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MINISTRY OF HEALTH - ETHIOPIA

NATIONAL GUIDELINE FOR BREAST HEALTH, EARLY DIAGNOSIS AND TIMELY BREAST CANCER MANAGEMENT IN ETHIOPIA

(2024-2028)

APRIL, 2024
ADDIS ABABA, ETHIOPIA

ACRONYMS

AACR	Addis Ababa City Cancer Registry
AAU	Addis Ababa University
AJCC	American Joint Commission on Cancer
BCa	Breast Carcinoma
BCAM	Breast Cancer Awareness Month
BCC	Behavioral Change Communication
BCS	Breast-Conserving Surgery
BHAC	Breast Health Awareness Campaign
BSE	Breast Self-Examination
CBE	Clinical Breast Examination
CHEW	Community Health Extension Worker
CHS	College of Health Science
CHV	Community Health Volunteer
CME	Continuous Medical Education
CNB	Core needle biopsy
COE	Center of Excellence
CxCa	Cervix Carcinoma
DHIS 2 2	District health information system
EDP	Early Detection Program
EKC	Else Kröner Center for Cancer Care
EMR	Electronic Medical Records
ER	Estrogen Receptor
FISH	Fluorescence in Situ Hybridization
FMOH	Federal Ministry of Health
FNA	Fine Needle Aspiration
FNAC	Fine Needle Aspiration Cytology
GBCI	Global Breast Cancer Initiative
GDP	Gross Domestic Product
HCW	Health Care Worker
HER-2	Human Epidermal Growth Factor Receptor 2
HF	Health Facility
HIS	Health Information System
HIV	Human Immunodeficiency Virus
HRIO	Health Records Information Officer
IDC	Invasive Ductal Carcinoma
IEC	Information Education and Communication
IHC	Immuno-Histochemistry
MDT	Multi-Disciplinary Team
MOH	Ministry of Health
MOU	Memorandum of Understanding
MRI	Magnetic Resonance Imaging
NBCTWG	National Breast Cancer Technical Working Group
NCCN	National Comprehensive Cancer Network
NCCP	National Cancer Control Plan
NCD	Non-Communicable Diseases

NRL	National Reference Laboratory
PHC	Primary Health Care
PMP	Performance Monitoring Plan
POCUS	Point of Care Ultrasound
PPP	Public Private Partnership
PR	Progesterone Receptor
QA	Quality Assurance
QI	Quality Improvement
RHB	Regional Health Bodies
SBCC	Social Behavior Change Communication
SC	Sub-City
SoP	Standard Operating Procedure
SS	Supported Supervision
TASH	Tikur Anbessa Specialized Hospital
TAT	Turn-around Time
TNM	Tumour, node, metastasis
TOR	Terms of Reference
TOT	Trainers of Trainers
TWG	Technical Working Group
UHC	Universal Health Coverage
UICC	Union for International Cancer Control
US	Ultrasound
WHO	World Health Organization
ZHD	Zonal Health Department

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FOREWORD

The Government of Ethiopia is resolved to ensure that our people are healthy and productive as this is the cornerstone of the socio-economic development and achievement of our vision of reaching middle-income status by 2035. Ethiopia faces a double burden of communicable and non-communicable diseases, we therefore continue to invest in high impact, evidence-based services to improve the health and wellbeing of our people by creating resilient and people-centered health systems.

In Ethiopia, breast cancer is the leading type of cancer with 16,133 new cases in 2020 and an age standardized incidence rate of 41.5/100,000. While, rare in males accounting for less than 1% of all breast cancer cases, it is now the leading cause of cancer morbidity among adult women in our country, accounting for one third of all cancer cases in women and one in five of all cancers. A key objective of our National Cancer Control Plan and National Strategic Plan for the Prevention and Control of major Noncommunicable Diseases (2020 – 2025) is to expand access to breast cancer awareness, early detection, treatment and palliative care in order to reverse the growing numbers of people suffering from this disease and to reduce the current mortality rate by 25% by the year 2025, in alignment with the World Health Organization, Global Breast Cancer Initiative.

On behalf of the Ministry of Health of Ethiopia, I am delighted to introduce the first ever National Guideline for Breast Health, Early Detection and Timely Breast Cancer Management in Ethiopia. A technical working group of Ethiopian experts from the fields of oncology, radiology, pathology, community health, policy, health financing and advocacy was formed with the goal of developing these guidelines to improve breast health care. I therefore invite you to consult and use it extensively. These guidelines will not only play a pivotal role in accelerating the reduction of distress, suffering and deaths due breast cancer amongst the affected individuals, they will also catalyze the reduction of healthcare costs and strengthen health services for all cancers, helping to improve health outcomes for all cancer patients.

Importantly, this document also outlines a high-level implementation plan to translate these guidelines into practice. I urge all health care workers, implementation partners and stakeholders to join us in operationalizing them. Your partnership will be critical to us fully utilizing these guidelines to improve the health and wellbeing of our people, particularly our women who continue to bear the biggest brunt of breast cancer in our country.

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ACKNOWLEDGMENT

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The Guideline has benefited from wide technical consultations with national and international partners. Special appreciation goes to the Else Kröner Center for Cancer Care (EKCC) project in collaboration with Addis Ababa University-School of Public Health and Martin Luther Halle University in Germany, the American Cancer Society, Clinton Health Access Initiatives (CHAI) and the World Health Organization-Ethiopia Country office for their technical guidance, mentorship and generous financial support of a series of consultations that provided foundational inputs into the design and development of this document. We would also like to share our appreciation of the GIZ funding program Hospital Partnerships on behalf of the German Federal Ministry for Economic Cooperation and Development (BMZ) for assigning an international consultant to review the guideline. With special thanks to Professor Dr. med. Eva Kantelhardt, Professor of Global Health and Gynecology at the University of Halle for her long term and un- wavering expert input and support, Dr Ju- lie Torode, Institute of Cancer Policy, Kings College London for her technical writing and advice in developing this document and Eva Schoening, Advisor GIZ funding program Hospital Partnerships for the ongoing valuable support.

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EXECUTIVE SUMMARY

The rising cancer burden is a major public health concern globally. There were an estimated million new cases and 10 million new deaths worldwide in 2020. Breast cancer has the highest incidence amongst all cancers, with over 2.2 million cases reported globally in 2020). While, rare in males accounting for less than 1% of all breast cancer cases, breast cancer is the most frequently diagnosed cancer in women, with 11.7% of all new cases and 15% of all cancer deaths. Most breast cancer cases and deaths occur in low-and middle-income countries. According to a review of breast cancer care in Africa, women with breast cancer had low levels of early health-seeking practices. In Ethiopia, rates are growing, and it is already the leading type of cancer (see Figure 1) with 16,133 new cases in 2020 and an age standardized incidence rate of 41.5/100,000. It is now the leading cause of cancer morbidity among adult women in the country, accounting for one third of all cancer cases in women and one in five of all cancers

in Ethiopia, breast cancer incidence is increasing and becoming a significant public health problem. Hence, due attention to be given to improve the breast cancer control program with improving awareness and access to information to the disease, referral for prompt diagnosis, improving the timely diagnosis and initiation of treatment with strong support and mentorship across the health system.

The identification, diagnosis, treatment and management of breast cancer in the earliest stages is more effective, less costly, has fewer complications, and greatly improves the quality of life of patients. It also provides consistency in patient care and outcomes. There are key opportunities to be harnessed in the country. For example, the maternal and child health service is a widespread platform that provides integrated services such as antenatal, postnatal, growth monitoring, vaccination and immunization against childhood diseases, nutrition care and family planning. In addition, synergies with cervical cancer prevention and screening services should be explored since clients of both services are mainly women under the age of 50 years and Breast Health Awareness (BHA) and Clinical Breast Examination (CBE) could be delivered by the same nurses providing these services at Primary Health Care (PHC) level clinics, without new infrastructure or additional personnel costs.

Building on early efforts to detect and manage breast cancer, the time is right for Ethiopia to develop a national breast cancer guideline and associated program of implementation shaping breast cancer prevention, early detection, referral and comprehensive management of early and advanced breast cancer, including palliative care.

The vision for Ethiopia is that breast health and breast cancer awareness in the community is high, women are supported in seeking help when they have breast concerns and breast cancer is diagnosed at early stages and received prompt treatment and care.

The overall goal of the 2024-2028 guideline is to provide a strategic guidance aimed at reducing breast cancer mortality in Ethiopia in alignment with the GBCI targets. The three key aims are to:

1. Provide a framework for health facilities on the provision of high quality and effective breast cancer care services at the national level.
2. Provide guidance to policymakers, managers, departmental heads, and other stakeholders on how to implement a breast cancer control program focused on shifting to early diagnosis of the disease over time.

3. Incrementally improve breast cancer management to increase survival and quality of life of patients with breast cancer.

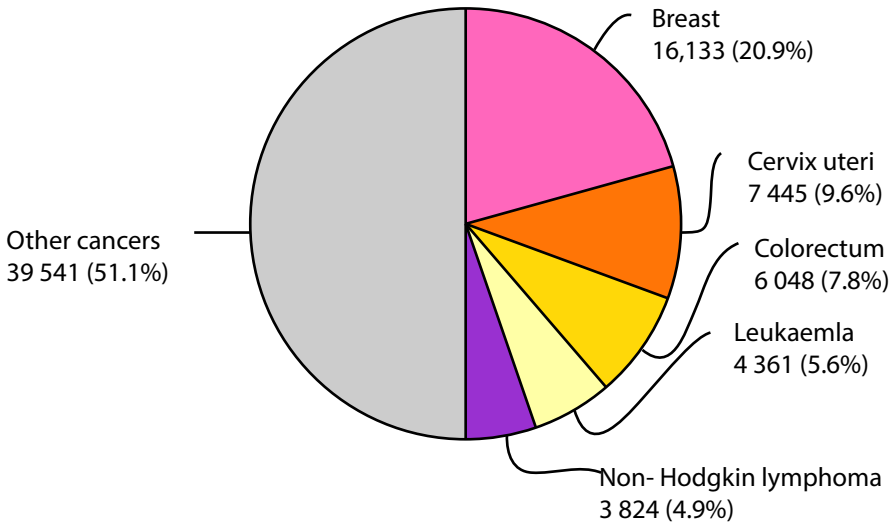
Three ambitious targets are set to halt the growing burden of breast cancer in our country: target 1 is that 60% of all breast cancers are to be diagnosed at Stage I or II of disease; this requires efficient referral systems and timely coordination of services between healthcare levels. We want all patients to have an accurate diagnosis and decisions on appropriate treatment and management plans through an expert multidisciplinary team. Therefore, target 2 sets a turnaround time of 60 days or less for full diagnosis and initiation of treatment within two months. We also want to see 80% of all patients completing their multidisciplinary treatment
in full, which is target 3.

This will represent the first document of its kind in Ethiopia, providing much needed guidance for coordinated, effective and high-quality service delivery and prioritizing aligned training, capacity development and associated infrastructural developments at all levels of the health system. Moreover, the guideline helps to orient the delivery of standard quality care to the patients at every level of health care system.

Chapter 1: Introduction

1.1 THE BURDEN OF BREAST CANCER

The rising cancer burden is a major public health concern globally. There were an estimated million new cases and 10 million new deaths worldwide in 2020. Breast cancer has the highest incidence amongst all cancers, with over 2.2 million cases reported globally in 2020 (1). While, rare in males accounting for less than 1% of all breast cancer cases, breast cancer is the most frequently diagnosed cancer in women, with 11.7% of all new cases and 15% of all cancer deaths (1). Most breast cancer cases and deaths occur in low-and middle-income countries. According to a review of breast cancer care in Africa, women with breast cancer had low levels of early health-seeking practices (2). In Ethiopia, rates are growing, and it is already the leading type of cancer (see Figure 1) with 16,133 new cases in 2020 and an age standardized incidence rate of 41.5/100,000. It is now the leading cause of cancer morbidity among adult women in the country, accounting for one third of all cancer cases in women and one in five of all cancers (1).



Total: 77 352

Source: GLOBOCAN 2020

Figure 1: Estimated age-standardized incidence rates in Ethiopia (2020, both sexes, all ages)

Although in high income countries more than 70% of cases are diagnosed at stage I or II and public health care systems provided prompt and adequate treatments (3), premature deaths due to breast cancer in Sub-Saharan Africa are predominantly due to presentation and diagnosis at advanced clinical stage of disease (4) resulting in limited and difficult therapeutic options and contributing to poor survival rates. This is also the case in Ethiopia with a current age standardized mortality rate of 24.1/100,000 as illustrated in Figure 2, posing a challenge to patients and their families as well as the health system.

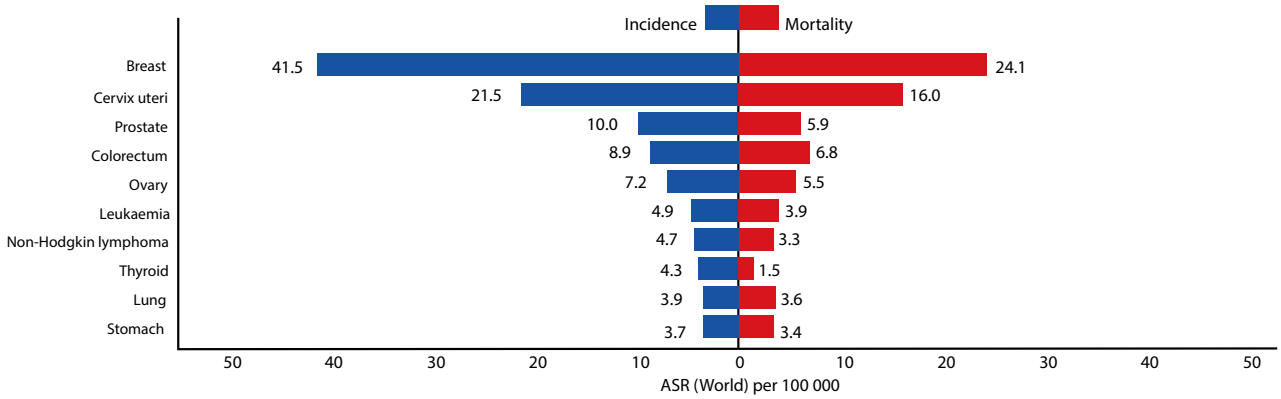


Figure 2: Estimated age-standardized mortality rates in Ethiopia (2020, both sexes, all ages)

Survival rates of BC patients are low compared to those in high income countries (5-7). The majority (65-75%) of BC cases are diagnosed in a late-stage of the disease (i.e. stage III or IV) (8-10). Delays in the diagnostic pathways of BC patients were observed in many patients in Ethiopia. Prolonged time intervals on the diagnostic pathway are associated with diagnosis of advanced stages of the disease (8,10). Patient- and health-system-related barriers for early diagnosis of breast cancer were lack of awareness to breast cancer, belief in traditional medicine, misdiagnosis, a long distance to referral facilities, the high cost of diagnostic services, long waiting times for diagnostic tests (11).

In summary, in Ethiopia, breast cancer incidence is increasing and becoming a significant public health problem. Hence, due attention to be given to improve the breast cancer control program with improving awareness and access to information to the disease, referral for prompt diagnosis, improving the timely diagnosis and initiation of treatment with strong support and mentorship across the health system.

1.2 CANCER POLICY AND AVAILABILITY OF CANCER SERVICES IN ETHIOPIA

Ethiopia is the second most populous country in Sub-Saharan Africa with one of the lowest ranking gross domestic products (GDP) per capita (1027 USD) (13) and lowest ratios of health care providers per population ratio (14). Despite these limitations and in response to the growing cancer burden, Ethiopia has been improving its capacity to diagnose and manage cancer including breast cancer over the last decade.

In 2016, Ethiopia developed a National Cancer Control Plan 2016-2020 to increase early detection and expand treatment capacity to regional referral centers around the country (15). Now, for a population of over 114 million people, there are currently close to 50 clinical oncologists trained to provide specialized cancer care to patients. Availability of radiotherapy services has expanded to a further two regional hospitals in addition to TASH which has been providing cancer care for more than two decades, and an additional four centers are in the process of setting up services. Furthermore, Ethiopia has adopted and is implementing the NCCN guideline developed for Sub-Saharan countries as of 2019 (16). Correspondingly, chemotherapy treatment services are now being provided at 24 public hospitals across the country and the appropriate accompanying pathology and laboratory services are being expanded in a phased manner. In addition, various private facilities are also providing diagnostic pathology and chemotherapy services in the country.

1.3 RATIONALE

The identification, diagnosis, treatment and management of breast cancer in the earliest stages is more effective, less costly, has fewer complications, and greatly improves the quality of life of patients. It also provides consistency in patient care and outcomes. There are key opportunities to be harnessed in the country. For example, the maternal and child health service is a widespread platform that provides integrated services such as antenatal, postnatal, growth monitoring, vaccination and immunization against childhood diseases, nutrition care and family planning. In addition, synergies with cervical cancer prevention and screening services should be explored since clients of both services are mainly women under the age of 50 years and Breast Health Awareness (BHA) and Clinical Breast Examination (CBE) could be delivered by the same nurses providing these services at Primary Health Care (PHC) level clinics, without new infrastructure or additional personnel costs.

Building on early efforts to detect and manage breast cancer, the time is right for Ethiopia to develop a national breast cancer guideline and associated program of implementation shaping breast cancer prevention, early detection, referral and comprehensive management of early and advanced breast cancer, including palliative care.

This will represent the first document of its kind in Ethiopia, providing much needed guidance for coordinated, effective and high-quality service delivery and prioritizing aligned training, capacity development and associated infrastructural developments at all levels of the health system. Moreover, the guideline helps to orient the delivery of standard quality care to the patients at every level of health care system.

1.4 GLOBAL INITIATIVES

Recognizing that breast cancer is the most common cancer worldwide and leading cause of cancer death among women and that it is women in low- and middle-income countries

that are disproportionally affected, the World Health Organization (WHO) has taken steps to bridge inequities in breast cancer outcomes represented by disparity in cancer 5-year survival rates which in high-income countries exceeds 90%, compared with 66% in India and 40% in South Africa.

The WHO Global Breast Cancer Initiative (GBCI), established in 2021 (12), brings together stakeholders from around the world and across sectors with the shared goal of reducing breast cancer by 2.5% per year, which over a 20-year period would save 2.5 million lives and address the chronic social disruption and financial harm that come with breast cancer. The initiative points systematic improvements in access to resource-appropriate and quality services as the levers for change. GBCI employs 3 key strategies to achieve these objectives: health promotion and early detection; timely diagnosis; and comprehensive breast cancer management.

The 60:60:80 targets (detailed in Figure 3) to be achieved by 2030 are encouraging the strengthening health systems, using sustainable, cost-effective, and equitable breast-cancer early detection and treatment services. To be successful, these efforts must be integrated within a community-health framework that engages primary-care facilities, secondary (district) level hospitals, and tertiary care centers. These efforts would not only support health promotion, but also empower women to seek and receive health care throughout the life cycle.

Ethiopia aims to harness this first ever breast cancer guideline to embrace the ambitions of the GBCI and work across these three pillars describing national steps towards incremental achievement of the 60:60:80 targets.

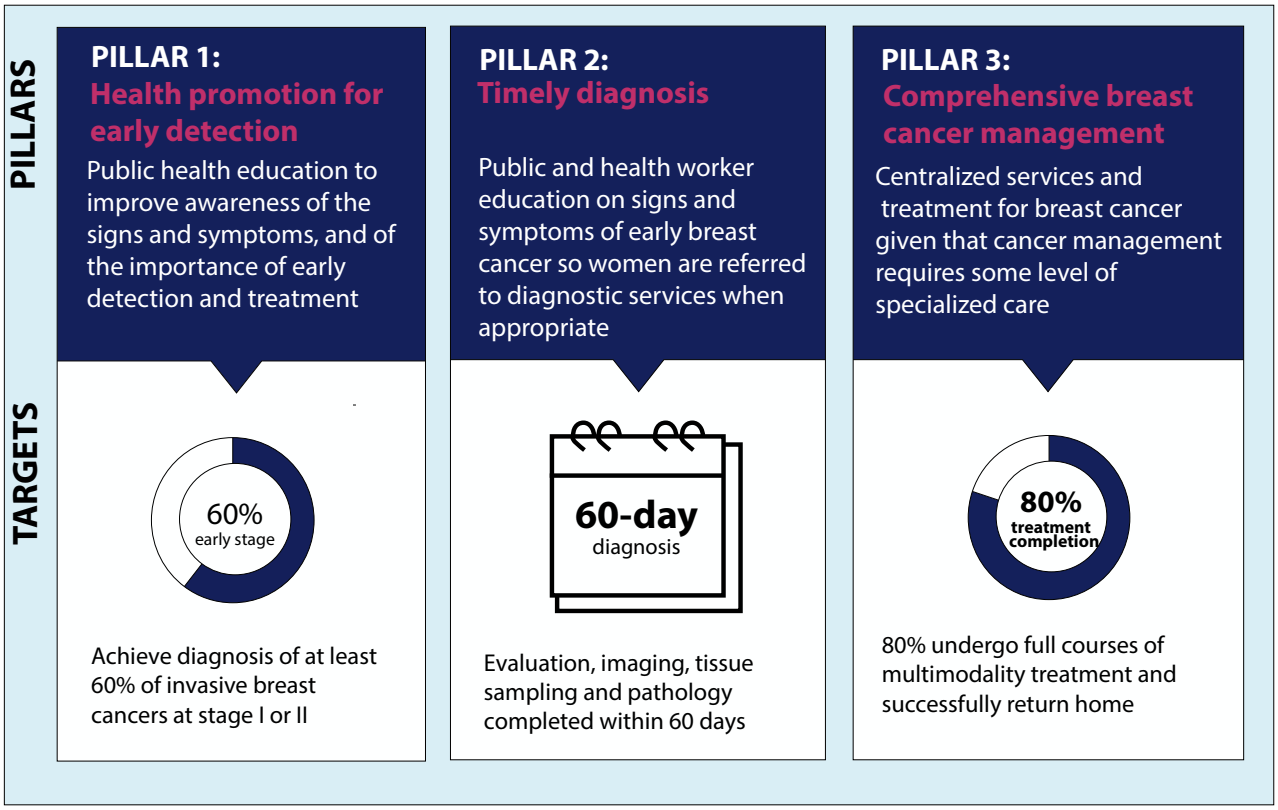


Figure 3: The three pillars of the WHO Global Breast Cancer Initiative

1.5 VISION, GOALS AND OBJECTIVES

The vision for Ethiopia is that breast health and breast cancer awareness in the community is high, women are supported in seeking help when they have breast concerns and breast cancer is diagnosed at early stages and received prompt treatment and care.

The overall goal of the 2024-2028 guideline is to provide a strategic guidance aimed at reducing breast cancer mortality in Ethiopia in alignment with the GBCI targets. The three key aims are to:

1. Provide a framework for health facilities on the provision of high quality and effective breast cancer care services at the national level.
2. Provide guidance to policymakers, managers, departmental heads, and other stakeholders on how to implement a breast cancer control program focused on shifting to early diagnosis of the disease over time.
3. Incrementally improve breast cancer management to increase survival and quality of life of patients with breast cancer.

Strategic objectives aligned with the three pillars of GBCI shape our approach and in chapter 2, key actions for the period of this guideline are described.

Strategic Objective 1:

(a) To promote breast health awareness in the community and reduce stigma of the disease by ensuring all school age children have had at least one course on common cancers including breast cancer and all women have access to information materials and community education on risk factors, signs and symptoms and ability to cure breast cancer if detected early by age 40 and

(b) To improve uptake of breast cancer early detection services to achieve the 2030 ambition of >60% of invasive cancers presented at stage I and II.

Strategic Objective 2:

(a) To strengthen diagnosis services for breast cancer (diagnostic evaluation, imaging, tissue sampling and pathology) and

(b) To establish return of a full diagnosis within 60 days for all women presenting with symptoms of concern.

Strategic Objective 3:

(a) To build quality treatment, supportive and palliative care services to achieve the 2030 ambition of >80% of breast cancer patients accessing and completing multidisciplinary treatment completion with no abandonment.

1.6 LEADERSHIP AND COORDINATION

The Ministry of Health ambition of universal health coverage (UHC) includes use of integrated health delivery platforms and primary health care systems to provide early diagnosis of breast cancer care services in Ethiopia. This will be achieved through the key principles of primary health care; equity of access; affordability; cost-effectiveness; accountability; partnerships and linkages; decentralization and leadership; and a clean, caring and competent health care environment.

Each health care level facility will be required to provide services toward the attainment of early breast cancer diagnosis through awareness and education programs, clinical breast examination (including patient initiated clinical breast examination), provision of breast radiological services (breast ultrasound (US) and mammography), US-guided core biopsy, pathology (specimen preparation and reporting), and MDT approach to breast cancer management and care.

Ethiopia has a wide based health care system (Figure 6) that is well positioned within the community. The health service is structured into a three-tier system: primary, secondary and tertiary levels of care. The primary health unit (PHCU) comprises of a health post, health centre and primary hospital. A single PHCU serves a total of 100,000 population. A general hospital serving about 500,000 population represent the secondary health care level while the specialized referral hospitals with a catchment population of 1,000,000 are labelled tertiary health care level.

In terms of breast cancer, the focus at the primary care is to ensure appropriate detection of suspicious cases and timely referral to and a primary or secondary and general tertiary level hospitals for further investigation, diagnosis and access for treatment and care. Primary care providers should also counsel patients on risk reduction such as behavioural modifications (such as smoking cessation, being physically active, and weight loss).

The health-care provider at the primary care level must have an appropriate index of suspicion and clinical skills to identify symptoms of concern and immediately referred to the higher level for confirmatory diagnosis and next steps. Primary care providers should also explain to patients that symptoms may be related to cancer and emphasize the importance of timely diagnosis and treatment.

Diagnostic tests (that may include imaging or laboratory tests), pathological confirmation of breast cancer and staging occurs at an appropriate diagnostic facility at secondary or tertiary level facilities, generally staffed by nurses and clinical officers. When discussing cancer management plans, effort should be made to include the patient's social support system and with further a second consultation. Clear steps to the tertiary level of care should be provided to minimize loss of patients to follow-up. To further reduce this risk, staff could standardize follow up contact of patients at predesignated intervals or develop a patient navigation program in the care follow up. Importantly, there is a reference manual for breast cancer management for health professionals at primary and secondary levels has been developed through a consultative process with the local technical working group and is geared to the various levels of health work care providers. This reference manual could be used also to develop a training material for health care professionals per standard manual. Maternal and child health services exist in all the health facilities countrywide, including some health posts. It would be cost effective to implement the breast health care service through these already existing platforms. The ministry of health, regional health bureaus and health partners will work in partnership to cascade training to primary and secondary levels.

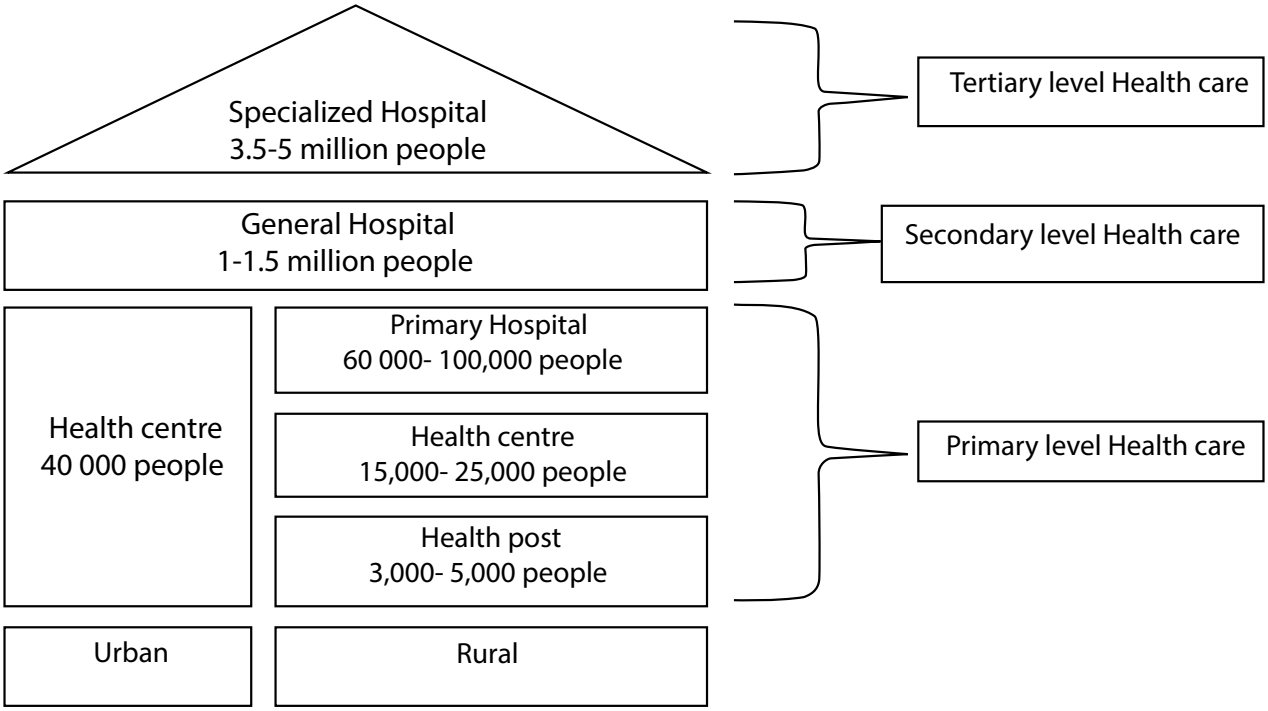


Figure 4: Ethiopian three step health tier system

CHAPTER 2: THE THREE PILLARS OF BREAST CANCER CARE

Although some reduction in risk may be achieved by improving health literacy of women and the community at large and encouraging prevention strategies, these strategies cannot eliminate most breast cancers and therefore early detection and screening together with timely diagnosis and effective treatment of early-stage tumours remains the cornerstone of breast cancer control.

2.1 PILLAR 1 – HEALTH PROMOTION FOR EARLY DETECTION

Pillar Goal: >60% of breast cancer detected at stage I and II

2.1.1 BREAST CANCER RISK FACTORS AND RISK REDUCTION

Several risk factors for breast cancer have been identified. These are described as modifiable or non-modifiable (Table 1), with associated prevention interventions. Modifiable risk factors such as obesity, harmful use of alcohol and physical inactivity can be addressed through lifestyle changes and in some high-risk cases, preventive surgery. Non-modifiable risks include hereditary and family history, previous breast pathology, high breast density and reproductive history such as early menarche and late menopause. The greatest contributions to breast cancer risk are increasing age, female gender and a family history of at least one first-degree relative or multiple family members with ovarian or breast cancer.

Table 1: Modifiable and non-modifiable breast cancer risk factors and interventions.

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/oophorectomy in selected high-risk groups
• Use of hormonal birth control methods	Secondary Prevention
• Tobacco use	• Screening
Non-Modifiable	• Early diagnosis
• Increasing age	• Chemoprevention
• Female gender	Tertiary Prevention
• Benign breast disease	• Use of selective estrogen receptor modulator medications (SERMS) and Aromatase Inhibitors (AIs) as chemoprevention in high-risk individuals
• Genetic factor (BRCA 1 or 2)	
• Family history	
• Early menarche/late menopause	
• Increased breast density	
• Previous exposure to chest wall irradiation	

2.1.2 BREAST CANCER SCREENING FOR EARLY DETECTION

Breast cancer screening aims to identify otherwise healthy women who may have as yet undiagnosed or asymptomatic cancer or pre-cancerous changes in the breast which impart an increased risk of breast cancer. Screening of women of the defined eligible age group enables early diagnosis and prompt treatment, which, if at an early stage of disease, improves prognosis and outcomes.

Globally, mammographic screening is the gold standard since it has proven to be effective in reducing breast cancer mortality in women over 40 years of age. However, it is a complex public health strategy that mandates resources for infrastructure and coordination. World Health Organization (WHO) recommends that screening programs only be undertaken when their effectiveness has been demonstrated in the local context, i.e., where resources are sufficient to finance a population-based service and the prevalence of the disease is sufficiently high to justify this investment. A recent study (1) in four Sub-Saharan Africa countries revealed that the overall prevalence of breast cancer screening was only 12.9% during the study period, ranging from 5.2% in Ivory Coast to 23.1% in Namibia, they went on to conclude that despite high breast cancer mortality rates in sub-Saharan Africa, the prevalence of breast cancer screening is low and varies across countries and in relation to factors such as education, age, health insurance coverage and household wealth index level. These results highlight the need for increased efforts to improve the uptake of breast cancer screening in sub-Saharan Africa.

In the absence of population-based mammographic screening, WHO recommends clinical breast exam (CBE), supported by measures to improve breast health awareness, especially in the target age group, accompanied by a fast-track referral and diagnosis in the case of suspicious cases. CBE is an important diagnostic method, identifying breast cancers as small as 1 cm, thus CBE skills are critical for primary care practitioners.

Male breast cancer represents between 0.5 and 1 percent of all breast cancers diagnosed each year. The incidence has been documented to be higher in Sub-Saharan Africa at 6% of all 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.

2.1.3 PUBLIC HEALTH LITERACY AND BOOSTING HELP-SEEKING BEHAVIOURS

Despite breast cancer being the most common cancer in Ethiopia, public awareness is low and help seeking is often delayed, contributing to the fact that 60-75% of breast cancer patients present at stage III and IV. This can be addressed by providing information and raising the understanding of breast cancer risk factors, promotion of breast health measures and the opportunity for early diagnosis and treatment with the general population as well as targeting women in the age group that is most at risk for breast cancer. In addition, women should be encouraged to reduce their risk of breast cancer by undertaking appropriate measures to curb the modifiable risk factors. This reduction will also contribute to their chances of developing other non-communicable disease (NCD) such as diabetes mellitus and hypertension. This guideline sets strategic objectives to boost both public awareness and improve health system responsiveness:

Strategic Objective 1: To promote breast health awareness in the community and reduce stigma of the disease by ensuring all school age children at high school and above have had

health education on common cancers including breast cancer and all women have access to information materials by age 40.

ACTION 1:

Establish school education materials to improve the breast cancer literacy of Ethiopians which introduces key concepts of risk factor reduction, breast health and early detection at the appropriate age.

ACTION 2:

Develop culturally, socially and religiously appropriate materials and conduct regular public awareness campaigns to promote knowledge in the community, introduces key concepts of risk factor reduction, breast health and early detection through CBE.

Strategic Objective 2: To improve uptake of breast cancer early detection services to achieve the 2030 ambition of >60% of invasive cancers presented at stage I and II

ACTION 1:

Develop culturally, socially and religiously appropriate information of the risk factors for and signs and symptoms of breast cancer for women and men, including educational materials on breast self-examination, knowing your own breast cancer risk and the importance of regular assessments.

ACTION 2:

Use the health extension program and family health team for implementation of CBE early detection services and integrate breast health education into existing programs, including reproductive health, NCDs, HIV-AIDS and cervical cancer screening programs at all levels of health care system. Also utilize campaign based-options such as BC awareness month.

ACTION 3:

Build the healthcare worker knowledge base on cancer breast cancer. Establish training and refresher courses for health care providers to counsel their community and patients on risk reduction such as behavioral modifications and the signs and symptoms of breast cancer as well as encouraging breast self-examination, knowing your own breast cancer risk and the importance of regular clinical breast exam.

2.2 PILLAR 2: TIMELY DIAGNOSIS

Pillar Goal: Evaluation, imaging, tissue sampling and pathology completed within 60 days

2.2.1 EARLY DIAGNOSIS OF BREAST CANCER

Cancers vary in terms of time to progression, depending on their underlying biology. Thus, health systems must be able to distinguish promptly between malignant and benign breast findings. Early diagnosis of breast cancer is intended for people who have signs and symptoms of the disease. This is distinct from cancer screening that seeks to identify unrecognized (pre-clinical) cancer or precancerous lesions in an apparently healthy target population. Appendix A-E provides supporting materials for healthcare facilities including eligibility criteria, intake cards and checklists as well as forms for consent and appointment management).

Every country that has shown a sustained decline in breast-cancer mortality rates of 2% per year or more for at least three consecutive years has achieved the benchmark of 60% of the total patient diagnosed being diagnosed as stage I/II. No country with late-stage breast-cancer detection has shown a sustained decline in breast-cancer mortality. These findings con-

vey the importance of strategies which focus on early diagnosis and prompt follow up. Key is that a cancer is staged at first diagnosis, after a complete diagnostic workup and prior to the initiation of treatment. Diagnosis at an early stage increases the chance of achieving cure.
For patients suspected with breast cancer(e.g., a lump or nipple discharge) risk assessment and evaluation of such a pathology needs to be discussed with the patient by the health care provider. This will reduce chances of the individual being lost to follow up and presenting later with advanced breast cancer that has complex treatment modalities and poor outcomes.
To establish the diagnosis, imaging (US and or mammography), fine needle aspiration cytology (FNAC) or biopsy should be done. Noting that most breast lesions that need biopsy are found to be benign (85-90%).
Early diagnosis requires effective and efficient referral systems, timely coordination of services that include imaging studies, biopsy of suspicious lesions, pathology (histology/cytology) reports, appropriate treatment and management plans. The algorithm for assessing suspected breast cancer in Ethiopia is depicted in Fig. 5.

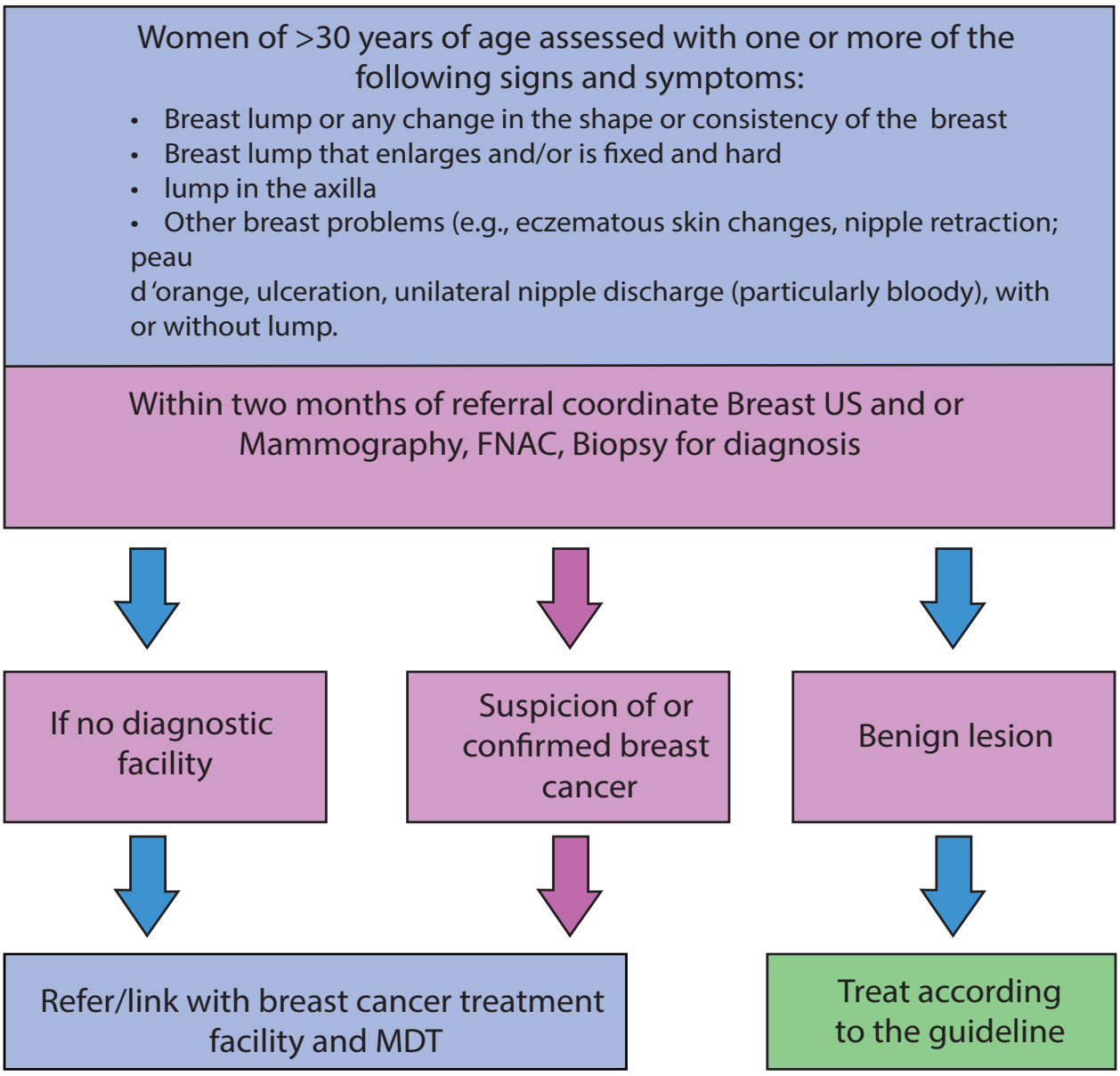


Figure 5: Stepwise workup of suspected breast lump or other symptoms for breast cancer

The achievement of prompt diagnosis within two months of referral requires the coordinated effort of radiologists, pathologists, oncologist and surgeons and depends on having an organized patient navigation system from the primary-care level facility where the patient first presents to the higher-level facility where diagnostic evaluation takes place. A diagnostic center needs to be available and accessible to conduct a work-up of breast abnormalities. By centralizing diagnostic services, quality is better maintained; however, centralized services are less convenient for patients who need to travel to access them, and this can be a source of diagnostic delay. It is therefore undesirable to locate all diagnostic services at a tertiary-care facility only, since the number of patients requiring services would be many times larger than the number of those who are ultimately found to have cancer. Secondary-level hospitals is the best location for breast diagnostic services as they are more likely to be geographically accessible, if they can secure the specialized expertise required to maintain quality.

Three early detection methods are employed in Ethiopia. The method and age at which is applied is described in Table 2, alongside purpose, key stakeholder groups that need to be involved.

Table 2: Early diagnosis methods, purpose, stakeholder group and accountability

Method	Purpose	Stakeholder Group(s)	Remark
BHA and breast self-exam from >20years of age, conducted monthly	Train in signs and symptoms, risk factors and risk reduction strategies.	Health care providers, Health extension workers (HEWs), health development army, , media, associations, , patients support group, religious leaders,	
Clinical Breast Exam from ≥30 years of age, conducted annually	Diagnostic tool and breast awareness / education tool. • CBE by a trained health provider • Physical exam of breasts and underarms • Palpation in upright and flat positions.	Health care professionals, associations, health facilities,	Women with family history and/or breast cancer at a young age, may have CBE and imaging from early age. Confirmatory diagnostic tool for women with suspicious CBE findings.
Diagnostic Imaging (US) / Mammography from >40 years of age, conducted once in 2 years	US as a diagnostic tool (mass solid or cystic); to guide biopsy; inform surgical approach and identify additional lesions in both breasts. Diagnostic mammography to evaluate extent of disease in the affected- and contralateral breast.	Health care professionals, associations, health facilities, CSO, NGOs	For high risk (see annex) women imaging studies must start at earlier age and screening with imaging annually

All the three methods mentioned above contribute to early diagnosis of breast cancer at key steps in the patient journey. Each method also has distinct an objective to achieve, guiding principles and context specific approaches. This strategy recommends how best the methods can be applied in Ethiopia to achieve the target turnaround time for breast cancer diagnosis. The following tables give a clear description of each of the methods.

Table 3: Breast health awareness (BHA)

Description	BHA is the education on risk factors and symptoms of breast cancer as well as the importance of seeking timely medical evaluation for breast concerns.
Objective	Improve knowledge and awareness about breast cancer among target populations (both the public and health professionals), and the importance of early diagnosis with appropriate subsequent management.
Principles	Responsibility: primary care physician (first point of contact), midwives, nurses, advocates/volunteers, cancer survivors and caregivers, traditional and religious leaders, civic leaders and the community at large. Education approach: This must be culturally acceptable and tailored to the educational level of key groups within the overarching target population. Representatives should participate in the design, development and implementation of educational activities. Content: Breast health awareness includes awareness on modifiable and non-modifiable risk factors, risk reduction and signs and symptoms.
Recommended steps	• Strengthen and support community outreach programs through trained health care providers and working with representatives of key populations (women, and men). • Advocate for integration of breast cancer awareness initiatives in existing health programs with all learning institutions. • Leverage internal Ministry of Health protocols and partners, such as community-based organizations (CBO) and faith-based organizations (FBO) to expand cohort of health facility and community outreach educators and volunteers. • Reach the target population with tailored, accurate, current, consistent, and evidence-based IEC materials, via a variety of channels (e.g., one-on-one communication, group discussions, health promotion talks at community venues such as clinics, markets, schools, churches, community meetings, women groups as well as through health campaigns, and social services. • Conduct social mobilization, particularly in hard-to-reach communities and with underserved groups, such as prisons and refugee camps. • Promote breast health through mass media channels, such as electronic, print and social media, billboards and street advertisement. • Improve referral at all levels of the health care delivery system: households, community, health post, health center and higher levels hospitals.

Table 4: Clinical breast examination (CBE)

Description	CBE performed by a trained health care provider involves a physical examination of the breasts and axillar through palpation, with the patient upright and lying flat.
Objective	To identify and evaluate breast complaints for appropriate triage and diagnosis.
Principles	CBE should be performed by health care providers. CBE should be offered to any woman (or man) with breast concerns or abnormalities and is the recommended early diagnosis approach in settings where screening mammography is not available. Incorporate as standard into medical and nursing school curricula and training programs such as those for reproductive health and the cervical cancer screening. Employ quality assurance measures to maintain health professional proficiency and ensure equitable and timely access these diagnostic services.
Recommended steps	• Develop CBE protocols and training materials. • Train all primary health care providers and specialists. Post information components of breast health care visits on facility walls.

Diagnostic imaging modalities such as breast US or mammography helps to distinguish benign from malignant masses, guide biopsy techniques, and inform surgical management. The common path to diagnose breast cancer (see table 6) is to begin with FNAC as an initial diagnostic modality. This will be followed by a core needle biopsy (CNB) or an incisional biopsy, which will typically be followed by an excisional biopsy. Each is described in (see table 7), noting the advantages and disadvantages of each option.

The selection of the type of the technique also depends on several factors such as size and accessibility, how suspicious the breast change looks or feels, whether there are single or multiple suspicious areas, the overall health of the patient and the personal preferences of the health provider.

Combining the diagnostic and evaluation modalities mentioned above is called the triple assessment procedure. These are:

1. Initial presentation for evaluation of a breast complaint, to include a medical history and a clinical breast examination
2. Imaging studies and biopsy of suspicious lesions
3. Pathology (histology/cytology) studies.

A lack of coordination and poor patient access to care can cause delays in definitive diagnosis and initiation of treatment, with the potential to negatively influence outcomes and survival rates.

Table 5: Diagnostic breast imaging

Description	Diagnostic breast imaging is the use of imaging tools (US or mammogram) to assess breast concerns or symptomatic palpable masses, not as a screening method among asymptomatic women.
Objective	To distinguish benign from malignant masses, guide biopsy techniques, and inform surgical management.
Principles	Evaluate the extent of disease in the affected breast and evaluate the opposite breast. The health system needs to ensure that patients referred for imaging follow through and obtain the procedure. Timely reporting of breast imaging reports to the appropriate health provider is critical to achieving optimal patient outcomes. • Diagnostic US to be used for triage of breast lumps, identifying enlarged lymph nodes and additional lesions in the same breast or opposite breast and to guide biopsy techniques and inform surgical management. • Diagnostic mammography to be used for confirmatory diagnosis following CBE or screening mammography. •
Recommended steps	• Develop and train protocols for breast imaging as appropriate at each health service level. • Establish BIRADS reporting.[22]

Table 6: Pathology

Description	Accurate clinical and pathologic work-up of a biopsy sample is required for a definitive diagnosis and should include staging and tumour receptor status (estrogen and progesterone receptors, HER2 neu/erbB2 and Ki67).
Objective	To enhance timely, accurate diagnosis and inform appropriate treatment.
Principles	The success of an effective breast health care program is directly related to the availability and quality of breast pathology. All women with a suspected breast mass require an accurate pathologic diagnosis before initiating treatment. Proper handling of the tissue during the pre-analytic phase and timely processing are essential to the quality and validity of the results. Timely reporting of breast diagnostic tests to the appropriate health provider is critical to achieving optimal patient outcomes.
Recommended steps	• Secondary level hospitals: Clinical assessment, tissue sampling , estrogen receptor (ER), progesterone receptor (PR), HER2 neu/erbB2 and Ki67 (IHCs) status depending on availability (ER assessment prioritized). Results should be recorded and communicated to the referring doctor. Regular quality assurance is recommended. • Tertiary hospitals and cancer centers/ super-specialized centers: Routine IHC testing to determine potential benefit of endocrine therapy and targeted therapy.

Table 7: Tissue biopsy techniques

Technique	Description	Advantages	Disadvantages
FNAC by a well-trained: • General practitioner • general surgeon • internist • breast surgeon or • pathologist	A small, hollow needle and syringe used to obtain cells from a palpable breast lump for cytopathologist. FNAC is not currently suitable for the evaluation of asymptomatic women without a palpable lump.	Rapid, safe and usually less painful than a surgical biopsy or CNB in women with a palpable breast lesion. In some settings used for preliminary cancer assessment, which may facilitate patient flow and assist in treatment planning.	The incidence of false negatives has been estimated to be 4–27%. Thus, the absence of cancer cells per FNAC does not rule out invasive cancer, and a tissue biopsy (large core needle or surgical) may be needed. Must be read by a trained breast cytologist.
CNB by a well-trained: • radiologist • surgeon, or • pathologist	Removal of a tissue specimen from the mass or lymph node with a hollow cutting needle (usually size 14-gauge). For specimens usually provides sufficient tissue for diagnosis. Can be conducted with stereotactic guidance (mammographic or tomosynthesis) or be US- or MRI- guided.	Lower sampling error and larger volume of tissue vs. FNAC. Pathologist able to document invasive vs. in-situ disease, grade tumour and perform tumour biomarker tests. Qualified cyto-pathologist not needed. CNB confirms benign findings at less cost, that may spare unnecessary surgical procedures.	False negative results can occur with CNB, especially if insufficient tissue is obtained.
Surgical biopsy	**A definitive diagnosis can be made, and biomarkers can be obtained on the biopsy specimen. This can either be excision biopsy (whole mass removed) or incisional biopsy (part of mass removed).**	**Provides definitive diagnosis. Often performed with local anaesthesia.**	**Higher cost as it is done in theatre.** **Requires waiting for the next available theatre space.**

Recommended Strategy	• Institutional standard operating procedures (SOPs) must be followed, including quality transfer of FNAC sample to the place where pathology service is available. • International Academy of Cytology Yokohama system of reporting applies.[23] • Reporting system of the UK NHS screening program applies (appendix F) US-guided CNB is recommended for all sites with equipment. • Incisional biopsy is recommended for facilities that do not have equipment for CNB. • Excisional biopsy is recommended for benign conditions and not for suspicious breast lesions in women above 25 years old.

2.2.2 STAGES OF DISEASE

Once cancer diagnosis has been confirmed, the patient should undergo staging to evaluate the extent of disease based on clinical features, radiological imaging, and surgical findings. Breast cancer characterization and staging is not only a critical component of diagnosis, but also required for treatment planning. There are standardized systems for describing a breast tumour: confirming non-invasive (pre-cancerous) or invasive disease, size, lymph node involvement and metastasis (cancer cells spread to other parts of the body).

The size and characteristics of a tumour and the extent of lymph node involvement can be assessed by CBE, biopsy and imaging. The degree of metastatic disease can be informed by physical examination, biopsy and imaging (chest x-ray and abdominopelvic US). The actual stage of disease (Stages I-IV) is determined by a combination of different characteristics reflected in Table 8 below.

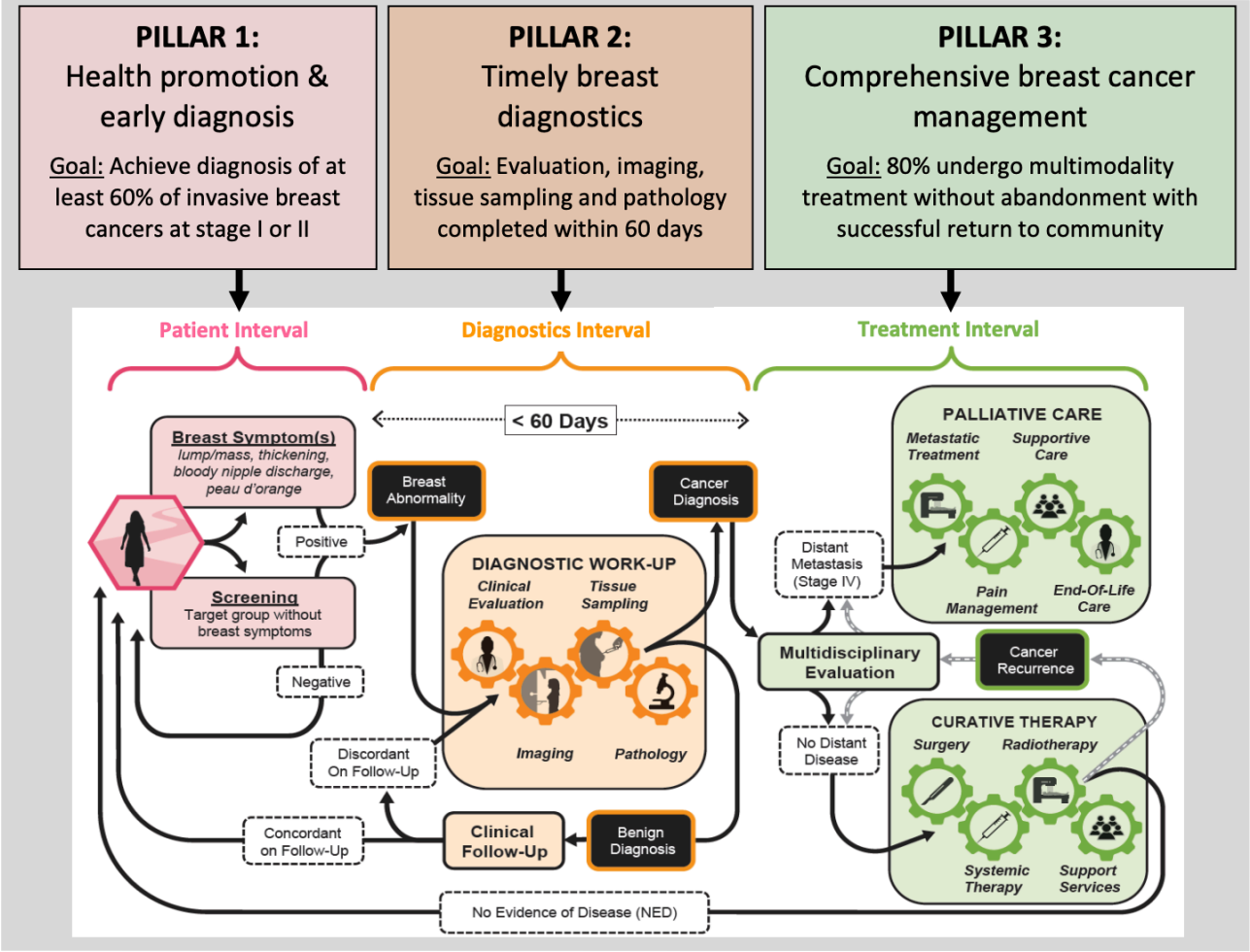
Table 8: Group staging of breast cancer

Stage 0	Ductal carcinoma in situ (DCIS)
Stage I	Invasive breast cancer with tumour up to 2cm and no suspicious axillary lymph nodes.
Stage II	Invasive breast cancer with one of the following: Tumour <2cm with spread to axillary lymph nodes; No tumour in the breast but cancer cells in mobile axillary lymph nodes; Tumour 2 to 5 cm with spread to axillary lymph nodes; or Tumour >5cm without spread to axillary lymph nodes
Stage III	Tumour has spread to axillary lymph nodes which are matted together, has spread locally to the chest wall or the skin of the breast or to infra and supra-clavicular nodes
Stage IV	Distant metastasis

2.2.2 PATIENT PATHWAY AND NAVIGATION ACROSS THE PILLARS OF ACTION

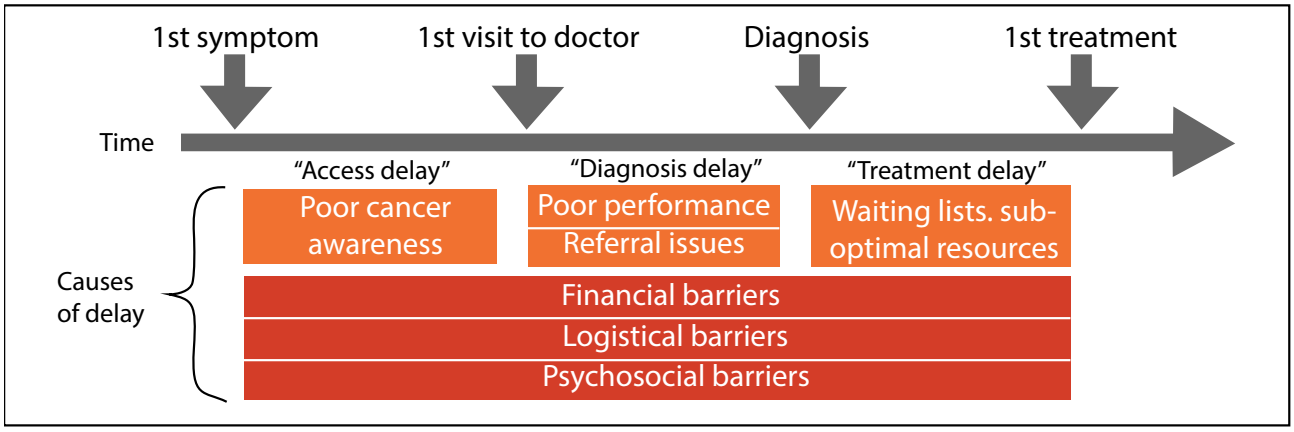
A focus on patient pathways across all pillars of action is critical as described in Figure 6 below from the GBCI, encouraging an integrated approach.

Figure 6: Patient Pathways Across the Three Pillars of Action in the GBCI



Geographical, social, and economic factors can impede the ability of patients to access breast cancer early detection, prompt diagnosis, and comprehensive treatment. Lack of knowledge about cancer and resources, fear and mistrust of medical care, distance to facilities, poor transportation infrastructure, and financial constraints are some of the challenges which individuals face and in turn contribute to disparities in breast cancer outcomes. Once patients enter the healthcare system, they can have difficulty at every step of the care continuum as illustrated in Figure 7, due to health system fragmentation and suboptimal communication among providers and between services.

Figure 7: Multifactorial causes of delay in cancer diagnosis and treatment (GBCI)



Introducing patient navigation programs is one evidence-based solution to overcoming barriers to care that individuals experience. Patient navigation is recognized as a key component of an integrated cancer system and is seen as a proactive, individualized assistance for patients and their families through an intentional process of dialogue with a patient and family to support then as they negotiate the complex processes of the cancer continuum. Patient navigation has shown effectiveness in increasing uptake of cancer early detection services and timely diagnosis as well as facilitating patient adherence and reducing acute care episodes.

There is no standardized patient navigation system in Ethiopia. However, there are institutional best practices that can be bench marked to establish national guidelines. Additionally, there is a cervical cancer referral linkage directory which can be built upon by the breast cancer program.

2.3 PILLAR 3 – COMPREHENSIVE BREAST CANCER MANAGEMENT

Pillar Goal: To achieve 80% of patients completing multimodality treatment

2.3.1 Introduction

Breast cancer is potentially curable cancer if diagnosed early and treated promptly with completion of the full course of therapy. Key elements that support this include, optimal navigation, staging, treatment decisions in MDTs and availability of quality surgery, radiotherapy and systemic therapies. While palliative care is important from diagnosis, requirements for management of complex symptoms including cancer-related pain increase with diagnosis of more advanced or metastatic disease and good coordination of all staff and communication and support of patients and their families are critical components of breast cancer management.

Effective management of breast cancer requires a multi-disciplinary approach and the development of a treatment plan that is documented and informed by a team of trained providers often referred to as a tumor board or MDT. WHO recommends as many patients as possible to start treatment within 30 days of the diagnosis.

In Ethiopia, effective implementation of these recommendation demands the creation of practical and feasible breast cancer service delivery structures interlinked with a bidirectional referral apparatus. Critically, the efforts of health-care provider at the primary care level to achieve timely referral need to be matched with well-organized care at the next level, supported by continuous communication between the two. MDTs are a key structure to facilitate this interaction.

2.3.2 SCOPE OF PRACTICE AT DIFFERENT TIERS OF HEALTHCARE

Health posts and health centers should be able to provide breast health awareness, clinical breast examination and refer clients to primary hospital of the PHCU for further evaluation. The local health providers should be trained in practical skills relevant to early breast cancer diagnosis and should be able to recognize the early signs and symptoms of the disease.
Symptomatic clients should receive a full clinical health assessment, including breast-specific history and detailed clinical breast examination by a general practitioner, health officer or midwife. These clients should then be referred to the nearest designated secondary or specialist tertiary center according to triage. Asymptomatic clients with high risk for developing breast cancer, as defined by the risk assessment tool, may be referred directly to the tertiary center. All patients should be educated on breast health care and awareness for example by a health officers or midwife.
Requirements for PHCU provision include:

- Primary health care nurses trained in breast health care.
- Protocols facilitating seamless transfer to the designated open access breast cancer unit at the district hospital level.
- Breast cancer referral forms with all relevant data (checklists and boxes) for audit and appraisal.
- Seamless clients' navigation to the next level of health care.

Table 9: Activities related to facility type

Activity	Health Post	Health center/Primary Hospital	General hospital	Tertiary Hospital
Awareness creation	X	X	X	X
Teaching self-breast examination	x	X		
Clinical breast examination		X	X	X
Referral of cases with suspicious breast abnormality for imaging and possible cytology or biopsy		X	X	
Breast and axilla surgery by trained surgeon		x	x	X
Referral for advanced treatment (advanced surgery, Radiotherapy, breast conservative therapy, chemotherapy, targeted therapies)			X	X
Do metastatic work-up – CXR and US of the abdomen			X	X
MDT or virtual consultation (VC) through responsible			X	X
All confirmed breast cancer cases discussed at MDT			X	X

The resources and level of care at secondary level hospitals can be variable between different health facilities but all provide standard management of patients with breast complaints. It is advisable that no unnecessary delay is incurred with investigations. The key responsibilities related to role is described in Table 10.
Requirements for secondary level facilities include:

- Health care professionals trained in breast health care including CBE should be available.
- Protocols facilitating seamless transfer to the next level of care should be in place.
- Mammography services should be considered at this level of care for age-eligible patents.
- Breast cancer diagnosis using Breast US/FNAC, Biopsy should be available.
- All confirmed breast cancer cases are to be discussed at MDT and staging workup completed before initiation of therapy to decide on sequence, duration, and type of treatment.
- For discipline specific activities and treatments refer to table 11.

Tertiary centers receive patients from primary and secondary health care facilities. The hospitals should be equipped with the necessary resources such as breast health care infrastructure, surgical facilities, and staffed with appropriately trained clinical expertise. These facilities equipped with a definitive diagnosis, provide staging investigations for biopsy-proven cancers, offer advanced breast surgical services, chemotherapy and radiotherapy services in line with NCCN guidelines adopted for sub-Saharan Africa. These centres should be fully functional, with MDTs, to offer comprehensive early breast cancer diagnosis, treatment and management.
Key roles in the MDT include are described in Table 11.

Requirements for tertiary level facilities include (can be within formal collaborations):

- Standardized breast cancer documentation tools (like formats, registration books, intake form, referral formats etc...).
- Image guided breast tissue sampling, histopathology, immunohistochemistry, laboratory and transport of specimens as needed.
- Timely standardized reporting (two weeks turnaround time) of specimens by the pathologist for staging and treatment decisions (including histopathology and IHC
- Follow up of patient after treatment for side effects of treatment, treatment response, disease recurrence and quality of life.
- Specific timelines for consultation after referral should be adhered to and work-up routinely completed within 45 days from presentation.
- Effective navigation of clients at the cancer care facilities
- Presence of MDT.

Table 10: Key activities by selected specialists

Radiologist	Pathologist	General Surgeon	Clinical Oncologist
Breast imaging (US /Mammography, US-guided FNAC or CNB, metastatic workup	FNAC; CNB and evaluation of biopsy specimen; Immunohistochemistry (ER, PR, ki67 and HER-2)	Present to MDT; Staging & metastatic workup; Modified radical mastectomy (MRM) for stage I / II patients; link for oncologic care.	Present to MDT ; Systemic therapy, palliative therapy; referral to radiotherapy; regular follow up of patients.

2.3.5 WORKING AS A BREAST MULTI-DISCIPLINARY TEAM

Resource-adapted MDTs are established with possible virtual communication to the next health care level. For example, there will be no MDT at the health center and primary hospital service levels, but decisions can be made at the general hospital level through telephone or virtual consultations. When the decision is for major surgical intervention, patients are referred to a higher hospital where there is a general surgeon. Further detail of the MDT quorum and engagement per health care level can be found in Appendix G.

Primary health care unit (PHCU): Primary hospital

Trained health care professionals can evaluate and order appropriate investigations. With virtual and telephone consultations, with higher level services as required, decisions can be made at the primary hospital level. Patients should be referred when the decision is for major surgical intervention, patient should be sent to a higher hospital where there is a general surgeon.

Secondary health care: General Hospital

There will be an MDT team at the general hospital consisting of the following members as a minimum requirement:

- Oncologist
- General surgeon preferably with training in breast surgery
- Radiologist
- Pathologist
- NB: If the hospital does not have a radiologist or pathologist, this competency can be covered by a professional from a tertiary-level hospital through virtual communication, referral, or transporting samples to a tertiary Hospital or a private facility.

Tertiary Hospital

Teams at the tertiary level have the required expertise to advise, manage and train other health professionals from the secondary and primary levels. MDT core members include:

- Oncologist
- General/Breast Surgeon
- Radiologist
- Pathologist
- Oncology nurses or trained nurses on breast cancer
- Optional (on-demand basis): Fertility specialist, Genetics specialist, Physiotherapist, Psychologist/Counselor

Continuation of care and follow-up at secondary facility after completion of treatment

Once breast cancer patients receive appropriate treatment at a higher level of the healthcare system, the remaining care and follow-up needs to be continued at the next lower healthcare system which is convenient for the patient and improves adherence. Each patient will be assigned a focal point. Use of the patient tracking database and the active engagement of the focal point are the keys to successful management and continuity of care.

For 2-3 years after completion of treatment, follow-up is especially important as this is the period when most of breast cancer recurrences are expected to occur. These follow-up visits must therefore take place in centers with an oncologist.

Priorities for this part of the patient journey are:

A. Timely access to quality multidisciplinary cancer treatment (surgery, radiation therapy, systemic treatment) completed with minimal abandonment. Including:
    - Multidisciplinary treatment planning based on resource-adapted guidelines.
    - Patient navigation for surgery, radiotherapy, and systemic therapy.
    - Systematic assessment to measure compliance & treatment abandonment.

B. Reintegration of women post-treatment into her community with minimal financial toxicity and social disruption, with attention to:
    - Follow-up care established at primary care.
    - Survivorship, psycho-social and palliative care available to women after treatment.

C. Palliative care and patient support services, including addressing cancer stigma.

CHAPTER 3: INFRASTRUCTURE, EQUIPMENT AND SUPPLIES

3.1 PRIORITY MEDICAL DEVICES FOR CLINICAL ASSESSMENT, CLINICAL LABORATORY AND PATHOLOGY, SURGERY, MEDICAL IMAGING AND NUCLEAR MEDICINE AND RADIOTHERAPY SERVICES

The following tables present the general medical devices required for clinical assessment and minor procedures at each health facility level. It also describes equipment and supplies that can be used for diagnosis, surgery, chemotherapy, and radio-therapy of breast cancer. Diagnostic imaging services require several utilities and services such as: water, stable electricity, installations with proper infrastructure and adequate sanitary conditions, among others, for the protection of patients, workers and the general public. Warning devices (e.g. signs, lights) to prevent inadvertent entry into controlled or supervised areas must be installed and employed. Additional design features are needed for optimal performance of diagnostic and interventional procedures in children.

Table 11: Availability of medical devices or equipment availability per health level facilities

Level of HF	Activities/ Services	Medical Devices or Equipment
Health Post	• BCa Awareness creation • CBE • Link suspect cases to a higher level	• Examination glove • Health education materials
Health Center	• BCa Awareness creation, • Clinical Breast Examination , • Link/refer suspect cases to a higher level • Virtual/verbal consultation through video call or other means of communication	• Examination Glove, • Internet access • Computer/patient tracking database
Primary Hospital	• BCa Awareness creation • CBE • Link suspect cases to a higher level • Virtual/verbal consultation through video call or other means of communication	• Examination Glove, • Internet access • Computer/patient tracking database
Secondary Hospital	• BCa Awareness creation • CBE • Referral to higher level services • Virtual/verbal consultation through video call or other means of communication • Minimal MDT/ Tumor Board • Diagnostic imaging • Pathology • Surgery	• Examination glove, surgical glove • Internet access • Computer system/patient tracking database • Dedicated MDT room • X-Ray • US • (Mammography) • CT scan • Pathology lab

	• Chemotherapy	• Functional operating theater • Bio-safety cabinet • Personal protective equipment & clothing
Tertiary	• BCa Awareness creation • CBE • referral to a higher-level services • Virtual/Verbal Consultation through Video call or other means of communication • Minimal MDT/ Tumor Board • Diagnostic imaging • Pathology • Surgery • Chemotherapy • Radiotherapy	• Examination Glove, surgical glove • Internet access • Computer system patient tracking database • Dedicated MDT room • X-Ray • US • (Mammography) • CT scan • US-guided biopsy of regional lymph and sentinel nodes • PatholoFunctional operating theater • Bio-safety cabinet • Radiotherapy machine • Personal protective equipment & clothing
Highly Specialized/ Advanced	• BCa Awareness creation, • Clinical Breast Examination , • referral for better services to a higher level • Virtual/verbal consultation through video call or other means of communication • Full MDT/ Tumor Board • Diagnostic imaging, • Pathology • Immunohistochemistry (IHC) assay, Genetic, molecular • Surgery , advanced surgery (Breast conservation and plastic reconstruction, sentinel lymph node biopsy) • Systemic therapy • Radiotherapy (external beam, Brachytherapy)	• Examination glove, • Internet access • Computer system patient tracking database • Dedicated MDT room • X-Ray • High resolution breast US • (Mammography) • CT Scan • US-guided biopsy of regional lymph and sentinel nodes • PET Scan • MRI • Pathology Lab • Functional operating theater • Bio-safety cabinet • Radiotherapy machine with External beam [Linear Accelerator (LINAC) • Personal protective equipment & clothing

CHAPTER 4: MONITORING, EVALUATION AND RESEARCH

Monitoring, evaluation and research is a process that helps assess performance, take steps to learn and respond to gaps and agree adjustments towards incremental achievement of the desired objectives. The goal is to shape current and future management of these national guidelines using appropriate existing and new mechanisms.

A National Breast Cancer Technical Working Group (NBCTWG) will be responsible for overseeing the implementation of the Performance Monitoring Plan (PMP) and associated processes and reporting. The NBCTWG will conduct periodic reviews and as required, timely update in line with current scientific standards and continuous programmatic learning.

The PMP will also be shaped by the following:

- Clearly defined and measurable (SMART) indicators
- Standard data collection tools that synergise with existing data processes and DHIS 22
- Data from population-based cancer registry database
- Clear guidelines for data management
- Effective scheduled collection of essential information
- Reciprocal data flow between all health care levels
- Generation of regular (weekly and monthly) monitoring reports

The PMP will detail the approaches to report, monitor and evaluate activities based on specific objectives linked with the Health Management and Information System and harness existing system protocols for data sharing between facilities. Analysis of the available information will be coordinated by the responsible unit at the Ministry of Health.

The key to health information system (HIS) effectiveness is routine collection of essential data and generation of regular monitoring reports. The National Breast Cancer Early Detection and Treatment Program lies under the responsibility and accountability of the NCD Case Team. Standardized national forms have been approved by the FMOH and are linked to the current district health information system (DHIS 2). The National Breast Cancer Early Detection and Treatment Program monitoring and evaluation protocol will follow the existing integrated DHIS 2 in Ethiopia, which is operational from the facility to the central level.

Health Information System at Facility Level

An adapted facility-level HIS should be used to monitor and evaluate the specific services provided at that facility, largely relying on registers to collect individual data and generate reports with aggregate data.

Documentation of services should take place daily by a trained health care provider. Information gathered from the registers will be used to calculate monthly statistics based on the program indicators. The health facility cancer focal person will be responsible to compile monthly data, analyze and report breast cancer screening and treatment performance to the health facility HIS officer. Health facility management needs to incorporate monthly analysis and review against facility level targets. In addition, the health facility HIS officer will regularly update data on DHIS 2 . If DHIS 2 is not functional, health facility HIS officers will be responsible for reporting to the Woreda (District) NCD focal person via their respective HMIS focal person.

Health Information System at Woreda

Performance targets will be agreed with the Federal Ministry of Health (FMOH). The Wore-

da NCD coordinator will be responsible for sharing these performance targets with selected health facilities in their Woreda responsible for screening all eligible women living there. Other health facilities in the Woreda are expected to refer eligible clients.

The Woreda NCD coordinators are responsible for ensuring timely reporting of early detection and treatment activities by health facilities via the DHIS 2. If the DHIS 2 system is not functional, the Woreda NCD coordinator will ensure HFs share the manual HMIS report. The Woreda NCD coordinator is also responsible in analyzing the performance of health facilities in their respective catchment area on monthly basis, reviewing this performance against agreed targets and supporting health facilities to develop performance improvement plans for gaps identified. In addition, the Woreda NCD coordinator will regularly conduct supportive supervision and quality assurance in HFs. Other responsibilities of the Woreda NCD coordinators include:

- Following the performance and reporting breast cancer early detection and treatment service conducted by non- governmental organizations and private HFs in the Woreda and,
- Ensuring distribution, continues availability and appropriate utilization of breast cancer early detection and treatment M&E tools, in the selected HFs in the respective Woreda.

Health Information System at Zone/ Sub city Level

The Zonal/ Sub city level (SC) NCD coordinator will take on the same responsibilities as above, zone-level. be responsible for ensuring that Woreda have shared the Woreda-level targets to implementing health facilities in their zone and tracking performance against target. As above the Zone/SC NCD coordinators will be responsible for ensuring timely by following the DHIS 2 report, analyzing the performance on a monthly basis, supporting development of performance improvement plans and conducting supportive supervision (SS) and quality assurance visits with high impact HFs. Based on the SS findings. the Zonal/SC NCD coordinator will be responsible in identifying best practices and identifying solutions to fill implementation gaps. In addition, Zonal Health Departments are responsible for ensuring breast cancer early detection and treatment service performance assessment is included in the regular Zonal review meetings. Other activities of Zonal/SC NDC coordinator include ensuring:

- Availability of the minimum requirement of staff and resourcing for initiation and maintaining breast cancer early detection and treatment services.
- Smooth initiation of breast cancer early detection and treatment service in new health facilities.
- Competency of newly trained HCPs by linking them with experienced service Providers.
- Post training follow up of newly trained HCPs,
- Distribution and continuous availability of M&E tools and their appropriate utilization in the health facilities.

Health Information System at Regional level

Regional NCD/MH case team focal points are responsible for ensuring Zones/SC are overseeing implementation and monitoring performance of all Woreda in their respective Zone/ SC and timely reporting of activities to FMOH. In addition, regional NCD case team/ cancer focal points will regularly conduct SS and quality assurance for health facilities by prioritizing high impact zones, woreda and health facilities and identifying best practices and solutions

to fill implementation gaps which will also inform additional responsibilities of this regional role:

- Planning and implementation of expansion of breast cancer early detection and treatment services.
- Planning and implementation of basic and refresher training related to breast cancer early detection and treatment service.
- Identifying and regularly updating a pool of trainers.
- Leading advocacy and community mobilization activities at regional, zonal and Woreda level.
- Resource mobilization and monitoring effective utilization of resources.
- Support zones in strengthening referral pathways at and between each health service level.
- Ensure breast cancer early detection and treatment service activities are included in the regular regional review meetings.
- Ensure continuous availability and appropriate utilization of M&E tools.

Health Information System at FMOH

The breast cancer focal point at the FMOH NCD/MH desk is responsible for ensuring that regional health boards (RHBs) are tracking breast cancer early detection and treatment services of all zones/SCs and monitor performance trends against their respective targets. Regular comparative analysis of the performance of the respective regions on monthly basis will support regions in optimizing their programs and developing performance improvement plans. The breast cancer focal point at the FMOH NCD/MH desk, in collaboration with RHBs, will also regularly conduct SS and quality assurance of breast Cancer early detection and treatment services.

Target setting:

This guideline sets the ambition to attain the shared goal of reducing breast cancer by 2.5% per year. Annual evaluation reports will adopt the global 60:80:60 targets and implementation plans will need to construct plans which achieve the following levers for impact incrementally in the next four years:

- Health promotion for early detection to diagnose >60% of invasive cancers at stage I or II
- Timely breast diagnostics with within 60 days
- Comprehensive breast-cancer management where >80% undergo multimodality treatment without abandonment

Implementation and Monitoring Tools for the Breast Cancer Early Detection and Treatment Program

The five main tools to be used are i) an eligibility assessment, ii) a triage and referral linkage plan, iii) a breast cancer early detection and treatment register, iv) a breast cancer early detection and treatment service reporting form and v) national program indicators. Each is described below.

Eligibility assessment, triage and referral linkage

To strengthen the linkage of eligible women from the general population to breast cancer early detection services, a Breast Cancer Early Detection Eligibility Assessment and Linkage Form (please see appendix H) supports health facilities where eligible clients are seen (such as, cervical cancer screening, family planning and maternal child health units, out-pa-

tient departments and hospital wards as well as antiretroviral therapy clinics and prevention of mother to child transmission clinics) to integrate this assessment into their schedules. This form supports a rapid eligibility assessment of the client by checking her age, family history, record of attending CBE and previous history of breast cancer.

HCPs must ensure all women of eligible age are navigated to breast cancer early detection services.

Breast cancer early detection and treatment register

The Breast Cancer Early Detection and Treatment Register is a register maintained at cervical cancer screening units and at out-patient departments. HCPs completes this paper form for each client and maintain these records. Instructions on how to use the register are included on the first page. The register has columns to capture key information, including:

- Client identification,
- Previous screening history
- Risk factors for breast cancer
- Screening modality employed
- Referral (self, facility)
- Follow up plan
- Intended treatment modalities (surgery, chemotherapy, radiotherapy, hormonal, biologic therapy)

Breast cancer early detection and treatment service reporting form

The Breast Cancer Early Detection and Treatment Service Reporting Form (Appendix XXX) summarizes the performance of breast cancer early detection and treatment service among eligible women. The reporting tool helps to generate information on Breast cancer early detection and treatment service provided for general population. The reporting format helps to generate data on breast cancer early detection and treatment services given for:

I. New clients, are defined as women aged >30 years who have been screened for the first time.
II. Repeat clients are defined as women aged >30 years who have been screened two or more times.
III. Clients that have received treatment and for which follow-up data is being provided.

The following key program indicators are included in the report. The number of secondary health care facilities providing diagnostic service including the private facilities should be noted, and per facility the following indicators are required:

- Number of CBEs performed
- Number of women screened by mammography
- Number of timely referred (noting reasons for delays)
- Number of patients diagnosed within 60 days (noting reasons for delays)
- Percentage of patients with cancer with full TNM stage
- Number of breast cancer cases detected (all stages)
- Percentage of breast cancer diagnosed at stage I and II
- Number of women receiving a treatment recommendation via an MDT
- Number of women receiving timely comprehensive treatment (i.e. treatment was initiated within 30 days of treatment decision
- Percentage that completed the intended treatment in full (noting reasons for non-completion)

National Program Indicators

The National Breast Cancer Early Detection and Treatment Program will track program-level indicators through the above-described reporting system. Appendix XXXX provides a summary of the rationale and calculation per indicator. The following key indicators will be incorporated within the DHIS 2-reported national health indicators:

Core Indicator 1: more than 60% of invasive cancers diagnosed at stage I or II

The percentage of women aged >30 years who have been screened for the first time with CBE/mammography in the reporting period. This indicator measures the volume of CBE/mammography screenings performed in the reporting period against set targets and will show the trend of shifting from first ever screens to repeat screens over time.

Core Indicator 2: Timely breast diagnosis within 60 days

The percentage of women diagnosed within 60 days of their CBE date against all women diagnosed with breast cancer within the same reporting period. This indicator provides a benchmark per region on how many women were diagnosed within 60 days in the reporting period and will also show the trend of increasing numbers of women receiving a timely diagnosis overtime.

Core Indicator 3: >80% of patients undergo timely multimodality treatment

The percentage of breast cancer patients who started comprehensive management within 30 days of the definitive diagnosis in the reporting period against all women diagnosed and treated for breast cancer within the same reporting period. This indicator measures provides a benchmark per region on numbers of patients receiving multimodal treatment and will also show the trend to timely treatment overtime.

CHAPTER 5: ADVOCACY, COMMUNICATIONS AND SOCIAL MOBILIZATION

5.1 INTRODUCTION

Community mobilization is an important component of a comprehensive breast cancer program. This section outlines the role of advocacy, and social mobilization in promoting breast cancer prevention, early detection, diagnosis and management.

advocacy and community mobilization are distinct and coordinated sets of activities, all of which have the shared goal of bringing about behavioral change. These activities complement health system improvements and help achieve breast cancer management goals by empowering communities and other stakeholders in their implementation as well as maintaining political will and financial support. They can be loosely grouped into three areas:

Advocacy primarily aims to secure the needed financial resources and change policies and guidelines by influencing stakeholders such as politicians, decision-makers and the media.

Social Behavior Change Communication (SBCC) seeks to increase awareness of breast health, influence social norms and facilitate behavior change amongst individuals, families, and communities to access breast health services.

Social mobilization is a broad-scale movement to engage people's participation in achieving a specific development goal of breast cancer early detection and prompt management by embracing the principle of community involvement, including partnerships with non-government organizations and development of supportive relationships with media partners.

5.1.1. Goal and objective of Advocacy and Social Mobilization

The following high-level goal and objectives will shape advocacy and community mobilization plans:

Goal:

To ensure allocation of adequate resource and strategic planning for optimal community engagement of the population and key partners for prevention, early detection and comprehensive treatment of breast cancer in Ethiopia.

Objectives:

1. To create and enhance recognition of community demand and foster commitments from decision-makers at all administrative levels.
2. To create and enhance awareness and ensure engagement of influencers, civil society organizations, survivors, patient groups, religious leaders and women groups to build knowledge in the community and demand for services from the target population.
3. To create and enhance knowledge and engagement on breast cancer among health workers, educators, media and communication workers.

5.2 THE MAIN ACTORS

Six main stakeholder groups have been identified. A set of targets to be achieved per stakeholder group will be an important part of the implementation plan for this guideline.

5.2.1 FEDERAL MINISTRY OF HEALTH

The Ministry of Health has the leadership role in breast cancer prevention, control, treatment and care. The Ministry is responsible for developing and providing national strategies, guidelines and training materials and is accountable for their implementation across the country. In addition, the Ministry will guide and assist regional health bureaus (RHBs) and implementing partners activities according to the national strategy and priorities, with regular communication.

Key elements of that accountability include regular communication generation of local evidence through research and surveillance, prompt adoption of international scientific recommendations and dissemination of new evidence and directions to national stakeholders. In addition, the Ministry will take steps to ensure uninterrupted supply to breast cancer screening and treatment supplies including ensuring availability of diagnostic, treatment and supportive care medicines and technologies.

5.2.2 ETHIOPIAN PUBLIC HEALTH INSTITUTE

The Ethiopian Public Health Institute (EPHI) has leadership and coordination role in developing national guidelines and standard operating procedures, overseeing the implementation of laboratory tests, and ensuring quality of service through supervision and proficiency testing. The institute has also a role in generating evidence through research and surveillance to inform the national efforts to control cervical.

5.2.3 NATIONAL TECHNICAL WORKING GROUP

Following the critical role of the National Technical Working Group (TWG) in generating this guideline, the TWG will continue as a support the FMOH and regional health bureaus (RHBs) in providing technical oversight of the implementation, monitoring, evaluation and learning to direct further implementation, including advise on new directions, global development and evidence based local data generation, analysis and recommendations. The TWG will also play key role in developing and revising, as appropriate, this national guideline, training materials, Standard Operating Procedures (SoP), program monitoring tools, job aids and IEC materials.

5.2.4 REGIONAL HEALTH BUREAUS

RHBs will have the responsibility to ensure availability, accessibility and utilization of health services. The RHBs will play a major role in planning, implementing, coordinating monitoring and evaluation of breast cancer prevention and control programs in their regions. The RHBs will set up TWGs at regional level to guide and support including adaptation of the national guideline to regional contexts.

5.2.5 HEALTH FACILITIES

Health facilities are responsible for the provision of standardized and quality healthcare (promotive, preventive and curative) as per the national standard. Health facilities should design and implement appropriate communication and advocacy strategies to increase the utilization of cervical cancer promotive, preventive and curative health services by their community. Health facilities should own the program, ensure service integration across all areas, ensure uninterrupted, sustainable and quality health service delivery. Active participation of communities and individuals in health service delivery and utilization must be coordinated within the health facilities themselves. The RHBs would ensure uninterrupted supply to cervical cancer screening and treatment program.

5.2.6 PARTNERS

In this document, “partners” is a broad definition and includes, but is not limited to: UN agencies, Bilateral agencies, international and domestic donors, NGOs, private sector, professional associations, patient associations, and Non-communicable Disease (NCD) consortia. Unless and otherwise stated, partners involved in the prevention and control of breast cancer in Ethiopia are required to operate within the framework of this guideline.

5.3 FRAMEWORK FOR BREAST CANCER ADVOCACY AND SOCIAL MOBILIZATION

To improve knowledge, it is important to first decide how best to frame the information by considering socio-cultural realities. Effective framing can help avoid social resistance. Community readiness and acceptance will help to ensure access of women to breast cancer screening and management services, which is essential to ensure program success.

To increase use of breast cancer services, an information and education plan that considers a combination of policy makers, influencers, facility, media and community-based strategies should be implemented about the benefits and accessibility of breast cancer services. Examples pf strategies and target setting are described in table 12.

Table 12: Examples of elements to be included in an advocacy and community mobilization plan

	Policy makers, partnerships and network-based	Influencers, survivors, patient support group based	Facility based	Media Based	Community Based
Strategies	Peer-reviewed articles, research reports and conferences Policy briefs Policy dialogues	Educational workshops Experience sharing Stories by people with lived experience IEC materials Social media	Education Workshops HCW-focused IEC materials Training and refresher courses Facility social media pages	Journalist workshops Press kits Stories by people with lived experience Media-focused IEC materials Social media	Public and family based education Family guide book Community conversations Institution (school, market, eder, religious centers, kebele)
Setting: Defined deliverables; SMART objectives; agreed annual targets with measurement criteria.	Political commitment in terms of policies, laws or legislation adopted; adequate resources mobilized and human capital allocated.	Number and impact of partnerships established; influencers engaged per activity;	Number and reach of iEC materails; of service-linked Health education sessions per month	Number of campaigns, their rah and impact Number of health journalists producing BCa related materials; numbers reached with media messages	Number and coverage of people/Worede reached with breast cancer messages

5.4 AN IMPLEMENTATION RESEARCH AGENDA

Evidence driven advocacy for policy- and decision-makers is the foundation to securing political commitment, mobilize resource and create efficient and responsive health system for breast cancer service delivery. While international recommendations, literature and best practice will guide work in Ethiopia, we will also use the first phase of implementation of this guideline to identify key areas for national research which will inform the next iteration and program design for breast cancer.

FIGURE 8: an integrated strategy for driving advocacy and community mobilization

Information communication for behavioral change with standardized health information, education is considered an integral part of the implementation of this national guideline. Key messages related to lifestyle change and disease education to support and empower individuals, families and communities to make informed choice and access screening and diagnosis service are critical. Hence, evidence-based advocacy, health education and information materials will be prepared, distributed, and appropriately used by all. The FMOH recommends that information and education strategies should be directed towards women who have never been screened before, and towards their partners and family members who can encourage them to solicit screening and comply with follow-up instructions. Healthcare providers should pass on clear and consistent messages in a language that is understood by the audience. Exploring their impact in terms of achieving knowledge translation and mobilizing action will be a critical element of the research agenda, shaping updates of materials as required.

Efficiency of the referral system, diagnosis and treatment services is in focus from this guideline. Exploration of the reach, coverage and integration of services as laid out in the guideline will be important as will the equity and quality of the services. The NBC TWG will therefore be tasked with prioritizing topics and developing a phased implementation research plan to accompany the implementation of this guideline in the next four years.

6. IMPLEMENTATION PLAN

Roll-out of the National Guideline for Breast Health, Early Diagnosis and Timely Breast Cancer Management in Ethiopia 2024-2028

A high-level dissemination plan

6.1 Introduction

Although there is demonstrable political will in Ethiopia for the control of Noncommunicable diseases, including cancer, there is need to sensitize leaders in all geographies and at all levels of healthcare to support the implementation of this guideline and make appropriate decisions that can lead to improvement in breast health care in the country. This dissemination plan serves as one element of the overarching implementation 2024-2028 and aims to support optimal uptake and utilization of the guidelines by all persons who would wish to advocate for improvement in breast health care in Ethiopia.

This dissemination plan states the objectives, the principles for good dissemination of the guidelines, and the key aspects to be considered for effective dissemination. It also lays out an implementation matrix with specific activities aimed at achieving each of the objectives and ultimately the intended goal/aim. The logical framework provided will enable the monitoring and subsequent evaluation of this dissemination plan to ascertain if the objectives have been attained.

6.2 Objectives

(a) To enable each target audiences to understand their own role in implementing these national guidelines and apply steps and processes relevant to fulfilling them.

b) Unite stakeholders behind the implementation of evidence-based guidelines for breast health in Ethiopia.

6.3 Principles of good dissemination

(a) Stakeholder register and engagement plan: This document permits a balanced and coordinated engagement of identified target audience. Ideally stakeholders should be involved as early as possible, and communication should be maintained throughout the project. Secondary audiences may also emerge during the process of dissemination and their further engagement should be added to the stakeholder engagement register and implementation plan.

b) Targeted information and implementation materials: Consider a range of tailored outputs for decision makers, patients, researchers, clinicians, and the public at national, regional, and/or local levels. Use simple language and consider different formats, tailored to the respective audiences.

c) Calendar for promotion and exchange: Use existing conferences, meetings and events to exchange knowledge and promote the guidelines. Establish plans and targets for partnerships, beginning with established relationships and networks.

c) Guideline Champions: identify and recruit influential opinion leaders to serve as champions for dissemination and promotion of the guideline.

d) Monitoring and evaluation of roll-out: Dissemination plans should not be limited to the first year following adoption of the guideline. Setting goals and objectives annually can improve the quality of stakeholder support for implementation and identify geographic or content gaps, which require attention.

6.4 Advocates for effective dissemination

Advocates to support the dissemination and of the guideline play a key role in maintaining

attention of the public and media as well as the focus on optimal implementation especially engagement the community and empowering women to harness their right to access breast cancer information and early detection, diagnosis and treatment services.

- Patients, survivors, and caregiver/families
- Civil society, community-based organizations and faith based institutions
- Community leaders
- Healthcare practitioners (nurses, physicians, community and volunteer health workers) at all levels of healthcare
- Professional bodies (breast health societies, surgeon associations, public health associations)
- Policy makers at all levels
- Media at all levels
- Academia

6.5 National breast health forum

Establishing an umbrella organization or forum to engage all stakeholders supports the collaborative approach and facilitates an annual exchange of implementation results, exchange of best practice and co-development of new solutions and innovation. The National Breast Cancer Technical Working Group could provide the initial oversight until an independent governance and terms of reference are established. Regional breast health forums could provide a platform for multistakeholder engagement that supports and assesses role out with the ability to report to the national forum annually.

6.6 High-level Dissemination Matrix

Dissemination objective 1: To enable each target audiences to understand their own role in implementing these national guidelines and apply steps and processes relevant to fulfilling them.								
Activity	Target audience	Methods of delivery/work	Responsible persons	Timeframe				
				Y1	Y2	Y3	Y4	Y5
1.1. Hold regional advocacy training of trainer's workshops for targeted audiences and dissemination partners, with action plans per region.	• NGOs • Health workers • Media • Patients and survivor advocates	• Power point presentations • Case presentations • Facilitated group work • Open discussion sessions with Q&A • Training assessment for change of knowledge (pre/post-test)	• Training facilitators • TWG	X	X			
1.1. Hold orientation meetings with policy and/or decision makers and establish a national breast health forum (BNHF).	• Legislators • District leaders • Local Govt councilors • Hospital Mgt.	• Power point presentations • Open discussion with Q&A • Action planning for each category	• Facilitators • TWG • NBHF	X	X	X	X	X
1.2. Conduct field support supervision (SS) to regions and woredas	• All trained staff	• Woreda and regional -level meetings • Data collection aligned with roll-out M&E plan • Review of activity reports, establish best practice	• TWG • NBHF	X	X	X	X	X

Dissemination objective 2: Unite stakeholders behind the implementation of evidence-based guidelines for breast health in Ethiopia.								
Activity	Target audience	Methods of delivery/work	Responsible persons	Timeframe				
				Y1	Y2	Y3	Y4	Y 5
2.1. Distribute copies of the National Guideline for Breast Health, Early Diagnosis and Timely Breast Cancer Management in Ethiopia using multimedia.	• Launch event • All trained participants and key stakeholder groups • All leaders at each health level	• Media release with FMOH • Print / online options • Disseminate at regional trainings and key meetings	• TWG • NBHF	X	X			
2.2. Review woreda action plans and provide comments for refinement and for effective implementation.	• All trained participants and key stakeholder groups	• Distribute action plans among training facilitators for input / review • Brainstorm on agreed on areas of improvement • Align all district action with one consolidated national roll-out plan	• Training Facilitators • TWG • NBHF	X	X			
2.3. Facilitate creation of district breast health forum, for ongoing assessment of roll-out and identification of barriers, facilitators and best practices.	• All trained participants and key stakeholder groups • Focal point per region	• Meetings and dialogues • Defining roles and responsibilities • Terms of reference for the district breast health forum and linkage to agenda item in NBHF	• All trainers and focal points • TWG • NBHF	X	X	X		

6.7 Monitoring and Evaluation – The Logical Framework

	Description / summary	Indicators	Means of Verification	Risks / assumptions for success
Objective 1	To enable target audiences, understand and apply set steps and processes in advocating for breast health care in Ethiopia.	• Number of regions/districts using the guidelines to plan and roll-out breast health campaigns	• Comparison between trained and untrained districts within the region • Activity reports	• Variable availability of funds for campaigns.
	1.1. Hold orientation meetings with policy and/or decision makers and establish a national breast health forum (BNHF).	• Number of orientation meetings held • Number of policy-decisionmakers engaged • BNHF	• Attendance record • Training reports • Post-training engagement assessment	• All trainers conduct good quality training • Participants apply learning in a timely manner
	1.2 Hold breakfast and/or orientation meetings with policy and/or decision makers	• Number of leaders who attended orientation meetings • Number of orientation meetings held	• Attendance and meeting record • Post-meeting engagement assessment	• Orientations are effectively conducted Leaders put to practice the knowledge receive • Funding available for implementation is available
	1.3 Conduct field SS to district trainers and address any regional gaps.	• Number of districts with focal points • Number of districts visited • Number of trainers who raised gaps/improvements	• Field visit reports	• Resources are available to support the field visits • District participants available for SS

Outputs	• 5 districts from each region attend training with ten participants from each district • Up to 50 leaders from each region oriented in breast health • 25 districts visited and provided with SS			
Outcomes	• Improved understanding of breast health issues • Demonstrable ability to use the guidelines and execute promotional campaigns	• Pre and post training assessment results show increased knowledge among participants	• Training reports knowledge assessment analysis findings	• Trainings are delivered effectively • Districts get budget support to implement some activities
Objective 2	To increase stakeholder motivation to use and apply evidence-based guidelines for breast health in Ethiopia.	• Number of individuals; stakeholder types and institutions involved	• Activity reports • Record supporting statements	• N/A
Activities	2.1. Distribute copies of the breast health advocacy guidelines to the target audience.	• Number of printed guidelines distributed	• Copies of printed guidelines • Record of districts signing for the copies received	• Resources are available to support printing and distribution
	2.2. Review district action plans and provide comments for refinement and for effective implementation	• Number of district action plans reviewed and refined	• Copies of district action plans	• Districts give time to develop action plans • Facilitators avail time needed to review district action plans
	2.3. Facilitate creation of district breast health forums	• Number of districts with breast health forums created and operating	• Copies of meeting minutes	• Stakeholders are motivated to run the forum • Resources for forum activities are available

Outputs	• Up to 100 copies of the guideline distributed • Up to 25 district action plans reviewed and refined for implementation • Up to 25 district BHF in operation • NBHF established			
Outcomes	• Increased engagement and share of voice for breast health care in the country	• Districts increasing budget requests for breast health activities	• District quarterly health budgets • Tracking over four years	• District leaders are supportive of breast health care activities

APPENDICES

Appendix A: Eligibility criteria

I. Eligibility Criteria

1. Is the age of the client above 30 years?
   Yes □ No □
2. Does the client have a family history of BCa?

   Yes □ No □

3. Has the client been screened for BCa in the past year?
   Yes □ No □

4. Has the client been treated for BCa in the past year?

   Yes □ No□

II. Is the client eligible for BCa screening?

   Yes □ No □

NB:

- If the answer is, Yes for Q# 1 and No for Q# 2, 3 &4. The client would be eligible for screening on this visit.

- All eligible clients for BCa early detection and management to be linked to cancer screening unit (preferably through escorted linkage).

……

Appendix B.1: Breast cancer early detection intake form (at primary and secondary level), including signs and symptoms checklist

Part I: Sociodemographic profile			
S/N	Question	Response	Skip
101	Date of visit	_____ (GC)	
102	Age of the woman	_____ (years)	
103	Marital Status	1. Married 2.Single 3.Divorced 4.Widowed	
104	Region/city of current residence		
105	Woreda	_____ (sub city & woreda no.)	
106	Phone number	_____	
Part II: Risk factors for breast cancer			
201	Family history of breast cancer	1. Yes 2. No →	203
202	If yes to question #201, which family relative?	1. First degree 2. Second degree 3. Third degree 4. Others _____	
203	History of oral contraceptive use (OCP)	1. Yes 2. No →	204
204	If yes to question #203, for how many years/months?	_____ (years/months)	
205	Age at menarche (first menses/period)	_____ (years)	
206	Age at first delivery (Delivery after 28 weeks gestation regardless of outcome (in years))	_____ (years)	
207	Parity (Number of births after 28 weeks' gestation regardless of outcome)	_____	
208	Number of abortion (Loss of pregnancy before 28 weeks gestation)	_____	
209	Average duration of breastfeeding	_____ (months)	
210	Age of menopause	_____ (years)	
211	Drinking alcohol	1. Yes 2. No	
212	Smoking cigarette	1. Yes 2. No	
213	Regular exercise	1. Yes 2. No	
214	Co-morbidity	1. DM 2. HTN 3. HIV 4. Others_____	

215	Previous breast Surgery	1. Yes 2. No	If yes 216 and 217
216	Type of surgery	Specify	
217	Date and result of surgery	__ /__ /__ (dd/mm/yy) result specify_____	

Part III: Presenting symptoms		
	Symptoms	Duration
301	Asymptomatic	
302	Which side is affected 1. Right 2. Left 3. Bilateral	
303	Breast lump	
304	Breast pain	
305	Nipple discharge	
306	Ulceration	
307	Axillary swelling	
308	Weight loss (specify in kg)	
309	Who discovered the above symptoms 1. Self 2.Spouse 3.Health care provider	
310	Symptoms Suggestive of metastatic disease 1. Cough 2. Abdominal swelling 3. Jaundice 4. Mental status change 5. Bone pain(mention the site) _____ 6. Others(specify)____	
311	Other Complaints (specify)	

Part IV: Physical examination			
401	Height	_____ (meters)	
402	Weight	_____ (kgs)	
403	Blood pressure	_____ (mmHg)	
404	Breast symmetricity	1. Symmetric 2. Asymmetric	

405	Right breast inspection	fullness	1. Yes 2. No	Depict on breast figure
		Abnormal discoloration	1. Yes 2. No	
		Venous distention	1. Yes 2. No	
		Rashes	1. Yes 2. No	
		Visible lump	1. Yes 2. No	
		Retraction	1. Yes 2. No	

		Edema	1. Yes 2. No		
		Axillary mass	1. Yes 2. No		
		Scaly nipple	1. Yes 2. No		
406	Left breast inspection	fullness	1. Yes 2. No		Depict on breast figure
		Abnormal discoloration	1. Yes 2. No		
		Venous distention	1. Yes 2. No		
		Rashes	1. Yes 2. No		
		Visible lump	1. Yes 2. No		
		Retraction	1. Yes 2. No		
		Edema	1. Yes 2. No		
		Axillary mass	1. Yes 2. No		
		Scaly nipple	1. Yes 2. No		
407	Right breast palpation	Asymmetric thickening	1. Yes 2. No		Depict on breast figure
		Axillary LAP	1. Yes 2. No		
		Supra/infraclavicular LAP	1. Yes 2. No		
		Mass	1. Yes 2. No		
		Size (longest dimension)	_____ (cm)		
		Consistency	1. Soft 2. Firm 3. Cystic 4. Hard		
		Tender	1. Yes 2. No		
		Mobility	1. Mobile 2. Restricted 3. Fixed		

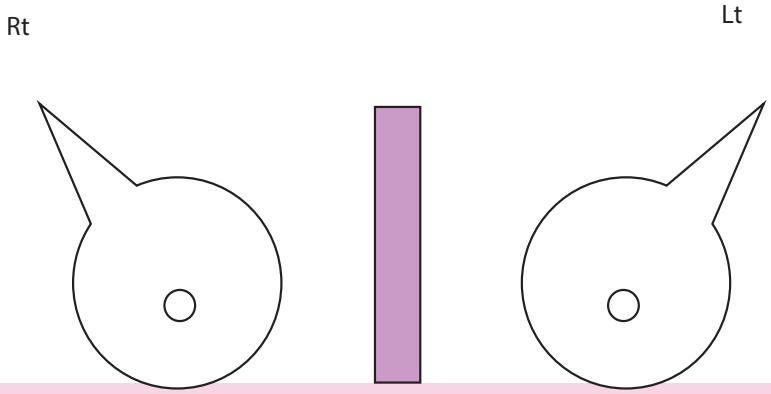
<table>
<tr><td>408</td><td>Left breast palpation</td><td><table>
<tr><td>Asymmetric thickening</td><td>1. Yes
2. No</td></tr>
<tr><td>Axillary LAP</td><td>1. Yes
2. No</td></tr>
<tr><td>Supra/infraclavicular LAP</td><td>1. Yes
2. No</td></tr>
<tr><td>Mass</td><td>1. Yes
2. No</td></tr>
<tr><td>Size (longest dimension)</td><td>_____ (cm)</td></tr>
<tr><td>Consistency</td><td>1. Soft
2. Firm
3. Cystic
4. Hard</td></tr>
<tr><td>Tender</td><td>1. Yes
2. No</td></tr>
<tr><td>Mobility</td><td>1. Mobile
2. Restricted
3. Fixed</td></tr>
</table></td><td>Depict on breast figure</td></tr>
<tr><td>409</td><td>Other systems findings</td><td></td><td></td></tr>
<tr><td colspan="4">Part IV: Diagnosis data</td></tr>
<tr><td>501</td><td>Abnormality detected during PE</td><td>1. Yes
2. No →</td><td>503</td></tr>
<tr><td>502</td><td>Clinical suspicion</td><td>1. Fat necrosis
2. Fibroadenoma
3. Mastitis
4. Breast cancer
5. Colloid tumor
6. Breast cyst
7. Others _____</td><td></td></tr>
<tr><td>503</td><td>Plan/recommendation (multiple response possible)-could be at referral</td><td>1. US
2. Mammography
3. FNA cytology
4. Follow-up at 6 months
5. Follow-up at 1 year
6. Minor surgery
7. Others _____</td><td></td></tr>
<tr><td>504</td><td>Reason if 'follow-up at 6 months' in 503.</td><td>_____</td><td></td></tr>
</table>

Appendix B.2: Breast cancer screening intake form (at secondary and tertiary level)

Part I: Diagnosis data			
101	US diagnosis	1. Suspected Fibroadenoma 2. Cyst 3. Ductal ectasia 4. Others _____	
102	BIARDS category of US	_____	
103	Chest x-ray: Metastasis	1. Yes 2. No	
104	Abdominal US: Metastasis	1. Yes 2. No	
105	FNAC finding	1. Malignant 2. Benign 3. uncertain	
106	If malignant in #409	1. In situ carcinoma 2. Cancer 3. Phyllodes 4. other	
107	If benign in #409	_____	
108	Mammography diagnosis	1. Asymmetric breast tissue 2. Microcalcification (needs histology) 3. Asymmetric density 4. Architectural distortion 5. Adenopathy 6. Others _____	
109	Mammography BIRADS category	_____	
Part II: Histopathology/pathology staging			
201	Tumor size	_____	
202	Tumor type	_____	
203	Tumor grade	_____	
204	Total number of lymph nodes	_____	
205	Number of positive lymph nodes	_____	
206	TNM and group stage		
Part III: Treatment Procedure			
301	Surgery	1. Yes 2. No	

302	Surgical procedure	1. Lumpectomy 2. Lumpectomy with axillary dissection 3. Breast conserving surgery 4. Simple mastectomy 5. Toilet mastectomy 6. Modified radical mastectomy 7. Others _____	
303	Radiotherapy	1. Yes 2. No	
304	If yes to #303	1. All breast with regional node 2. Chest wall with regional node 3. Others _____	
305	If yes #303-dose in Gy and fractionation	Specify	
306	Chemotherapy	1. Yes 2. No	
307	If yes to #306	1. Adjuvant 2. Neoadjuvant 3. Palliative 4. Others _____	
308	If yes to #306	Name Cycle Dose	
309	Hormonal therapy	1. Yes 2. No	
310	If yes to 309	Name Dose Duration	
Part IV: Follow-up and referral			
401	Referred to other facility	1. Yes 2. No →	403
402	Reason for referral	1. US 2. Further investigation and management 3. Others _____	
403	Any further comment	_____	

Figure: LGS (use the pictorial representation)



Part V: Evaluation of breast Cancer Patients After Completion all the Planned Treatments Vital status: Alive____ Dead (date of death)_____								
Complaints (with grade 1-4 if applicable)		Date						
Vomiting								
Diarrhea								
Dysphagia								
Chest pain								
Shortness of breath								
Skin desquamation	Moist							
	Dry							
Symptoms suggestive of recurrence(locoregional/distant)	Breast Lump							
	Axillary lump							
	Bone pain							
	Cough							
	Mental status change							
	Supraclavicular LAP							
Nutritional evaluation								
Psychological evaluation								
Other complaints (specify)								
P/E (Pertinent)								
Investigations (if needed)								
Assessment (using RECIST criteria)								
Plan								
Next appointment								
Evaluator's name and Signature								

Appendix C: Consent form

የካንሰር ህክምና ለመውሰድ የመስማሚያ ቅጽ

እኔ_____የተባልኩግለሰብተገኝብኝየ_____ካንሰርምክንያትበሃኪሜየካንሰር (ኬሞቴራፒ፣ የጨረር ፣የቀዶ ህክምና እና የሆርሞን) መውሰድ እንዳለብኝ ተነግሮኛል፡፡ በዚህም ---------- ጥቅም የጐንዮሽጉዳት መደረግ ስለሚገባቸው ጥንቃቄዎችና ስለ አወሳሰዱ በቂ ገለፃ ከተደረገልኝ በኋላ ለመውሰድ መስማማቴን በፊርማዬ አረጋግጣለሁ፡፡

የታካሚስም_____

ቀን _____

ፊርማ _____

ምስክሮች

ቤተሰብ/ አስታማሚስምናፊርማ

1. _____

መድሀኒቱንየሰጠውጤናባለሙያስምናፊርማ

1. _____

Appendix D: Appointment Card

FRONT OF THE CARD:

Medical Record Number/UAN: _____/_____-Serial Number: _____

Name_____

Age: ____

Address: _____

Health facility Name: _____ Region: _____ City/Town: _____

Date of First Visit to Cx Ca screening unit: _____

Date of Appointment	Signature of Provider (if seen on the appointment date)

Note: Do not forget to bring the appointment card with you when you visit the facility for follow up. It is important for your health that you come on your appointment date.

Appendix E: Appointment calendar

Monday, ----------					
SN	Name	MRN	Attendance	Action Taken	Outcome
1					
2					
3					

Tuesday, ----------					
1					
2					
3					

Wednesday, ……..					
1					
2					
3					

Thursday, ----------					
Serial No.	Name	MRN	Attendance	Action Taken	Outcome
1					
2					
3					

Friday, ----------					
1					
2					
3					

Saturday, ----------					
1					
2					

Instruction for appointment calendar:

1. Name- write name of the client.
2. MRN: Write Medical Record Number.
3. Attendance: Write "√" if the clients attend as per the appointment or "X" if the client did not attend.
4. Action taken: For those who did not attend write "Telephone call" if the missed appointment client is contacted through phone and/or write "Home Visit" if Peer educator/other team members have contacted the missed appointment client using home visit. If he/she is not contacted at all due to lack of address or wrong address, write "Not contacted".
5. Outcome: Write the outcome of action taken for those clients who did not attend.

- Return to care
- Refused to return to care
- Seen in other HF
- Died
- Unknown

Appendix F: Reporting System

Appendix G: Summary scope of practice for early detection, diagnosis and treatment per health care level

Primary health care unit (PHCU):

Health Center - There will be no MDT at the health center. The responsible health officer will evaluate and refer the patient to the primary hospital. Consultation can be made with a surgeon or oncologist virtually.

Primary hospital - There will be no MDT at the primary hospital. The responsible health officer can evaluate and order appropriate investigations. With virtual and telephone consultations decisions can be made at the primary hospital level. Patients can be referred when the decision is for major surgical intervention, patient should be sent to a higher hospital where there is a general surgeon. CNB or Incisional/excisional biopsy can be done by a general practitioner with appropriate experience or training. Modified radical mastectomy including axillary dissection can be done by a trained surgeon.

Secondary health care: General Hospital - There will be an MDT team at the general hospital consisting of the following members:

- Oncologist, or (Internist after short training on breast Ca systemic management)
- General surgeon preferably with training in breast surgery
- Radiologist
- Pathologist
- NB: If the hospital does not have a radiologist or pathologist, this can be covered by a professional from a tertiary-level hospital through virtual communication, referral, or transporting samples to a tertiary Hospital.

Tertiary Level, Referral Hospital - The team at the tertiary level has all the expertise to manage and train other health professionals from the secondary and primary levels. MDT core members include:

- Oncologist
- Breast surgeon
- Radiologist
- Pathologist
- Breast care nurse
- Oncology nurse
- Optional (needed on-demand basis): Plastic surgeon, Fertility specialist, Genetics specialist, Physiotherapist, Psychologist/Counselor

Appendix H: Comprehensive Baseline Assessment Checklists for the BCa Management Program

Region: _____Zone_____ Town/SC: _____Date of Assessment conducted _____

Assessing Team members				
Name of Person conducting the assessment	Organization	Position	Contact address(Telephone)	Contact Address (email)
1.				
2.				
3.				
RHB / Zone /Sub city/Facility Team contacted				
Name of contacted Person in the site supervised	Health Facility Name	Position	Contact Address (Telephone)	Contact Address (email)
1.				
2.				
3.				

Objective of the Assessment:

1. To assess the status of BCa early detection & management program implementation at RHB, Zone/Sub city & HF level
2. To review data on BCa screening & management performance activities at RHB, Zone/Sub city & HF level
3. To develop PIP on the identified gaps & provide focused mentorship at the visited HFs &above site support

Section I: RHB /Zone /Sub city level Assessment			
1.Leadership, planning and coordination on BCa early detection & management			
Sr. no.	Activities / indicators	Availability	Remark /gaps Identified
1.1	Does the RHB have plan on BCa early detection & management activities? Check	Yes No	
1.2	Is BCa coordinator/focal person assigned at RHB	Yes No	
1.3	Does the RHB have facility level target for BCa early detection & management? Shared to the HFs? Check	Yes No	
1.4	Is BCa early detection & management review meeting conducted? (Separate or integrated in the Regional RM) , check minute	Yes No	
1.5	Is BCa early detection & management mentorship support integrated in the regional mentorship platform? Check mentorship checklist or report	Yes No	
1.6	Are demand creation activities on BCa early detection & management being conducted by RHB? how?	Yes No	
1.7	Total number of facilities with BCa early detection & management service in the region?		
2. Trainings, National Guideline, PSTs, and other tools availability			
2.1	Is National guideline for BCa early detection & management available?	Yes No	
2.2	Is Training manual for BCa early detection & management available?	Yes No	
2.3	Are BCa early detection & management PSTs (E.g. Flow chart, CxCa management algorithm, cue card etc.) available ?	Yes No	
2.4	Are IEC /BCC materials available and distributed?	Yes No	
2.5	Is Training manual for mammography available?	Yes No	
2.6	Are HCWs from the region attended TOT trainings provided by MOH on (write number trained)	Yes No	
2.7	Is Basic training provided on CBE (write number trained)	Yes No	
3. BCa early detection & management service monitoring & evaluation mechanism at RHB level			
3.1	Is there M&E system from facility to RHB level?	Yes No	
3.2	If yes, to 3.1, mention the reporting		

	flow?		
3.3	Is BCa early detection & management Register available?	Yes No	
3.4	Is BCa early detection & management monthly reporting format being available (Both DHIS and DATIM format)	Yes No	
4. Partners support on BCa early detection & management			
4.1	List of partners supporting the regional BCa early detection & management activities including they focus and level of support		
4.2	Any other support needed.		

Section II: HF level assessment			
1. Leadership and coordination on BCa early detection & management			
Sr. no.	Activities / indicators	Availability	Remark /gaps Identified
1.1	Is BCa early detection & management service available in the HF? Currently being provided?	Yes No	
1.2	Does the HF have plan on BCa early detection & management activities? Check	Yes No	
1.3	Is BCa early detection & management focal person assigned in the HF?	Yes No	
1.4	Does the HF have facility level target for BCa early detection & management ? Check	Yes No	
1.5	Does the HF team receive mentorship from an external body on BCa early detection & management service? Check feedback	Yes No	
1.6	Did you review BCa indicators on monthly PRM /PMT? Check minute	Yes No	
1.7	Are demand creation activities on BCa early detection & management being conducted in the HF? How?	Yes No	
2. Trainings, National Guideline, PSTs, and other tools availability			
2.1	Is there a certified trained staff in BCa early detection & management, mainly for CBE? If yes, # of trained staffs currently available for each training	Yes No	
2.2	Is National guideline for BCa early detection & management available?	Yes No	
2.3	Are BCa early detection & management PSTs (E.g.? Flow chart, management alogrithm, cue card etc.) available?		
2.4	Are IEC /BCC materials available and utilized?	Yes No	
2.5	Are all formats available in the HF? Intake forms, pre BCa screening and linkage form, consent forms etc.	Yes No	
3. BCa Service Monitoring & Evaluation Mechanism			
4.1	Is BCa early detection & management Register available?	Yes No	
4.2	Is Bca monthly reporting format available?	Yes No	
4.3	Is BCa counselling tracking tool available and being utilized?	Yes No	
4.4	Does the facility review Bca Program performance on regular basis?	Yes No	
4.5	Does the facility submit (Monthly & Semi-annual) BCa program reports regularly?	Yes No	

Appendix I: HF BCa Early Detection & Management Performance Data Reporting & Review Template

Indicators/ Measures	Performance	Achievement # (%)	Remark
# Women aged > 30 years			
# Counselled about BCa early detection and management			
# Eligible for BCa screening			
# CBE done (total)			
# Breast abnormality detected			
# Refereed for diagnostic workups			
# women with definitive BC diagnosis			
# of women diagnosed at stage I and II			
# of women referred for BC treatment			

Section IV. Identified gaps/challenges and action plans developed for Improvement

Focus Area	Identified Gap	Proposed action item	Responsible person	Timeline

Appendix G: Performance indicator calculation support

Indicator1 – Core	Breast cancer diagnosed at stage I or II
What it measures?	Percentage of women aged >30 years who have been screened for the first time with CBE/mammography in the reporting period. This monitoring indicator measures how many CBE/mammography screenings were performed in the reporting period against target of women aged above 30 years.
Rationale	Program managers should aim to achieve more than 60% of early breast cancer diagnoses(stage I and II) during the reporting period.
Numerator	Number of women aged above 30 screened with CBE/mammography
Denominator	Number of women aged above 30 years in the population (HF/ Woreda Target)
Data source	The numerator should be collected through the HIS (facility level breast cancer register); the denominator should come from the Woreda based target
Frequency	Monthly
Proposed target	Woreda should share the Woreda level Annual target to the respective selected breast cancer early detection and treatment HF.
Disaggregation	Numerator: by Screening type (CBE and mammography), By outcome CBE(any lamp); by mammography) any suspicious for breast cancer)

How to calculate the screening rate

Total screening rate =

$$\frac{\text{total \# first screened CBE/mamo.}}{\text{\# of the target population for a specific place (HF/ Woreda) in the reporting period}} \times 100\%$$

NB: this indicator can further be desegregated by screening modalities

% first screened by CBE=	% first screened by mammography =
$\frac{\text{total \# screened with CBE}}{\text{Total \# Number of women aged above 30 years in the population./facility (HF/ Woreda Target) in the reporting period}} \times 100\%$	$\frac{\text{total \# screened with mammography}}{\text{Total \# Number of women aged above 40 years in the population (HF/ Woreda Target) in the reporting period}} \times 100\%$

Indicator1 – Core	Timely breast diagnosis within 60 days
What it measures?	Percentage of women diagnosed within 60 days. This monitoring indicator measures how many women were diagnosed within 60 days in the reporting period against all women diagnosed with breast cancer within the same reporting period.
Rationale	Program managers should aim to achieve all diagnostic workups to be completed within 60 days
Numerator	Number of women diagnosed within 60 days
Denominator	Number of women diagnosed with breast cancer within the same reporting period
Data source	The numerator and denominator should be collected through the HIS (facility-level breast cancer register)
Frequency	Monthly
Proposed target	Woreda should share the Woreda level Annual target to the respective selected breast cancer early detection and treatment HF.
How to calculate the timely diagnosis	
Total screening rate = $\frac{\text{total \# of women diagnosed within 60 days.}}{\text{\# of women diagnosed with breast cancer within the same reporting period}} \times 100\%$ NB: this indicator can further be desegregated by basis(modalities) of diagnosis confirmation(FNAC, CNB, incisional biopsy, excisional biopsy)	

Indicator1 – Core	>80% undergo timely multimodality treatment
What it measures?	Percentage of breast cancer patients who received comprehensive management. This monitoring indicator measures how many women started comprehensive management within 30 days of the definitive diagnosis in the reporting period against all women diagnosed and treated for breast cancer within the same reporting period.
Rationale	Program managers should aim to achieve more than 80% of breast cancer patients receiving timely multimodality treatment
Numerator	Number women started comprehensive management within 30 days of the definitive diagnosis
Denominator	Number of women diagnosed and treated for breast cancer within the same reporting period
Data source	The numerator should be collected through the HIS (facility level breast cancer register); the denominator should come from the Woreda based target
Frequency	Monthly
Proposed target	Woreda should share the Woreda level Annual target to the respective selected breast cancer early detection and treatment HF.
How to calculate the timely multimodality treatment	
Total treatment rate = $\frac{\text{total \#of women started comprehensive management within 30 days of the definitive diagnosis.}}{\text{\# of women diagnosed and treated for breast cancer within the same reporting period}} \times 100\%$ NB: NB: this indicator can further be desegregated by type of treatments(surgery, chemotherapy, radiotherapy, hormonal and biologic therapy)	

Appendix H: Equipment

Procedure	Medical Devices Category (M. Eqpt, Med Furn'r, PPE….)	Capital Equipment	Accessories/ Hardware/ Software, Consumables
	Radiation Therapy		
Radiotherapy treatment delivery	Medical equipment	Linear Accelerator (LINAC) (otherwise, Cobalt-60 Unit)	• 3D Conformal therapy • At least 6 MV with multileaf collimator and electronic portal imaging.
		Single-patient physiologic monitoring system	Patient Positioning/tracking System:- Blood pressure cuffs for adults and infants, Thermometer probes (in case it is needed)
		Resuscitation trolley, equipped with medicines and defibrillator	• Laryngoscope for adults and infant
	Radiation safety devices	Personal Dosimeter, Geiger–Müller (GM), survey meter, Large volume ionization chamber (consider requirements from IAEA)	
Imaging and Treatment Planning	Medical equipment	Computed Tomography (CT) System (16 slices minimum) CT Overlay fat table Laser patient positioning system Contrast media injection system (optional) Conventional simulator (only if a CT simulator is not available) Computerized treatment planning systems (three-dimensional) including Colour printer Hardware and software, virtual simulation software, and	

		plan review software Digitizer	
Mould making process (Immobilization and patient positioning system)	Equipment	Hot water bath for thermoplastic immobilization system, Hot wire cutter Drill Pot for cerrobend cadmium free low melting point alloy (if needed according to the technique and the type of accelerator)	
	Instruments		Tray, dressing, stainless steel.
	Personal protective equipment and clothing		Apron, protection, plastic Eye protection glasses, safety, regular size Gloves, examination, latex, non-sterile, single use (various sizes) Coat, medical, woven (various sizes)
Treatment delivery, brachytherapy		• Equipment for source applicator localization, • Portable X-ray equipment (dedicated X-ray equipment e.g. C-arm fluoroscopy is preferred) General-purpose suction system, Vacuum Pharmacy refrigerator. • Operating light, light source (lamp & flashlight) • Resuscitation trolley, equipped with medicines and defibrillator with laryngoscope Single-patient physiologic monitoring system	

	Systemic Therapy		
Drug Infusion, chemotherapy administration	Medical equipment	Fixed examination/treatment light Pharmacy refrigerator Stethoscope, adult, binaural and pediatric Thermometer, clinical, digital 32–43°C	Tympanic probe covers (if tympanic thermometers are used)
		Resuscitation trolley, equipped with medicines and defibrillator With Sphygmomanometer (include pediatric size tubes if applicable) Basic vital signs monitor (availability in the setting) Vein finder device (optional) Monitoring electrodes General physical examination set Ophthalmoscope, Otoscope, Lamp) Adult stand up scale Stadiometer (wall mounted) Oxygen therapy flowmeter, dialtype (if pipeline available) Suction availability (accessories for wall or portable equipment	laryngoscope (for adult and pediatric patients) Infant/pediatric blood pressure cuffs
	Medical furniture	Reclining chair, Patient lifting hoist, Hospital stretcher with side rails General cabinet Stand, infusion, double hook, on casters Table, instruments, Mayo, stainless steel, on castors Trolley, dressing, stainless steel, 2 trays Trolley, soiled linen Wheelchair, adult/child Cabinet, medicine, with lock (consider national regulations) Cribs Bedside tables/commodes	
	Instruments		Dressing set

	Personal protective equipment and clothing		Glasses, safety, regular size Gloves, nitrile non-sterile, single-use Gloves, non-sterile, single-use General purpose sterile drape Surgical face mask Gown, impermeable single use Apron impermeable.
Treatment delivery, brachytherapy		• Equipment for source applicator localization, • Portable X-ray equipment (dedicated X-ray equipment e.g. C-arm fluoroscopy is preferred) General-purpose suction system, Vacuum Pharmacy refrigerator. • Operating light, light source (lamp & flashlight) • Resuscitation trolley, equipped with medicines and defibrillator with laryngoscope Single-patient physiologic monitoring system	
	Laboratory and Pathology		
Reception		Table Label printer attach with LIS (optional but very useful)	

Grossing/ Prosection	Laboratory and pathology equipment/medical equipment	Professional grossing bench with sink and exhaust system/ grossing station Refrigerator/freezer laboratory Cassette printer (Optional) Permanent marker pen (for cassette) Strainer Organ balance, Ruler or measuring tape Cutting board	
	Instruments	Forceps, Knife for specimens, Rotary saw (optional), Scissors, Spatula, Scalpel handle with blades	
General Analytical procedure	Laboratory and Pathology equipment	Refrigerator, laboratory Refrigerator/freezer, laboratory Freezer, laboratory Microscope, binocular Camera for microscope (for telemedicine and documentation) Timer, digital Timer, 60 min, mechanical Thermometer, glass, min/max -20°C/100°C Thermometer, min/max -30°C/60°C Magnifying glass Centrifuge Accessories for serology Centrifuge, micro - hematocrit Distillation unit, 2 L/h, with tank Hot plate, with stirrer Incubator, 30 L, up to 80° C pH meter Rotator, agglutination test Scale, digital, 1500 g/0.1 g	

		Scale, precision, digital, 500 g/0.01 g Basic laboratory mixer/ Laboratory shaker vortex Shaker, orbital Spectrophotometer, ultraviolet/ visible Sterilizer steam autoclave, 24 L Water bath, 7L Hygrometer	
	Instruments	Forceps, dressing, 155 mm, straight Spatula, stainless steel (various sizes) Clamp, test tubes	
	Medical furniture	Adequate furniture for the laboratory devices	
	Personal Protective Equipment		Coat, medical, woven, white (various sizes) Gloves, examination, latex, non-sterile, single use (various sizes), Gloves, nitrile, powder-free, non-sterile, single use Mask, surgical, non-woven, Glasses, safety, regular size
Tissue processing	Laboratory and pathology equipment, medical equipment	Tissue Processor	
Embedding	Laboratory and pathology equipment	Tissue embedding unit or station	Heated forceps Mould (various sizes) Paraffin Wax

Microtomy	Laboratory and pathology equipment	Microtome, Water bath, Slide label printer (optional)	Cooling device, Low Profile Blades, Forceps, Glass slides, Hot Plate, Brush
Frozen Sections	Laboratory and pathology equipment	Cryostat, Stool Chair (optional)	Histofreezer, OCT Compound, Chuck Forceps, Small Paint Brush, Slides High/Low Profile Blades, Rack
		Biomarker analysis	

Appendix I: Priority medical devices for clinical assessment, clinical laboratory & pathology, surgery, medical imaging & nuclear medicine and radiotherapy

Procedure	Medical Devices Category (M.Eqpt, Med Furn'r, PPE….)	Capital Equipment	Accessories/ Hardware/ Consumables	Remark
Clinical Assessment	Medical Equipment	Aneroid sphygmomanometer		
		Stethoscope		
		Thermometer		
		Examination table		
	Medical Furniture	Trolley, dressing, stainless steel, 2 trays		
		Cabinet, instruments, double door		
	Personal Protective Equipment & Clothing			
	Single Use devices			
Surgery	Medical Equipment			
	Medical Furniture			
	Personal Protective Equipment & Clothing			
	Single Use devices			

Clinical Laboratory & Pathology	Medical Equipment			
	Medical Furniture	Trolley, dressing, stainless steel, 2 trays		
		Cabinet, instruments, double door		
	Personal Protective Equipment & Clothing			
	Single Use devices			
Medical Imaging & Nuclear Medicine	Medical Equipment	Mammography		
		Stereotactic-guided CNB of primary tumour or metastatic lesions		
		US scan		
		US-guided biopsy of regional lymph and sentinel nodes		
		Breast Tomosynthesis		
		Image guided procedures to place catheter for chemotherapy		
	Medical Furniture	Patient Procedure Table / Couch		

		Table, instruments, Mayo type, stainless steel, on casters		
		Drug cupboard (local anesthesia for pain, contrast reaction)		
	Personal Protective Equipment & Clothing	Surgical cap for patients and healthcare worker		
		Surgical face mask		
		Eye protective wear		
		Operator sterile gown		
		General-purpose sterile drape		
	Single Use devices			
Radiotherapy	Medical Equipment			
	Medical Furniture			
	Personal Protective Equipment & Clothing			
	Single Use devices			

Appendix K: Clinical Breast Examination Register

		Client Identification										
SN	Client Full Name (will not be used for reporting)	Address (Woreda, Sub city, Kebele)	MRN	Phone #	Age	Marital Status (enter code)	Education (enter code)	Risk factors (enter code)	Suspected site (enter code)	Screening methods	Screening Date	Referral (enter code)

Codes:

Marital Status:
1= Single
2=Married
3= Divorced
4= Widow

Education:
1= Illiterate
2= Can read and write
3=Elementary/junior
4= High school
5= College/University

Risk factors for breast cancer:
1= History of oral contraceptive use
2=Alcohol
3=Age at menarche (first mensus /period)
4=Smoking cigarette
5=Regular exercise 6.
6=Pervious History of breast Cancer
7=Previous History of Breast cancer
8=Family history of breast cancer
9=Lack of breastfeeding

Suspected site:
1=Left Breast
2=Right Breast
3=Both Breast

Screening methods:
1=Clinical Breast Exam
2=Ultrasound
3=Mamography

Referral Linkage:
1=Diagostic center/Other HF
2=Not linked for DX

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