information in the management of patients (23).

FNA is also key in the diagnosis of other diseases, like certain infections, inflammations (e.g. granulomas in sarcoidosis) or infiltrations like amyloidosis (22). The need for an accurate, timely

and reliable cytopathology report has become highly important in this era, not to forget a society that is both erudite and critical (24). Fine needle aspiration is readily applicable and accepted by most patients (children and adults) as a minimally invasive method for evaluating lymphadenopathy. It is notably useful in patients with deep-seated lymphadenopathy (e.g. mediastinal, retroperitoneal, abdominal), for which surgical intervention carries great risk of morbidity (25). Although thyroid nodular lesions raise suspicion of cancer, less than 5% are malignant. Due to the high prevalence of thyroid nodules, FNA plays a vital role as a screening tool (25). It is a recognized standard of care in the diagnosis of head and neck tumor lesions. Occasionally fine needle aspirations become useful in treatment of certain benign diseases like peritonsillar abscess (26). However, lymphadenopathy is mostly the source of concern and a prime target. FNA nevertheless is extensively used for evaluating breast lumps, breast cysts and also non palpable mammographic abnormalities.

In a study by Ron et al, FNA was found to be a commonly performed procedure in otolaryngology- head and neck surgery, with most surgeons referring their FNAB to pathologists despite the specialists' intimate knowledge of the head and neck anatomy that qualifies them to perform FNA (26). Hence need for education regarding the merits and skills in performing fine needle aspiration biopsy. Another study by Silas et al, looking at the role of fine needle aspiration biopsy as a diagnostic tool in paediatric head and neck lymphadenopathy, demonstrated an overall specificity of 100% and sensitivity of 100% for diagnosis of malignant lesions by FNA (24).

2.3 Initiatives for capacity building in the healthcare setting.

2.3.1 Capacity building through training in BMA and BM Trephine biopsy.

In most clinical set-ups in Kenya BMA and bone marrow trephine biopsy procedures are often performed by pathologists. However, in low resource settings pathologists tend to be scarce and overworked hence, the need to train other health cadres to carry out the procedures. In a study done in Germany, clinical nurse specialists were trained and found to proficiently obtain bone marrow aspirates and trephine biopsies in a nearly painless procedure (27). This was a prospective study where clinical nurse specialists (CNS) were trained to do BMAs and trephine biopsies to ensure continuity and assess feasibility, patient satisfaction, and biopsy quality. The main goal was to determine whether BMEs by nurse specialists obtain results similar to those of

physicians, analyzing patient satisfaction, pain induced and quality of aspirates and trephine biopsies. A total of 574 BMEs in cancer patients done between January 2012 and February 2013 were evaluated. A multidisciplinary team developed a standard operating procedure (SOP) adhering to the hospital guidelines. The clinical nurse specialists then underwent a training program addressing anatomy knowledge, biopsy site selection and practical skills required before they could perform the BMA procedures (27).

2.3.2 An educational intervention to improve disease/clinical outcomes.

In an effort to provide effective medical care to people with AIDs related Kaposi sarcoma and its early diagnosis in community care settings, an educational intervention program was developed in Zimbabwe in 2012 employing similar training model to our capacity building initiative. In the study by Borok M et al (28), strategies to improve Kaposi sarcoma outcomes (SIKO) were devised comprising three interventions:

- i) Kaposi sarcoma standardized evaluation, as a simple examination tool to enhance bedside diagnostic skills.
- ii) Implementation of training program for all care givers involved in management of AIDS-KS at eight primary care sites.
- iii) Development of algorithm-based KS management strategy to educate community and health providers.

The SIKO strategy could be easily integrated into the WHO training guidelines and the national Zimbabwe guidelines as well as help provide evidence for improved KS outcomes in Zimbabwe. The SIKO implementation phase involved training of trainers who served to train the SIKO site monitoring teams with periodic site visits during intervention period. The SIKO intervention unlike our study model employed only a training component that was geared towards improving a particular cancer type through development of an examination tool and a management algorithm. There was no guarantee however, that the model would improve/impact on timely diagnosis of other cancer types and offer capacity building for better outcomes.

In a similar intervention with a view to reduce maternal and newborn mortality and morbidity in resource poor settings, a Life Saving Skills- essential obstetric and newborn care (LSS-EOC-NC) was developed by Grady K et al of the Royal College of Obstetricians and Gynaecologists in 2010 (29). This initiative assessed the effectiveness of a training model as strategy for reducing

maternal and newborn mortality and morbidity in 7 countries in sub-Saharan Africa Kenya included. The main focus was on signal functions of basic and comprehensive essential obstetric care and early newborn care comprising maternal and newborn resuscitation methods, obstetric haemorrhage and obstructed labor management. In the implementation phase of this initiative, primary care providers in maternal and newborn units were trained on basic requirements of handling common emergencies during and after delivery. This intervention resulted in improved maternal and newborn care, improved resource allocation to the obstetric care units and eventual decrease in maternal and newborn mortality rates.

2.3.3 Implementation of a twinning program to improve cancer care.

Being an implementation research study, it was necessary to examine other operational research initiatives that have successfully devised programs to improve service delivery. This included programs meant to improve quality service provision to cancer patients through sharing knowledge and skills and supporting implementation of an effective treatment plans.

In an attempt to improve paediatric cancer care in LMIC, the St Jude Children's Research hospital in the United States, devised an outreach program (30). This international outreach program (IOP) had a mission of improving the survival of children with cancer in poor resource settings. This was to be done by sharing knowledge and organizational skills and supporting implementation of paediatric oncology units in public paediatric hospitals in selected countries. The model employed was of a twinning program geared towards long-term, close relationships with centers in low- and middle income countries. The twinning program emphasized a horizontal distribution of resources dedicated to improving survival rates in pediatric cancer overall. The ultimate goal would see an improved cure rates and access to care for children with cancer. The study demonstrated that it was feasible and affordable to improve cure rates of children with cancer in countries with limited resources through a twinning program.

2.3.4 Initiative to increase uptake of a test through enhanced availability.

Several challenges have been met in attempts to introduce programs that would translate to better health care delivery as seen in other efforts to increase uptake of a service in LMICs. In a study in Malawi, an initiative was established to increase the uptake of HIV testing and counseling among the poorest households through a home based service provision (31). This study was largely informed by the low uptake of HIV testing and counseling (HTC) that hampered the

enrolment of infected individuals in treatment programs. The main objective was to measure uptake of home- based HIV testing and counseling and estimate HIV prevalence among poorest households. Residents of six villages of a small island in Malawi, aged 18-35 and their partners were offered home- based HTC services. Other variables like the socioeconomic status, HIV testing history and HIV risk factors were assessed. The home- based HTC services were offered without regard to previous testing history, and done with prior sensitization meetings conducted in each village. HTC uptake was found to be high during the campaign especially among the poorest, hence having the potential to reduce the existing socioeconomic gradients in HTC uptake.

2.3.5 Use of basic laboratory tests to improve diagnosis and treatment outcomes in rural health centers.

The adoption of training as a component to champion evidence based medical diagnosis is a fast reality in many LMICs. Different models have been used in form of on job trainings or capacity building initiatives with other components like monitoring and evaluations. The use of basic and relatively cheap methods/tests has proved beneficial in resource poor settings.

In another study in Kenya, the use of basic laboratory tests to improve diagnosis and treatment outcomes in outpatients attending rural primary healthcare facilities was determined (32). This was to assess whether laboratory tests in health centers result in altered clinical plan, and if access to laboratory testing actually improve the quality of patient care. The study involved observing the performance of clinical officers in outpatient departments of six health centers taking part in the research. A baseline survey was conducted before the study, to assess clinical laboratory and public health activities and staffing. Basic laboratory tests were selected according to their relevance in diagnosing common entities in outpatient service; their operability in resource poor settings; their rapidity and cost. On site refresher training on good diagnostic practices through one on one training of clinical officers and laboratory technicians were conducted. Data comparison between pre- and post-test diagnosis and treatment were done, showing that diagnosis and treatment were changed in 45% of tested patients who returned with their laboratory results. It was concluded that an effective use of laboratory tests at rural health centers greatly improves diagnosis and patient treatment.

2.3.6 Cost efficient implementation of a diagnostic test

It is important to document several challenges that come along with an implementation research initiative. These challenges are encountered at various stages of implementation and help determine the success or failure of a program/ initiative. In one article, Schito et al outlined opportunities and challenges for cost efficient implementation of new POC diagnostics for HIV and tuberculosis (33). This was given by need for implementing molecular point-of-care diagnostics for HIV and TB, two conditions that are co-endemic in high prevalence areas making parallel diagnosis a key consideration. Various aspects were outlined that provide lessons in implementing HIV and TB diagnostics. The concept of POC was agreed on to avoid confusion. Similarly, ‘impact’ of the diagnostic device was defined as not just the test accuracy but also positive effect on epidemiological or patient centered outcomes.

The following points formed the main areas of discussion (33):

- i. Current diagnostic challenges (for HIV and TB). These included gaps in early detection and diagnosis as in the case of cancer for instance, where infrastructure requirements and cost pose the main challenge.
- ii. The obstacles to uptake of point-of-care technologies.
- iii. Laboratory strengthening to support the test methods. This being an important priority in the resource limited settings with poor access to health services. Therefore, implementing diagnostic initiatives will place demands on laboratory systems to ensure high quality and reliable testing.
- iv. HIV and TB operational challenges with regards to point-of-care diagnostics. These included test accuracy concerns, lack of trained personnel, poor quality test kits, need for financial and implementing partners and lack of national regulatory frameworkse.g.poor accountability and infrastructure.

Thus, it was important to strike a balance between point-of-care testing and conventional laboratory testing through other diagnostic techniques to attain highest benefits and improved disease diagnosis.

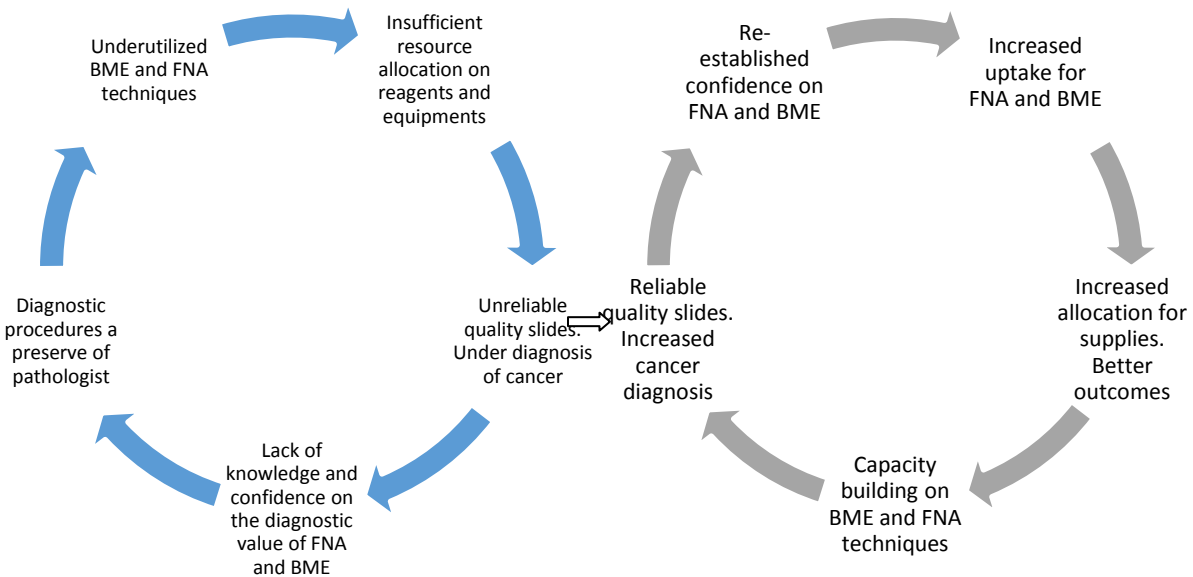
2.3.7 Quality aspects in global laboratory medicine

Quality assurance is very important in strengthening global laboratory practice (34). Hence, the need for a constant review of existing policies that ensures continuous improvement of quality

systems. In low income countries, QA in laboratory medicine is grossly neglected and thus an impediment to efficient healthcare delivery and disease surveillance. Most physicians tend to rely more on history and physical examination for patient management due to lack of confidence in laboratory test results. As a result, little resources are allocated to these laboratories resulting in less optimal quality outcome and eventual neglect of laboratory systems (34). Quality in laboratory medicine therefore, is valuable to patient outcomes and management and it reduces wastage, minimizes sample rejection, prevents unneeded diagnostic testing and improves turn-around-time. Due to challenges in implementing QA in laboratory medicine, low and middle income countries have given less attention to the significant role of laboratory diagnosis in patient care. Consequently, realizing the international organization for standardization (ISO) 15189 requirements for clinical laboratory has become elusive (34).

There is need to create performance-enablers that will incentivize and energize laboratory medicine through aspects of implementation, measurement, reward and improvement. For instance, the stepwise laboratory quality improvement process towards accreditation (SLIPTA) is a framework implemented by African Society of Laboratory Medicine (ASLM) for improving quality of public health laboratories in African countries to achieve accreditation (34). To ensure sustainability, there is need to identify system drivers that will enable the country to reach a tipping point through initiatives that are affordable, feasible, scalable and effective (35). The overreliance for instance on history and physical examination by physicians to diagnose malignancies due to lack of FNAB and BMA has led to little confidence on these diagnostic techniques hence their underutilization and inadequate resource allocation for the same (Figure 1).

Figure 1: The vicious cycle perpetuated by poor quality versus impact of a capacity building initiative.



In a 2008 editorial, Ljung et al outlines content of the NCI thyroid FNA state of the science conference in Bethesda. The article provides summary of matters pertaining to training for the performance of thyroid FNA via palpation, ultrasound imaging and credentialing/re-credentialing for procurement of thyroid FNA (36). Since the level of proficiency in FNA performance has significant impact on the accuracy of the test and may lead to missed or delayed cancer diagnosis, a separate credential of training in FNA procurement is necessary. Measuring proficiency in FNA procurement based on monitoring the frequency of inadequate material was found to be difficult since it required many cases and a long term follow-up of the same. Instead, rates of unsatisfactory samples are mostly used as a measure for the level of proficiency. A conclusion was reached to have a complete residency training involving FNA procurement and documentation of number of total FNA procedure per year for operator re-credentialing. Unsatisfactory specimens were found to be the cause or contributing factor in the majority of failed diagnosis. This could be improved by the establishment of FNA clinics where as small number of trained physicians both collected and interpreted the sample by on-site adequacy assessment.

Four components of an FNA training program were suggested as follows (36):

- I. Studying of illustrated texts and audiovisual teaching aids
- II. Bench practice under supervision to learn basic needle manipulation and master techniques of sample preparation.
- III. Sampling of nodules via palpation/ ultrasound guidance.
- IV. Stipulation of specific number of samples to be collected during training and proficiency assessment in FNA sampling and specimen preparation.

2.4 Impact Assessment

Many models have been employed therefore in different research initiatives with a view to assess service delivery improvement as well as achieve impact outcomes in various fields of study. In all these initiatives, different stages of implementation have followed the laid down framework of operational research as recommended by the WHO (37). In this regard, knowledge and skills transfer through training has been an important aspect in project impact evaluation. The need for a universal access to cancer diagnostic modalities in Kenya became the driving force for a multi-faceted approach to improve diagnosis through capacity building program.

Impact assessment is an unpretentious tool that majorly produces information about potential fundamental outcomes of an undertaking to allow decision/policy-makers to act appropriately. Effective scoping therefore is key in any assessment to determine the right focus of effort across a range of sustainability targets (38). Several approaches have been designed to describe research impact assessment (39). The payback framework and associated literature for example, has been used to demonstrate the need for impact assessment to distinguish between different types and stages of impact and to draw on numerous sources of data (40). The conceptual framework would help organize data collection, analysis and reporting to promote clarity in the impact assessment made. One of the major criticisms linked to impact assessment is that certain components may not be adequately addressed in comparison with the rest (38).

3.0 JUSTIFICATION

This capacity building initiative responds to the Kenya National Cancer Control Strategy objectives for timely and quality diagnostic outcomes (9). Diagnosis and staging of cancers such as leukemia and lymphoma often rely on bone marrow aspiration (BMA), bone marrow trephine biopsies and fine needle aspiration, which are relatively simple and inexpensive techniques.

According to the National Cancer Control Strategy (9), diagnostic tests such as BMA are not often performed and some level-5 hospitals lack basic infrastructure to ensure quality specimen processing. Inadequate sample preparation is also due to the fact that training for these procedures is limited to post-graduate training in Pathology currently only done at two universities.

Increasing diagnosis through this capacity building initiative would provide cancer data for future planning.

This study was carried out in order to assess the impact of a capacity building initiative using bone marrow evaluation and fine needle aspiration biopsy, with a view to improve cancer diagnosis in resource limited settings. The study would enable us improve on patient management since the clinicians would be competent enough to perform the necessary diagnostic procedures (BME and FNAB). There would be timely submission of sample specimens for laboratory analysis, proper sample processing and ultimate quality cancer diagnosis.

3.1 Study question

Does equipping non-pathologists (clinicians and laboratory technologists) with skills and knowledge on bone marrow and fine needle aspiration biopsy techniques increase quality cancer diagnosis in resource limited settings?

3.2 Objectives

3.2.1 Broad objective

To assess the impact of training clinicians and laboratory technologists on bone marrow and fine needle aspiration procedures in two level-5 hospitals on improving cancer diagnosis.

3.2.2 Specific objectives

1. To assess each facilities existing capacity to perform FNA and bone marrow aspirate and biopsy procedures prior to training.
2. To train and assess the competency level of the non-pathologists (clinicians) in quality specimen collection after training.
3. To document quality of preparation and processing of specimen collected (especially for laboratory technologists).

4. To determine the institutional uptake of FNA and bone marrow aspirate and biopsy as diagnostic techniques including cancer diagnosis.

3.3 Conceptual Framework

The impact of this capacity building initiative involved several quantitative and qualitative parameters that were dependent on a training model as well as the institutional uptake of the diagnostic techniques. The impact measures included number of quality FNAs, BMAs and trephines performed monthly after the training, institutional uptake, available trainees and retained competencies. Quality in this case was determined by the staining characteristics, specimen adequacy and report generation. The number of cancer cases diagnosed also acted as an impact measure.

The institutional uptake that entailed the availability of facility, clinics, duty rotas and the inclusion of the diagnostic techniques in the test menus for revenue generation as well as availability and retention of competencies affected the study outcomes. Competency provides effectiveness of the training which affected the efficient utilization of skills given.

The training of non-pathologists utilized a model with several components (independent variable) on which the impact would depend on. This involved competent resident and laboratory technologist trainers who had undergone training to proficiency. Other components included resource provision in form of materials and tools, training curricular as well as constant engagement of the institutions. There was an assumption that both facilities were performing the diagnostic procedures to some extent. Therefore, the training was provided irrespective of the existing capacity to perform FNA, BMA and trephine biopsies.

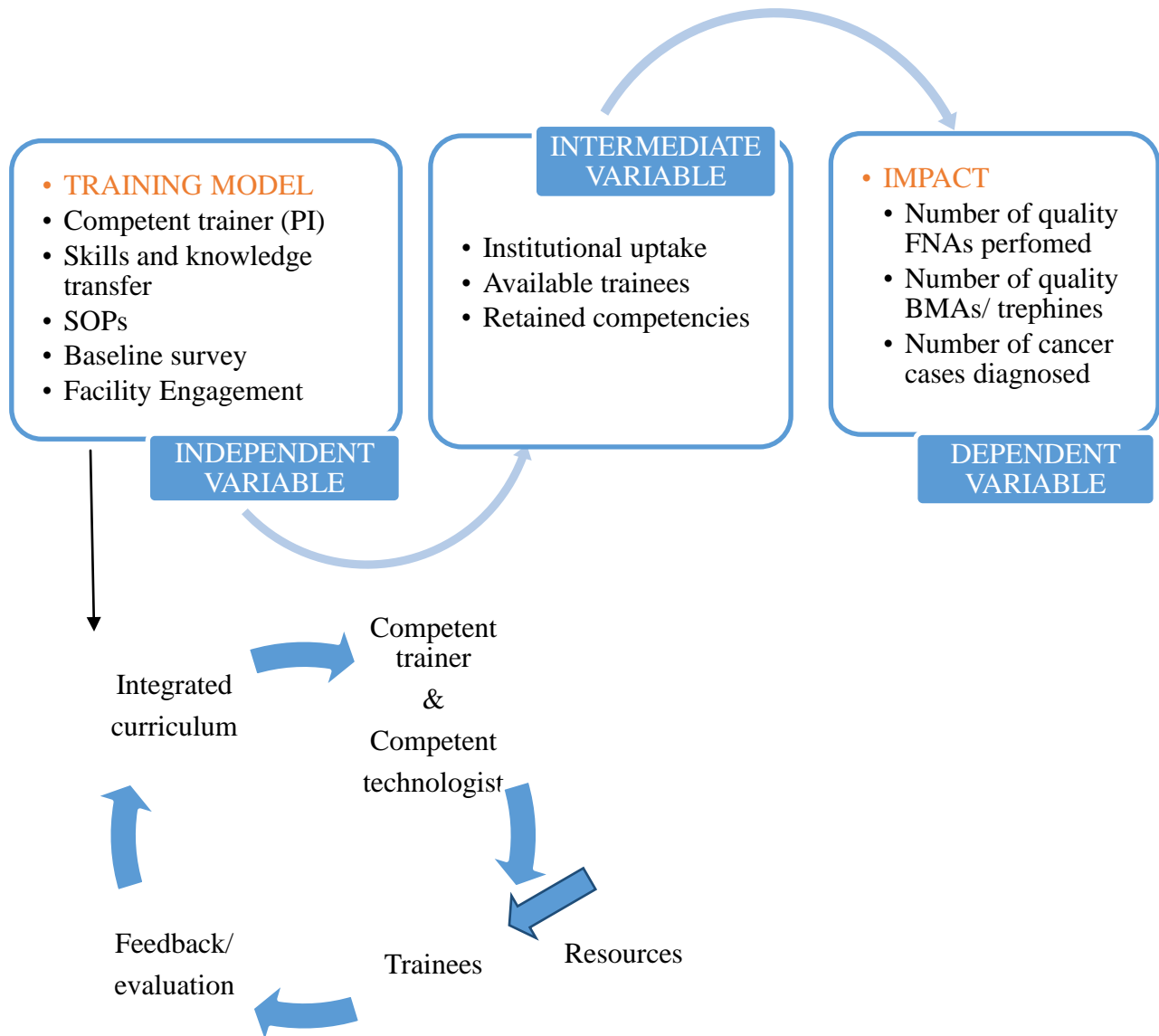


Figure 2: Conceptual Framework

4.0 METHODS AND MATERIALS

4.1 Study Design

This was a prospective interventional study aimed at assessing the impact of training non pathologists and laboratory technologists on BME and FNA procedures in two level-5 hospitals in order to improve on cancer diagnosis.

Investigator training

The principle investigator and his research assistants were trained to proficiency by master trainers in the FNA procedures and bone marrow aspirate & biopsy specimen collection, as well as in laboratory aspects of smear preparation and staining. Other pathology residents and laboratory technologists in the program would undergo a similar training in order to work as TOTs.

4.2 Project implementation sites

The study was conducted at Nyeri Provincial General Hospital and Coast General Hospital. The sites were chosen because of their capacity as regional referral centers, and they form part of the future cancer centers ear-marked by the Government. Nyeri PGH is a 350 bed capacity regional referral hospital, situated in Nyeri County in the Mt Kenya region about 160km from Nairobi. It is a government owned hospital with a catchment population of 693,558 (2009 census), and receives referral cases from eight other neighboring counties. The hospital's bed occupancy is 110-120% with outpatient consultations of 700 - 800cases per day. The hospital has 16 consultants, 15 medical officers, 320 nurses and 25 laboratory technologists. The hospital has a palliative and chemotherapy unit and an oncology clinic run with assistance from Kenyatta National Hospital Oncology Department. It has an expansive laboratory that is semi-automated and with several sections, including histopathology and haematology.



Figure 3: Map showing project implementation sites (stars)

The Coast General Hospital on the other hand, is situated in Tononoka in the coastal city of Mombasa. It is a 700 bed capacity government owned facility and the second largest public hospital in Kenya after Kenyatta National Hospital. It is a teaching and referral hospital whose service area comprises the six counties in coast region. The facility caters for a primary area population of over 1 million people and a secondary population of about 3 million. It has ten general wards and three maternity wards for inpatient services as well as an 8 – bed intensive care unit. The hospital has general and specialized outpatient services with average annual outpatient visits of 197,810 patients. The hospital has 26 consultants, 43 medical officers and 310 nurses and technologists. The hospital has an oncology unit that is run with assistance from KNH, and an expansive laboratory for research and clinical investigations. The laboratory has good infrastructure with haematology and biochemistry equipment, electrolyte analyzer and a PCR machine. The main challenges of this facility include inadequate staff and high number of referrals.

4.3 Project Implementation Process/ Methods

4.3.1 Facility Engagement Methods

Upon receipt of ethical approval, the investigator sought permission from the relevant authorities of the selected level 5 hospitals. A letter was written to the respective medical superintendents detailing the purpose of the study, the procedures involved, and the benefits to the institution as

well as the catchment population. The principal investigator with his research assistant conducted planned visits to different study areas (clinics and laboratories) of the health facility to familiarize themselves with the staff. The investigator then with the help of the hospital administrator invited the various cadres of clinicians, including the facility pathologists and hematology and histopathology laboratory technologists to a short briefing session. The staff was informed of the objectives of the study, the procedures, the risks, if any, and the benefits of the study. Information on the need to conduct situation analysis regarding the procedures in question was provided.

4.3.2 Selection of Trainees

Doctors, clinical officers and laboratory technologists were selected to take part in the training. These comprised of clinicians mainly from the departments of surgery, internal medicine, pediatrics and the outpatient department. A minimum of two laboratory technologists were included from both histopathology and haematology sections.

The study sites were allowed to identify clinicians and laboratory technologists who had shown the willingness to take part in the project. The non-pathologists who demonstrated the enthusiasm in learning the procedures as well as being used as point men in their respective institutions to run the FNA and BMA clinics were given priority. Eligible laboratory technologists from hematology and histopathology sections were included depending on the numbers available.

4.3.3 Pre-training Preparation

The 'resident-driven' FNA and bone marrow project mainly addressed four components in its efforts to provide capacity building to the local institutional laboratories. These included the training component, administrative support, quality assurance and monitoring and evaluation. Pre-training preparation was carried out before the actual training was conducted in the two selected institutions. The principal investigator having undergone a TOT course on BMA, FNA and trephine biopsy, conducted a baseline survey through a structured questionnaire to assess the actual capacity of the facilities to perform the diagnostic techniques. The hospital administration was tasked with provision of logistical support by making available the patients, trainees and training sites. The patients were sourced from the clinics, outpatient departments, wards and were those in which an FNA, BMA or trephine biopsy had been indicated as part of their clinical

care. Patients who travelled from home (outpatients) were given transport reimbursement after the procedures.

The investigator with his assistants (a resident from the Department of Human Pathology and a proficient laboratory technologist from the University of Nairobi) travelled to the study sites with the necessary materials and equipments for the training.

4.3.4 Training Procedures

The investigator would conduct the training of the eligible participants on the agreed dates with the help of other members of the training team including:

- I. The project administrator, who would ensure that all the supplies are availed to the identified point persons
- II. Two supervisors, consisting a haematopathologist and a cytopathologist
- III. The onsite pathologist, who had undergone a retraining course for proficiency
- IV. A research assistant, who was a pathology resident from the UON and was trained to proficiency on BME and FNA.
- V. Two laboratory technologists from the UON laboratory already trained to proficiency in the processing of bone marrow and needle aspirate specimens.

The course curriculum had theoretical and practical aspects. The theory part was delivered in a plenary session with all the participants present. The practical part was given in form of practical training with a patient. The patients were those with medical indications for either BME or FNA and were sourced from inpatient and outpatient departments. Patients were not required to pay for the services and were informed on the TAT expected before they came for their results.

Theoretical and practical training

The content was delivered according to the training program lasting three days and a re-training conducted after a period of one month. The first day of the training involved meeting the participants to be trained, checking the designated clinics and patient identification. The plenary addressed theoretical aspects of the BME and FNAB curriculum. This was given by the investigator in form of didactic sessions through power points on the requirements of setting up a BMA and FNA service. All the non-pathologists were prior to this subjected to pre-training assessment of knowledge in a multiple choice question (MCQ) format, both for bone marrow evaluation and fine needle aspiration (**appendix IIc**). The tests were designed for clinicians addressing aspects of sample collection, indications and complications of the diagnostic techniques.

The practical skills sessions were carried out in the set aside clinics, with both the clinicians and laboratory technologists present. The non-pathologists were taken through the process of bone marrow sample collection by the investigator and his assistants. This involved the consenting process using a template consent form (**appendix II**), infection prevention and control (IPC), site identification and the actual specimen collection in form of marrow aspiration and trephine biopsy. The clinicians were then taught how to perform a fine needle aspiration and make good smears fixed in 95% alcohol and an air dried one in case of special staining like ZN. For this purpose, a dummy training using ripe bananas and hand cream were conducted by the investigator to demonstrate the correct technique of acquiring a diagnostic FNAB sample and preparation of smears for staining (**appendix VIII**). These hands on exercise were supervised by the haematopathologist and a cytopathologist.

Technical component training: The technologists were taken through the standard operating procedures in FNA, BMA and trephine biopsy sample processing, and advised to adopt these in their respective institutions. Thus, the laboratory technologists would focus on sample preparation and processing (adequacy, smear making, preservation and staining).The FNA technical component addressed the following aspects on the specific SOPs:

- a. Preparation of the procedure room and consumable requirements for the FNA/BMA/Trephine tray.
- b. Preparation of reagents and buffers and quality control for each

- c. Setting up staining and identification and storage of reagents.
- d. Performing routine Giemsa and Pap staining technique
- e. Special stains methodology (Ziehl-Neelsen, PAS)

Post- Training Evaluation: This was the immediate assessment of the participants after the provision of skills and knowledge session. The same MCQ were re-administered to the participants in form of post-test to test the immediate recall and the noted gaps re-emphasized during practical and re-training sessions.

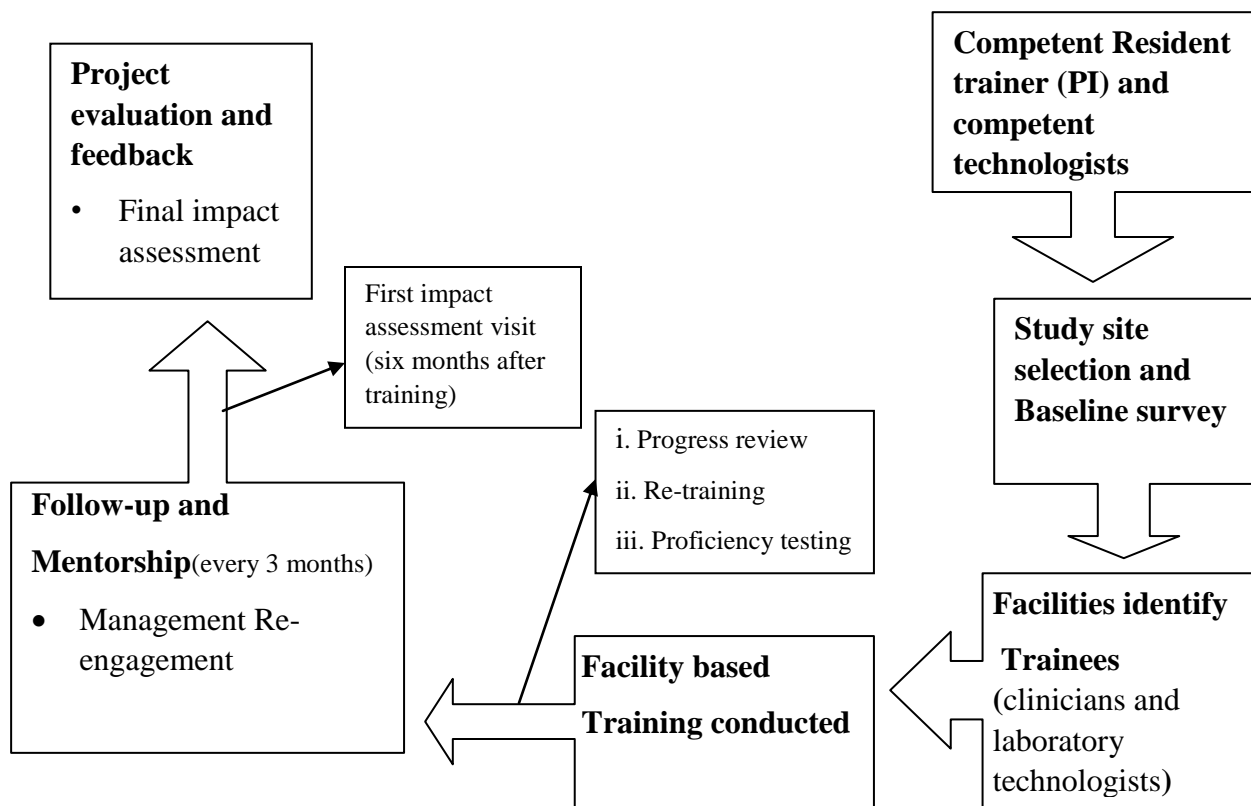


Figure 2: Study methodology workflow

Proficiency testing

Proficiency assessment on fine needle aspiration biopsy and bone marrow sample evaluation for the trainees was carried out one month post training and was supervised by the investigator and

the two cytopathologist and haematopathologist. This was to allow for the trainees to gather confidence in performing the procedures. An elaborate proficiency testing check list was used. For bone marrow aspirate and biopsy procedures, the trained clinicians each was required to perform at least four BMAs to be considered ready to undergo the proficiency testing. The bone marrow aspirate and biopsy reports were given a TAT of ten days after on site processing since they were sent to the UON for reporting and signing out by the investigator and two supervisors. The FNAs performed were processed and reported by the local pathologist and for each patient, the archived slide was sent to the investigator to audit aspects of quality control for which there was a check list. For NPGH where the pathologist later had a transfer, the FNA cases were sent to the PI for reporting at the University of Nairobi. Monitoring and evaluation sessions were conducted by the PI after every three months through site visits where matters of concern were addressed.

4.4 Data Collection

4.4.1 Clinical Data

The following data were sought from the various cadres of staff members through a structured proforma questionnaire administered by the investigator; number of FNA, BMA and trephine biopsies done in a month, setting in which the procedures are done, availability of equipments and SOPs, patient handling, use of informed consent, sample processing and staining. This information which is important for the baseline survey was recorded in a coded proforma sheet for the purpose of this study (**appendix I**).

4.5 Materials

4.5.1 Equipment

The project was provided with the necessary equipments for the purpose of training the participants. The investigator would carry to the study sites bone marrow aspirate and trephine biopsy needles (Jamshidi type), slides and other consumables like gloves, syringes, and 10% formal saline and alcohol fixatives. In addition, a total of 50 BMA needles would be left with the institution in the custody of the onsite pathologist.

4.5.2 Supplies

These consisted of mainly consumables (syringes, needles of different gauges, special stains and frosted slides) and non consumables (BMA needles, SOPs and training manuals), which were made available during the training practicals.

4.6 Quality assurance procedures

The research assistants were trained to proficiency on the techniques under study.

All laboratory safety precautions were strictly adhered to during the training, such as wearing of protective gears while working in laboratory and during sample collection.

Study generated standard operating procedures (SOP) were followed to the letter, which included checking of reagents expiry dates before using them, proper preparation, labeling and storage of reagents.

The principle investigator examined all the slides and trephine blocks received from the study sites and assess for correct labeling, adequate fixation, smear adequacy, staining characteristics and ability to make diagnosis. Reporting of the slides was done initially by the principle investigator and signed out by two pathologists. For bone marrow evaluation, the structured reporting protocol was adhered to (41).

Data were carefully entered into respective audit proformas avoiding mix-ups and errors.

At the time of study, the external quality control of the selected site laboratories was not yet in place. This study acted as external quality control for these laboratories.

4.7 Data collection instruments

Data collected were both quantitative and qualitative. The following tools were used to collect data for impact assessment:

- i. A structured questionnaire assessing the capacity to perform FNA, BMA and trephine biopsy in the facilities.
- ii. Questionnaire and discussions with hospital management
- iii. Questionnaires proficiency pre-test and post-tests and discussions with trainees
- iv. Proficiency assessment tools (clinicians and laboratory technologists)
- v. Review of FNA and BME samples for quality, reporting, TAT and archiving

4.8 Ethical considerations

Approval for permission to conduct this study was sought from KNH/UON Ethics and Research Committee.

Permission to conduct the study in the two level-5 hospitals was sought from the relevant authorities of the institution and their respective research committees.

All patients were given full information about the purpose of the study and sample collection procedures and consent form administered. These were patients with clinical indications for either BMA, FNA or trephine biopsy and no extra costs would be incurred by them for the procedures.

In the course of training and in the process of result/report generation, patient confidentiality was maintained.

The patient results once generated were sent in form of soft copy to the site pathologist and the point technologist who would have the same recorded before their final dispatch. The original copy was filed by the principle investigator for future reference.

4.9 Data management and statistical analysis plan.

4.9.1 Data storage

Data obtained from the baseline questionnaires and the proficiency assessment tools and that obtained following re-checking of slides was stored in hard cover register, Microsoft excel as well as the SPSS version 22 software used for data analysis. Information stored in soft copies was protected with a pass-word against access from any unauthorized persons. The register was kept in lockable cabinets where only the researcher and the supervisor would have the key for confidentiality. The questionnaire was identified by a study number and the data collected was under custody of the project database manager for which the investigator had access.

4.9.2 Data presentation

Descriptive summary statistics were performed and presented as proportions and percentages in form of tables, charts and narratives.

4.9.3 Data analysis

Data was entered in the statistical software SPSS version 22 for analysis. Descriptive analysis using frequencies and proportions were computed. Association between dependent variables and independent variables was analyzed using binary logistic regression. Bivariate associations of clinical and laboratory factors to the outcomes were also analyzed using t-tests and analysis of variance (ANOVA) as deemed appropriate while reporting the respective p values. Qualitative data were analyzed using descriptive methods and narratives. In all the analyzed data, a P-value of < 0.05 was considered significant (**appendix IX for dummy tables**).

4.9.4 Data Dissemination

The data acquired was disseminated to the two level -5 hospitals, Department of Human Pathology UON, Kenyatta National Hospital, respective county governments and the MOH. Presentations will be done in local and international conferences, and data published in peer review journals.

4.10 RESULTS

This study was conducted in a period of one year between February 2016 and January 2017. In the period under review, the initial 2 months formed the planning phase of the implementation process before the actual capacity building was initiated. In this initial phase, the principal investigator was trained as a TOT, the 2 study sites (NPGH and CPGH) were identified and a baseline situation analysis conducted by the PI in the facilities.

BASELINE SITUATION ANALYSIS

To meet the objective of assessing the existing capacity of the two level-5 facilities to perform FNAB and BME diagnostic techniques, a baseline survey that covered a two year period was conducted in both study sites with several findings documented. Both sites were found to be performing the FNAB and BMA except for the trephine biopsy as shown in **Table 1** below. These numbers were however limited given the two year period for a level-5 regional referral hospitals. No information was available on the proportion of the FNABs and BMAs that were considered unsatisfactory or whether the few BMA samples had been procured and processed within the local laboratory. This depicted a deficient archiving system that required improvement. As shown in the table, there was no proper procedure consenting in place and no

SOPs were used in specimen processing with sample collection being a preserve of only the pathologist.

Table 1: Baseline situation analysis findings in NPGH and CPGH

Attributes (In 2014 and 2015)	NPGH	CPGH
Number of respondents	18	16
Respondents by cadre	Laboratory technologists (5), MOs (5), Cos (6), pathologist (1), paediatrician (1).	Laboratory technologists (5), MOs (4), Cos (2), surgeon (2), paediatrician (1), pathologist (2)
Procedure consenting	Nil	Nil
Use of SOPs in sample processing	Nil	Nil
Dedicated clinics/space for procedures	Nil	Nil
Staff collecting BMA, FNA samples	Only by pathologist	Only by pathologist
Unsatisfactory rates	41	42
FNABs performed over the period	723	443
BMAs performed over the period	9	5
Trephines biopsies	Nil	Nil
Cancer diagnostic rates	23	27

Reasons for limited utility of the diagnostic techniques

From the information gathered in the baseline situation analysis, also cited were possible reasons attributed to the limited use of BMA, FNAB and trephine biopsy procedures. The following were the main reasons cited in the 2 facilities:

- I. Inadequate specimen collection and processing skills- 52.9% (18) of the respondents felt that they lacked the necessary knowledge on sample collection due to their perceived

complexity. Most (8 out of 10) laboratory technologists admitted challenges in sample preparation and processing noting the use of private laboratories in processing BME specimens.

- II. Lack of standard operating procedures (SOPs). Most laboratory technologists sited this as their main draw-back in realizing quality specimen analysis.
- III. Unavailability of equipments, consumables and special stains. Lack of bone marrow needles, coplin jars, procedure tables and local anaesthetic agents were cited by the local pathologists as reasons for unavailability of services. The laboratory technologists however were concerned by poor/ no supply of special stains apart from the usual pap and H/E stains.
- IV. Few pathologists to report the cases. Six (6) clinicians cited this as a reason especially in Nyeri PGH, where there was only one pathologist and with a planned transfer to Nairobi.
- V. Lack of internal quality control processes. Laboratory technologists also noted the non existence of quality control mechanisms to ensure proper sample processing and sustainability.
- VI. Lack of awareness of the existence of the service by the hospital physicians. Some clinicians reported having no information of the existence of FNAB and BMA services in their facility, citing this as reason for opting for the private laboratories.

CAPACITY BUILDING AND POST TRAINING ANALYSIS

In this initiative a total of 23 non-pathologists from NPGH and CPGH underwent training in the FNAB and BME procedures, majority being medical officers (15) and also two clinical officers being trained in CPGH. In Nyeri PGH 10 medical officers and 2 technologists were trained, while a total of 4 laboratory technologists, 5 medical and 2 clinical officers were trained in Coast PGH (**Figure 5**).

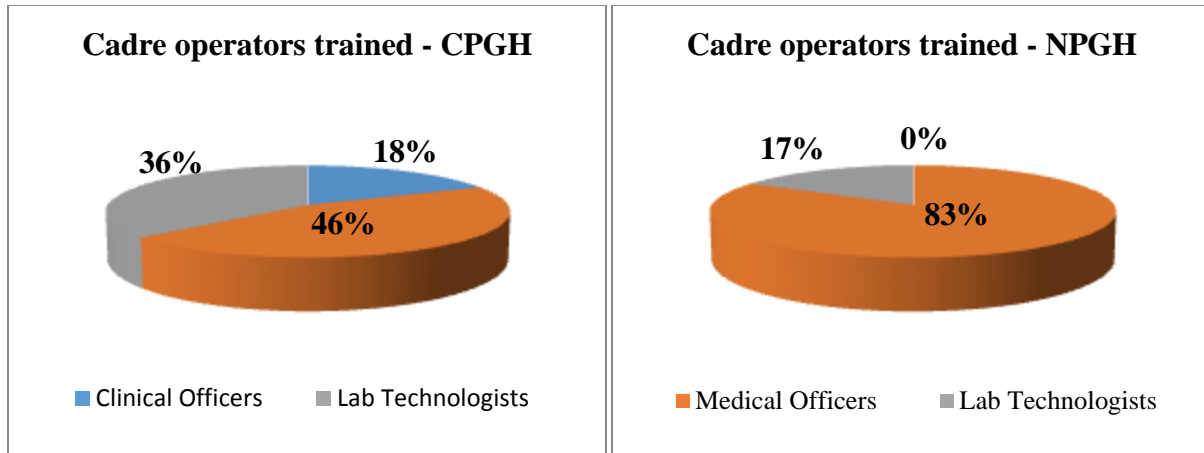


Figure 3: Trained cadre operators in both facilities.

BME and FNAB pre and post test analysis

There was a significant improvement in the knowledge between the pre- and post-test scores on BME with a p-value of 0.00. **Figure 6** and **7** below shows the results of test scores of the BME knowledge-based MCQs pre and post-test for clinicians. The median post-test mark was 8 compared to 6 in the pre-test in CPGH (**Table 2**), while in NPGH a median BME post-test mark of 10.5 was registered compared to 4 in the pre-test (**Table 3**).

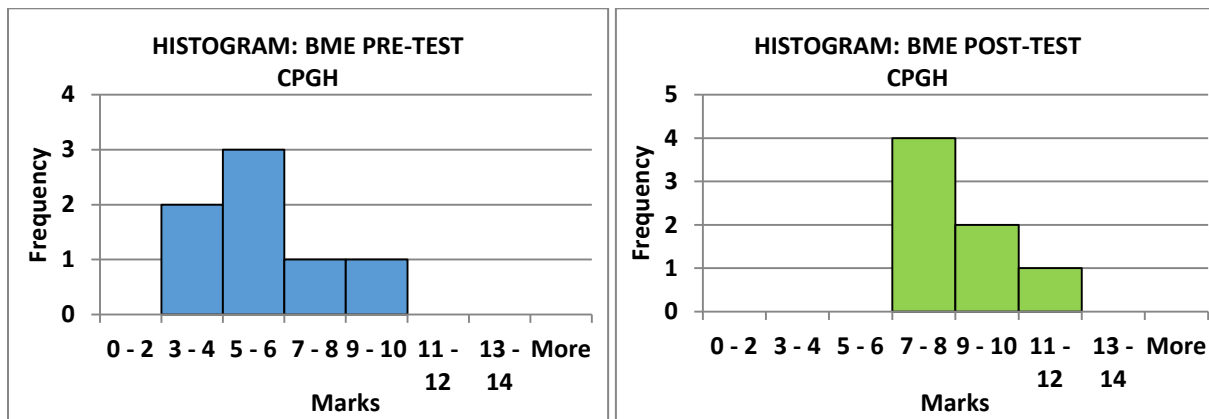


Figure 4: Bone marrow evaluation pre and post-test results for CPGH.

Table 2: Showing source data for figure 6 above.

BME TESTS - COAST PROVINCIAL GENERAL HOSPITAL						
	Number of Participants	Mean Marks (Out of 14)	Mode	Median	Range	*Sig. (2-tailed)
PRE	7	6.00	4.00	6.00	4 - 9	.000
POST	7	8.86	8.00	8.00	7 - 12	

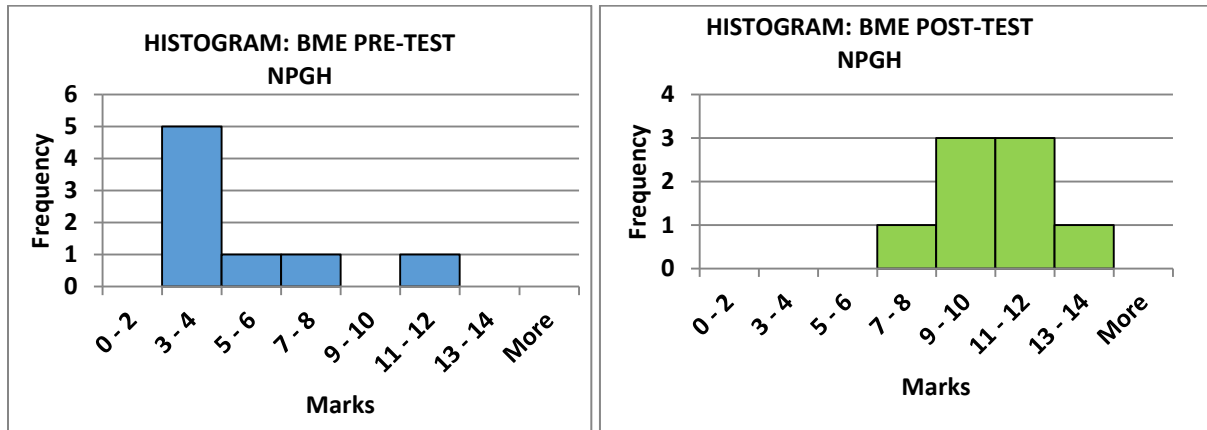


Figure 5: Bone marrow evaluation pre and post-test results for NPGH

Table 3: Showing source data for figure 7 above

BME TESTS - NYERI PROVINCIAL GENERAL HOSPITAL						
	Number of Participants	Mean Marks (Out of 14)	Mode	Median	Range	*Sig. (2-tailed)
PRE	8	5.25	4.00	4.00	3 - 11	.000
POST	8	10.38	11.00	10.50	8 - 13	

The results of test scores of the FNA knowledge-based MCQ pre- and post-tests are as shown below (**Figure 8 and 9**). In CPGH a median mark of 7 out of 10 was noted in the FNA post-test compared to 5 recorded in the pre-test(**Table 4**), while in Nyeri PGH participants recorded a median mark of 9 out of 10 in the post-test compared to 5 registered in the pre-test (**Table 5**). Both facilities registered significant improvement in the knowledge between pre- and post-test scores on FNA ($p= 0.001$).

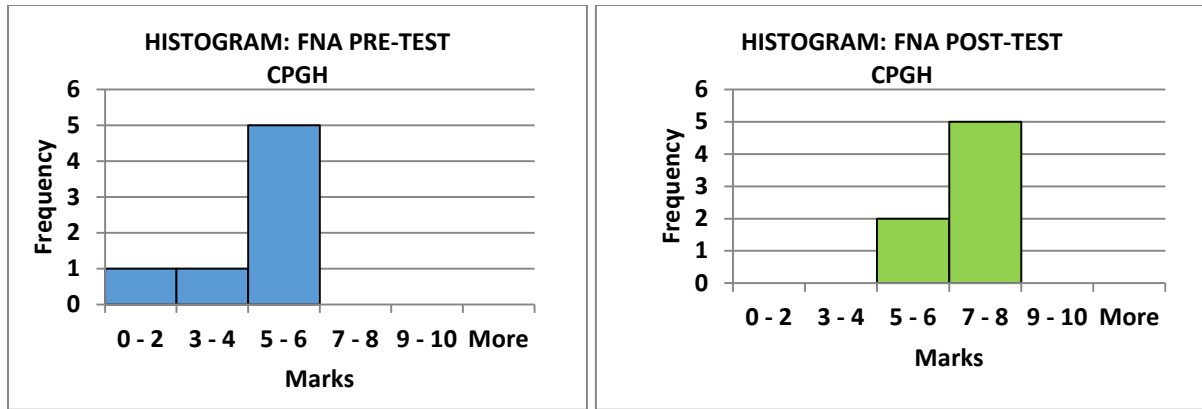


Figure 6: Fine needle aspiration biopsy pre and post-test analysis results for CPGH

Table 4: Showing source data for figure 8 above

FNA TESTS - COAST PROVINCIAL GENERAL HOSPITAL						
	Number of Participants	Mean Marks (Out of 10)	Mode	Median	Range	*Sig. (2-tailed)
PRE	7	4.57	5.00	5.00	1 - 6	.001
POST	7	7.00	8.00	7.00	5 - 8	

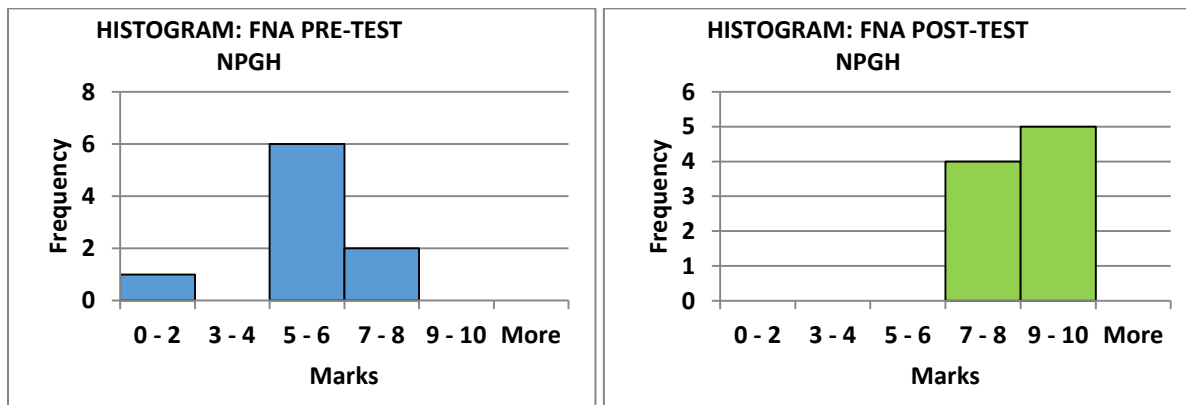


Figure 7: Fine needle aspiration biopsy pre and post-test analysis results for NPGH

Table 5: Showing source data for figure 9 above

FNA TESTS - NYERI PROVINCIAL GENERAL HOSPITAL						
	Number of Participants	Mean Marks (Out of 10)	Mode	Median	Range	*Sig. (2-tailed)
PRE	9	5.33	5.00	5.00	2 - 7	.001
POST	9	8.33	9.00	9.00	7 - 9	

Trainee proficiency testing

Majority of the operators trained on sample collection using FNA, BMA and trephine biopsy, exhibited high level of competency given by the low levels of unsatisfactory rates and number of procedures performed (**Table 6** and **Table 7**). Each trainee was expected to perform a minimum of 15FNABs and 5 BME procedures to be considered proficient. Some trainees (6 for FNA and 5 for BME) due to staff attrition or lack of interest never performed more diagnostic procedures in the post-training period. Note that Table 6 and 7 only shows procedures done by trainees (in the post-training period) who were certified proficient in both facilities excluding those done by the site pathologists during the study period.

Table 6: Trainee proficiency on fine needle aspiration biopsy technique

Name	Institution	No. done	Unsatisfactory
Trainee 001	NPGH	127	17 (13%)
Trainee 002	NPGH	42	8 (19%)
Trainee 003	NPGH	40	2 (5%)
Trainee 004	NPGH	38	1 (2.6%)
Trainee 005	NPGH	50	2 (4%)
Trainee 006	NPGH	65	3 (4.6%)
Trainee 007	CPGH	33	5 (19%)
Trainee 008	CPGH	21	3 (14%)
Trainee 009	CPGH	15	1 (6.7%)

Table 7: Bone marrow evaluation trainee proficiency in both facilities.

Names	Institution	Number done	Unsatisfactory
Trainee 001	NPGH	10	1 (10%)
Trainee 002	NPGH	15	1 (7%)
Trainee 003	NPGH	5	1 (20%)
Trainee 004	CPGH	10	2 (20%)
Trainee 005	CPGH	5	0 (0%)
Trainee 006	CPGH	5	0 (0%)
Trainee 007	CPGH	5	0 (0%)
Trainee 008	CPGH	5	1 (20%)
Trainee 009	CPGH	4	0 (0%)
Trainee 010	CPGH	4	1 (25%)

Analysis of total procedures performed compared to the previous year.

A total of 1371 diagnostic procedures were performed during the one year period of the initiative. As shown in **figure 10** below, a total of 483FNABs were procured in Coast PGH during the implementation phase compared to an average of 222 in the year before, while in Nyeri PGH, 723procedures were performed and processed compared to 415 recorded the previous year.

In terms of BMA a total of 60 (4.4%)procedures were conducted in Coast PGH, compared to an average of 3 processed the year before, while 35 (2.6%) cases were processed in Nyeri PGH, compared to an average of 5 reported the previous year. A total of 45 (3.3%) and 25 (1.8%)trephine biopsy procedures were performed in CPGH and NPGH respectively, a service that was nonexistent previously.

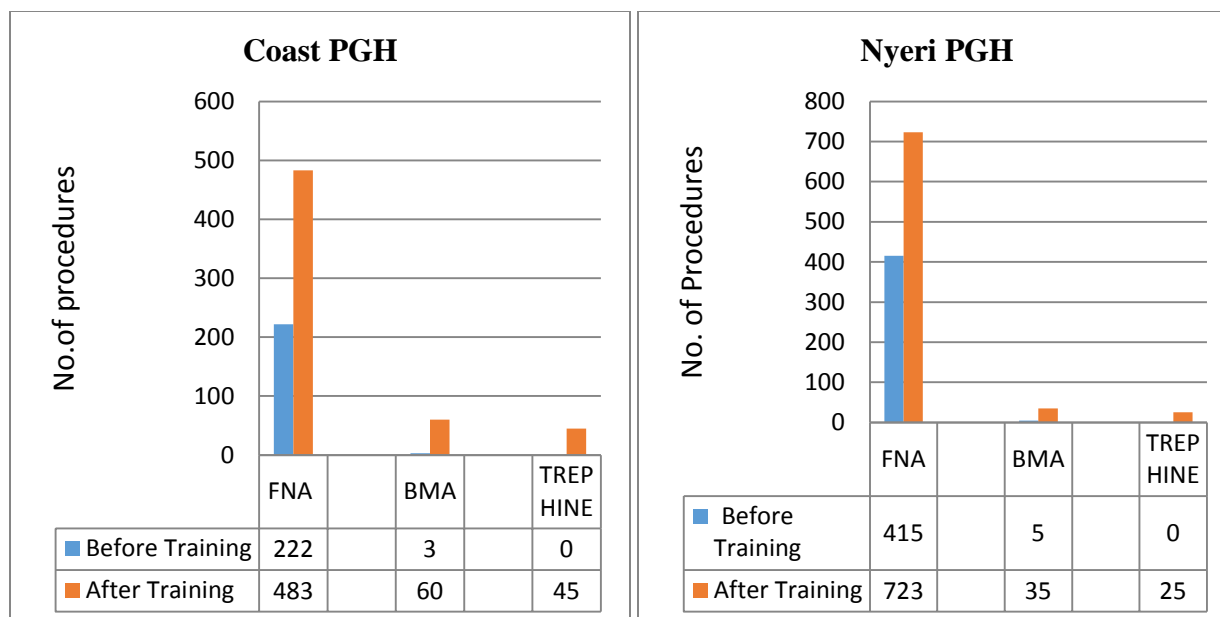


Figure 8: Number of diagnostic procedures performed in both Nyeri PGH and Coast PGH

Turn Around Time in sample processing

The average TAT for FNAB was 10 days in CPGH similar to the previous year. (Table 8). This is in contrast to NPGH where the TAT increased from 7 days the previous year to 19 after the training. The average TAT for BMA in CPGH improved from 10 days to average of 7 days during the study period while it was maintained at 7 days in NPGH. However, trephine biopsy which was previously not performed had an average TAT of 16 and 22 days for CPGH and NPGH respectively.

Table 8: Turn-around time in days per institution

Average TAT in days	Coast PGH			Nyeri PGH		
	FNAB	BMA	Trephine Bx	FNAB	BMA	Trephine Bx
Before Initiative	10	10	-	7	7	-
After Initiative	10	5	16	19	7	22

Audit of BMA, FNA and Trepine biopsy satisfactory procedures

Post training quality audits were carried out on reported slides looking at staining properties, smear preparation and sample quality in terms of cellularity and spicularity of marrow aspirate. As shown in **Table9**, FNAB slide preparation and processing was satisfactory (100%) in both facilities with up to 93.1% and 95.9% specimen quality rates in NPGH and CPGH respectively. Thus, minimal rates of reprocess or re-stain that contributed to reduced TAT.

Good smear preparations (spreads and squash) were noted in 91.7% of CPGH BMA procedures and 91.4% in NPGH; while 71.4% and 75% satisfactory staining was recorded in NPGH and CPGH respectively. In terms of quality of the marrow aspirate, only 5 (14.3%) cases from NPGH were considered aparticulate and 7 (11.7%) from CPGH, showing improved quality technical preparation and processing.

Table 9: Audit of BMA and FNAB satisfactory rates per institution

Institution	No. of Satisfactory Procedures		
	Fine Needle Aspiration (FNAB)		
	Smear making	Staining	Specimen Quality
Nyeri PGH (n=723)	723 (100%)	723 (100%)	673 (93.1%)
Coast PGH (n=483)	483 (100%)	483 (100%)	463 (95.9%)
	Bone Marrow Aspiration (BMA)		
Nyeri PGH (n=35)	32 (91.4%)	25 (71.4%)	30 (85.7%)
Coast PGH (n=60)	55 (91.7%)	45 (75%)	53 (88.3%)

Both facilities showed 100% satisfactory rates in the technical preparation of the trephine biopsy imprints /trails (**Table 10**). In terms of quality of the trephine cores regarded mainly based on its length (minimum of 10mm long), all the 25 samples from NPGH were properly processed with up to 95.6% adequacy rates in CPGH.

Table 10: Audit of trephine biopsy specimen satisfactory rates

Institution	No. of Satisfactory Procedures (Trephine Biopsy)	
	Imprints made	Specimen Quality
Nyeri PGH (n=25)	25 (100%)	25 (100%)
Coast PGH (n=45)	45 (100%)	43 (95.6%)

Comparison of Cancer diagnostic rates

Out of the 588 total procedures reported in Coast PGH, there were 50 (8.5%) new cancer cases diagnosed through the FNAB and BME techniques compared to 27 (6.0%) cases recorded before the training for a p-value of 0.132 (**Figure 11**). In the case of Nyeri PGH, of the 783 diagnostic procedures performed, 36 (4.6%) new cancer cases were diagnosed using the two techniques compared to 23 (2.7%) cases recorded over a similar period of time before the capacity building initiative (p-value = 0.047).

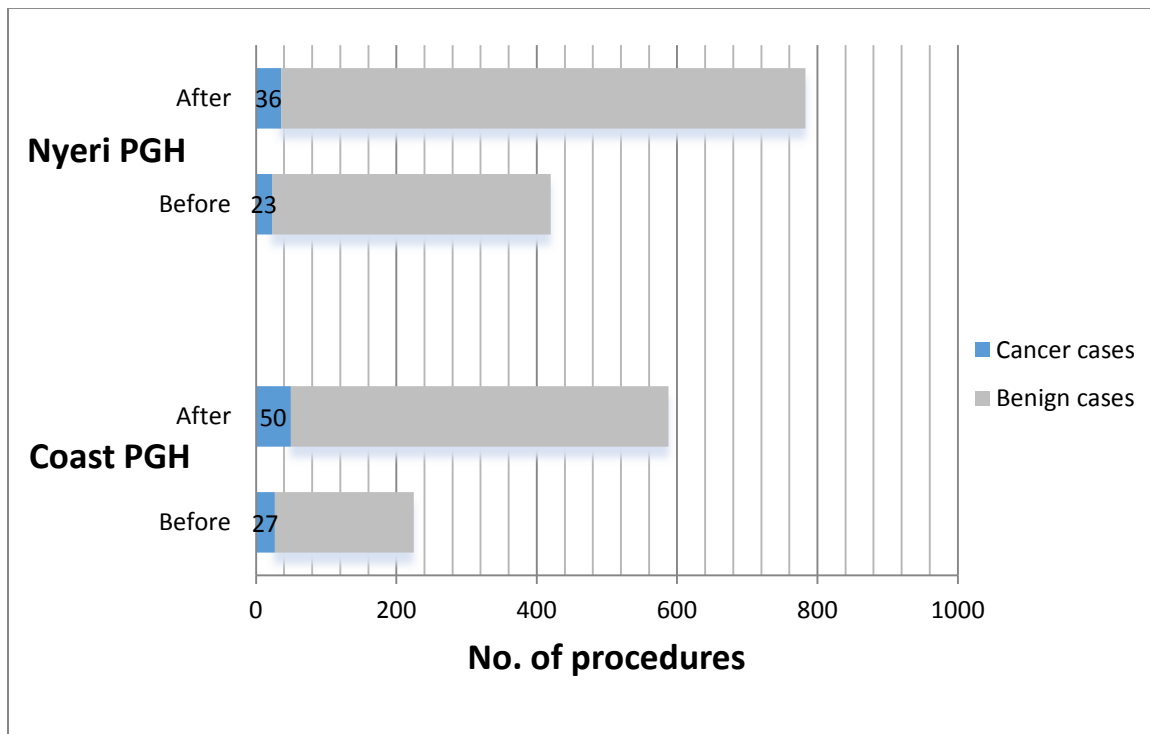


Figure 9: Cancer diagnostic rates before and after the initiative

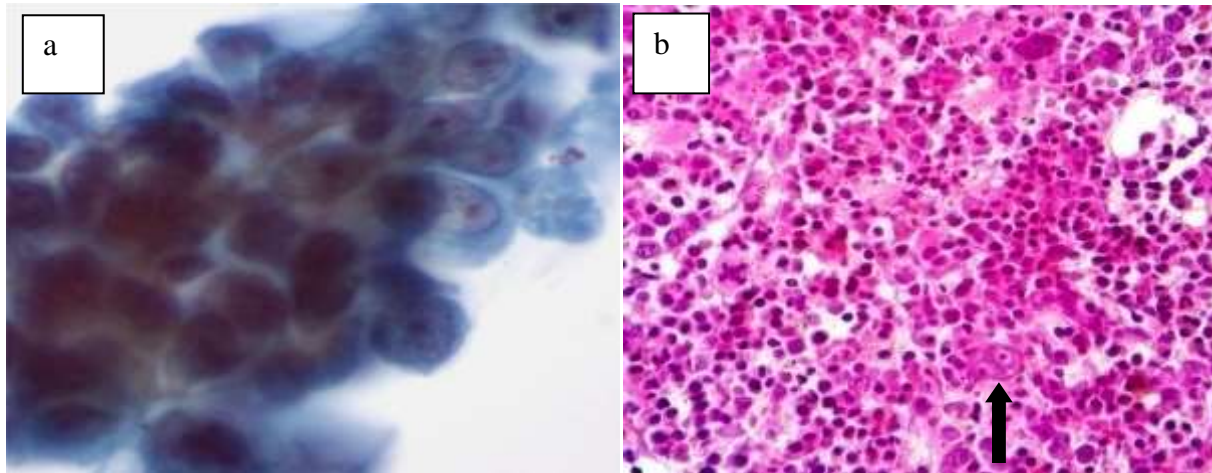
Other Capacity building Outcomes

This operational study initiative also managed other outcomes as shown below:

- I. During the implementation phase, the initiative managed to cascade the number of trainees to eight more operators who were trained to proficiency by the previous trainees. These operators included 3 clinical officers in NPGH and 5 medical officers in CPGH, effectively demonstrating importance of skills and knowledge transfer.
- II. Through this initiative, patient consenting procedures were developed for routine use and standard operating procedures (SOPs) for FNAB, BMA and trephine processing generated.
- III. The project managed to set up dedicated BMA and FNAB procedure rooms in NPGH. This would ensure having the necessary equipments in one place, apart from faster on site evaluation of specimen adequacy.
- IV. This initiative resulted in the inclusion of FNAB, BMA and trephine in the hospital laboratory test menus. This would ensure sustainability and laboratory support in terms of relevant consumables.
- V. In both facilities, the trainees developed working rotas and clinic days for FNABs and BME diagnostic techniques. This would ensure efficient and better working program among the trained cadres.
- VI. This capacity building initiative also contributed to both study sites showing administrative commitment and cooperation to buy necessary consumables like bone marrow needles and special stains. This was important as it guaranteed sustainability beyond the lifetime of the initiative.

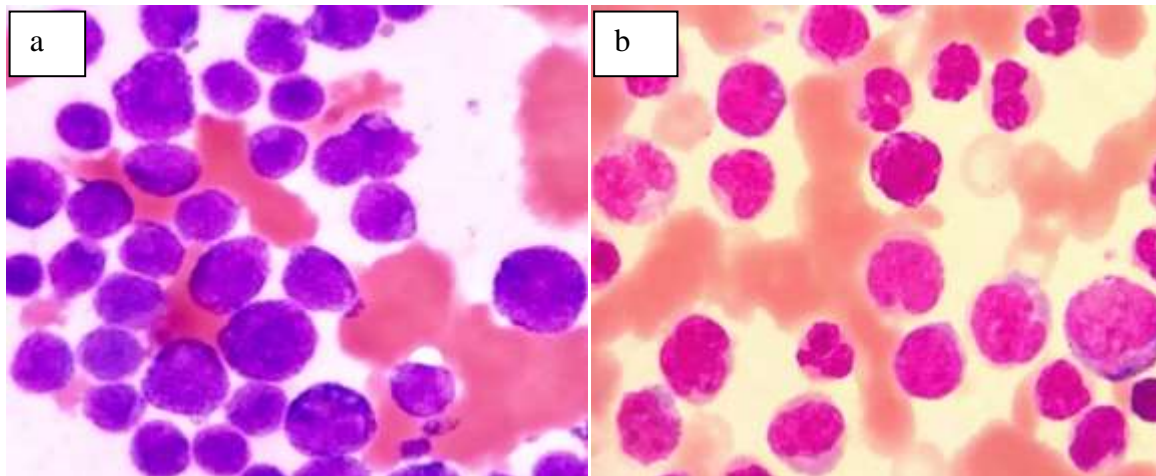
4.11 CYTOPATHOLOGY AND GRAPHIC APPEARANCES (PHOTOMICROGRAPHS)
Histology and cytology features of confirmed cancer diagnoses and graphic images captured during training in Nyeri and Coast PGH.

Plate 1:



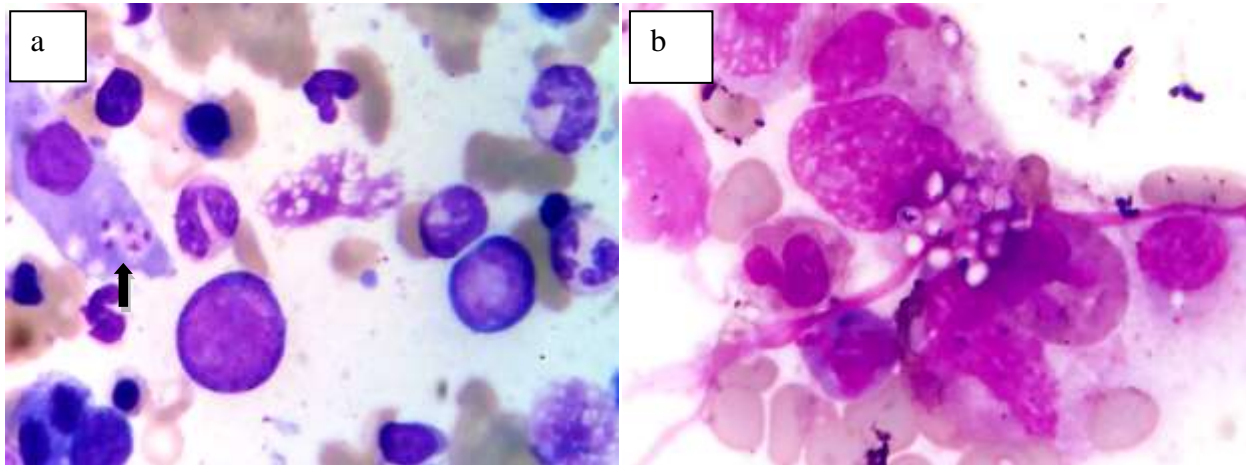
(a) FNA aspirate showing ductal carcinoma of breast (pap stain x400). (b) Image showing a Reed Sternberg cell (arrow) in a trephine biopsy of a patient with Hodgkin's Lymphoma (H/E x400).

Plate 2:



(a) Bone marrow aspirate of a patient with AML (MGG x1000), (b) Bone marrow aspirate of patient with CML chronic phase (MGG x1000).

Plate3:



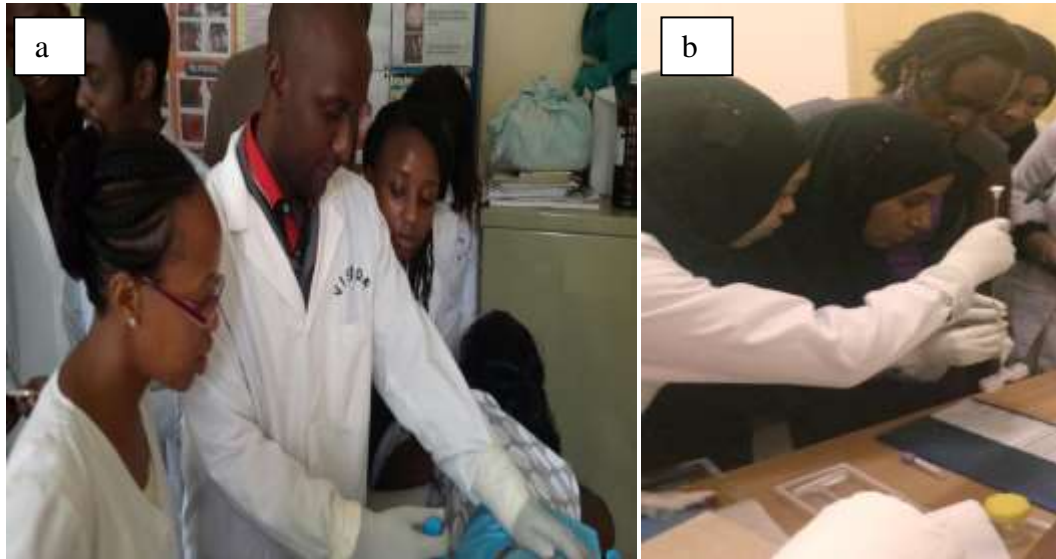
(a) Bone marrow aspirate of a patient with leishmaniasis, showing a macrophage containing numerous organisms -LD bodies illustrated by the arrow (MGG x1000). (b) Bone marrow aspirate showing histoplasma fungal bodies (MGG x1000).

Plate 4:



(a) Principal Investigator offering training and mentorship to trainees on procurement of BMA. (b) Technical demonstration of smear preparation techniques.

Plate 5:



(a and b) Trainees showcase skills learnt during trephine biopsy and BMA procurement respectively.

4.12DISCUSSION

The capacity building initiative

This research study was part of a ‘resident- driven FNA, BMA and trephine biopsy project’ an initiative of the University of Nairobi in conjunction with the Aga Khan University (AKU) in collaboration with the National Cancer Institute of the USA and Kenya Ministry of Health (MOH). The project had been as a result of a multidisciplinary stakeholders meeting that was carried out in Naivasha Kenya in 2011, triggered by the existing state of late and under-diagnosis of cancer as a critical aspect associated with poor patient outcomes. Roles were assigned to various entities including medical universities especially the department of pathology to come up with workable programs and initiatives that would ensure improved diagnostic outcomes.

The 2012 GLOBOCAN estimates project the cancer burden as having shifted to low and middle income countries (LMICs), with Kenyan annual incidence placed at about 37,000 new cases (2). This would necessitate urgent and focused multidisciplinary approach with pathology playing a leading role.

The study was conducted in two level-5 hospitals both being regional referral centers outside Nairobi with resident pathologists and sizable catchment populations. The capacity building initiative was delivered to non-pathologists (clinicians and laboratory technologists) and

employed an operational study framework with components of training, mentorship and monitoring and evaluation. The main objective was to offer skills and knowledge transfer on sample collection and processing through FNAB, BMA and trephine biopsy techniques to improve quality cancer diagnosis.

Utility of diagnostic tools and Situation Analysis

Prior to the study, a baseline situation analysis was conducted to assess the existing gaps in the county level-5 hospitals with regards to the utility of BME and FNAB as diagnostic techniques. The two diagnostic tests were found to be underutilized in the two county hospitals mainly due to inadequate specimen collection and technical processing skills, lack of SOPs and unavailability of necessary equipments, consumable and special stains. Both sites were found to be performing the FNAB and BMA except for the trephine biopsy. These numbers were however limited given the two year period for a level-5 regional referral hospitals. No information was available on the proportion of the FNABs and BMAs that were considered unsatisfactory or whether the few BMA samples had been procured and processed within the local laboratory. This depicted a deficient archiving system that required improvement. There was no proper procedure consenting in place and no SOPs were used in specimen processing with sample collection being a preserve of only the pathologist. Other institutional findings on the under utility of the diagnostic procedures included lack of clinician awareness of the existence of the service, lack of pathologists and laboratory factors bordering on the technologist competencies. This state of affairs relates well with the findings of an integrated missions (imPACT) study by the MOH which found out that obstacles to the diagnostic system include; delays in analysis and reporting, lost specimens, poor supply of consumables, prohibitive costs and inaccessible services (42).

According to their service charter requirements, the level-5 hospitals as shown in the study by Masese and Wanja et al (43) ought to provide affordable and accessible diagnostic services as regional referral centers. Despite BMA, FNAB and trephine being relatively inexpensive procedures this however was not the case as prior to this initiative, the numbers were few and specimen quality sub-optimal with no supporting infrastructure. This situation underscoring the mandates of the level-5 hospitals leading to referrals that would result in delayed diagnosis and consequently poor patient outcomes. According to WHO National Cancer Control Program (NCCP), the first step in cancer management is to make accurate diagnosis (44). The guidelines

recommend efforts be made to obtain adequate and appropriate material for cytological or histological examination.

Knowledge Transfer and Quality Proficiency Assessment

The trainees exhibited good grasp of knowledge and skills during implementation, demonstrating high level of competency achieved through increase in the number of procedures performed and improved proficiency levels in sample collection as well as laboratory technical preparation and processing. The level of proficiency obtained through training of non-pathologists was manifest through the quality of BME specimens procured and processed. Impact was therefore achieved in this sphere, since the single most important parameter of specimen readability was the quality of sample aspirate. This compares with a study by Difrancesco et al (45) where 92.3% of non diagnostic BMAs were due to poor quality aspirate. The competency skills acquired by the clinicians and laboratory technologists infer on the curriculum used and its delivery which was deemed of good quality to impact outcomes.

Several studies where transfer of skills and knowledge has delivered impact in similar settings have been discussed. Study by Naegelle et al (27) where a similar training model on BMA sample collection was used, showed that nurse specialists could be trained to proficiency to collect quality bone marrow specimens with no reported complications. Similarly, studies by Ljung BM et al (36,46) have demonstrated that effective training in sampling and sample preparation is likely to improve the diagnostic accuracy of FNA. Training of the non-pathologists especially laboratory technologists, improved quality of specimen for BME and FNA through improved smear preparation, satisfactory staining characteristics and adequate marrow aspirate and trephine biopsy, leading to reduced unsatisfactory rates.

In this study therefore, a multifaceted model initiative involving knowledge transfer, mentorship and management engagement expected to ascertain improved cancer diagnostic outcomes in two level-5 facilities using FNA and BME techniques. The mentorship provided enhanced the uptake of the training by the operators as it has been used to promote job satisfaction, career development and adoption of new skills as shown in study by Gagliardi A. et al (47). The study recommends combining workshop-based training with individual mentorship to improve implementation outcomes. Our study program ensured a combined preliminary workshop-based training and in-person mentoring offered for at least an hour periodically over a minimum of six

months. This ensured proficiency and guaranteed a holistic approach towards improved impact outcomes.

In a different approach at the international level, the model of partnerships or twinning between healthcare institutions in high-income countries and low- or middle-income countries has a role to play in addressing deficiencies in quality of human resources for cancer control. The Tropical Health and Education Trust (THET) directly implements health workers capacity building initiatives in Zambia and Somaliland providing training and grant support to health projects (48). In the article by M Collins et al, unique characteristics of health partnership model are used to improve cancer control capacity. These offer a means for clinicians, technologists and other cadre operators to work with counterparts in other countries in a structured and strategic way for the long term (48).

The introduction of project generated standard operating procedures improved quality of procedures and ensured good internal quality control measures in specimen processing methods by the laboratory technologists. The use of SOPs also ensured that the FNAB and BME results are reported within the stated turnaround times (TATs) as the need for reprocessing was significantly reduced. However, there was an increase in FNAB TAT in NPGH because of delays occasioned by the absence of the site pathologist, which meant that all the FNA cases be reported by the principle investigator in the UoN. This is in line with the requirements for all laboratories seeking WHO-AFRO accreditation as demonstrated by Clement Zeh et al (49), that 80% of laboratory specimens should be processed within the stated TAT to receive an accreditation rating. In another study by Yao K and Nkengasong et al (50), an innovative approach to accelerate laboratory accreditation through the SLMTA program, it was demonstrated that practical, task-based improvement projects were able to realize laboratory improvement without large policy intervention or resource reallocation. The SOPs were cited as major contributors to the desired outcomes in the areas of laboratory testing, specimen collection and processing and documentation and records management.

Institutional Uptake of the Diagnostic Techniques

Through this capacity building initiative, there was a notable increase in the cancer diagnostic rates in the two level-5 facilities. A total of 86 new cancer diagnoses were made using BMA, FNA and trephine biopsy techniques compared to a combined total of 50 that had been reported the previous year. These numbers meant a significant increase in cancer cases diagnosed using FNAB and BME techniques in these institutions despite the fact that majority (1206 out of 1371) of the procedures performed were FNAs whose reports needed further tests for a definitive diagnosis of cancer to be made. This improvement outcome was attributed to the uptake of the diagnostic procedures and administrative support by both Nyeri PGH and Coast PGH.

Administrative engagement from inception of the study was key and enhanced the institutional uptake of the initiative. This was given by the realization that the diagnostic service would improve patient outcome hence useful, and the fact that provision of essential services improved facility image. Securing administrative support is a significant step when implementing/introducing a service or an initiative such as this since the approach and execution should be responsive to the demands of your subject and your audience (51). This was evident in the study by Grady K. et al (29) where for successful implementation of the LSS-EOC program to the public hospitals, there had to be intense engagement of the facility administrators as well as the county and national reproductive health coordinators. To get them to buy-in the idea, it was explained that the program would ensure reduced maternal and infant mortality and morbidity in the respective hospitals and eventually improve the national maternal health indices.

The skills and knowledge transfer program ensured improved competencies for the trained doctors and the laboratory technologists when they are able to perform the procedures to proficiency. This was not only a morale booster for the trainees but also it increased confidence in the local laboratory's capacity by the physicians. The establishment of a dedicated area/clinic in Nyeri PGH for performance of BME and FNA procedures was a welcome impact outcome as this guaranteed quick specimen collection and evaluation leading to reduced TAT. Studies have demonstrated that having well equipped special and dedicated procedure clinics reduced the number of unsatisfactory specimens due to limited passes made in a particular nodule especially in head and neck FNAB cases (36,52). They would also ensure immediate on site evaluation of specimen adequacy and triage for ancillary studies (53).

The institutional uptake was also enhanced by the development of schedules/work rotas in both NPGH and CPGH leading to improved work planning and service delivery. Through this, each trainee would get equal opportunity to showcase their skills leading to improved confidence rating and job retention.

In order to ensure sustainability beyond the lifetime of the initiative, the ‘Resident driven FNA, BMA and trephine biopsy project’ provided management support and supply of the necessary consumables (BMA and trephine needles, frosted slides, stains etc) during the intervention period. In addition, the two level-5 facilities were advised on the need to carry out cost evaluation/ analysis of the diagnostic procedures as avenue for revenue generation and provide the necessary supplies for sustainability for long term impact realization. Other important measures would see the expansion of cancer diagnostic menus to include BME and FNAB as was already noted in both facilities, and increased laboratory personnel and infrastructure support. An increase in training of pathologists, strengthened BMA procurement and analysis at the masters of medicine program level as well as promotion of inter-institution collaboration would ensure long-term sustainability.

4.13 STUDY LIMITATIONS

This initiative successfully realized its main objective of effective skills and knowledge transfer with majority of the trainees expressing confidence in their technical ability in quality sample processing as well as collection. However, several challenges were encountered during the implementation phase as follows:

1. Trainee attrition was a major challenge as was occasioned by trained non-pathologists either leaving the facilities for further career progression or seeking transfer altogether, thus affecting performance rates.
2. Several prolonged county and national health industrial actions limited the performance during the implementation period.
3. There was limited follow up of the sustainability of the impact outcomes beyond the initiative lifetime.

4.14 CONCLUSIONS

1. Prior the initiative both study sites registered few diagnostic procedures as revealed in the baseline situation analysis and the basic infrastructure for performing the tests was inadequate.
2. This multi-faceted initiative involving skills transfer, mentorship and management engagement improved quality diagnosis through quality BME and FNA sample collection exhibited by high proficiency ratings of the non-pathologists and a total 1371 procedures performed.
3. Quality technical preparation and specimen processing led to reduced unsatisfactory rates. This was exhibited through improved smear preparation and quality staining, both parameters showing average 90% satisfactory rates demonstrating high level of competency achieved.
4. After the initiative there was a significant increase in the cancer diagnostic rates in the two level-5 facilities. A total of 50 (8.5%) new cancer cases were diagnosed in CPGH compared to 23(6.0%)the previous year for a p-value of 0.132, while in NPGH 36 (4.6%) new cancer cases were reported compared to 23 (2.7%) the previous year for a p-value of 0.047.

4.15RECOMMENDATIONS

1. Clinicians and laboratory technologist training in BME and FNAB techniques as well as hospital management engagement should be maintained for future sustainable utility of the diagnostic tests.
2. Given the high level of competencies acquired by the non-pathologists on specimen collection and preparation, a cost evaluation of the approach should be carried out for possible future national scale up to all health institutions and county hospitals in Kenya.
3. Customized capacity building tools such as curriculum and bench training with standard operating procedures (SOPs) for the two diagnostic tests should be adopted and implemented in all level-4 and level-5 hospitals in Kenya.
4. Level 5 institution management should review facility structures (budget, personnel, infrastructure to support the service), and expand their cancer diagnostic menu to include FNA, BMA and BMTB.

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APPENDICES

APPENDIX I: Questionnaire on Capacity to Perform BME and FNA (Given to clinicians-procedure, and laboratory technologists-sample processing and staining)

Procedure:

1. A) Do you perform bone marrow evaluation and FNA at your facility?
 - Yes
 - NoIf No, Proceed to Question 9.
2. If Yes, on average how many BMAs do you perform in a month?
 - 1-5
 - 6-10
 - >10
3. Do you have a standard operating procedure (SOP) in place to guide on how the procedures are to be performed?
 - Yes
 - No
4. What is your job description?
 - Pathologist
 - Physician/Paediatrician
 - Surgeon
 - Medical Officer
 - Clinical Officer
 - Lab Technologist
5. In what setting is the procedure done? (Tick all that apply)
 - Inpatient
 - Outpatient
 - A dedicated procedure room
6. Do you get informed consent from the patients before carrying out the procedure?
 - Yes
 - No
 -
7. If yes, how is this documented?
 - As notes in the patient's file
 - On a formal consent form
 - Other: _____

8. A) When is assessment of the BMA sample quality done?
- At collection
 - After collection
 - Not done.
- B) Do you have all that is needed to carry out the procedure at your facility?
- Yes
 - No
9. If you answered No to question 1,
- A. Why not? (Tick all that apply)
- Lack of skill to carry out procedures
 - Lack of relevant equipment/supplies to carry out procedure
 - Lack of lab capacity to process sample
 - Lack of a pathologist who can interpret the samples
 - Other: _____
- B. How do you handle patients that need it?
- Referral to KNH for the procedure
 - Referral to nearby private facility
 - Other (Specify): _____

Sample Processing and staining

1. Do you have a standard operating procedure (SOP) that gives guidance on FNA,BMA and trephine biopsy sample processing
- Yes
 - No
2. How would you rate your skill level as pertains processing the sample? (For Technologists) (0 being poor at it and 5 being an expert)
- 0 1 2 3 4 5
3. Are FNA and BME smears stained within the hospital laboratory?
- Yes
 - No
- If No, what are the reasons for not doing it in-house?
- a) Lack of staining material
 - b) Lack of expertise
 - c) Interpretation done elsewhere
 - d) Others: _____
4. Is there an internal control process in place to address the quality of slide staining?
- Yes

APPENDIX II: STUDY DOCUMENTS FOR SITE IMPLEMENTATION

APPENDIX II: (a) Patient consent form.

I the undersigned have been asked by my doctor to get an FNAC/BM procedure done on (site) _____ at the pathology department of the Hospital.

The procedure, with its associated complications has been explained to me by the doctor carrying out the procedure.

I agree to subject myself to the same

PROCEDURE EXPLAINED

PROCEDURE UNDERSTOOD

Signature of doctor : _____

Date(dd/mm/yy): _____

Signature of Patient: _____

Date(dd/mm/yy): _____

No

Thank you for participating in this baseline survey.

APPENDIX II: (b) FNA/BME training program

Location		
Date		
DAY1		
TIME	ITEM	FACILITATOR
09:00-09:15	Arrival and Registration	
09:15-09:30	Welcome and introduction of Participants	
09:30-09:45	Overview of Project	
09:45-10.15	Pre course proficiency Test	
11.00-12.45	Bone marrow curriculum delivery(Handbook detailing preparation, aspiration techniques, complications, indications and contraindications etc).	
14:00-16:00	Parallel sessions Bone marrow practicals Bone marrow laboratory practicals	
DAY 2		
08:45-09:00	Arrival and Registration	
9:00- 11:00	Parallel sessions Bone marrow Practicals	
11:30-12:30	Post course proficiency test(BM)	
	Post course evaluation for BMA/BM trephine	
14:00-15:45	FNA Preparation of room, checklists and SOPs FNA Technical SOPs	
DAY 3		
8:45-9:00	Arrival and Registration	
9:00-9:30	Pre course proficiency test (All participants)	
9:30-10:30	FNA Curriculum delivery (All Participants)	
11:00-3:00	Parallel sessions	
	FNA Practicals	
	FNA Laboratory practicals	
15:00-15:45	Post course proficiency test and Teach back sessions(All participants) Post course evaluation for FNA (All Participants)	
END OF TRAINING		

APPENDIX II: (c).BME, FNAB pre/post test

BME

1. Indications for bone marrow examination include all the following **EXCEPT:**
 - a) Unexplained focal bony lesions on radiological imaging
 - b) Diagnosis of haemolyticanaemia
 - c) Investigation for splenomegaly
 - d) Investigation for pyrexia of unknown cause
2. The preferred site for a trephine biopsy in an adult:
 - a) Anterior iliac crest
 - b) Lateral iliac crest
 - c) Posterior superior iliac spine
 - d) Manubrium sternum
3. Complications/side effects of a bone marrow aspirate include all **EXCEPT:**
 - a) Cardiac tamponade in sternal aspirate
 - b) Allergic reaction to anaesthesia
 - c) Infection
 - d) Haemolysis
4. Sternal bone marrow aspirates should be avoided in all the following patients **EXCEPT:**
 - a) Obese patients
 - b) Suspected plasma cell myeloma
 - c) Osteoporosis
 - d) BMA should be avoided in all (a) to (c)
5. Causes of a dry tap include all **EXCEPT:**
 - a) Poor technique
 - b) Marrow fibrosis
 - c) Extensive marrow infiltration by tumor
 - d) Reduced marrow cellularity
6. The following is not true regarding the bone marrow examination
 - a) An ideal trephine should be at least 20mm in length
 - b) Aspirate should be particulate
 - c) Should be accompanied with a PBF and full haemogram
 - d) Bone marrow is absolutely contraindicated in thrombocytopenia
7. Short answer question. Fill in the table below

Age of patient	Preferred site for bone marrow aspirate
10 month old female	
8 year old male	
17 year old male	
32 year old extremely obese male	
70 year old female	

FNA

1. Which of the following needle sizes is MOST SUITABLE for aspiration of superficial lymph nodes?
 - A. 21G
 - B. 23G
 - C. 18G
 - D. 14G
2. Which of the following is TRUE with regard to infection control in the FNA clinic?
 - A. Universal precautions must always be followed when dealing with patient samples
 - B. The amount of material aspirated during FNA is too little to pose a health hazard
 - C. Needle-stick injuries cannot occur if good technique is followed
 - D. Hollow needles have reduced risk of transmitting HIV compared to solid needles
3. Which of the following is useful in eliminating the common problem of excessively haemorrhagic aspirates when performing thyroid FNAs?
 - A. Proper positioning of the patient
 - B. Use of smaller 25 or 27G needles
 - C. Rapid smearing of material on the slides
 - D. Reducing the amount of pressure exerted when smearing material onto the slides
4. Which of the following is NOT TRUE about examining FNA smears for adequacy
 - A. A microscope can be carried to the Procedure room to check for adequacy
 - B. Gross examination of the prepared slides can indicate whether or not the smear is adequate for some lesions
 - C. A completely aspirated and collapsed cyst does not require evaluation of the material for adequacy
 - D. Most thyroid aspirates do not require evaluation for adequacy
5. Features of a well-prepared smear from FNA material include:
 - A. Varying thickness of the smear
 - B. Well preserved tissue particles at the periphery of the slide
 - C. Oval smear shape
 - D. Patchy distribution of diagnostic material on the slide
6. What is the MOST COMMON complication of transthoracic fine-needle aspiration (FNA) biopsy of the lung?
 - A. Hematoma
 - B. Pneumothorax
 - C. Anaphylactic shock
 - D. Seeding of the tumor cells along the needle track
7. Which of the following is the reason why the aspirator should allow the pressure in the syringe to equalize prior to withdrawing the needle from the lesion while performing a FNA?
 - A. To prevent infection
 - B. To reduce the pain experienced by the patient
 - C. To minimize the trauma to the lesion being aspirated
 - D. To prevent the cells from being drawn from the barrel of the needle into the syringe

8. Prior to expressing the aspiration material onto a slide from the syringe it is important to remove the needle and pull back the plunger then replace the needle in order to accomplish which of the following?
- A. Reduce the risk of needle stick injury
 - B. Allow sufficient air in the syringe to blow material in the barrel of the needle out
 - C. Prevent air drying of the material in the barrel of the syringe
 - D. Ensure that the plunger does not stick while attempting to express the material onto the slides
9. Which of the following is an absolute contraindication for FNA?
- A. Deep seated lesion
 - B. Abscess
 - C. Close proximity of the lesion to a vital structure
 - D. There are no absolute contraindications

APPENDIX III: Questionnaire and Discussions with Hospital Management

1. In your opinion, was the capacity building initiative of importance to your facility?

Yes

No

If not, give reason _____

2. Did the study have an impact with regards to;

i. Patient management/ care

ii. Quality case diagnosis

3. What in your opinion are the areas that would need improvement?

APPENDIX IV: Questionnaires Proficiency Testing and Discussion with Trainees

1. With regards to FNA, BMA and trephine biopsy techniques, how would you execute the following attributes?
 - a. Patient handling
 - b. Indication assessment
 - c. Procedure
 - d. Smear preparation
 - e. BMA and trephine smear and trails preparation
 - f. Staining as per SOPs
 - g. Archiving as per ISO 15189 requirements

2. Was the capacity building initiative relevant to you as a healthcare provider?

- Yes
- No

If no above, state why _____ if yes, would you recommend up scaling of the course?

3. Did the training meet your expectations as a participant?

- Yes
- No

4. If No in (3) above, what in your opinion are the areas that need improvement?

APPENDIX V: Review of FNA, BMA and Trephine Samples For Quality

Attributes	Satisfactory	Unsatisfactory	Observations
Sample quality			
Smear making			
Staining			
Diagnosis (clinical and final diagnosis)			
TAT (= < 10 days)			
Archiving			

APPENDIXVI: Informed Consent Form for Study Participants (Trainees)

I the undersigned agree to take part in the capacity building initiative at the pathology department of the hospital.

Project Title: Resident driven FNA, BMA and trephine biopsy project: A capacity building initiative to improve cancer diagnosis.

Introduction

One major challenge that the medical fraternity in Kenya is facing today is that of poor cancer detection rates and late diagnosis. This has made us to contend with the fact that most cases will only benefit from basic palliative care as well as lack the necessary cancer registries that can help in policy formulation. It is on this premise that the Kenyan MOH has come up with strategies to ensure improved cancer diagnosis and to work with various stakeholders to realize this goal. The UON and the AKUH in collaboration with the National Cancer Institute designed a ‘resident driven’ FNA, BMA and Trephine project that is meant to offer skills on the basic diagnostic techniques in four level-5 hospitals, yours included.

Purpose of the study

The main aim of this initiative is to have the various cadres of physicians and the laboratory technologists trained on sample collection and processing using the FNA, BMA and trephine biopsy techniques. This is given by the fact that there are few pathologists in our hospitals against a huge backlog of patients that need these vital diagnostic procedures.

Benefits and risks

If well adopted, this initiative will increase the number of medical cadres with skills and knowledge to perform FNA, BMA and trephine biopsy and not just the pathologists. Many patients therefore will be attended to and the peak up rates of cancer will improve leading to quality diagnosis and easy accessibility among others. There are no risks associated with the procedures involved in the study and no victimization of any nature will be meted on one who do not participate or acquire the knowledge given. Note however, that no monetary payments will be given to the subject participants as compensation. The sole aim is for capacity building and for the benefit of our patients and the community.

Signature and cadre _____

Date (dd/mm/yy) _____

Thank you for participating

APPENDIX VII: Dummy Tables for Data Analysis

1. Number of cases performed per institution

Attributes	Coast PGH	Nyeri PGH
FNA		
BMA		
Trephine biopsies		

2. Assessment per institution in terms of numbers, insufficiencies/unsatisfactory and diagnoses before and after training.

Attributes	Before training(one year)	After training(one year)
FNAs		
Insufficient/unsatisfactory		
BMAs		
Insufficient/unsatisfactory		
Trephine biopsies		
Insufficient/unsatisfactory		
Cancer cases diagnosed		
TAT		

3. Number of cadre operators trained and procedures done per cadre.

Attribute	C.Os	M.Os	Physicians	Surgeons
Nyeri PGH				
Procedures done				
Coast PGH				
Procedures done				

4. Audit of sample quality, staining and smear making (in numbers) after training.

a). FNA

	Sample quality		Staining		Smear making	
Sites	Good	Poor(repeat)	Good	Poor(re-stain)	Good	Poor
Nyeri PGH						
Coast PGH						

b). BMA

	Sample quality		Staining		Smear making	
Sites	Good	Poor(repeat)	Good	Poor(re-stain)	Good	Poor
Nyeri PGH						
Coast PGH						

c). Trephine biopsy

	Sample Quality(>10mm core)		Staining		Imprints made	
Sites	Good	Poor	H/E	Special stains	Good	Poor
Nyeri PGH						
Coast PGH						

5. Pre and post test analysis

		A	B	C	D	Confidence rating(1 to 5)
Name		1 to3	4 to 6	7 to 9	10 to 12	
Participant x	Before					
	After					

APPENDIX VIII: Detailed training on FNA and BME sample collection.

COLLECTION OF FINE NEEDLE ASPIRATE FOR CYTOLOGY.

Examination of the patient

Ask the patient to point at the lump using a finger. The site of the mass or lesion is examined and described.

SAMPLE ASPIRATION

Clean the skin overlying the lump with alcohol swabs. Fix the lump firmly between the index finger third finger.

Non aspiration Technique: For superficial lumps like thyroid and Lymph nodes. Select a suitable needle gauge preferably the gauge 25 the orange coded. Insert the needle into the lesion and move the needle up and down within the lesion. This may also be combined with a sideways motion to liberate cells in the lesion. The examination sample is collected in the bore of the needle by capillarity action. The needle is withdrawn as soon as material or blood is seen within the hub of the needle. Expel the bore contents on the slides and make quick thin films/smears and preserve immediately in 95% ethanol while one slide is air dried for special staining.

Aspiration Technique: For breast lumps and suspected cystic lesions. Fit a needle onto a 10ml syringe and insert in the lesion. Ordinary injection needle is used, gauge 22-23-25-27. The choice of length varies with the depth at which the lesion is situated. Using a negative pressure with the syringe draw out the aspirate from the tumor. Withdraw the needle gently without releasing the negative pressure. The negative pressure is released and needle is withdrawn. Pressure is applied on the site of puncture using sterile swab until bleeding stops. Several aspirations may be required to ensure that sample is adequate.

PREPARATION OF THE SMEAR Disconnect the syringe; fill with air by withdrawing the plunger. Reconnect the needle with the syringe and push gently a small drop of the aspirated material on to the 2 or 3 clean slides. Make a smear by touching the sample with the spreader slant then push forward with quick motion and fixing it with minimum delay as possible in 95% ethanol alcohol.

BONE MARROW ASPIRATION AND BIOPSY

Once local anesthesia has been achieved, make a small (3 mm) skin incision with a scalpel blade at the site of insertion of the aspiration needle, in order to facilitate its entry and promote organized healing of the wound.

Hold the bone marrow needle (with stylet in place) perpendicular to the skin at the previously marked point, and gently advance it to the periosteum. In order to be sure that the needle is entering correctly, the second and third fingers on the hand not being used to insert the needle should be placed on the iliac crest or spine and the needle inserted between them.

Use a steady twisting back and forth motion. Do not twist more than 180 degrees to penetrate the periosteum and the cortical bone; a “give” is felt when the needle enters the marrow cavity.

Remove the stylet, attach a 2 mL syringe to the aspiration needle, and again advise the patient that the aspiration may cause a brief period of pain.

Aspirate 0.2 to 0.5mL of marrow contents and remove the syringe. In general it is prudent to avoid aspirating more than 0.5mL per syringe, as greater amounts may be prone to contamination with peripheral blood or to clotting

For biopsy, prepare the Jamshidi needle and advance it into the cortical bone, using the same incision but a slightly different site, with a steady twisting movement until it is firmly lodged. This may require a greater amount of pressure than was used for the aspiration. Remove the stylet and with a rotating motion advance the needle another 15 to 20 mm.

Redirect the needle tip and rotate it 360 degrees in both directions to separate the biopsy specimen from the surrounding marrow tissue. Following this step, the needle should be advanced a very short distance prior to removal.