REPUBLIC OF KENYA

MINISTRY OF HEALTH

BREAST CANCER SCREENING AND EARLY DIAGNOSIS ACTION PLAN

2021-2025

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Nairobi, October 2021

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Published by:
Ministry of Health
Afya House, Cathedral Road
P. O. Box 30016 - 00100
Nairobi
http://www.health.go.ke

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Foreword

Breast cancer is the leading type of cancer in incidence in Kenya accounting for 16.1% of all cancers. An estimated 6,799 cases were diagnosed in 2020, compared to 5,985 new cases in 2018. Deaths due to breast cancer also rose from 2,553 in 2018 to 3,107 in 2020, making it the second-leading cause of all cancer deaths in the country (GLOBOCAN,2020). Breast cancer affects women earlier in Kenya, in the prime of their lives, mostly between the ages of 35 to 45 years. Unfortunately, most of these women are diagnosed at late stages when it is more difficult to achieve a cure resulting in low overall survival rates.

The Ministry of Health conducted a breast cancer pilot in Nyeri County between October and November 2019. The findings of this pilot within the context of a rising breast cancer burden necessitated development of an Action Plan to provide guidance for a country-specific implementation framework for scale up of a breast cancer screening and early diagnosis program that will lead to a reduction in incidence and mortality of breast cancer. This Action Plan therefore, brings together current evidence and identifies key strategies for addressing breast cancer in the Kenyan context.

The goal of this Action Plan is to ensure that women with breast cancer are diagnosed in early stages This is to be achieved through putting in specific mechanisms to improve uptake of mammography screening in the eligible populations; ensuring that at least 90% of symptomatic women are linked to timely further evaluation and management within 60 days from their first encounter with a healthcare worker and improving the capacity and availability of breast cancer early diagnosis services at the primary level.
The overall objective is to ensure timely access to screening, early diagnosis and further management for breast cancer for every eligible woman in Kenya.

The Ministry of Health will take the lead in implementing this Action Plan and calls upon all stakeholders to utilize the guidance provided and implement it towards a reduction in the breast cancer burden in Kenya.

Dr. Patrick Amoth, EBS
AG. DIRECTOR GENERAL FOR HEALTH

Executive Summary

This Action Plan has been developed against a backdrop of a robust policy framework in Kenya that provides a suitable environment for cancer prevention and control. It is aligned to the WHO-led Global Breast Cancer Initiative which seeks to avert an estimated 2.5 million breast cancer-related deaths by 2040. The Action Plan is informed by the need to identify an effective, evidence-based strategy for early detection of breast cancer that is customized to the Kenyan setting, a breast cancer screen-naïve population where seven out of every ten cancer cases are diagnosed in advanced stages.

Chapter 1 sets the background of the action plan by outlining the current burden of the disease. That breast cancer is the leading type of cancer in incidence both globally and in Kenya is highlighted; with late diagnosis being the current scenario as about 68% of all breast cancer cases in Kenya are diagnosed in advanced stages. The epidemiological basis and policy framework of breast cancer screening is highlighted in this chapter with reference made to the National Cancer Screening Guidelines 2018.

Chapter 2 outlines the current situation of the capacity of the various health systems building blocks in supporting breast cancer early detection in Kenya. In particular, this chapter focuses on the findings and lessons from the breast cancer screening pilot conducted in 2019, including recommendations.

Chapter 3 describes the approach and the rationale for the Action Plan. An evidence synthesis section is provided as well as various algorithms are provided, including early detection, breast lump diagnosis, axillary node management and universal breast cancer pathway. Five key result areas namely; Governance and Policy; Demand creation and community education and engagement; Training and professional development; Service delivery and Monitoring and evaluation framework and research are prioritized and a logical framework is also presented.

Chapter 4 outlines the proposed strategic interventions in breast cancer screening, which includes supplies and human resource needs for various screening and diagnostic approaches. An implementation matrix, with proposed activities, sub-activities, key performance indicators, responsible entities and timeframe is also included.

Chapter 5 describes the monitoring and evaluation framework for the action plan, with three levels of indicators: process, outcome and impact. This chapter also includes the breast cancer screening targets for the period 2021-2025, both at national and county levels.

The **annexes** section of the action plan provides an overview of the distribution of the digital mammography equipment provided under the Managed Equipment Scheme in Kenya where all the forty-seven (47) county referral facilities received the equipment. An algorithm adapted from the World Health Organization Package of Essential Non-Communicable (PEN) protocol for assessment and Referral for women with suspected breast cancer at primary health care as well as the costing of the Breast Cancer Action Plan is also included.

It is my expectation that all stakeholders will join hands in conducting specific activities to reduce the burden of disease from breast cancer in Kenya.

Dr. Andrew Mulwa
Ag. DIRECTOR OF MEDICAL SERVICES, PREVENTIVE AND PROMOTIVE HEALTH

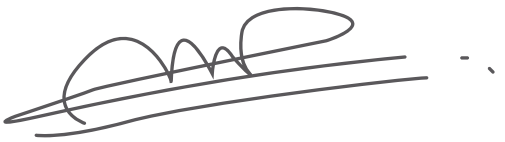
Acknowledgements

This action plan was developed through an extensive process involving experts and stakeholders from both public and private sector institutions.We sincerely appreciate the support from the offices of the Cabinet Secretary, Chief Administrative Secretaries, Principal Secretary, Director General, Directorate of Medical Services, Preventive and Promotive Health and Head Department of Non- Communicable diseases for their strategic guidance and support for the development of this document.

In a special way, we wish to recognize members of National Cancer Prevention, Screening & Early Diagnosis Technical Working Group, specifically the following Breast Cancer Committee members, who developed this document: Dr, Daniel Ojuka, Dr. Veronica Manduku, Eizabeth Ragui, Dr. Moki Mwenda, Dr. Miriam Mutebi, Boniface Mbuki, Ruth Muia, Roselyne Okumu, Dr. Richard Njoroge, Dr. Shahin Sayed, Dr. Hellena Musau, Lucy Kariuki, Dr. Beatrice Mugi, and Dr. Rose Ndumia. They portrayed tremendous dedication to the whole process to ensure the document was completed. Special thanks to the Head, National Cancer Control Program Dr. Mary Nyangasi for her leadership and guidance role and to Ms. Lilian Genga and Dr. Joan-Paula Bor who coordinated the entire process. The contribution of Dr. Valerian Mwenda, Lydia Kirika, Hannah Gitungo, Betty Nthusa, Hillary Changwony, Bruce Orangi and Woki Mburu is also much appreciated. We also wish to recognize our external reviewers: Mr. Ashu Gandhi and Mr. Rajiv Dave from the Nightingale & Prevent Breast Cancer Center at Wythenshave Hospital, Manchester University NHS Foundation Trust in the United Kingdom as well as Dr. Andrew Odhiambo of the University of Nairobi and Prof. Jana Macleod of Kenyatta University for their extensive inputs which helped improve this document.

We recognize GE Healthcare and its agencies for their financial and technical support and Nyeri County Government for their partnership towards the successful Breast Health Awareness Campaign pilot project whose findings contributed immensely to this action plan. We wish to recognize the following institutions: Kenyatta National Hospital, Kenyatta University Teaching and Referral Hospital, Aga Khan University Hospital, University of Nairobi, Kenya Network of Cancer Organizations, National Cancer Institute-Kenya, KEMRI, Kenya Association of Family Physicians, Professional Associations (Nursing Council and Clinical Officers' Council of Kenya), Kenya Medical Training College, Clinton Health Access Initiative, Takeda and Non-Communicable Diseases Alliance Kenya.

I look forward to our collaboration in the implementation of this action plan.



Dr. Ephantus Maree
HEAD, DEPARTMENT OF NON-COMMUNICABLE DISEASES

Acronyms / Abbreviations

BCAM	Breast Cancer Awareness Month
BCS	Breast-Conserving Surgery
BHAC	Breast Health Awareness Campaign
BSE	Breast Self-Examination
CBE	Clinical Breast Examination
CHEW	Community Health Extension Worker
CHMT	County Health Management Team
CHV	Community Health Volunteer
CIDP	County Integrated Development Plan
CME	Continuous Medical Education
COE	Center of Excellence
CORH	Clinical Officer (Reproductive Health)
CRH	County Referral Hospital
ER	Estrogen Receptor
EMR	Electronic Medical Records
FISH	Fluorescence in Situ Hybridization
FNA	Fine Needle Aspiration
GEHC	General Electric Health Care
HBCT	Hope Beyond Cancer Trust
HCW	Health Care Worker
HER-2	Human Epidermal Growth Factor Receptor 2
HIV	Human Immunodeficiency Virus
HRIO	Health Records Information Officer
IDC	Invasive Ductal Carcinoma
IEC	Information Education and Communication
IHC	Immuno-Histochemistry
KACP	Kenya Association of Clinical Pathologists
KAFP	Kenya Association of Family Physicians
KAR	Kenya Association of Radiologists
KESHO	Kenya Society of Haematology and Oncology
KCOA	Kenya Clinical Officers Association
KDHS	Kenya Demographic and Health Survey
KEMRI	Kenya Medical Research Institute
KEPH	Kenya Essential Package for Health
KESHO	Kenya Society of Haematology and Oncology
KHIS	Kenya Health Information System
KMTC	Kenya Medical Training College
KNCR	Kenya National Cancer Registry
KNH	Kenyatta National Hospital
KOGS	Kenya Obstetrical and Gynaecological Society
KUTRRH	Kenyatta University Teaching Referral and Research Hospital
MDT	Multi-Disciplinary Team
MES	Managed Equipment Service
MeTRH	Meru Teaching and Referral Hospital
MOH	Ministry of Health
MOU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
MTRH	Moi Teaching and Referral Hospital
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCCP	National Cancer Control Program
NCD	Non-Communicable Diseases
NCI	National Cancer Institute
NCRH	Nyeri County Referral Hospital
NNAK	National Nurses Association of Kenya
NORL	National Oncology Reference Laboratory
PHC	Primary Health Care
POCUS	Point of Care Ultrasound
PPP	Public Private Partnership
PR	Progesterone Receptor
QA	Quality Assurance
QI	Quality Improvement
RH Nurse	Reproductive Health Nurse
SORK	Society of Radiography in Kenya
SSK	Surgical Society of Kenya
TAT	Turn-around Time
TOR	Terms of Reference
TOT	Trainers of trainers
TWG	Technical Working Group
UHC	Universal Health Coverage
WHO	World Health Organization

Definition of Terms

Asymptomatic	Not causing, marked by, or presenting with signs or symptoms of disease
Benign	Refers to a condition, tumor, or growth that is not cancerous
Biopsy	A procedure that involves removal of a small sample of tissue for examination under a microscope by a pathologist
BRCA1/2	BRCA1 (BReast CAncer gene 1) and BRCA2 (BReast CAncer gene 2) are genes that produce proteins that help repair damaged DNA
BHA	Breast health awareness is the education on risk factors and symptoms of breast cancer, as well as importance of seeking timely medical evaluation for breast concerns.
BSE	A technique that involved assessing one own's breast regularly to detect lumps or any other abnormalities as part of early detection for breast cancer
Breast Cancer Centers of Excellence (COEs)	Selected facilities that have been identified to provide the comprehensive breast cancer services, including screening, rapid diagnosis, treatment and supportive care.
CBE	Clinical Breast Examination performed a qualified trained health care provider
Chemoprevention	The use of chemical agents to prevent or slow the development of cancer
Core biopsy	A procedure where a needle is passed through the skin to take a sample of tissue from a mass or lump.
Early menarche	Usually defined as menstruation before the age of 12 years
Excisional biopsy	A procedure in which an entire lump of a suspicious area is removed
Family history of breast cancer	Women with one first-degree relative (i.e. daughter, sister, or mother) or multiple (two or more) family members on either mother's or father's side with invasive breast cancer.
Immunochemistry	A method for the detection and localization of proteins and other cellular components using antibodies that specifically label the materials.
Malignant	Refers to the presence of cancerous cells that have the ability to spread to other sites in the body (metastasize) or to invade nearby (locally) and destroy tissues
Mammography	A specialized x-ray imaging method that uses a low-dose x-ray system to examine the breast for the early detection of cancer and other breast diseases.
Nulliparity	A condition or state in which a woman has never given birth to a child, or has never carried a pregnancy.
PAC system	A medical imaging technology used to securely store and digitally transmit electronic images and clinically-relevant reports primarily in healthcare organizations.
Prophylactic surgery	A form of surgery whose purpose is to minimize or prevent the risk of developing cancer in an organ or gland that has yet to develop cancer and is known to be at high risk of developing cancer.
Rapid breast diagnostic units	Hospital-based assessment clinic that allows for the early and rapid detection of breast cancer.
Risk stratification	The process of assigning a health risk status to a patient, and using the patient's risk status to direct and improve care
Screening	The identification of pre-clinical lesions in an apparently healthy target population
Stereotactic tru-cut biopsy	The sampling of non-palpable or indistinct breast lesions by using techniques that enable the spatial localization of the lesion within the breast
Tele Pathology	The practice of pathology at a distance by visualizing an image on a video monitor rather than viewing a specimen directly through a microscope
Tomosynthesis	An imaging, or X-ray, technique that can be used to screen for early signs of breast cancer in people with no symptoms
Triple Assessment	Hospital-based assessment that allows for the early and rapid detection of breast cancer through clinical examination, imaging and histopathology.

CHAPTER ONE

Introduction & Background

The Cancer Burden

The rising cancer burden is a major concern globally. There were an estimated 19 million new cases and 10 million new deaths worldwide in 2020. In Kenya, cancer is the third leading cause of death after infectious and cardiovascular diseases, accounting for 7% of overall mortality, with 42,116 new cases and 27,092 deaths in 2020 (GLOBOCAN, 2020). Majority of cancers are diagnosed at advanced stages, when prognosis is poor and few options for curative treatment are available.

Breast cancer has the highest incidence amongst all cancers, with over 2.2 million cases reported globally in 2020. It is, however, rare in males accounting for less than 1% of all breast cancer cases. Majority of breast cancer cases and deaths occur in low-and middle-income countries. In Kenya, it is the leading type of cancer with 6,799 new cases in 2020 and an age standardized rate of 41/100,000. Preliminary data from the Kenya National Cancer Registry 2014-2019 (KNCR) show that 7 out of 10 cancers are diagnosed at advanced stages (stage III and stage IV). It tends to occur at a relatively young age (35-50 years) in Kenya, in comparison to Western countries (50-55 years). About 90% of breast cancer cases occur sporadically, while only 5-10% can be attributed to genetic predisposition. Invasive ductal carcinoma (IDC) is the most common histological type diagnosed accounting for up to 75% of all breast cancers. Key challenges in breast cancer control include limited access to cancer preventive, diagnostic, treatment and rehabilitative services.

Estimated age-standardized incidence and mortality rates (World) in 2020, Kenya, both sexes, all ages.

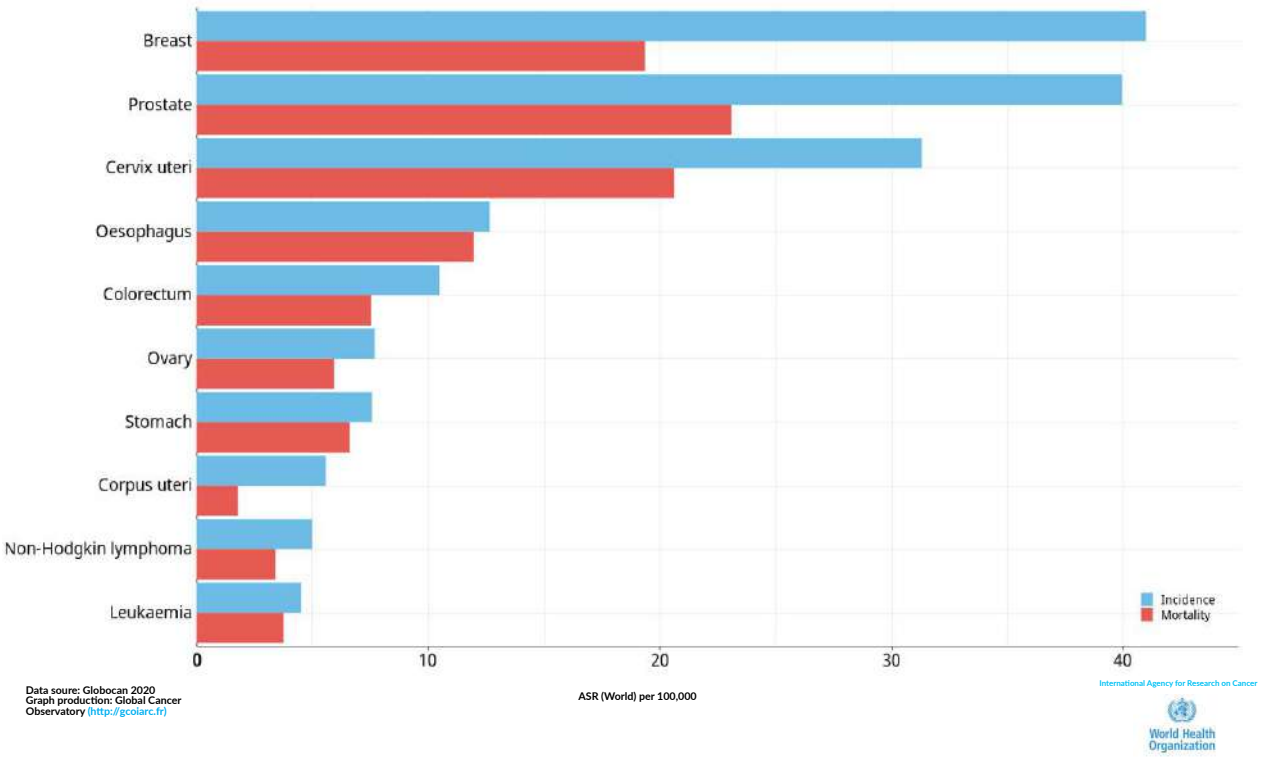


FIGURE 1: CANCER INCIDENCE AND MORTALITY IN KENYA (GLOBOCAN, 2020)

Cases per stage (number [row%])						
Cancer Type	**In Situ**	**Stage I**	**Stage II**	**Stage III**	**Stage IV**	**Total**
Cervix uteri	1 (0.1)	139 (7.5)	709 (38.1)	774 (41.5)	240 (12.9)	1863
Breast	8 (0.9)	37 (4.2)	232 (26.3)	269 (30.5)	335 (38.0)	881
Colorectal	0 (0)	8 (2.6)	49 (16.0)	122 (39.7)	128 (41.7)	307
Oesophagus	0 (0)	4 (1.7)	30 (12.4)	81 (33.5)	127 (52.5)	242
Stomach	2 (1.1)	6 (3.3)	28 (15.2)	43 (23.4)	105 (57.1)	184
Other Sites	4 (0.2)	145 (8.1)	286 (16.1)	446 (25.1)	899 (50.5)	1780
Grand Total	**15 (0.3)**	**339 (6.4)**	**1334 (25.4)**	**1735 (33.0)**	**1834 (34.9)**	**5257**

TABLE 1: CANCER CASES BY STAGE IN KENYA (The Kenya National Cancer Registry 2014-2019 Preliminary Report)

Breast Cancer Prevention

Several risk factors for breast cancer have been identified which may be modifiable or non-modifiable. Modifiable risk factors include obesity, harmful use of alcohol and physical inactivity and use of Hormone Replacement Therapy (HRT). Non-modifiable risk factors include heredity and family history, genetic mutations, previous breast pathology, history of chest wall radiation before the age of thirty, high breast density and reproductive history (such as early menarche, late menopause). The highest risk factors for breast cancer are associated with increasing age, female gender and a family history of at least one first-degree relative or multiple family members with ovarian or breast cancer.

The main approaches to breast cancer prevention is through lifestyle modifications such as limiting alcohol and tobacco use, maintaining a healthy body mass index, eating a healthy diet, being physically active and promoting breastfeeding in nursing women.

RISK FACTORS	PREVENTION
Modifiable	**Primary Prevention**
• Age at first childbirth	• Dietary modification
• Obesity	• Physical activity
• Physical inactivity	• Avoidance of alcohol/tobacco use
• Menopausal hormone therapy	• Avoidance of exogenous use of estrogens and progestins
• Alcohol intake.	• Reducing exposure to ionizing radiation
• Lack of breastfeeding	• Pregnancy and breastfeeding
• Unhealthy diet	• Chemoprevention in high risk individuals
• Nulliparity	• Prophylactic mastectomy, and/ or oophorectomy in selected high-risk groups
• Use of hormonal birth control methods	
• Tobacco use	**Secondary Prevention**
Non-Modifiable	• Screening
• Increasing age	• Early diagnosis
• Female gender	• Chemoprevention
• Benign breast disease	**Tertiary Prevention**
• Genetic factor (BRCA 1 or 2)	Use of selective estrogen receptor modulator medications (SERMS) and Aromatase Inhibitors (AIs) as chemoprevention in high risk individuals
• Family history	
• Early menarche/late menopause	
• Increased breast density	
• Previous exposure to chest wall irradiation	

TABLE 2: TABLE OF RISK FACTORS

Although some risk reduction may be achieved by employing modifiable risk factor reduction and prevention strategies, these strategies cannot eliminate most breast cancers and therefore early detection, timely diagnosis and effective treatment of early stage tumours remain the cornerstone of breast cancer control to improve survival rates.

Why Breast Cancer Screening Is Important

Breast cancer screening aims to identify otherwise healthy women who may have as yet undiagnosed or asymptomatic cancer, or who may have risk-modifying or pre-cancerous changes in the breast which would confer an increased risk of breast cancer. Screening aims to enable early diagnosis and prompt treatment and therefore improves prognosis and outcome.

Globally, mammography is the gold standard method for screening for breast cancer since it has been proven effective in reducing mortality from breast cancer in women over the age of forty. However, it is a more complex public health strategy that mandates additional resources, infrastructure and coordination. WHO recommends that screening programs only be undertaken when their effectiveness has been demonstrated, resources are sufficient to cover the target group, facilities exist to confirm diagnoses and ensure treatment, and the prevalence of the disease is high enough to justify screening.

The rate of breast cancer screening in Africa is low at 12.9% in women in the reproductive age group (15-49 years), ranging from about 13.6% in Kenya, 5.2% in Ivory Coast to 23.1% in Namibia. Further, only about 25% of Kenyan women aged 15-49 have performed a self- breast examination (SBE), while 14% have had a clinical breast examination (KDHS, 2014). These rates are likely to be lower in women in rural areas as well as those of low socioeconomic status.

Unless urgent action is taken to improve breast cancer screening and early diagnosis, breast cancer will compound Kenya's disease burden, increase poverty and gender inequalities as well as reverse current global gains against maternal mortality

Breast Cancer Screening in Men

Male breast cancer represents between 0.5 and 1 percent of all breast cancers diagnosed each year in the western world. The incidence is documented to be higher in sub-Saharan countries accounting for about 6% of breast cancers. Male breast cancer has typically been diagnosed at a more advanced stage than female breast cancer, most likely due to a lack of awareness that men can also develop breast cancer.

Currently, screening guidelines globally **do not** recommend breast cancer screening programs for men and there is lack of evidence to support such screening.

Breast Cancer Policy Framework

Global

In response to the rising breast cancer incidence, WHO in collaboration with multi-sectoral stakeholders is establishing a new Global Breast Cancer Initiative to avert an estimated 2.5 million deaths by 2040, anchored on three pillars; health promotion, timely diagnosis and comprehensive treatment, including supportive care.

Health promotion aims at detection of breast cancer at early stages (I & II) through education of the general public and primary health workers on breast cancer signs and symptoms and risk reduction measures. Timely diagnosis means reducing the time between the client's initial encounter with the health system and the confirmation of a breast cancer diagnosis which involves clinical evaluation, imaging and pathology and the initiation of appropriate breast cancer treatment. The Global Breast Cancer Initiative is expected to spur collective global action and provide momentum to halt the rising breast cancer burden.

Kenya

In response to the growing cancer burden including breast cancer, the Kenyan government has made tremendous progress in developing national policies, strategies and legislation for cancer control. The National Cancer Control Strategy 2017-2022 has prioritized specific cancer control interventions including for breast cancer across the care continuum. The National Cancer Screening Guidelines 2018, The National Cancer Specimen Handling Guidelines 2020 and National Cancer Treatment Protocols 2019 are being implemented for cancer screening, diagnosis and treatment activities in the country. This Action Plan aims to operationalize these guidelines for the establishment of comprehensive breast cancer early detection program in Kenya. This program will prioritize early detection, timely diagnosis and treatment of breast cancer using a resource-stratified and implementation approach within the context of a largely screen-naive population.

The National Cancer Screening Guidelines 2018 recommends population-based screening for breast cancer based on a specified risk assessment and stratification. The guideline promotes education of women on breast health and breast self awareness as key aspects in early detection of breast cancer. While it recommends mammography as the screening method of choice among the average population, as it is the only screening modality shown to reduce breast cancer mortality, it also recognizes that clinical breast examination (CBE) can improve diagnosis of early stage cancer through detection of symptomatic cancers at an earlier stage.

A summary of the guideline recommendations including the age to start screening as well as frequency is captured below:

Age Group	Recommendation	Interval
25 - 34 years	CBE every 3 years *Mammogram is not recommendeed*	1 to 3 years
35 - 39 years	CBE and Ultrasound **OR** mammography*	1 to 3 years
40 - 55 years	CBE + mammography	Annual
56 - 74 years	CBE + mammography	Every 2 years
75 years and older	Consider individual health factors and woman's preference to continue screening	Discuss with patient

TABLE 3: SUMMARY OF KENYA NATIONAL SCREENING GUIDELINES RECOMMENDATIONS

Notes:

** The balance of benefits and risks is not great enough to recommend routine screening. Clinical judgment may be used to adjust the frequency of screening considering individual differences. Ultrasound use is operator dependant, and quality control will be key, as this will require a well-coordinated training program, or research trial, where protocols and processes can be standardized.*

Women who have had surgery for breast augmentation, breast reduction or sex-reassignment should follow the same recommendations below for mammographic screening as those in the average risk population. The clinician should clearly state presence of breast implants in the mammography requisition form.

The recommendation that women aged 25-34 years receive clinical breast examination (CBE) every 1-3 years is effective in raising awareness of breast diseases and breast cancer amongst the target population.

The National Cancer Screening Guidelines also outline breast cancer screening activities to be conducted at the various service delivery levels defined in the Kenya Essential Package for Health (KEPH), as follows:

LEVEL	TYPE	CADRE	EXPECTED SERVICES	OUTPUT
1	Community	Community Health care worker	Education on Breast Self Awareness, BSE	Increased early detection rate and referrals for screening
			Mobilization	
2	Dispensary	Nurses	Education on Breast Self Awareness, BSE, CBE	Increased early detection rate and increased referrals for screening
			Mobilization and Referral	
3	Health Centres	Clinical officers	Education on Breast Self Awareness, BSE, Performs CBE, Referral	Increased early detection rate Increased referrals for screening
		Nurses		

4	Sub-county	Nurses	Education on Breast self awareness, BSE, Perform CBE	Increased early detection rate Increased imaging for breast cancer (breast ultrasound) Increased FNA and breast core biopsies
		Clinical officers	BSE, CBE, FNA	
		Medical officers/ Physicians	BSE, CBE, Core Biopsy, Ultrasound	
		General surgeon	BSE, CBE, Ultrasound, Core Biopsy	
		Sonographers/ Radiographers	Ultrasound	
		Radiologist	Ultrasound	
		Pathologist	CBE, FNA, Core Biopsy	
5	County/ Regional	Nurses	Breast awareness, BSE, CBE	Increased early diagnosis rate Increased screening mammograms, ultrasounds Increased breast FNA and biopsies Down-staging of breast cancers at treatment with better outcomes
		Clinical officers	Breast awareness, BSE, CBE, Core Biopsy	
		Medical officers/ Physicians	BSE, CBE, Core Biopsy, Ultrasound	
		General surgeon	BSE/CBE/ Ultrasound/Core Biopsy	
		Radiographers	Mammogram	
		Sonographers	Ultrasound	
		Radiologist	CBE/BSE, Mammography	
		Pathologist	CBE/ Core Biopsy	
		Oncologist	CBE/BSE/ Core Biopsy/ Treatment	
6	National Referral Facilities	Nurses	Breast awareness/CBE/BSE	Increased screening rate Increased early detection rate Increased screening mammograms, breast ultrasounds, breast MRI for eligible women Increased breast FNA and biopsies Down-staging of breast cancers at treatment with better outcomes
		Clinical officers	Mobilization/ Breast awareness/ CBE/BSE	
		Medical officers/ Physicians	BSE/CBE/ Treatment	
		Breast surgeon	BSE/CBE/Core Biopsy/ Surgery	
		Radiographers	Mammogram	
		Sonographer	Ultrasound	
		Radiologist	CBE/BSE, Mammography	
		Pathologist	CBE/Core Biopsy/ Reporting	
		Oncologist	CBE/Treatment, Palliative Care & Survivorship Care	

TABLE 4: BREAST CANCER SCREENING ACTIVITIES AT DIFFERENT LEVELS OF SERVICE DELIVERY

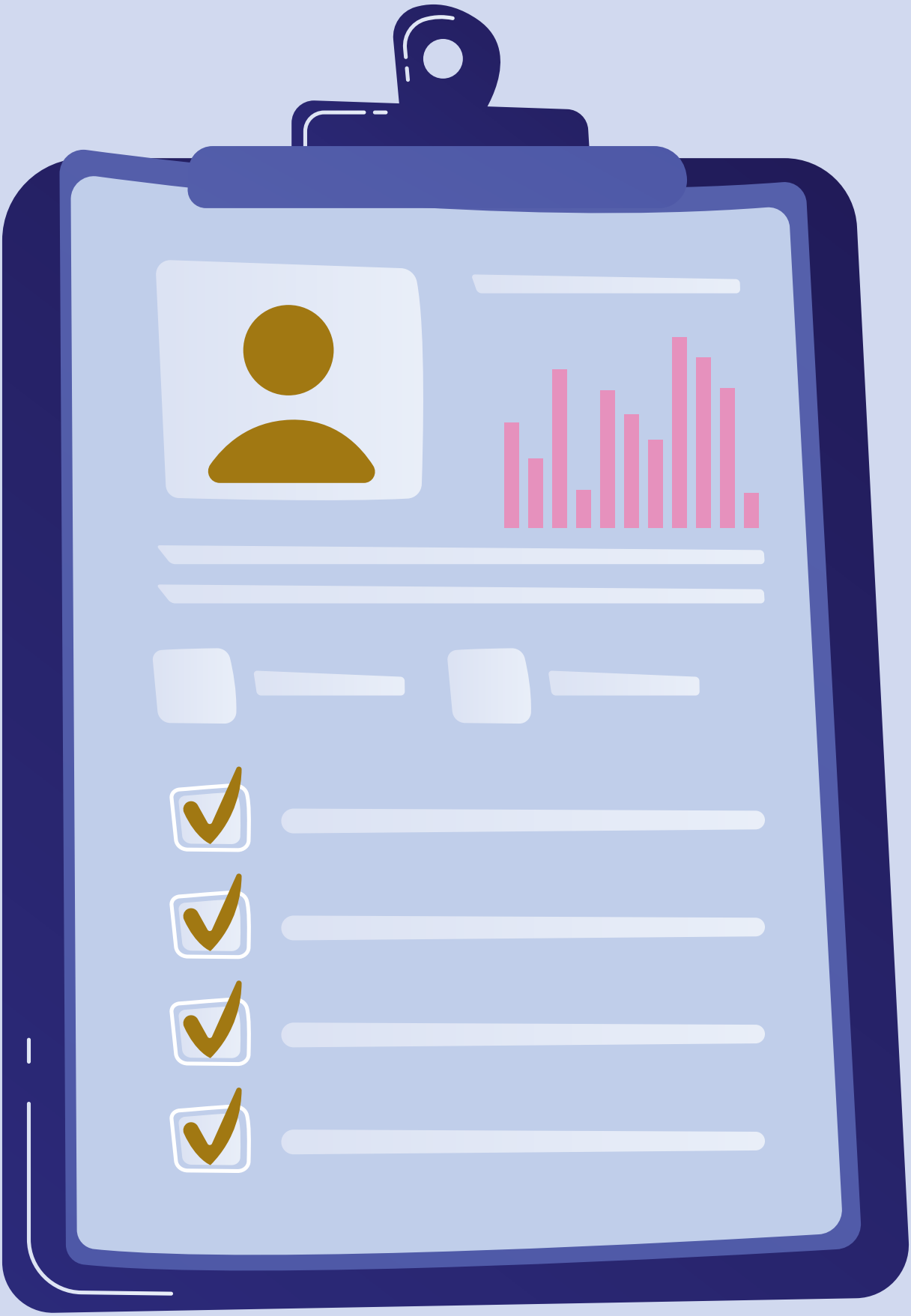
Note: Appropriate and continuous on-the-job training is needed for the respective cadres to carry out the recommended activities as listed in the table

Every facility should be actively involved in early detection of breast cancer to identify clients who may have signs and symptoms consistent with the disease and link them to diagnosis and treatment without delay.

The National Cancer Treatment Protocols 2019 provide guidance on the clinical evaluation (involving comprehensive history-taking and inquiry on risk factors and symptoms, and physical examination) of breast lesions; diagnosis through imaging and pathology; staging and multimodality treatment, palliative and rehabilitative care for breast cancer patients. The protocols recommend that ALL women found to have suspicious breast lesions (symptomatic women) should undergo a **Triple Assessment** as outlined below:

- Clinical examination preferably by an experienced clinician or breast surgeon
- Bilateral breast imaging: a bilateral mammogram (>35 years)/ Ultrasound (<35 years) or an MRI as appropriate
- Histopathology: Core biopsy

In breast cancer diagnosis, timeliness of the service access to avoid excessive delay, availability of diagnostic imaging studies of the breast and axilla, staging studies to detect metastatic disease and tissue sampling methods are important.



CHAPTER TWO

Breast Cancer Screening Situational Analysis

Current Capacity for Breast Cancer Screening

The Government of Kenya, through the Managed Equipment Service (MES) project has introduced digital mammography machines in the country distributed across the county referral hospitals in all the 47 counties. This was a major upgrade from the previous total of 11 analog mammogram machines in Kenyan government hospitals. According to an Impact Assessment conducted by the MOH and GEHC in Kenyan Counties in 2018, the decentralization of mammography increased geographical access to the services. However, the utilization of these machines for screening mammography remains low. Though relatively fast and accurate, mammography is highly technological and requires highly-trained personnel and elaborate accessories. During the Breast Cancer Screening Pilot, reasons for low utilization was attributed to a number of barriers including: insufficient regularly trained specialists (radiographers & radiologists) to offer the services at public health facilities, lack of awareness among the population about the availability of mammography services, and cost of the services limiting access for clients.

Despite the widespread availability of the mammography infrastructure, there is currently no organized breast cancer screening program in the country. Breast cancer screening is largely opportunistic and information management, resources for diagnostic imaging and tissue sampling, and quality assurance systems are lacking necessitating the conduct of a pilot to guide an appropriate scale up strategy that is applicable in the Kenyan context.

Breast Cancer Screening Pilot in Kenya 2019

Background & Methodology

The Ministry of Health through the National Cancer Control Program (NCCP) undertook a Breast Health Awareness Campaign (BHAC) Pilot project in Nyeri County between October to November 2019, whose findings were intended to inform the scale-up of breast cancer screening in Kenya. The campaign strategy involved information dissemination to the targeted women through Community Health Volunteers (CHVs), radio advertisements, social media platforms (WhatsApp and Facebook), among others. Women who presented at the Levels 2 and 3 facilities were triaged using the Clinical Breast Examination (CBE) and those eligible for mammography screening and further evaluation were referred to the Nyeri County Referral Hospital (NCRH) where they were taken through a breast health education session before undergoing a Clinical Breast Examination and mammography.

Key findings

The majority (80%) of the clients who attended screening had been reached by the awareness campaigns. While the majority of the respondents (77%) were aware of self-breast examination (SBE), 75% did not practice it regularly. Majority of the respondents (87%) had never previously undertaken a mammogram while over half of the respondents (58%) had previously undertaken a CBE. During the campaign, clients were notified of a waiting period of 1 week to collect their mammogram results; however, 6 months later, 33% of the mammogram reports were yet to be collected. Out of 49 clients who had lesions suspicious for breast cancer, only 22 (45%) had undergone biopsies and were linked to treatment by the end of the campaign. Uptake of mammography dropped sharply when the awareness campaign ended and the Hospital was tasked to continue with follow up and linkages to care.

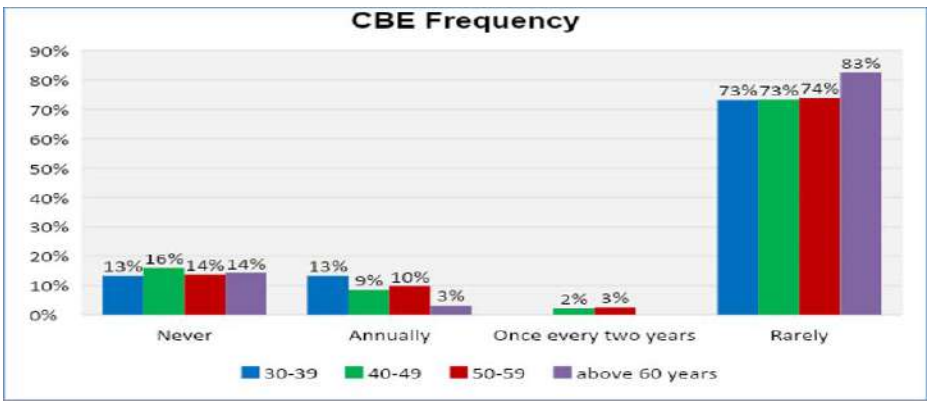


FIGURE 3: FREQUENCY OF PERFORMANCE OF CBE AMONG ELIGIBLE WOMEN, NYERI COUNTY, 2019

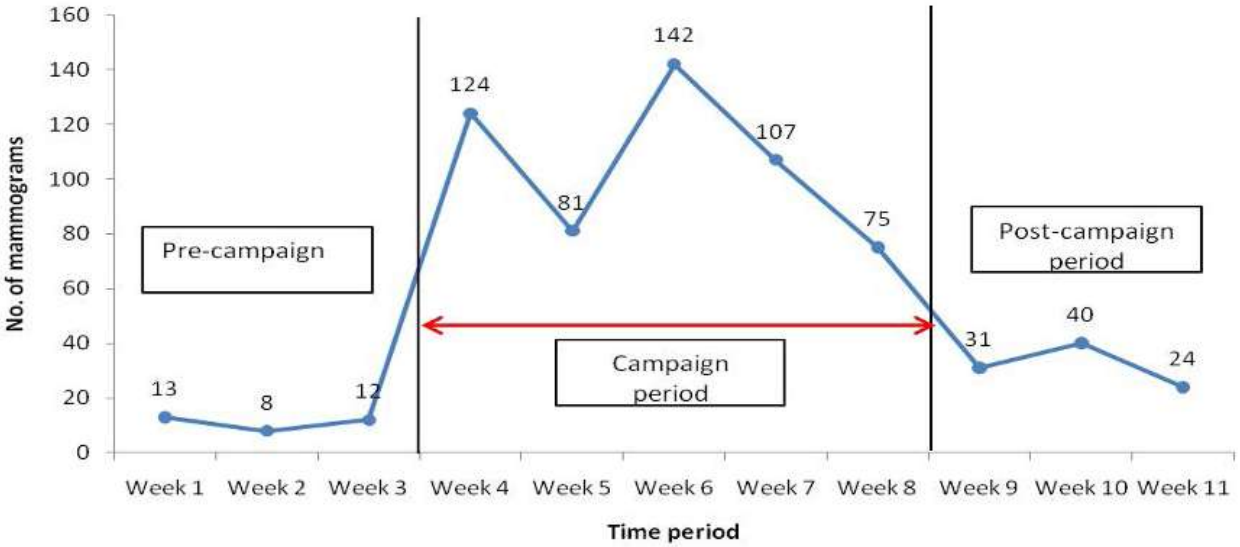


FIGURE 4: MAMMOGRAPHY UTILIZATION DURING THE BREAST CANCER SCREENING PILOT IN KENYA, 2019

Recommendations

The pilot provided important insights for the establishment of a breast cancer screening and early diagnosis program, both on the demand side (awareness and uptake of services) as well as the supply side (health system). For awareness, it is important to consider tailoring information, education and communication materials (IEC) to have the highest impact on recall, which includes the using locally-relevant images, simple language, as well as greater involvement of the target audience in the design process. Use of community strategy is very effective in information dissemination and behavior change. Sustained demand generation mechanisms need to be developed for long-term campaign benefits. Community strategy is a good example of this as it is a sustainable and cost-effective awareness creation and invitation approach to a breast cancer screening program.

On the supply side requirements, the health facility preparedness needs to be adequately addressed. Capacity and availability of health workers to provide breast health education, examine and refer clients is a crucial component. The approach to screening needs to be customized to the available resources and capacity of facilities, for example, depending on the level of care, with primary care facilities focusing on health promotion, early diagnosis of breast cancer through simple methods such as clinical breast examination and prompt referral to higher levels of care where ultrasound and mammography machines are available. It is also necessary to support the higher-level facilities in terms of provision of adequate trained staffing needs and availing the necessary consumables in order to provide optimal screening services. Linkage to treatment for screen-positive cases needs to be well planned and executed sustainably.

Depending on the existing health facility infrastructure, there may be need to establish standalone facilities to enable rapid breast cancer diagnosis and further management including triaging for timely surgical intervention to avoid unnecessary delays.


Consultation Room
ROOM 12 B
FIGHT
BREAST
CANCER
GET
SCREENED
TODAY

CHAPTER THREE

The Breast Cancer Screening And Early Diagnosis Action Plan

Rationale and Approach

In many developed countries, the mortality of breast cancer declined by between 13-36% between 1990 and 2010, a period in which incidence remained relatively stable. This decline in mortality was attributed to two major factors: early detection through mammography and advances in adjuvant treatment. In many low-resource settings, the use of inexpensive early diagnosis approaches such as Clinical Breast Examination (CBE) has been proven to be of benefit. Majority of cancers are diagnosed at advanced stages and the Kenyan population being largely screen-naïve, an effective phased strategy would involve CBE for detection of early-stage tumors to allow for triage and linkage to diagnostic mammography and further management. This enables identification, prioritization and linkage to care of clients with early breast cancer while avoiding overstretching the already strained health system. This was a key learning point from the Breast Health Awareness Campaign pilot. Ultimately, the result will be increased utilization of mammography for triple assessment of suspicious breast cancer lesions for diagnosis and over time as more and more breast cancer cases get the care they need, it is anticipated that screening service delivery, screening mammography rates and general equipment utilization will eventually improve.

Community Health Volunteers are instrumental in the community health strategy and can help to ensure women receive timely and adherent breast cancer care. The CHVs can communicate to community residents and engage them in breast cancer prevention, screening and treatment services and link them to the health facilities for the needed appropriate diagnosis and referral. The breast cancer screening program will be integrated and leveraged within the Universal Health Coverage (UHC) which is being actualized through primary health care in Kenya. Integrated service delivery holds promise for increased coverage in screening services. This action plan therefore supports the integration of breast cancer screening in various programs and service delivery points such as Cervical Cancer Screening, Family Planning Clinics, Maternal and Child Health Clinics, Comprehensive Care Clinics which is feasible and can result in fewer missed opportunities for cancer screening.

Role of CBE in Breast Cancer Screening: Evidence Synthesis and Summary

While mammography is the gold-standard method for breast cancer screening, many studies in various settings have shown that CBE has some benefit in breast cancer early detection. The table below summarizes the evidence available on CBE:

I: Randomized trials on Clinical breast examination (CBE) for early diagnosis		
Article title and type	**Conclusion**	**Reference**
Effect of screening by clinical breast examination on breast cancer incidence and mortality after 20 years: prospective, cluster randomised controlled trial in Mumbai	Clinical breast examination conducted every two years by primary health workers significantly down staged breast cancer at diagnosis and led to a non-significant 15% reduction in breast cancer mortality overall (but a significant reduction of nearly 30% in mortality in women aged ≥50). No significant reduction in mortality was seen in women younger than 50 years. Clinical breast examination should be considered for breast cancer screening in low- and middle-income countries.	Mittra I, Mishra G A, Dikshit R P, Gupta S, Kulkarni V Y, Shaikh H K A et al. Effect of screening by clinical breast examination on breast cancer incidence and mortality after 20 years: prospective, cluster randomised controlled trial in Mumbai BMJ 2021; 372: n256 doi: 10.1136/bmj.n256cluster randomised controlled trial in Mumbai
Canadian National Breast Screening Study-2: 13-Year Results of a Randomized Trial in Women Aged 50–59 Years	In women aged 50-59 years, the addition of annual mammography screening to physical examination has no impact on breast cancer mortality.	Miller AB, To T, Baines CJ, Wall C. Canadian National Breast Screening Study-2: 13-year results of a randomized trial in women aged 50-59 years. J Natl Cancer Inst. 2000 Sep 20;92(18):1490-9. doi: 10.1093/jnci/92.18.1490. PMID: 10995804.

II: Role of CBE in early diagnosis in LMICs		
Article title and type	**Conclusion**	**Reference**
Breast cancer early detection methods for low- and middle-income countries, a review of the evidence	Clinical down staging programs through CBE are an appealing alternative when resources are scarce, and should be considered as the first option in regions where the majority of tumors diagnosed are at late stages. In low resources settings CBE could achieve almost the same mortality reduction as mammography screening, but at a much lower cost.	Corbex M, Burton R, Sancho-Garnier H. Breast cancer early detection methods for low- and middle-income countries, a review of the evidence. Breast. 2012 Aug;21(4):428-34. doi: 10.1016/j.breast.2012.01.002. Epub 2012 Jan 30. PMID: 22289154.
Effectiveness of clinical breast examination as a 'stand-alone' screening modality: an overview of systematic reviews	Indirect evidence suggests that a well-performed CBE may bring about the same effect as mammography regarding mortality despite its apparently lower sensitivity. With respect to the intermediate outcome of down staging, CBE contributes between 17 and 47% of the shift from advanced to early-stage cancer. The results are promising and of interest for LMICs where a national screening programme based on mammography is not a realistic option.	Ngan, T.T., Nguyen, N.T.Q., Van Minh, H. et al. Effectiveness of clinical breast examination as a 'stand-alone' screening modality: an overview of systematic reviews. BMC Cancer 20, 1070 (2020). https://doi.org/10.1186/s12885-020-07521-w
Performance and Reporting of Clinical Breast Examination: A Review of the Literature	CBE identifies some breast cancers not detected on mammography. CBE also could provide an opportunity to identify palpable masses in women who either had no access to mammography, or who were averse to having mammograms.	McDonald, S., Saslow, D. and Alciati, M.H. (2004), Performance and Reporting of Clinical Breast Examination: A Review of the Literature. CA: A Cancer Journal for Clinicians, 54: 345-361. https://doi.org/10.3322/canjclin.54.6.345
IARC handbook on breast cancer screening	CBE for primary breast screening takes on importance in low- and middle-income countries (LMICs) where mammography screening is not feasible and/or affordable. Sensitivity has been estimated at 61-85% and specificity 94.5-96% with appropriate training	International Agency for Research on Cancer. IARC handbooks of cancer prevention. Vol. 15. Breast cancer screening. Lyon, France: IARC Press, 2015.
Breast Cancer Screening in Low- and Middle-Income Countries: A Perspective From Malawi	The relative advantages of CBE over mammography in an LMIC setting include • Lower cost • Lower technical requirements • Wider implementability • More easily packaged with other health services	Gutnik LA, Matanje-Mwagomba B, Msosa V, Mzumara S, Khondowe B, Moses A, Kohler RE, Carey LA, Lee CN, Gopal S. Breast Cancer Screening in Low- and Middle-Income Countries: A Perspective from Malawi. J Glob Oncol. 2015 Dec 23;2(1):4-8. doi: 10.1200/JGO.2015.000430. PMID: 28717676; PMCID: PMC5497737.
Breast Cancer Screening Program in Morocco: Status of implementation, organization and performance	Clinical breast examination is a promising approach provided effective diagnosis, timely treatment, and adequate resources.	Basu P, Selmouni F, Belakhel L, Sauvaget C, Abousselham L, Lucas E, Muwonge R, Sankaranarayanan R, Khazraji YC. Breast Cancer Screening Program in Morocco: Status of implementation, organization and performance. Int J Cancer. 2018 Dec 15;143(12):3273-3280. doi: 10.1002/ijc.31749. Epub 2018 Sep 26. PMID: 30006933; PMCID: PMC6637920.
Cost-Effectiveness of Clinical Breast Assessment-Based Screening in Rural Egypt	Clinical breast assessment-based screening is feasible. Its implementation can increase awareness about breast cancer, especially in the younger age group. It also can positively affect the clinical pathway for women in developing countries with limited resources who frequently present with advanced disease.	Denewer A, Hussein O, Farouk O, Elnahas W, Khater A, El-Saed A. Cost-effectiveness of clinical breast assessment-based screening in rural Egypt. World J Surg. 2010 Sep;34(9):2204-10. doi: 10.1007/s00268-010-0620-3. PMID: 20533039.

Limited effectiveness of screening mammography in addition to clinical breast examination by trained nurse midwives in rural Jakarta, Indonesia	In an unscreened population in LMICs, CBE is nearly as effective as mammography in detecting prevalent breast cancers.	Kardinah D, Anderson BO, Duggan C, Ali IA, Thomas DB. Short report: Limited effectiveness of screening mammography in addition to clinical breast examination by trained nurse midwives in rural Jakarta, Indonesia. Int J Cancer. 2014 Mar 1;134(5):1250-5. doi: 10.1002/ijc.28442. Epub 2013 Sep 16. PMID: 24037942.

TABLE 5: CLINICAL BREAST EXAMINATION EVIDENCE SYNTHESIS AND SUMMARY

Conclusion

This action plan, in line with the national screening guidelines, therefore recommends a phased approach for implementation of appropriate early detection strategies as per different levels of care if with ongoing monitoring to assess the impact so that next steps in each critical phase in breast cancer diagnosis and treatment can be recognised and reprioritised. This can increase overall uptake of breast cancer screening and early diagnosis services in Kenya. At all levels from the community, health promotion through effective communication on breast health awareness and education on Self-Breast Examination (SBE) for all women of reproductive age will be fundamental. At primary health care facilities, patient education and awareness on breast self examinations and clinical breast examinations should be encouraged and deployed with appropriate referrals. Upon referral to a secondary facility level, Clinical Breast Examination should be performed by an experienced clinician and those with abnormal findings (symptomatic women) should be referred for imaging (either breast ultrasound if <35 yrs or mammogram if >35 yrs) and fine needle aspirate or core biopsy in addition to Clinical Breast Examination preferably in a rapid breast diagnostic clinic where turnaround time for the results are shortened. It is recommended that breast cancer clients requiring surgical interventions are triaged appropriately and prioritised for timely surgical management to avoid unnecessary delays that contribute to poor outcomes. At tertiary level facilities, in addition to all the above services, appropriate breast cancer treatment, palliative and rehabilitative services should be provided.

1. Breast Cancer Screening and Early Detection Algorithm

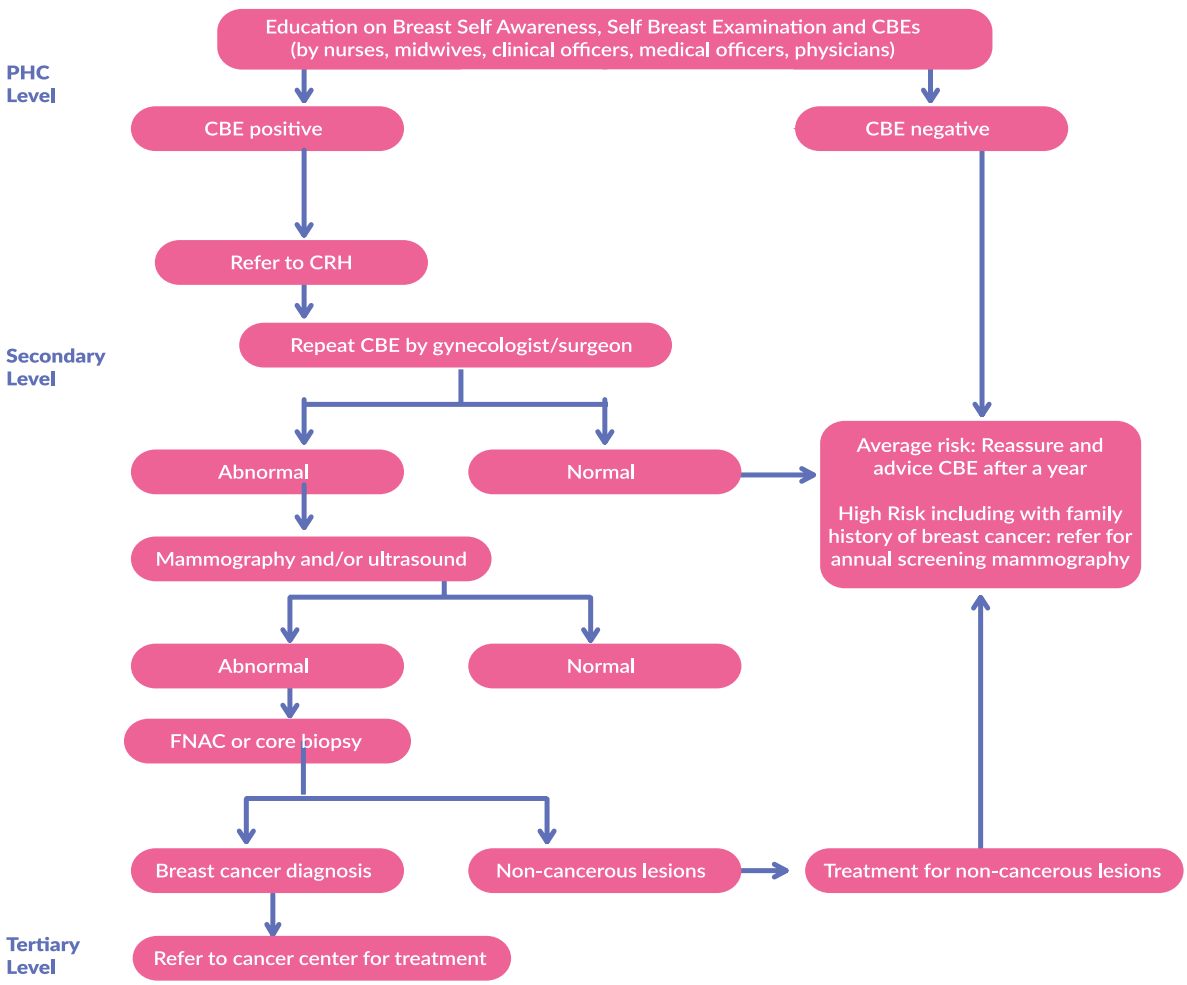


FIGURE 5: BREAST CANCER SCREENING AND EARLY DIAGNOSIS ALGORITHM BY LEVEL OF CARE

2. Algorithm for Breast Lump Diagnostic Work-up

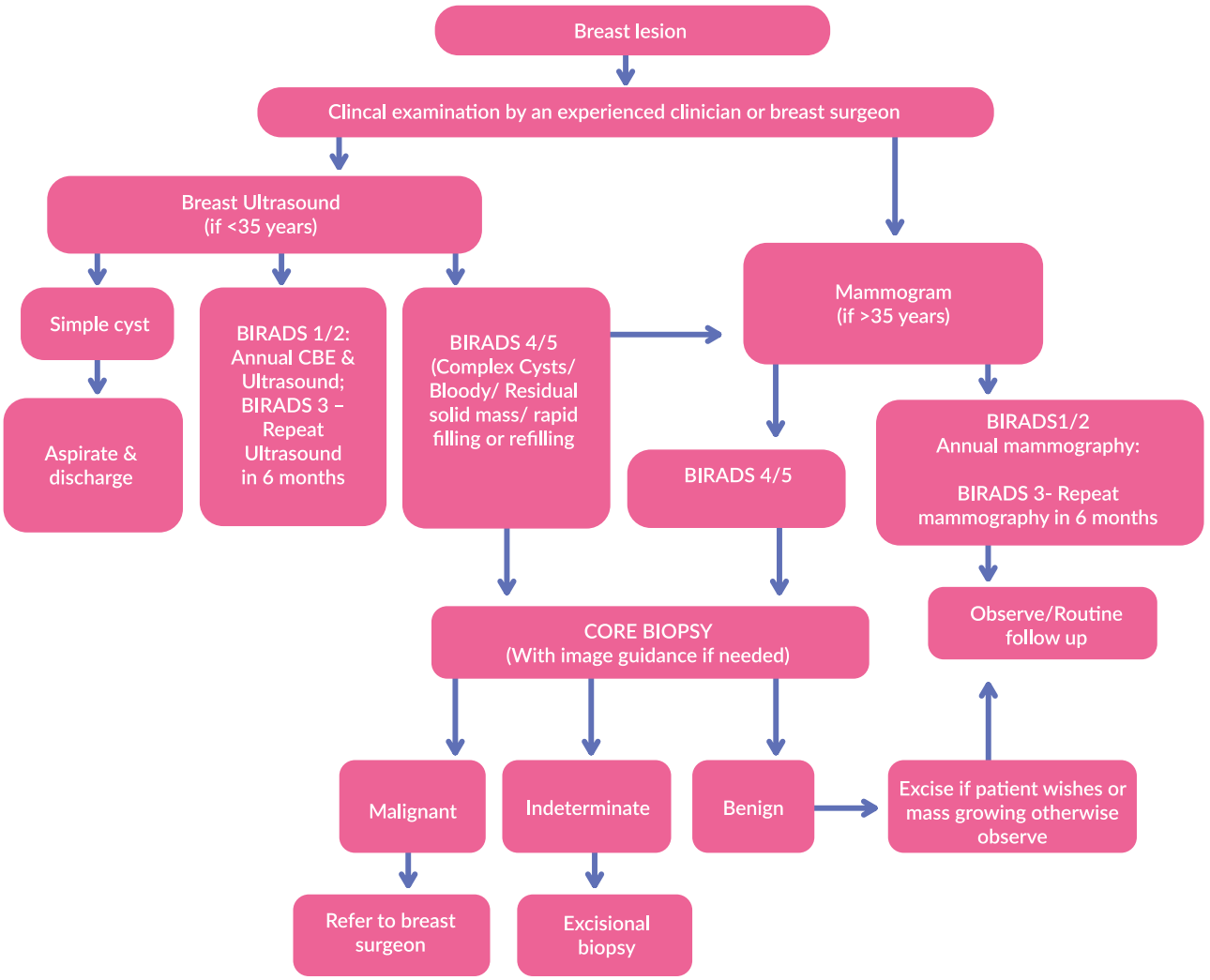


FIGURE 6: ALGORITHM FOR BREAST LUMP DIAGNOSTIC WORK-UP

Notes:

- *It is recommended that breast ultrasound should be done by an experienced trained sonographer or by a radiologist and reporting for ultrasound and mammogram be done using the BIRADS classification. Telereporting should be considered where possible.*
- *Core biopsy is mandatory before treatment, which is usually guided by molecular subtypes and staging, through a multi-disciplinary approach.*
- *All biopsies should be reviewed by a multidisciplinary team, together with imaging and clinical findings in order to pick out discordant results.*
- *Excisional biopsy is only recommended if the results of image- guided core biopsy are still indeterminate.*
- *Health facilities should facilitate triage and prioritise breast cancer patients for timely surgical management to improve clinical outcomes.*

3. Algorithm for Breast Axillary Node Management

The National Cancer Treatment Protocols, 2019 provide an Algorithm to guide Axillary Staging as shown below:

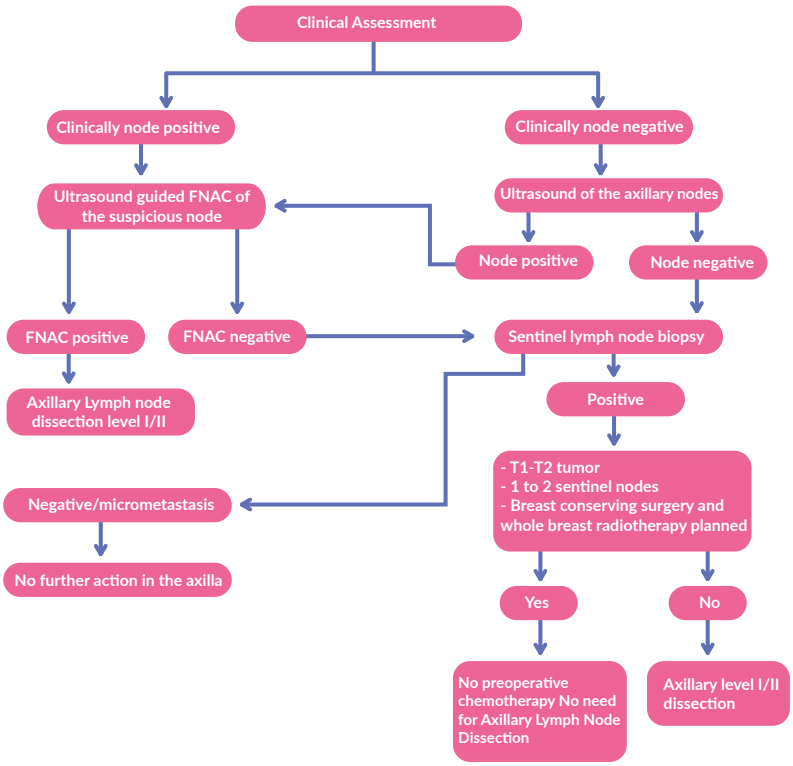


FIGURE 7: ALGORITHM FOR BREAST AXILLARY NODE MANAGEMENT

4. The Universal Breast Cancer Patient Pathway

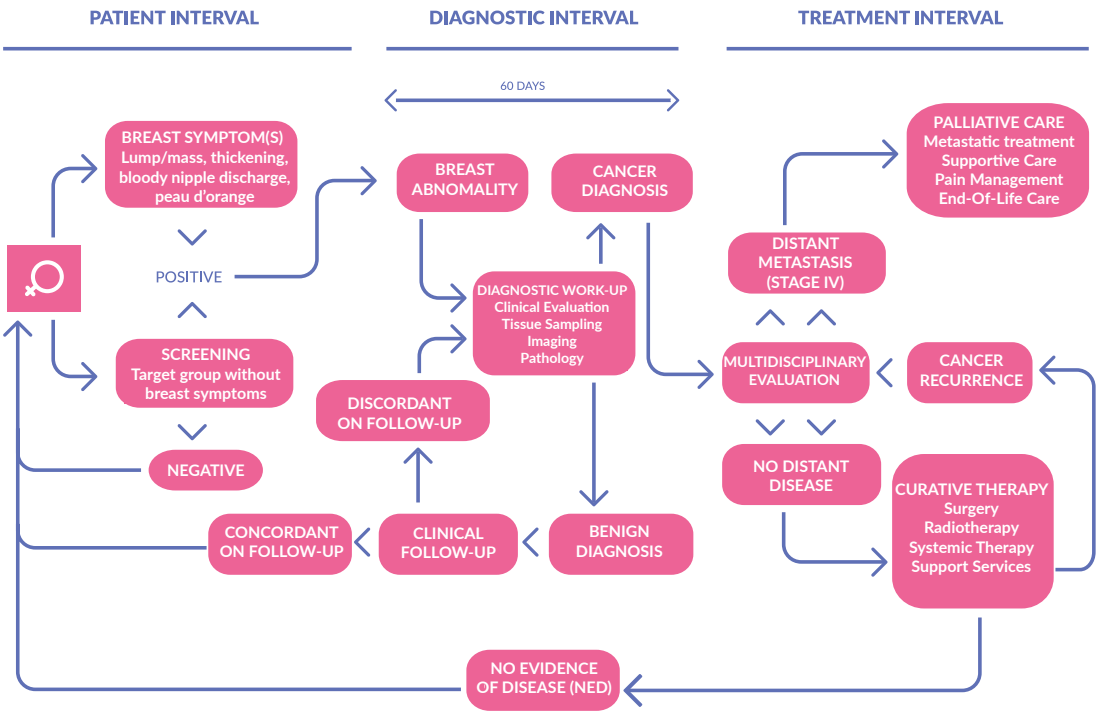


FIGURE 8: THE UNIVERSAL BREAST CANCER PATIENT PATHWAY

(Source: The Breast Health Global Initiative: A guide for developing resource appropriate breast cancer management guidelines)

Broad Objective of The Action Plan

The purpose of this Action Plan is to provide guidance for the implementation of a resource-appropriate country-specific breast cancer early diagnosis program in Kenya. The goal is to ensure that all women with breast cancer are diagnosed in early stages of the disease and appropriately linked for timely further management.

Specific Objectives

1. To increase Clinical Breast Examination and mammography screening coverage for the eligible population to at least 30% by 2025.

2. To improve the availability and utilisation of breast cancer screening, diagnostic, management and associated supportive services.

3. To ensure at least 90% of symptomatic women are linked to further evaluation and management within 60 days of their first encounter with a healthcare worker.

4. To improve health workforce availability and capacity to provide appropriate breast cancer services across the continuum of care as per level of care

Key Result Areas

Five thematic areas have been identified as listed below with the activities to be undertaken to achieve the objectives above:

1. *Governance & Policy to create an enabling environment for breast cancer screening*
2. *Demand Creation and Community Education & Engagement*
3. *Training and Professional Development*
4. *Service Delivery (Screening, diagnostics, patient navigation and referral)*
5. *Monitoring & Evaluation Framework & Research*

1. Governance & Policy

a) Establish national and county-level breast cancer early detection governance structures
b) Identify and sensitize key stakeholders for engagement
c) Establish a quality assurance and improvement process within an active screening program to monitor key performance indicators.
d) Mobilize resources to support breast cancer screening and early detection programs
e) Promote adherence to national clinical guidelines for breast cancer screening, early diagnosis and management.

2. Awareness, Demand Creation and Community Education & Engagement

a) Development, printing and distribution of education and communication materials to health facilities and communities
b) Engage Community Health Volunteers to provide information on breast health and breast cancer awareness through dialogue sessions and other fora
c) Engage & equip key influencer groups such as cancer survivors, religious, administrative, community leaders, celebrities, the media/TV personalities and opinion leaders with advocacy skills for breast cancer awareness
d) Conduct breast cancer screening mobile clinic outreaches in targeted settings

e) Create community to facility linkages for breast cancer further assessment and appropriate referral.
f) Sustained Breast Cancer Awareness campaigns on mainstream, social media and other channels.
g) Institute breast cancer work place programs that encourage early detection of breast cancer.

3. Training and professional development of health workforce

a) Appropriate training of CHVs, CHEWs and Health Promotion Officers on promoting education of early breast cancer signs and symptoms and risk factors and creating accurate breast cancer awareness.
b) Appropriate training of relevant health workers across all levels of care on promoting breast health awareness, self-breast examination, conducting Clinical Breast Examination, diagnosis, appropriate management and referral
c) Appropriate training of imaging personnel on breast imaging techniques including image-guided biopsies.
d) Appropriate training of laboratory personnel on handling, processing and interpretation of pathology specimens.
e) Training of health records and information officers and other healthcare workers on breast cancer screening data management.
f) Integration of breast cancer content into Undergraduate and Post Graduate Health Training programs.

4. Service Delivery (Screening, diagnostics, patient navigation and referral)

a) Set up Breast Cancer Centers of Excellence (COEs) at three (3) National referral Hospitals.
b) Establish rapid diagnostic units for prompt diagnosis of breast abnormalities in county referral hospitals with provision of histopathology services.
c) Establish and strengthen hormonal testing (immunohistochemistry for ER/PR/HER2) for breast cancer at the National Cancer Reference Laboratory, National Referral Hospitals and select high volume county referral facilities with regional cancer treatment facilities.
d) Activate breast cancer screening mammography services in all the 47 county referral facilities.
e) Establish linkages and referral structures (including psychosocial support) for patients and specimens.
f) Avail commodities for provision of comprehensive breast cancer services as per level of care
g) Develop public private partnerships to provide screening and early diagnostic services.
h) Integrate breast cancer screening services to other screening services, including but not limited to maternal and child health, postnatal, HIV and NCDs management.

5. Monitoring & Evaluation and Research

a) Develop a clear Monitoring and Evaluation framework for the breast cancer screening program in Kenya, including awareness, with indicators and suggested data sources.
b) Conduct a baseline, midterm and end term assessment of breast cancer screening program
c) Strengthen and improve data systems to enable computation and tracking of selected breast cancer screening diagnosis, treatment and follow-up indicators.
d) Enhance timely monthly reporting of breast cancer indicators and advocate for the utilization of this information by all stakeholders, including counties.
e) Identify research priority areas and conduct research to guide breast cancer care across the entire continuum.

Summary of Key Inputs, Interventions, Outcomes & Impact

FIGURE 9: SUMMARY OF KEY INPUTS, INTERVENTIONS, OUTCOMES & IMPACT

Adapted from National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Logic Model Framework, available at www.NBCCEDP.org

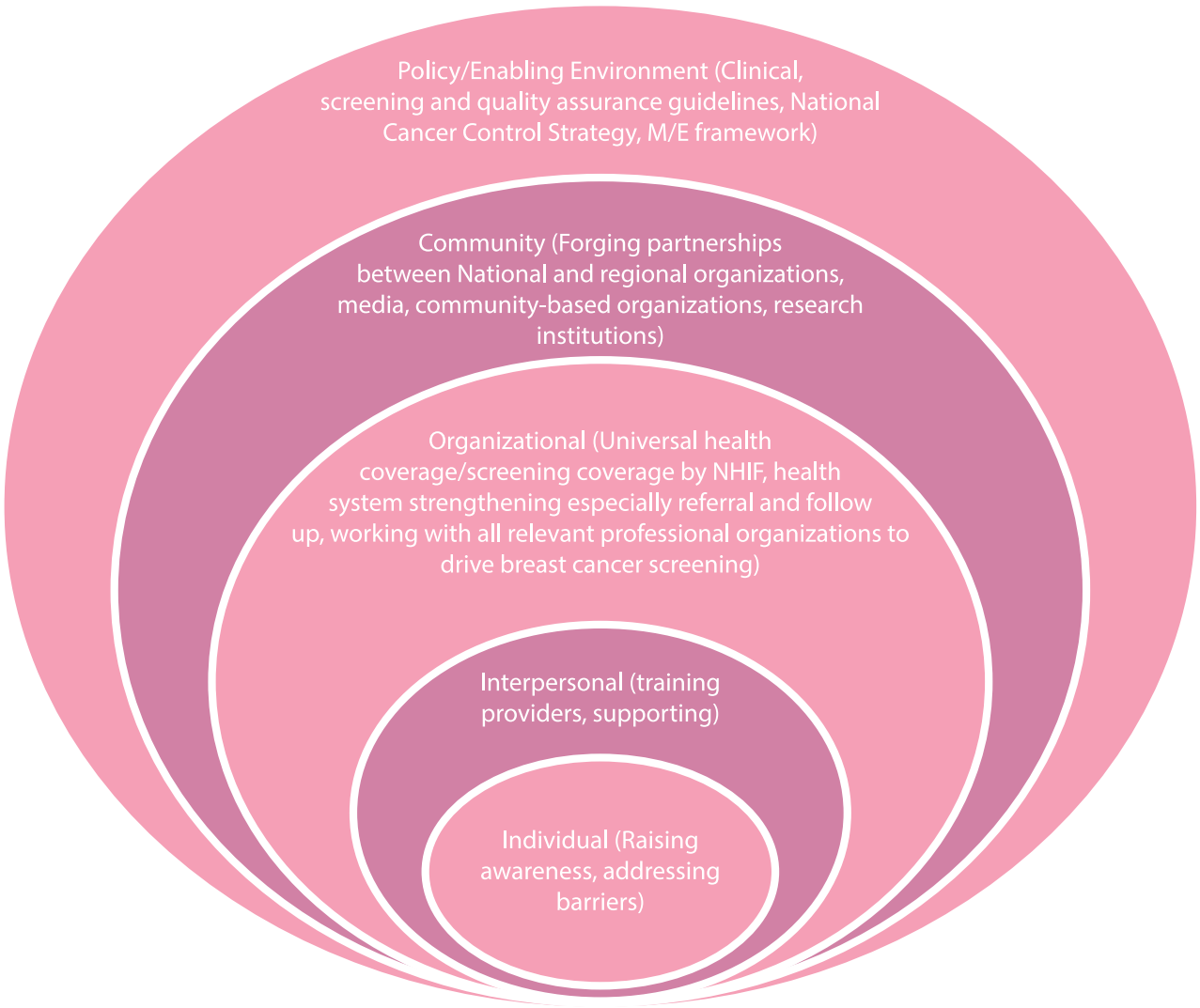


FIGURE 10: SOCIAL-ECOLOGICAL MODEL, ADAPTED FOR BREAST CANCER SCREENING PROGRAMME IN KENYA


CASUALTY DEPT
I.C.U
A.E RECEPTION
LABORATORY
CHEMIST
RECEPTION
Rapid Diagnostic
Breast Clinic

CHAPTER FOUR

Strategic Actions In Establishing Breast Cancer Screening and Implementation Framework

Establishing a Breast Cancer Screening and Early Diagnosis Service

A. Essential Supply Needs for Breast Cancer Screening & Early Diagnosis Service Provision

Clinical Breast Exam

1. Screens for privacy
2. Water & soap for handwashing/ sanitizer
3. Clean gloves
4. Examining table and bed-spread (consider disposable sheet cover roll)
5. Adequate Lighting
6. Job aids
7. Stationery

Mammography

1. Fixed or mobile Digital Mammography unit
2. Appropriate room with radiation protection measures (Consider Mostaloy for radiation protection)
3. Patient privacy: secure exam room, gowns, private dressing room and closet
4. Reading room: Dedicated areas to interpret mammograms
5. Electric supply (with back-up system)
6. Appropriate waste disposal and ablution
7. Disinfection/infection prevention and control: handwashing, cleaning of the unit, sanitizers
8. Proper storage and preservation of images or films (consider storing images on CDs, cloud storage or PACS)
9. Digital scanners for telereporting
10. Compression devices for additional projections, e.g., cone compression (compatible with the collimators)

Other Breast Cancer Devices and Accessories

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Stereotactic-guided core needle biopsy of primary tumor or metastatic lesions	Medical equipment	Mammographic stereotactic biopsy system (cone compression devices could be used with normal mammographic system) Optional: vacuum-assisted biopsy device and driver	
	Single use devices/ disposables/medical supplies		Biopsy needle

			Wire localization needle (e.g. Kopan's Needle 21G, 20G)
			Fiducial markers/soft tissue markers
Ultrasound guided biopsy of regional lymph and sentinel nodes	Medical equipment	Biopsy gun	Biopsy needle (semi and automatic devices)
		Ultrasound probe or transducer/ Linear array, high-frequency transducers, small-footprint, large-bandwidth transducers with central frequency above 10 MHz are ideal	Ultrasound probe cover
	Single use devices/ disposables/medical supplies		Sterile ultrasound coupling gel
Core needle biopsy	Medical equipment	Biopsy Gun	Biopsy needle
	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Skin-cleaning wipe
			Skin-cover adhesive strip
	Solutions and reagents		Formalin 10%, or tissue fxation reagents
			Alcohol or iodine preparation cleansing agent
	Other		Label or pen for labelling sample
			Ruler
Fine needle aspiration (FNA)	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Syringes for the biopsy and holder (optional)

TABLE 5: OTHER BREAST CANCER DEVICES AND ACCESSORIES (World Health Organisation, 2017)

B. Essential Human Resource Needs for Breast Cancer Screening

The Mammography Workforce

Essential staff required to offer quality mammography services include:

i. **Radiologist/ Interpreting Physician** – a medical doctor with post-graduate training in radiology (general radiologist) and where possible, specializing in breast imaging. They have the overall responsibility for the clinical aspects of the mammography services offered and interprets mammograms. Continuous experience and CME hours in mammography. Must interpret a minimum of 960 mammograms every 24 months. Each center must also have one audit interpreting physician to review and analyze the medical outcomes audit data.

ii. **Radiologic technologist:** Performs mammographic examinations and prepares films or digitized images for interpretation. Must be trained and licensed to perform general radiographic procedures.

iii. **Medical physicist:** Responsible for surveying the mammography equipment and overseeing equipment related quality assurance practices of the facility. They may not necessarily be based at each mammography facility, but can support several mammography facilities.

iv. **Radiation protection officer** - responsible mainly for ensuring that the health workers and the public are protected from the harmful effects of radiation. In big facilities, the radiation protection officer is normally employed on a full-time basis, while in small facilities, their role is often played by the radiologist or by the medical physicist.

v. **Support staff** including Clerical staff, data officers and receptionists – they handle patient registration, booking appointments and communication.

C. Rapid Diagnostic Breast Clinic for Symptomatic Women

Patients presenting with symptoms such as nipple discharge and lumps will need to be seen in a one stop rapid diagnostic clinic that provides Triple Assessment services. This is a dedicated specialist breast clinic at level 5 and above that aims to diagnose benign and malignant conditions during the same visit. It requires workforce expertise and infrastructure that enables same day imaging and biopsy when necessary (see diagnostic algorithm above).

Essential staff required to run this breast cancer clinic will include:

- Breast surgeon
- Administrative/Support staff including clerical staff, data officers/receptionist
- Nursing personnel
- Breast clinician (Medical/Clinical officer trained in breast cancer screening & early diagnosis)
- Radiologist with interest in breast imaging
- Radiographer to perform the imaging procedures
- Clinical Pathologist
- Cytologist/Histotechnicians
- Oncologist

Procedure	Medical devices category	Capital equipment	Accessories/hardware/software/ consumables/single use devices
Excisional biopsy	Instruments	Excisional breast biopsy set	
Breast-conservation surgery-lumpectomy/ partial resection	Instruments	Mastectomy set	
	Single use devices/ disposables/medical supplies		Surgical clip
Core needle biopsy	Medical equipment	Biopsy Gun	Biopsy needle
	Single use devices/ disposables/medical supplies		Specimen container
			Needles and syringes for local anaesthetic
			Skin-cleaning wipe
			Skin-cover adhesive strip
	Solutions and reagents		Formalin 10%, or tissue fxation reagents
			Alcohol or iodine preparation cleansing agent
	Other		Label or pen for labelling sample
			Ruler
Procedure	**Medical devices category**	**Capital equipment (for specialized hospitals)**	**Accessories/hardware/software/ consumables/single use devices**
Modifed radical mastectomy (includes nodes)/Total mastectomy	Instruments	Mastectomy set	
	Single use devices/ disposables/medical supplies		Closed-wound drainage reservoir system with closed wound drain connector

TABLE 6: MEDICAL DEVICES FOR BREAST CANCER SURGERY (World Health Organisation, 2017)

Implementation Matrix

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
I. GOVERNANCE AND POLICY								
Integrate Breast Cancer Prevention, Screening & Early Diagnosis agenda in the national & county-level committees with representation of relevant stakeholders and experts	Sensitization meeting for selected CHMT members and other stakeholders	Number of sensitization meetings held	MOH, County Health Management Teams, Partners	X	X			
	Establish county level breast cancer committees	Number of county breast cancer committees established	Counties, National Breast Cancer TWG		X	X	X	X
	Hold quarterly Breast Cancer TWG committee meetings at national and county level	Minutes of quarterly meetings; Implementation of action items	Breast cancer TWGs, Counties		X	X	X	X
	Provide technical support on creation & maintenance of county-level committees: membership, TORs & work plans	Technical support provided	Breast Cancer TWG, Counties		X	X	X	X
Identify and sensitize key stakeholders for engagement	Conduct national stakeholder mapping exercise	Stakeholder database developed	Breast Cancer TWG, Counties, Partners		X			
	Hold annual stakeholder engagement forums/progress review meetings	Annual progress reports			X	X	X	X
Establish a Quality Assurance and improvement processes	Develop relevant audit and data tools; Conduct annual breast cancer screening and quality of care audits	Annual quality audit reports; Annual publication of the breast screening program	Breast Cancer TWG, NCCP, NORL, KACP, KESHO, Counties		X	X	X	X
	Disseminate and implement National Cancer Specimen Handling Guidelines	Number of dissemination meetings/ counties reached;		X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
	Technical support for counties on pathology QA improvement: County QA team formation, QI processes, and training	Technical support provided	Breast Cancer TWG, NCCP, NORL, KACP, KESHO, Counties	X	X	X	X	X
	Lobby regulators for inclusion of Clinical Breast Exam as a key competency requirement for Primary Health Care clinicians	CBE included as a key competency	Breast Cancer TWG, MOH-NCCP, PHC division, MOE	X	X			
	Develop and launch Breast Imaging QA Guidelines	Imaging QA guidelines developed	NCCP-Pillar 2 TWG, MOH Department of Quality and Standards, Specialised Services, KAR, Kenya Nuclear Regulatory Authority		X	X		

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Mobilize resources to support breast cancer screening and early detection programs	Identify essential inputs to support a breast cancer screening program	Key inputs identified and included in essential lists of health products and technologies	MOH, NCI-K, NCCP, NHIF, Counties, KEMSA, Treasury	X				
	Include breast cancer screening and early detection activities in National and County Annual Work Plans and County Integrated Development Plans to ensure funding	Number of County AWPs and CIDPs integrating breast cancer activities. Number of MDAs with breast cancer screening in AWPs		X	X	X	X	X
	Include Breast Cancer Screening, Early diagnosis and further management in UHC Benefit Package at NHIF and other insurance packages to ensure access to care	Breast Cancer comprehensively included in the UHC Benefit Package Number of other insurance packages including Breast Cancer Screening, Diagnosis and Management	MOH-UHC, NCCP, Health Promotion, Family Health, PHC, NHIF	X	X	X	X	X
	Prepare policy briefs on investment case in breast cancer screening and early diagnosis.	Number of policy briefs finalized & presented in high level forums	Breast Cancer TWG, MOH-NCCP	X	X	X		
Promote adherence to national guidelines (National Cancer Screening Guidelines and National Cancer Treatment Protocols)	Printing & distribution of guidelines; development of popular versions/ clinical decision aids and SOPs derived from guidelines	Number of facilities with guidelines; Number of sensitization forums; popular versions, SOPs and other clinical decision aids developed	MOH-NCCP, TWG, Partners, County Govts	X	X	X	X	X
	Sensitization forums for health managers & health workers	Number of health managers & health workers sensitized; Number of facilities implementing the guidelines			X		X	

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
II. DEMAND CREATION AND COMMUNITY EDUCATION & ENGAGEMENT								
Development, printing and distribution of IEC materials to all health facilities	Develop IEC materials, including translation to local languages	IEC materials developed, printed and disseminated	Breast Cancer TWG, NCCP, Health promotion, Counties, Partners	X	X			
	Development, design, printing and dissemination of requisite Breast Cancer Job aids	Job aids materials designed, printed and disseminated		X	X	X	X	X
Engage Community Health Volunteers to provide information on breast health and breast cancer awareness through dialogue sessions and customize programs for different settings	CHVs to conduct health Awareness talks	Number of Health talks conducted	MOH, Counties, Partners	X	X	X	X	X
	Disseminate breast cancer information through Chief's barazas	Number of dissemination sessions		X	X	X	X	X
	Sensitize Religious Associations & opinion leaders on breast cancer awareness	Number of sensitization forums held		X	X	X	X	X
	Engage community welfare groups on breast cancer Awareness	Number of welfare groups engaged		X	X	X	X	X
Engage & equip key influencer groups including cancer survivors, religious, administrative, community leaders, celebrities, TV/ media/social media personalities and opinion leaders with advocacy skills for breast cancer awareness	Sensitization workshops on Advocacy skills for Breast Cancer held and breast health awareness champions engaged	Number of sensitization workshops done; Number of key influencer groups/ persons engaged as breast health champions	MOH-Communications/PRO, NCCP, NCIK, Counties, Partners	X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Conduct breast cancer screening mobile clinic outreaches in targeted settings (community, workplace, etc.)	Incorporate breast cancer screening facilities in mobile clinic outreaches	Number of mobile clinics providing breast cancer screening services; number of outreaches done;	MOH, Counties, Facilities, Partners	X	X	X	X	X
Create a platform to facilitate individual breast cancer screening invitations with community to facility linkages	Platform developed for eligible women to receive personalized screening invitations	Number of invitations sent; Number of women accessing screening through invitation; Number of women linked to facilities	MOH- NCCP, HMIS, DCH, Ministry of ICT, Counties	X	X	X	X	X
Sustained Breast Cancer Awareness campaigns on mainstream and social media among other channels	Commemoration of annual breast cancer awareness month (BCAM)	BCAM commemorated	MOH- NCCP, NCI-K, Health Promotion, Counties, Media Council of Kenya, Communications Authority of Kenya, Partners	X	X	X	X	X
	Develop and disseminate social Media toolkit	Social media toolkit developed and disseminated		X	X	X	X	X
	Annual Media Breakfast to sensitize media on Breast Cancer	Number of media breakfasts/ journalists reached		X	X	X	X	X
	Dissemination of key breast cancer messages on mainstream media including radio and TV stations	Number of Key messages shared/ Number of TV spots/Number of newspaper advetisements placed/ Number of radio mentions on breast cancer		X	X	X	X	X
Institute work place programs that encourage early detection of breast cancer.	Establish workplace programs for breast cancer early detection including at employment/ workplace assessments	Number of MDAs/ organizations with programs in place; number of sensitization forums held; number of women linked to care	MOH-NCCP, NCI-K, MDAs	X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
III. TRAINING AND PROFESSIONAL DEVELOPMENT								
Improve on job training for breast cancer across the care continuum	Conduct training needs assessment	Training needs assessment conducted, responsible	Breast Cancer TWG, Partners	X	X			
	Ensure supportive supervision for on-job skills based training for breast cancer screening	Number of supportive supervisions conducted	Breast Cancer TWG, NCCP, Counties, Partners		X	X	X	X
Appropriate training of CHVs, CHEWs and Health Promotion Officers on promoting SBE and creating breast cancer awareness	Develop training materials on breast cancer awareness	Training Materials developed	NCCP, Counties, Division of Community Health, Division of Health Promotion, County Breast TWGs, Partners	X		X		
	Identify & train master trainers at national level	Number of Master Trainers at national level		X		X		
	Identify & train county-level Community Health Extension Workers (CHEWs) as trainers of trainers (TOTs)	Number of TOTs trained per county - 20		X		X		
	Identify & train CHVs country-wide	Number of CHVs trained		X	X	X	X	X
Appropriate training of imaging personnel on breast imaging techniques including image-guided biopsies	Identify & train Radiographers and Sonographers in facilities with the service	Number of Radiographers & Sonographers trained per facility with the service	MOH-NCCP, Clinical Services, National Referral Hospitals, Breast TWGs, Professional bodies, Partners, NCCP, KAR, COEs,		X		X	
	Identify radiologists for sub-specialization training in breast imaging (Liaison with KAR & COEs)	Number of Radiologists identified; number of radiologists trained		X		X		
	Establish partnerships/ collaborations for fellowships	Number of MOU's / Collaborations developed and signed		X	X	X	X	X
	Conduct continuous breast cancer medical education (CME) in collaboration with relevant stakeholders	Number of CMEs conducted; number pf HCWs attending CMEs		X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
	Fellowships in breast specialization in Radiology	Number of fellows trained in breast imaging specialization		X		X		X
Appropriate training of laboratory personnel on involved in handling, processing and interpretation of pathology reports	Identify &train Pathologists and laboratory technologists	Number of pathologists and technologists identified and trained	MOH-NCCP, HR division, National Cancer Reference Laboratory, NPHLS, Professional bodies, National Referral hospitals, Partners, Breast TWGs, Counties		X		X	
	Establish partnerships and collaborations for fellowships	MOU's / Collaborations in place/signed			X	X	X	X
	Fellowships in Onco-Pathology specialization	Number of fellows trained in Onco-Pathology - 2 per county (94)			X	X	X	X
Appropriate training of primary care clinicians, family physicians, gynecologists and surgeons on promoting BSE and breast health awareness, CBE, breast cancer screen-ing, diagnosis, management, palliative care and appropriate referral.	Conduct Continuous Medical Education (CME) in collaboration with professional bodies	Number of Breast CME's delivered to the various cadres - 1 in each quarter (4 in total)	NCCP, SSK, KESHO, KOGS, KAFP, KACP, KCOA, NNK, Breast TWGs, Partners, Counties, Health Facilities	X	X	X	X	X
	Develop training packages (short courses) for Breast cancer screening/biopsy/ management for various cadres (RH COs, MOs, Family Physicians, gynecologists/ surgeons)	Training materials developed		X		X		
	Identify and train RH COs, MO's, Gynecologists, surgeons, family physicians and relevant cadres on breast cancer screening and early diagnosis in health facilities in each county	Number of relevant cadres of health workers		X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Training of health records & information officers and other healthcare workers on breast cancer screening data management	Develop training packages (short courses) for Breast cancer screening/ data management for HRIO's	Training material developed and integrated in KMTC curriculum	MOH-NCCP, KMTC, HMIS, Counties, Partners	X	X		X	
	Identify and train Health Records and information officers & other HCWs on breast cancer data and reporting per county	Number of HRIO's trained			X		X	
Integration of breast cancer content in Training curriculum into Undergraduate and Post Graduate Training in health Programs	Liaise with parent training institutions on integration of breast cancer training	Number of meetings, number of training institutions integrating breast cancer screening; content developed	NCI-K, Professional bodies, Partners		X	X	X	X
	Engagement with regulators post curriculum development for the various health care cadres	Meeting with regulators on the various curriculums		X	X		X	

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
IV. SERVICE DELIVERY (SCREENING, DIAGNOSTICS, PATIENT NAVIGATION AND REFERRAL)								
Set up Breast Cancer Centers of Excellence at three National Referral Hospitals	Set up Breast interdisciplinary/ MDT coordination teams on screening and rapid diagnosis in the centers of excellence	Number. of MDTs activated Number of meetings held	MOH-NCCP,HPTs, National Referral Hospitals, KEMSA, Counties	X	X	X	X	X
	Avail essential Supply Needs for Breast Cancer Screening & Early Diagnosis Service Provision	Availability of essential supplies		X	X	X	X	X
	Ensure availability of specialized human resource for screening, early diagnosis, treatment, palliative care and survivorship	Number of facilities with requisite specialists/ number of specialists available	MOH-NCCP, HPTs, County Breast TWGs, County Public Service Board, Facility Health Management Teams, Partners	X	X	X	X	X
	Provision of specialized imaging (mammography, ultrasound) and Stereotactic tru-cut biopsies, tomosynthesis, MRI, FISH,	Number of specialized services provided/ number of patients utilizing the services		X	X	X	X	X
	Provision of genetic counseling and testing services for evaluation & follow-up of women in the high-risk population(At least one center)	Genetic testing services in place; Number of patients evaluated, number of high-risk patients on follow-up/Number of patients tested and counselled	MOH-National Referral Hospitals, National and County Breast TWG, NCCP, NCRL, Partners				X	X
	Monitoring the quality of laboratory diagnostic and imaging services	Establish a TWG on QA, TAT, accuracy of tests, no. of facilities with laboratory and imaging centre accreditation	MOH- NCCP, NCRL, Breast Cancer TWGs, Counties, Professional bodies	X	X			

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Provision of quality breast cancer pathology services including rapid breast diagnostic units for prompt tissue sampling of breast abnormalities in county referral hospitals and hormonal testing (immunochemistry for ER/PR/HER-2)	Establish rapid diagnostic units to enable timely diagnosis for symptomatic women	Number of rapid diagnostic units established	MOH- NCCP, Health Infrastructure, National Cancer Reference Laboratory, Counties, professional bodies, Partners	X	X	X	X	X
	Establish systems for accreditation second opinions for breast imaging and pathology/ Establish formal linkages with accredited facilities for breast imaging and pathology	Number of facilities with accreditation for breast pathology and imaging Number of rapid diagnostic units with formal linkages to accredited facilities for breast imaging and pathology	MOH, Counties, professional bodies, Partners, Accreditation Service providers, Facilities		X	X	X	X
	Establish functional histopathology services in county referral laboratories with good turnaround times for results	Number of counties performing in-house tissue diagnosis, Turnaround times for results; Number of facilities utilizing guidelines	MOH-NCCP, National Cancer Reference Laboratory, Counties, Facilities	X	X	X	X	X
	Provide adequate human resources such as pathologists, histo/ cytotechnologists and laboratory technologists to support cancer diagnostic service delivery at national and county level	Number of pathologists/ histopathologists with employed & appropriately deployed at national and county level	MOH, National Cancer Reference Laboratory, Counties, County Referral facilities, National Referral facilities	X	X	X	X	X
	Provide equipment & consumables for tissue diagnosis	Equipment inventory, stock levels of consumables	MOH-NCCP, Counties, County Referral facilities, National Referral facilities, Partners, MOH-HPTs, KEMSA	X	X	X	X	X
	Report all confirmed cases to the National Cancer Registry	Number of facilities reporting cases to cancer registry	Counties, Facilities	X	X	X	X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Activate breast cancer screening mammography services in all county referral hospitals	Develop protocols for breast imaging services	Protocol developed, number of institutions utilizing protocols	MOH, Counties, professional bodies, Service providers	X	X	X	X	X
	Provide human resources such as radiographers, sonographers, radiologists at ultrasound/ mammography service delivery points	Number of radiographer / sonographers/ radiologists trained, number employed and appropriately deployed to support breast imaging	Counties, Facility Management Teams, Partners		X	X	X	X
	Development of tele-radiology services and link them with a centralized data repository	Percentage of completion of infrastructure/ Number of facilities linked / number of patients supported	MOH, Counties			X	X	X
Provision of patient navigation to ensure linkages to care at various service delivery points	Capacity building for in-facility navigators	Number of facilities with all three cadres of patient navigators.	MOH, County TWG, Facilities, Partners		X	X		
	Maintain a client/ patient database for the purpose of call back and follow up	Client databases created & maintained	MOH, County TWG, Facilities		X		X	
	Establish breast cancer patient support groups for psychosocial support	Number of psychosocial support groups established	Civil society groups, Facilities, County TWG	X	X	X		
Establish supra-national and interlaboratory linkages and referral structures for specimens	Establish a national lab tissue referral network with telepathology services & link it to the National Oncology Reference Laboratory (NORL)	Referral structures established and number of centers linked	MOH-NCCP, NORL, Counties, partners	X	X	X	X	X
Avail commodities for provision of comprehensive breast care services as per level of care.	Timely procurement and availability of commodities for screening, diagnosis & management-	Stock levels; Days of stockouts	MOH-NCCP, Health Facilities, MOH-HPTs, KEMSA, County Health Management Teams				X	X

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Initiate public private partnerships to provide screening, diagnostic, treatment and palliative care services	Exploit existing PPP mechanisms to provide services	Number of strategic MOUs between COEs and private entities	MOH, Counties, Partners	X	X	X	X	X
	Develop access mechanisms for patients for services in both private and public facilities	Number of agreements developed and in use	MOH, Counties, Partners		X	X	X	X
Integrate breast cancer screening services to other services including cervical cancer screening, FP, MCH, HIV and NCDs	Leverage existing screening interventions to provide a one-stop center for screening of common conditions	Number of facilities linking screening services	MOH-DMPPH, Counties		X	X	X	X
V. MONITORING AND EVALUATION								
Develop a clear Monitoring and Evaluation framework for the breast cancer screening program in Kenya, including awareness, with indicators and suggested data sources.	Develop M/E framework, with indicator matrix and targets	Complete framework	MOH- NCCP, Breast Cancer TWG, MER TWG	X				
	Training on breast cancer indicators and surveillance	Training conducted	MOH-NCCP, Counties, Partners	X	X	X	X	X
Conduct a comprehensive baseline, midterm and end term assessment of breast cancer screening program	Prepare, train on evaluation, conduct data collection, analyze and disseminate results	Evaluation tools developed; training done; data collection done; dissemination of results	MOH-NCCP, Counties, Partners	X		X		X
Strengthen and improve data systems to enable computation and tracking of selected breast cancer screening, diagnosis, treatment and follow-up indicators.	Pilot oncology EMR	A piloted oncology EMR	MOH-NCCP, HMIS, Counties, Health-IT	X				
	Roll-out oncology EMR in health facilities	Oncology EMR available in all level 4-6 facilities	MOH, HMIS, NCCP, Counties, Health-IT	X	X	X	X	

Proposed Activities	Sub-activities	Key Performance Indicators	Responsible Persons	2021	2022	2023	2024	2025
Enhance timely monthly reporting of breast cancer indicators and advocating utilization of this information by stakeholders, including counties.	Monthly reporting of breast cancer indicators & Advocate for utilization of the information by stakeholders, including counties	Timely monthly reports; Information utilized by stakeholders	MOH, County health facilities	X	X	X	X	X
Identify research priority areas and conduct research to guide breast cancer care across the entire continuum	Refine national breast cancer research agenda	Refined breast cancer research agenda developed	MOH-NCCP, Division of Research & PolicyNCI-K, Counties, Research institutions, KESHO	X				
	Number of funded priority breast cancer research topics		NCI-K, National Research Fund, Partners, MOH-NCCP	X	X	X	X	X

CHAPTER FIVE

Monitoring & Evaluation

Key Performance Indicators and Data Sources

The Ministry of Health will be overall responsible for the implementation of this Action Plan and will ensure data is systemically generated, captured and used to guide proper decision making throughout the implementation of the Action Plan to achieve its goal.

The county health committees will ensure that these indicators are measured and reported in the Kenya Health Information Management System and also through specially designed and customized monitoring and evaluation frameworks.

The following key set of performance indicators will continuously be monitored and evaluated through the National Breast Cancer Technical Working Group:

Indicator Type	Indicator	Indicator Definition	Data Source	Baseline	Target	
					Mid-Term (2023)	End-Term (2025)
Process	Breast cancer screening human resource capacity	Number of HCW of various cadres trained in CBE	Health facility assessments	100	5,000	25,000
		Number of radiographers and radiologists trained in breast imaging	Health facility assessments	50	10	500
	Breast cancer service availability	Number of county referral facilities that offer histopathology services	Health facility assessments, KHIS	10	20	40
		Proportion of health facilities, per level of care, performing breast imaging (ultrasound, mammography)	Health facility assessments, KHIS	3%	10%	15%
Outcomes	Invitation coverage	% of women who receive individual invitation to screening as a proportion of the entire eligible population	Screening invitation database, KNBS	0	0	50
	Participation Rate	% of women who undergo screening as a proportion of the invited population in the index year	KHIS, invitation database	1%	10%	30%
	Screening coverage	% of women who undergo screening as a proportion of the eligible population	KHIS	1%	10%	30%
	Positivity rate	Number of women with screen positive results per 1000 women screened	KHIS	Unavailable	30	50
	Biopsy rate	Proportion of Ultrasound-guided Biopsies (USG) Performed out of those eligible at centers of excellence	Oncology EMR	Unavailable	-	25%
	Advanced cancer detection rate	Proportion of breast cancer cases diagnosed at stage 3 or 4	Oncology EMR, KNCR	69%	60%	40%
	Treatment initiation rate	Proportion of women diagnosed with breast cancer who initiated treatment	Screening clinics, Kenya EMR, KNCR	Unavailable	-	90%
Impact	Breast cancer mortality	Breast cancer mortality per 100,000 women	KNCR, CRVS	19.4	18.9	17.1

Breast Cancer Screening Targets by County

Country	(Women 40-74 years)	(Women 40-74 years) by 2021	Target for 2021 (5%)	(Women 40-74 years) by 2022	Target for 2022 (8%)	(Women 40-74 years) by 2023	Target for 2023 (10%)	(Women 40-74 years) by 2024	Target for 2024 (15%)	(Women 40-74 years) by 2025	Target for 2025 (20%)
Nairobi	306484	313288	15664	320243	25619	327352	32735	334620	50193	342048	68410
Nyeri	112504	115002	5750	117555	9404	120164	12016	122832	18425	125559	25112
Marsabit	29518	30173	1509	30843	2467	31528	3153	32228	4834	32943	6589
Isiolo	16810	17183	859	17565	1405	17955	1795	18353	2753	18761	3752
Kirinyaga	86917	88847	4442	90819	7266	92835	9284	94896	14234	97003	19401
Bungoma	141995	145147	7257	148370	11870	151663	15166	155030	23255	158472	31694
Nandi	79043	80798	4040	82591	6607	84425	8442	86299	12945	88215	17643
Nakuru	191554	195806	9790	200153	16012	204597	20460	209139	31371	213782	42756
Meru	170916	174710	8736	178589	14287	182554	18255	186606	27991	190749	38150
Machakos	160907	164479	8224	168131	13450	171863	17186	175678	26352	179578	35916
Kakamega	185954	190082	9504	194302	15544	198616	19862	203025	30454	207532	41506
Nyamira	64663	66099	3305	67566	5405	69066	6907	70599	10590	72166	14433
Makueni	117872	120489	6024	123164	9853	125898	12590	128693	19304	131550	26310
Embu	77175	78888	3944	80640	6451	82430	8243	84260	12639	86130	17226
Kiambu	241501	246862	12343	252343	20187	257945	25794	263671	39551	269525	53905
Kisumu	97177	99334	4967	101540	8123	103794	10379	106098	15915	108453	21691
Kitui	125023	127799	6390	130636	10451	133536	13354	136500	20475	139531	27906
Kericho	75116	76784	3839	78488	6279	80231	8023	82012	12302	83832	16766
Busia	83266	85115	4256	87004	6960	88936	8894	90910	13636	92928	18586
Baringo	51743	52892	2645	54066	4325	55266	5527	56493	8474	57747	11549
Homabay	99177	101379	5069	103629	8290	105930	10593	108282	16242	110685	22137
Kisii	125258	128039	6402	130881	10470	133787	13379	136757	20514	139793	27959
Murang'a	148641	151941	7597	155314	12425	158762	15876	162286	24343	165889	33178
Laikipia	54526	55736	2787	56974	4558	58239	5824	59532	8930	60853	12171
Kilifi	128583	131438	6572	134355	10748	137338	13734	140387	21058	143504	28701
Elgeyo-Marakwet	37739	38577	1929	39433	3155	40309	4031	41203	6181	42118	8424
Siaya	104489	106809	5340	109180	8734	111604	11160	114081	17112	116614	23323
Vihiga	70562	72128	3606	73730	5898	75367	7537	77040	11556	78750	15750
Nyandarua	102652	104931	5247	107260	8581	109642	10964	112076	16811	114564	22913
Bomet	69890	71442	3572	73028	5842	74649	7465	76306	11446	78000	15600
Kwale	71491	73078	3654	74700	5976	76359	7636	78054	11708	79787	15957
Tharaka	49100	50190	2510	51304	4104	52443	5244	53607	8041	54798	10960
Migori	83617	85473	4274	87371	6990	89310	8931	91293	13694	93320	18664
Trans Nzoia	85117	87007	4350	88938	7115	90913	9091	92931	13940	94994	18999
Kajiado	81177	82979	4149	84821	6786	86704	8670	88629	13294	90597	18119
Narok	74386	76037	3802	77725	6218	79451	7945	81215	12182	83018	16604
Mombasa	92681	94739	4737	96842	7747	98992	9899	101189	15178	103436	20687
Samburu	19394	19825	991	20265	1621	20715	2071	21174	3176	21644	4329
Turkana	58053	59342	2967	60659	4853	62006	6201	63382	9507	64789	12958
Uasin Gishu	94768	96872	4844	99022	7922	101221	10122	103468	15520	105765	21153
Garissa	41989	42921	2146	43874	3510	44848	4485	45844	6877	46861	9372
Wajir	33432	34174	1709	34933	2795	35708	3571	36501	5475	37311	7462
Lamu	12770	13053	653	13343	1067	13640	1364	13942	2091	14252	2850
Taita Taveta	39006	39872	1994	40757	3261	41662	4166	42587	6388	43532	8706
West Pokot	39564	40442	2022	41340	3307	42258	4226	43196	6479	44155	8831
Tana River	22725	23229	1161	23745	1900	24272	2427	24811	3722	25362	5072
Mandera	33849	34600	1730	35369	2829	36154	3615	36956	5543	37777	7555
KENYA	**4,290,774**	**4,486,399**	**219,301**	**4,483,390**	**358,672**	**4,582,930**	**458,293**	**4,684,672**	**702,701**	**4,788,671**	**957,734**

Assumptions

1. CBE is done annually for all women from 25 years of age. Mammography is done annually from 40-55yrs.

2. The annual target is 20% of the eligible population over the five year period. This target is to be achieved progressively.

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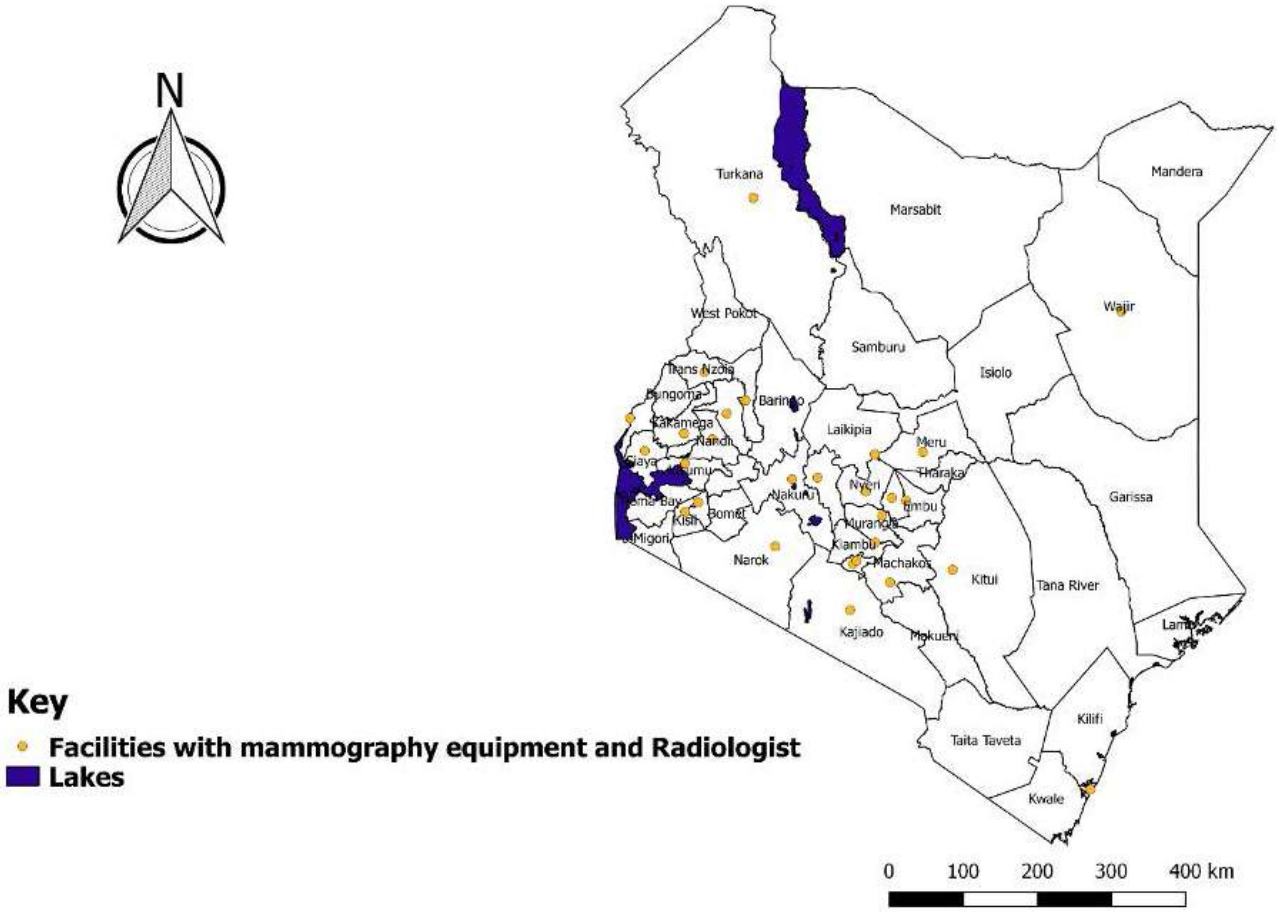
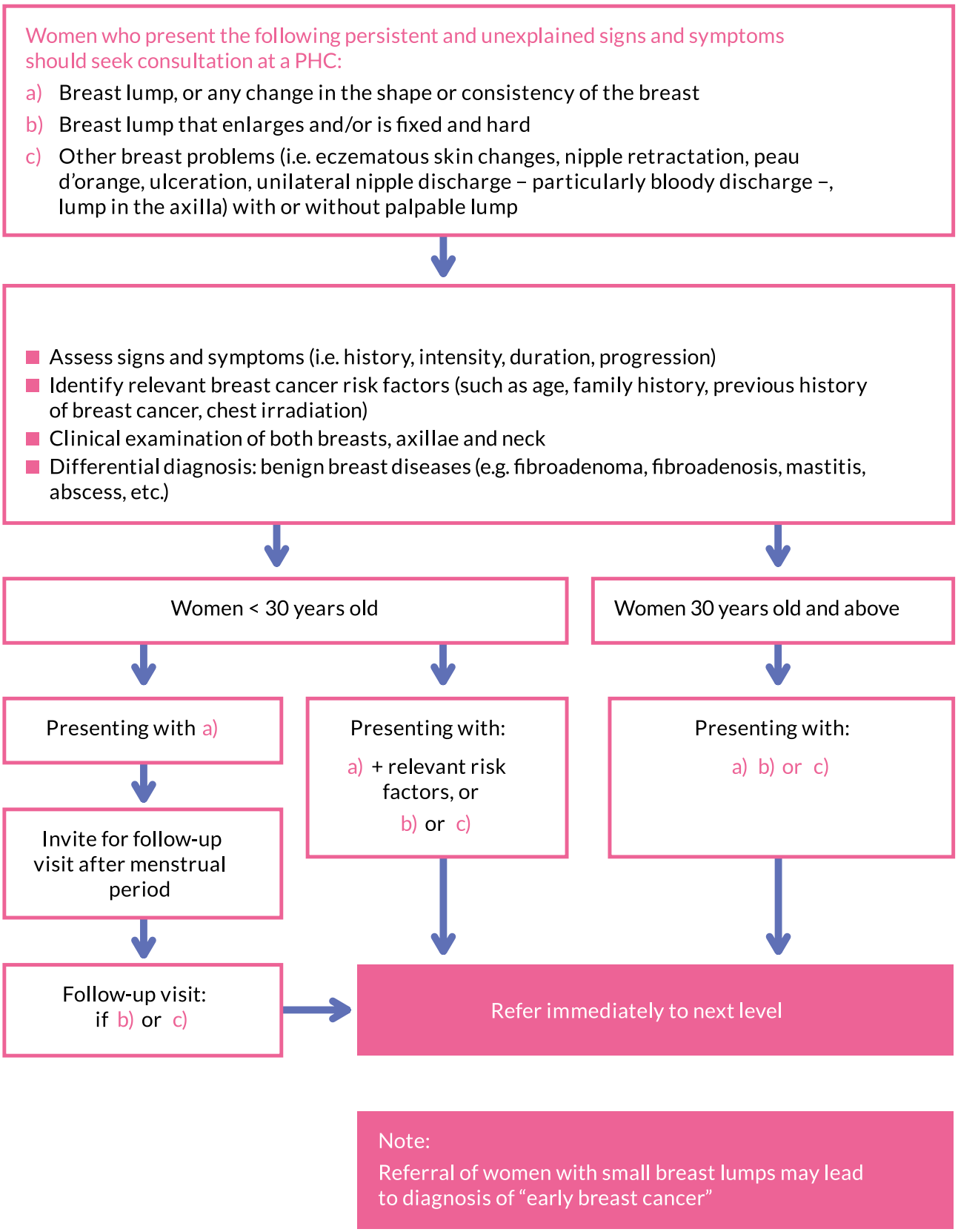
Annexes

Annex 1: Distribution of Mammography machines in Kenya_2019



Annex 2: WHO PEN Protocol for Assessment and Referral of Women with Suspected Breast Cancer at Primary Health Care



Annex 3: Costing of the Breast Cancer Action Plan 2021-2025 (Cost Estimates)

Result Area	Proposed Activities	Estimated Total Cost	2021	2022	2023	2024	2025
Governance and policy	Integrate Breast Cancer Prevention, Screening & Early Diagnosis agenda in the national & county-level committees with representation of relevant stakeholders and experts	7,796,000	X	X	X	X	X
	Identify and sensitize key stakeholders for engagement	8,000,000	X	X	X	X	X
	Establish a Quality Assurance and improvement process for CBE / breast imaging /breast pathology/ treatment	26,694,000	X	X	X	X	X
	Promote adherence to national guidelines (National Cancer Screening Guidelines and National Cancer Treatment Protocols	13,625,000	X	X	X	X	X
	RESULT AREA SUB-TOTAL	**56,115,000**					
Demand Creation and Community Education & Engagement	Development, printing and distribution of IEC materials to all health facilities	16,210,000	X	X	X	X	X
	Engage Community Health Volunteers to provide information on breast health and breast cancer awareness through dialogue sessions and other for a	69,000,000	X	X	X	X	X
	Engage & equip cancer survivors, religious, administrative, community leaders, the media and opinion leaders with advocacy skills for breast cancer awareness	20,210,000	X	X	X	X	X
	Conduct breast cancer screening mobile clinic outreaches in targeted settings (community, workplace, etc.)	164,500,000	X	X	X	X	X
	Create a platform to facilitate individualized breast cancer screening invitation and referral linkages for breast cancer management	40,000,000	X	X	X	X	X
	Sustained Breast Cancer Awareness campaigns on mainstream and social media	267,500,000	X	X	X	X	X

Result Area	Proposed Activities	Estimated Total Cost	2021	2022	2023	2024	2025
Establish work place breast cancer early detection programs	Workplace programs in place with establishment of linkages to care	29,500,000	X	X	X	X	X
	RESULT AREA SUB-TOTAL	**606,920,000**					
Training and Professional Development	Appropriate training of CHVs, CHEWs and Health Promotion Officers on promoting SBE and creating breast cancer awareness	131,606,000	X	X	X	X	X
	Appropriate training of relevant cadres of health workers at all levels of care promoting BSE & breast health awareness, CBE, screening, diagnosis, management and appropriate referral.	128,332,000	X	X	X	X	X
	Appropriate training of imaging personnel on breast imaging techniques including image-guided biopsies	128,700,000	X	X	X	X	X
	Appropriate training of laboratory personnel on involved in handling, processing and interpretation of pathology specimens	385,200,000	X	X	X	X	X
	Training of health records & information officers and other healthcare workers on breast cancer screening data management	26,460,000	X	X	X	X	X
	Integration of Training curriculum into undergraduate and postgraduate training programs	30,000,000	X	X	X	X	X
	RESULT AREA SUB-TOTAL	**868,096,000**					

Result Area	Proposed Activities	Estimated Total Cost	2021	2022	2023	2024	2025
Service Delivery (Screening, diagnostics, patient navigation and referral)	Set up of Breast Centers of Excellence (COEs) in five (5) designated regional county cancer centers and 3 national referral hospitals	1,751,435,800	X	X	X	X	X
	Provision of quality breast cancer pathology services including rapid breast diagnostic units for prompt tissue sampling of breast abnormalities in county referral hospitals and hormonal testing (immunochemistry for ER/PR/HER-2)	968,090,000	X	X	X	X	X
	Provision and/or activation of quality breast cancer imaging services in all 47 counties	56,572,000	X	X	X	X	X
	Provision of patient navigation to ensure linkages to care at various service delivery points	18,875,000	X	X	X	X	X
	Establish linkages and referral structures (including psychosocial support) for specimens	23,500,000	X	X	X	X	X
	Avail commodities for provision of comprehensive breast cancer services as per level of care	91,000,000	X	X	X	X	X
	Initiate public private partnerships to provide screening, diagnostic, treatment and palliative care services	0	X	X	X	X	X
	Integrate breast cancer screening services to other screening services, including but not limited to MCH, postnatal, HIV & NCDs management	0	X	X	X	X	X
	RESULT AREA SUB-TOTAL	**2,909,472,800**					

Result Area	Proposed Activities	Estimated Total Cost	2021	2022	2023	2024	2025
M&E and research	Develop a clear Monitoring and Evaluation framework for the breast cancer screening program in Kenya, including awareness, with indicators and suggested data sources.	4,522,000	X	X	X	X	X
	Conduct a comprehensive baseline, midterm and end term assessment of breast cancer screening program	4,790,000	X	X	X	X	X
	Strengthen and improve data systems to enable computation and tracking of selected breast cancer screening, diagnosis, treatment and follow-up indicators.	7,360,000	X	X	X	X	X
	Enhance timely monthly reporting of breast cancer indicators and advocating utilization of this information by all stakeholders, including counties.	100,000,000	X	X	X	X	X
	Identify research priority areas and conduct research to guide breast cancer care across the entire continuum	151,585,000	X	X	X	X	X
	RESULT AREA SUB-TOTAL	**268,257,000**					
	GRAND TOTAL	**4,708,860,800**					

List of Contributors

1.	Agnes Betty Nthusa	MOH-National Cancer Control Program
2.	Boniface Mbuki	Kenyan Network of Cancer Organizations
3.	Bruce Orangi	MOH - National Cancer Control Program
4.	Dr. Beatrice Mugi	KNH/Kenya Association of Radiologists
5.	Dr. Daniel Ojuka	University of Nairobi
6.	Dr. Joyfrida Chepchumba	MOH- National Cancer Control Program
7.	Dr. Moki Mwendwa	Kenyatta University Teaching and Referral Research Hospital
8.	Dr. Miriam Mutebi	Aga Khan University Hospital
9.	Dr. Mary Nyangasi	MOH- National Cancer Control Program
10.	Dr. Joan Paula Bor Malenya	MOH- National Cancer Control Program
11.	Dr. Shahin Sayed	Aga Khan University Hospital
12.	Dr. Richard Njoroge	Cancer Control MOH - National Program
13.	Dr. Rose Ndumia	Aga Khan University Hospital
14.	Dr. Njoki Njiraini	Kenyatta University Teaching and Referral Research Hospital
15.	Dr. Helena Musau	Meru Teaching and Referral Hospital
16.	Dr. Mugambi Joy	Kenya Association of Family Physicians
17.	Dr. Elizabeth Onyango	MOH, Department of NCDs
18.	Dr. Gladwell Gathecha	MOH, Department of NCDs
19.	Dr. Ephantus Maree	MOH, Department of NCDs
20.	Dr. Faith Mudachi	MOH- National Cancer Control Program
21.	Dr. Vera Manduku	Kenya Medical Research Institute
22.	Dr. Valerian Mwenda	MOH-National Cancer Control Program
23.	Dr. Waqo Ejersa	MOH - Non-Communicable Diseases
24.	Dr. Oren Ombiro	MOH - Department of NCDs
25.	David Machera	Kenya Medical Training College
26.	David Njuguna	MOH
27.	Dr. David Soti	MOH
28.	Elizabeth Ragui	Hope Breast Cancer Trust
29.	Eunice Kuria	Clinical Officers Council
30.	Francis Tawuo	MOH- National Public Health Laboratory Services
31.	Gilbert Mboro	MOH
32.	Gladys Mugambi	MOH
33.	Grace Midigo	MOH
34.	Hannah Gitungo	MOH- National Cancer Control Program
35.	Hillary Changwony	MOH- National Cancer Control Program
36.	Jacqueline Aloo	MOH

List of Contributors

37.	Joyce Wamicwe	MOH
38.	Kigen Bartilol	MOH- Referral Services
39.	Lilian Genga	MOH - National Cancer Control Program
40.	Lydia Kirika	MOH - National Cancer Control Program
41.	Dr. Laura Oyiengo	MOH
42.	Maryline Chebii	Nursing Council of Kenya
43.	Manaseh Bocha	MOH
44.	Dr. Michael Gichangi	MOH
45.	Dr. Nasirumbi Magero	MOH DNCDs
46.	Perez Wawire	Clinical Officers Council
47.	Rachel Githiomi	MOH
48.	Roselyne Okumu	ONC-K /Kenyatta National Hospital
49.	Ruth Muia	National Cancer Institute-Kenya
50.	Scholastica Mwende	MOH
51.	Stephen Mutiso	MOH
52.	Dr. Valeria Makory	MOH
53.	Wamae Wanjohi	MOH
54.	Dr. Hilda Mubisi	Kakamega County Referral Hospital
55.	Dr. Bahaty Riogi	Kisii Teaching and Referral Hospital
56.	Dr. Eric Hungu	Kenyatta National Hospital
57.	Dr. Robai Gakunga	Independent Research Scientist
58.	Stephen Musya	Nyeri Hospice
59.	Joyce Mwende	Isiolo County
60.	Dr. Maryam Badawy	Coast General Teaching and Referral Hospital
61.	Dr. Sharon Mweni	Machakos County Referral Hospital
62.	Dr. Wanja Mutura	Garissa County Referral Hospital
63.	Dr. Orangi Gavin	Makueni County Referral Hospital

The most important thing to focus on in cancer is "CAN" - that you can do it and can overcome it"
- Cancer Survivor -


EARLY
DETECTION
SAVES
LIVES