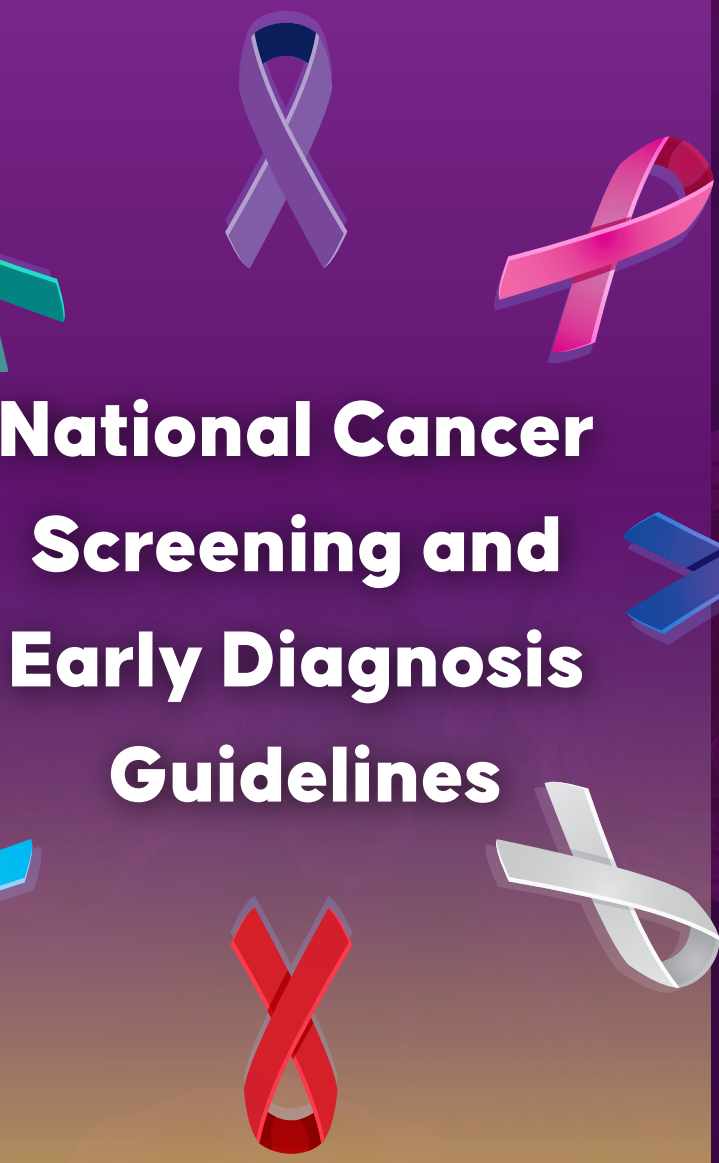

REPUBLIC OF KENYA

MINISTRY OF HEALTH

National Cancer Screening and Early Diagnosis Guidelines

Second Edition, 2024

Ministry of Health

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ABBREVIATIONS & ACRONYMS

ACOG	American College of Obstetricians and Gynecologists
ADR	Adenoma detection rate
ART	Antiretroviral therapy
ASCCP	American Society of Colposcopy and Cervical Pathology
BSE	Breast Self-Examination
CBE	Clinical Breast Cancer
CHA	Community Health Assistant
CHP	Community Health Promoter
CIN	cervical intraepithelial neoplasia
CIR	Caecal Intubation rate
CRC	Colorectal cancer
DRE	Digital rectal Examination
EUA	Examination under anaesthesia
FIT	Faecal immunochemical test
FOBT	Faecal Occult Blood Test
GCO	Global Cancer Observatory
GFOBT	guaiac-based faecal occult blood test
GICC	Global Initiative for Childhood Cancer
HPV	Human papillomavirus
IARC	International Agency for Research on Cancer
KDHS	Kenya Demographic and Health Survey
KHIS	Kenya Health Information System
LBC	Liquid-based cytology
LCC	left-sided colon cancer
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large Loop Excision of the Transformation Zone
LMIC	Low and middle-income countries
MRI	Magnetic Resonance Imaging
NAAT	Nucleic Acid Amplification Tests
NCCN	National Comprehensive Cancer Network
NCCP	National Cancer Control Program
NCCS	National Cancer Control Strategy
OSCC	Oral squamous cell carcinomas
PET	Possitron emmission tomography
PSA	Prostate-Specific Antigen
RB	Retinoblastoma
RCC	right-sided colon cancer
SCC	squamous cell carcinoma
SCJ	squamocolumnar junction
SGO	Society of Gynecologic Oncology
SIL	squamous intraepithelial lesions
TNM	Tumour, Nodes, Metastasis

USPSTF	Unites States Preventive Services Task Force
VAIN	vaginal intraepithelial neoplasia
VIA	Visual inspection with acetic acid
WHO	World Health Organization
WLHIV	women living with HIV
WT	Withdrawal Time

FOREWORD

The cancer burden is increasing globally, but in an unequal fashion; low and middle-income countries carry the largest burden the of disease. Consequently, policymakers need to work closely with other stakeholders to strengthen health systems to respond to this burden. In fact, during the 2018 United Nations General Assembly, world leaders committed to cancer prevention, including protecting people from cancer-causing products, promoting evidence based care and making reforms to achieve universal health coverage.

Cancer control is structured as a continuum; from prevention and early detection, to treatment, survivorship and palliative care. Currently, it is estimated that between 30 and 50% of cancers can be prevented by avoiding risk factors and implementing existing evidence-based prevention strategies, including vaccination and treatment of precancer lesions. Unfortunately, not all cancers are amenable to prevention or screening strategies; however, even when prevention is not possible, early diagnosis can save lives and help to reduce the social and outcome inequalities in cancer globally.

The Ministry of Health is currently implementing the National Cancer Control Strategy 2023-2027 (NCCS), in collaboration with county governments and other stakeholders. One of the interventions spelt-out in the NCCS was to undertake the revision of the National Cancer Screening Guidelines 2018. First published in 2018, these guidelines are supposed to guide the establishment of national cancer early detection programs, based on local disease epidemiology, evidence and stakeholder consensus. After five years of implementation, there was a need to review progress and update recommendations in the guidelines.

It is expected that these revised guidelines will be adopted by all health facilities, both public and private, and that this will standardize the national approach towards cancer early detection in Kenya. By so doing, they will act as an effective cog in the wheel of the national response towards reducing the preventable burden of cancer.

Dr. Patrick Amoth, EBS
Director General for Health
Ministry of Health Kenya

ACKNOWLEDGEMENTS

The Ministry of Health would like to express its sincere gratitude to the dedicated team of professionals who contributed to the development of this screening guideline. Their expertise and commitment were instrumental in ensuring the document's comprehensiveness and effectiveness. We are particularly thankful to the leadership of the Ministry of Health, including the Cabinet Secretary, Principal Secretary Medical Services, Director General for Health, Director of Family Health, and Head of the Division of Cancer and Non–Communicable Diseases. Their strategic guidance and support were essential to the successful development of this cancer screening guideline.

We gratefully acknowledge the financial and technical assistance provided by WHO, FIND Diagnostics, ROCHE, USAID, and CHAI during the development of this document. We are also deeply grateful to Dr. Valerian Mwenda for their leadership as the lead consultant, which provided crucial guidance throughout the process. Special thanks to the National Cancer Control Program team, led by Dr. Joan–Paula Bor. The coordinating role of NCCP pillar 1 program officer Lilian Genga, is also greatly appreciated. Additionally, we recognize the invaluable contributions of experts from public, private, and faith–based institutions. In particular, we thank the Council of Governors, county representatives, professional bodies (KESHO, SSK, KPA, KRA, KAUS, KDA, KOGS, GSK), academia, hospitals, development partners, regulatory bodies, industry, other MOH departments, and the various Cancer Technical Working Groups.

In conclusion, the Ministry of Health would like to reiterate its sincere appreciation to all the individuals and organizations involved in the development of this cancer screening guideline. Their collective efforts have resulted in a valuable resource that will significantly contribute to improving cancer prevention, early detection, and treatment in Kenya. We are confident that this guideline will play a crucial role in enhancing the health and well–being of our citizens.

Dr. Issak Bashir
Ag. Director – Directorate of Family Health
Ministry of Health

EXECUTIVE SUMMARY

These guidelines are structured into four sections, as summarized below:
Section A is the introduction, which gives the epidemiological basis of cancer early detection at both global and national level. The principles of primary, secondary and tertiary prevention of cancer are also discussed. The concept of early detection as a combination of screening and early diagnosis is also elaborated. It also includes the process, target audience and scope if the
revised guidelines.

Section B focuses on cancer screening. Based on the local cancer epidemiology as well as stakeholder consensus, the following cancers are included in this section:

- Cervical, breast and colorectal cancer (population-level screening)
- Prostate, retinoblastoma, and oral cancers (targeted screening)

The main recommendations in this section are as follows:HPV is recommended as the primary screening modality for cervical cancer; while a clinical breast examination (CBE) based program, coupled with prompt diagnostic evaluation is proposed for down-staging breast cancer in Kenya. For colorectal cancer, FIT is recommended as the screening modality for the average risk population, but since gFOBT is widely available in the health facilities, the program can be launched based on gFOBT and transition to FIT made progressively. For prostate cancer, individualized screening using PSA test is recommended. Visual examination and exfoliative cytology are the recommended screening modalities for individuals at high risk for developing oral cancer.

Section C covers Early Diagnosis. Since this principle applies to all cancer types, it includes a general component for most common cancers, as well as separate ones for lung cancer, childhood cancer, and oesophageal cancer, based on local epidemiological considerations.

Section D covers Appendices: Various appendices are provided at the end of the guideline document, including steps in program planning, global cancer control strategies, monitoring/evaluation tools and checklists. They can be adopted and adapted as needed by clinical teams to aid their service provision.

We encourage all stakeholders to support the comprehensive adoption and implementation of these guidelines across all levels of healthcare service delivery, in order to reduce the cancer burden in Kenya.

Dr. Gladwell Gathecha,
Ag. Head, Division of Non-communicable Diseases
Ministry of Health

SECTION A:
INTRODUCTION

INTRODUCTION

Global Cancer Burden

Cancer incidence and mortality rates continue to rise globally, with an estimated 20 million new cases and 9.7 million deaths in 2022 (GLOBOCAN, 2022). The detailed cancer patterns in different world regions, however, are complex. The number of new cases is expected to rise by about 70% over the next two decades, with significant and rising economic effects. The direct and indirect economic costs related to prevention and treatment of the cancer globally are expected to exceed 25.2 trillion dollars between 2020 and 2050 (Kreier, 2023).

Globally, the most common cancer types are breast; lung; colon and rectum; prostate; skin (non-melanoma) and stomach. However, lung cancer has the highest mortality, followed by colon and rectum; liver; stomach; and breast, in that order (figure 1). Each year, approximately 400, 000 children are diagnosed with cancer, with the highest burden in low - and middle-income countries (GLOBOCAN, 2022).

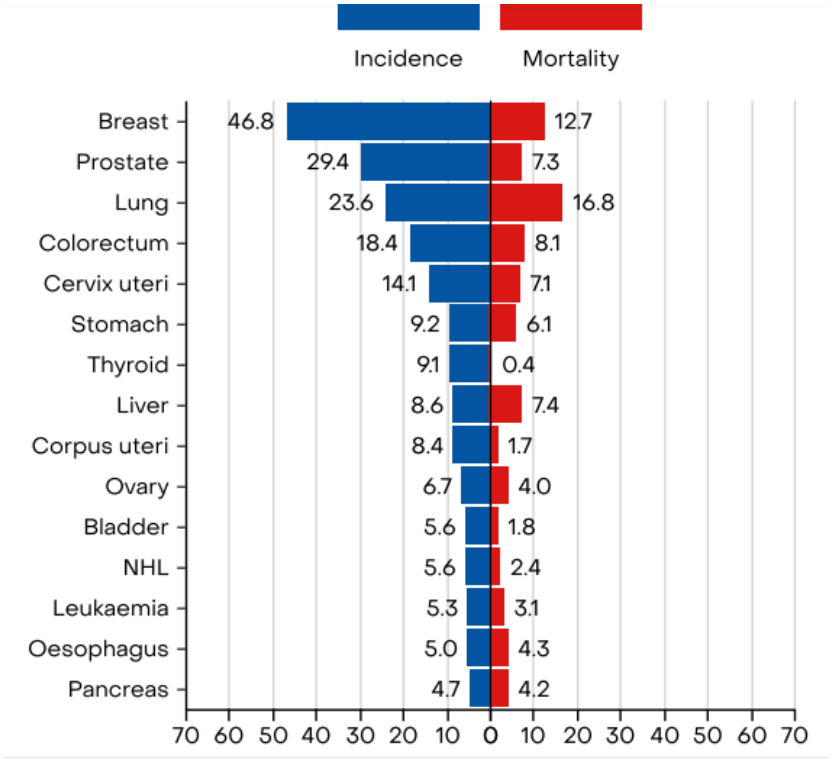


Figure 1: Global Incidence & Mortality rates (Age-standardized) for most common cancer types.
Source: Global Cancer Observatory (GLOBOCAN, 2022).

Kenyan Situation

In Kenya, cancer is the third leading cause of death after infectious and cardiovascular diseases. The annual incidence of cancer was estimated at 44,726 cases, with an annual mortality of 29,317 in 2022 (GLOBOCAN, 2022). Among men, prostate, oesophageal and colorectal are the leading cancers, while among women, breast, cervical and oesophageal cancers are most common. The leading cause of cancer death in Kenya is prostate cancer, followed by cervical and breast (figure 2).

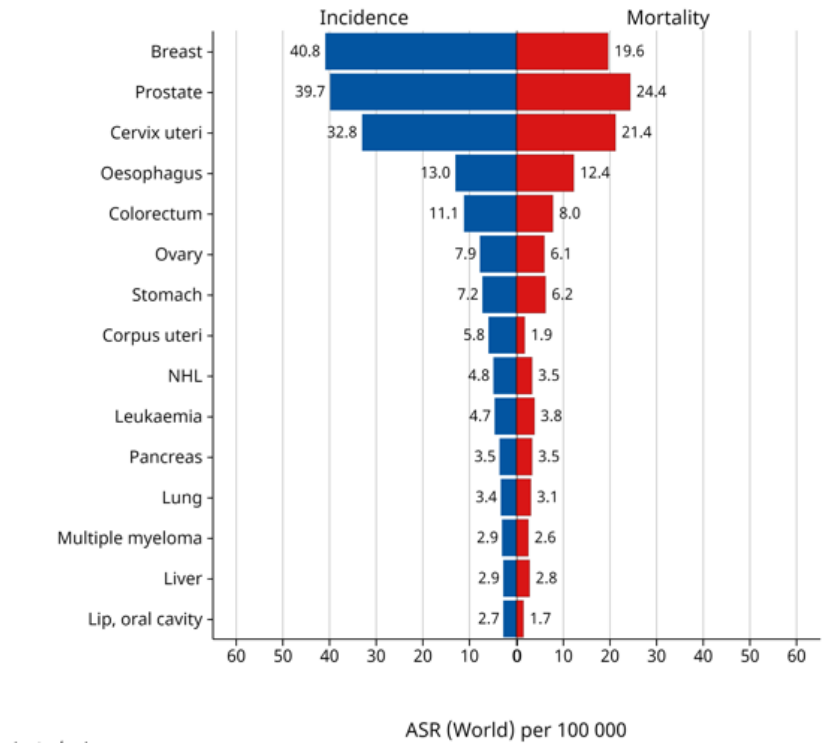


Figure 2: Cancer Incidence & Mortality rates in Kenya, 2022 (Age-standardized) for most common cancer types (GLOBOCAN 2022).

Late-stage diagnosis with poor treatment outcomes is still prevalent in Kenya, despite investments in screening, diagnosis and treatment in the last five years (Mwenda et al., 2023; Nyangasi et al., 2023; WHO | Regional Office for Africa) . While about a third to half of cancers can be prevented, the cancer burden can be significantly reduced through early detection and management of precancerous conditions. However, there is low uptake of screening services in Kenya. For example, uptake of cervical cancer screening is 24% among women aged 25-49 years, (secondary analysis of Kenya Demographic and Health Survey (KDHS) 2022, unpublished data).

One of the strategic interventions proposed in the National Cancer Control Strategy 2023-2027 was to undertake revision of the National Cancer Screening Guidelines 2018, to incorporate most recent evidence in cancer prevention and early detection, align with global cancer control initiatives and situate them within the current policy framework in Kenya (Kenya National Cancer Control Strategy 2023-2027).

Principles of Cancer Prevention

Approximately 30-50% of cancers can currently be prevented by avoiding risk factors and implementing existing evidence-based prevention strategies.
Cancer prevention is stratified into three levels (figure 3):

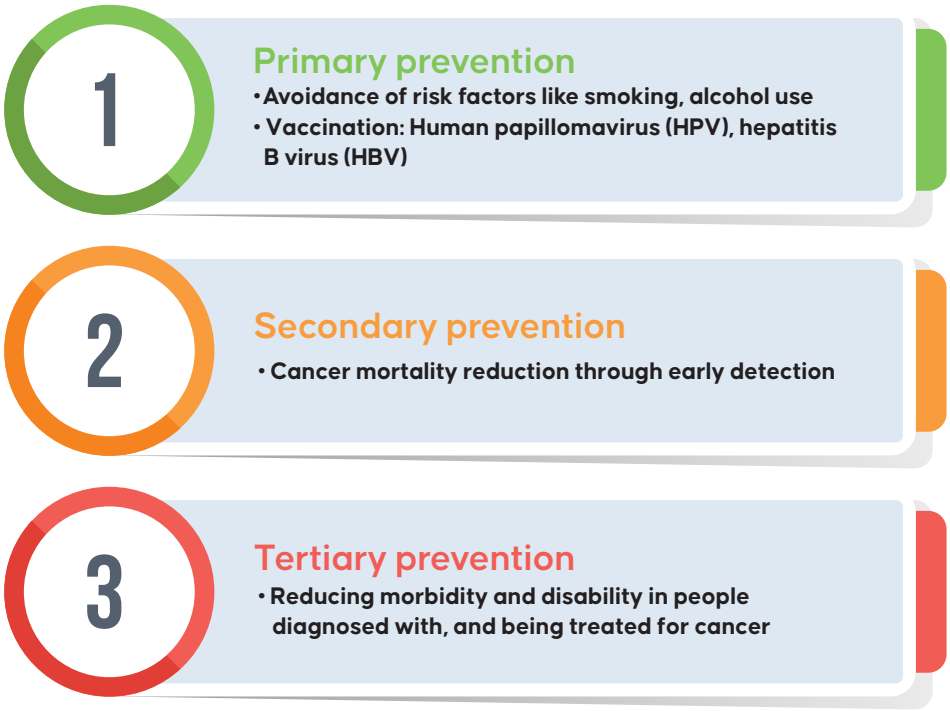


Figure 3: The three tiers of cancer prevention

Early Detection

There are two major components of early detection of cancer:

1. Early diagnosis
2. Screening

Screening

Screening is the application of simple tests/examinations, to identify individuals with findings suggestive of a specific cancer or pre-cancer before they developed symptoms. If abnormalities are identified, further **diagnostic tests** should follow, and **referral** for treatment if cancer is proven to be present. Screening programmes are effective for **some but not all cancer types**. Screening programmes are more complex and resource-intensive than early diagnosis as they require special equipment and dedicated personnel. Establishment of screening programmes does not preclude early diagnosis; early diagnosis programmes are still necessary to identify cancer cases occurring in people who do not meet the age or risk factor criteria for screening.
Participant selection for screening is based on two key factors to avoid excessive false positive results, overdiagnosis and overtreatment:

- Age
- Risk factor profile

Screening, by itself, has no actual preventive value and must be linked to treatment. All the activities along the continuum of patient care must be implemented in a coordinated manner. These include awareness creation, screening, diagnosis, referral, treatment and follow up. In addition, a well-functioning quality control and quality assurance programme; monitoring and evaluation, advocacy and resource mobilization are vital.

Considerations before establishment of screening programs

Patient/Community/Population Considerations

- Acceptability/desirability by patient and community
- The historical precedent for screening
- The sufficient burden of disease: the disease prevalence must be high enough to justify the expenditure of screening

Epidemiological/Medical Considerations

- Different populations have a distinct and different distributions of disease
- The natural history of disease supports early detection
- The screening programmes must have been proven to be effective
- Availability of ‘adequate’ screening tests
- Availability of confirmatory diagnostic facilities
- Availability of and compliance with ‘effective’ treatment and follow up
- Acceptability by the provider and health care system

Resource Considerations

- Will of the political and healthcare systems
- Availability of resources - funds, equipment, trained personnel to cater for most of the entire target population group should be assured
- Cost-effectiveness of screening

Other key considerations

- Governance/Leadership of the program and coordination of services
- Availability of services to deliver screening tests
- Evidence-based guidelines and protocols
- Affordability
- Clear referral pathway
- Information system, for tracking the participant and for collection of data for measurement of key performance indicators
- Logistics for supplies and sample management
- Quality assurance

Early Diagnosis

This focuses on detection of symptomatic patients as early as possible through recognition of possible warning signs of cancer in order to take prompt action. The aim is to improve treatment outcomes by providing care at the earliest possible stage.

Early diagnosis of cancer involves 3 steps:

1. Improving awareness and access to care.
2. Building diagnostic capacity and improving referral mechanisms.
3. Improving access to timely cancer treatment by addressing the relevant barriers.

Guideline Objectives and Target Audience

These guidelines are meant to build on the achievement of the previous guidelines as well as strategic plans, to guide and standardize cancer screening, provide operational protocols and improve the outcome of cancer screening and treatment. They are to serve as a general guide for health care providers in selecting the appropriate tests for their patients and should be applied through an individualized patient-centered approach. They are not intended to be a basis upon which patients seeking screening services are denied their right to be screened. Therefore, while specific target screening ages are advised based on risk stratification, individual clients presenting to the healthcare system should be handled through information and shared decision-making, especially if they fall out of the target ages.

These guidelines are designed for use by all cadres of health care providers (doctors, nurses and clinical officers, among others) across the KEPH levels of the health care system **(public, faith-based and private)**. Strengthening of the referral systems is important to ensure optimal services to the clients.

Panel Selection and Composition

The guideline revision technical working group was constituted by the Ministry of Health - National Cancer Control Program (NCCP) and comprised program officers from NCCP and other relevant MOH Divisions/ Programs, and subject-matter expert teams from academic institutions, health research organizations, international agencies (WHO, CHAI, USAID), relevant civil society organizations, cancer survivors as well as cancer specialists from various cancer treatment centers and representatives from the county departments of health. The group held several consultative meetings and workshops that culminated in the development of the working draft, which subsequently underwent external review and validation, before publication of this final version of the second edition of the screening guidelines. The process was led by a consultant, who provided technical guidance and coordination.

The Approach

The process started with a scoping review of the current cancer screening guidelines, especially in contexts similar to Kenya, as well as global guidelines from organizations such as WHO, NCCN, USPSTF and others. Evidence synthesis of relevant research publications in form of systematic reviews and meta-analyses, existing international guidelines and guidance statements from several cancer care organizations globally was conducted and the findings made available to the guideline review working group. Local context was considered and expert opinion employed where there was paucity of evidence. Both the evidence synthesis and consensus building were structured around five priority questions:

Which types of cancer have evidence of effect of population-level screening on mortality?

1. What approaches/modalities are recommended for screening of each cancer?
2 What's the eligibility criteria, in terms of age and sex and risk profile?
3. What's the recommended screening interval?
4. What are the population implementation strategies?

The revised guidelines have adopted a computable format, with recommendations presented in clear, concise statements, and judicious use of diagrams, flow-charts, textboxes and algorithms.

Scope of the Guidelines

These guidelines cover cancer types that are major contributors to cancer morbidity and mortality in Kenya and are amenable to screening and early diagnosis as per currently available evidence. For screening, these include cervical, breast, colorectal, prostate, oral cancers, and retinoblastoma. A separate section for early diagnosis is included, which focuses on oesophageal cancers, childhood cancers, lung cancer, as well as all the other priority cancer types combined. A summary of the structure of the guidelines is shown below:

Table 1: Scope of the guidelines

Approach	Cancer types	
Screening	Population-level screening	Cervical cancer
		Breast cancer
		Colorectal cancer
	Targeted screening	Prostate cancer
		Oral cancer
		Retinoblastoma
Early diagnosis	Childhood cancers	
	Oesophageal cancer	
	Lung cancer	
	Other adulthood cancers	

References

1. IARC. Global Cancer Observatory. Retrieved June 7, 2024, from https://gco.iarc.fr/
2. Kenya National Cancer Control Strategy 2023-2027 | ICCP Portal. Retrieved May 20, 2024, from https://www.iccp-portal.org/news/kenya-national-cancer-control-strategy-2023-2027
3. Kreier, F. (2023). Cancer will cost the world $25 trillion over next 30 years. Nature. https://doi.org/10.1038/D41586-023-00634-9
4. Mwenda, V., Bor, J. P., Nyangasi, M., Njeru, J., Olwande, S., Njiri, P., Arbyn, M., Weyers, S., Tummers, P., & Temmerman, M. (2023). Integrating human papillomavirus testing as a point-of care service using GeneXpert platforms: Findings and lessons from a Kenyan pilot study (2019-2020). PloS One, 18(5). https://doi.org/10.1371/JOURNAL.PONE.0286202
5. Nyangasi, M. F., McLigeyo, A. A., Kariuki, D., Mithe, S., Orwa, A., & Mwenda, V. (2023). Decentralizing cancer care in sub-Saharan Africa through an integrated regional cancer centre model: The case of Kenya. PLOS Global Public Health, 3(9), e0002402. https://doi.org/10.1371/JOURNAL.PGPH.0002402
6. On the path to expanding cervical cancer screening in Kenya | WHO | Regional Office for Africa. (n.d.). Retrieved July 22, 2024, from https://www.afro.who.int/countries/kenya/news/path-expanding-cervical-cancer-screening-kenya

SECTION B:
SCREENING

CERVICAL CANCER

CERVICAL CANCER SCREENING

Key messages

- Screening all women in the target age group, followed by treatment of detected precancerous lesions, can **prevent the majority of cervical cancers.**
- Decisions on screening and treatment approaches depend on factors such as risk of loss to follow-up, cost, and resource availability.
- **HPV testing** is recommended as the primary screening method.
- Where HPV testing is unavailable or risk of loss-to-follow-up is high, consider **Visual Inspection with Acetic acid (VIA)** or **cytology**
- Implement a **screen-triage-and-treat** strategy for efficient management, in a single-visit approach if practical.
- Any suspected cancer case after screening should be **immediately referred** to a gynecologic oncologist for diagnosis and treatment.
- The health information system should be strengthened to ensure an effective fail-safe mechanism (linkage to treatment for those testing positive)

Overview

The 2030 target as per WHO Cervical Cancer Elimination Strategy is to achieve 70% of women screened by a high-performance test [Human Papillomavirus (HPV) test] and to treat 90% of those with pre-cancer or confirmed cancer. Kenya has improved in screening of women aged 25 – 49 years from 5% in 2018 to 30.3% in 2024. However, only 33% of those who had a positive screen test (regardless of screening method used) received treatment according to the Kenya Health Information System data (KHIS, 2024). These rates are still remarkably low for our national targets.

The 2018 guidelines recommended primary testing using the HPV test. HPV testing was introduced through a pilot program in 2019 and scaled up to 33 facilities in line with these recommendations. However, the majority of healthcare facilities continued to rely on visual inspection with acetic acid (VIA) as the primary screening test at 93% or cytology (Pap smears) at 4%, while HPV was only at 2.5%. This was predominantly due to inadequate resources particularly HPV testing equipment and reagents. On the other hand, a lot of gains have also been made in the treatment of pre-cancer lesions, with a major shift from use of cryotherapy to use of thermal ablation using portable devices that are applicable in low level care facilities.

Now, with stronger endorsements for HPV testing, the revised policy is poised to drive broader adoption to achieve cervical cancer prevention and early detection targets. This guideline also recommends expansion of treatment devices and appropriate navigation to link patients with pre-cancer to care.

Introduction

Globally, cervical cancer ranks 8th in incidence and 9th in cancer-related mortality amongst women with an estimated 661,021 new cases and 348,189 deaths in 2022. The World Health Organization (WHO) reports that more than 1 million women worldwide are currently living with cervical cancer. Unfortunately, many of these women lack access to essential health services for prevention, curative treatment, or palliative care. Consequently, a significant number of patients present late, leading to more challenging treatment options, increased costs, and dismal chances of cure. Cervical cancer accounts for 3.3% of all global cancer sites. In Eastern Africa, cervical cancer remains the most common cancer in women with estimated age-standardized incidence and mortality rates of 14.1% and 7.1% (GLOBOCAN, 2022).

In Kenya, cervical cancer contributes 5,845 (13.1%) of the new cancer cases annually and 3,591 (12.2%) of all cancer deaths annually. It is the leading cause of cancer related deaths in Kenya and the 2nd most common cancer among females. (GLOBOCAN, 2022). Screening allows for detection of precancerous disease and initiation of appropriate treatment in the asymptomatic stage (WHO, 2024). Cervical cancer is primarily caused by persistent infection with high-risk types of the HPV. There are 15 high-risk oncogenic types (types 16, 18, 31, 33, 35, 39, 41, 51, 52, 56, 58, 59, 66, 67 and 68) commonly associated with development of over 99% of invasive squamous cell carcinoma (SCC). HPV 16 and HPV 18 cause 70% of cervical cancers worldwide. (Bruni, 2023). These types of HPV are transmitted through sexual contact. In most cases, the body's immune system can clear the virus, but in some instances, the virus persists, leading to changes in the cells of the cervix that can eventually progress to cancer.

The lifetime risk for HPV infection among sexually active women is high with 7 in 10 (50-70%) women in the general population harboring cervical HPV-16/18 infection at a given time. (Bruni, 2023)

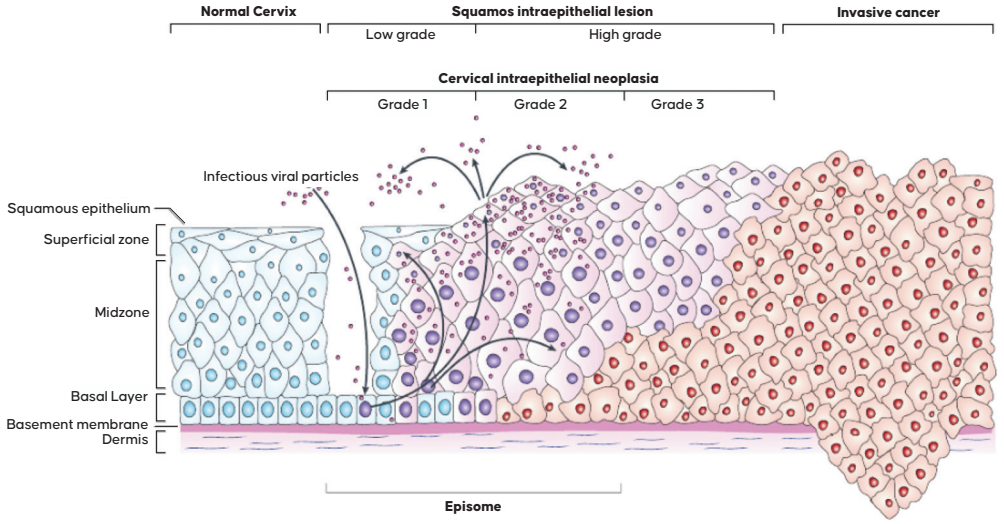
Table 2. Lifetime risk of HPV Acquisition

	Women	Men	Adolescents
Lifetime Risk of HPV Acquisition	84.6% (53.6%-95.0%)	91.3% (69.5%-97.7%)	50–80% within 12 months of sexual debut

Adapted from Chesson, 2014: Every sexually active woman and man will have HPV at some point in their life (85% and 91% risk respectively). Sexually active adolescents have an 80% chance of acquiring HPV within the first year of initiating sexual contact.

Fortunately, over 80% of HPV infections are transient, asymptomatic and resolve spontaneously in 1-2 years due to the natural cell-mediated immunity, hence most women who get infected with high-risk oncogenic HPV types do not develop cervical cancer. (Mosiscki, 2004, Arbyn, 2015)

Of the 20-30% of infections that persist, the HPV viral gene is incorporated into the DNA of cervical cells stimulating abnormal cell division. This may cause a range of cytological abnormalities referred to as cervical dysplasia or cervical intraepithelial neoplasia (CIN) or squamous intraepithelial lesions (Low/High grade, LSIL/HSIL) that may progress to invasive disease.



is no chronological progression of the cervical intraepithelial neoplasia, CIN. CIN 2/3 are referred to as high grade squamous intraepithelial lesions and require treatment to prevent progression to carcinoma.

CIN I or LSIL typically signifies the presence of cytopathic HPV-related infection. Importantly, it often regresses spontaneously without requiring active treatment. Monitoring and follow-up are essential, but immediate intervention is usually unnecessary. CIN II and CIN III represent more significant cellular changes. These lesions are considered precancerous and have the potential to progress to invasive cervical cancer. Interestingly, they can coexist in different areas of the same cervix, and their development isn't strictly sequential (i.e., not from CIN I to II to III). (WHO, 2014)

The time to regression or progression varies with each individual person's factors. The timeline for persistence of HPV infection to development of high grade squamous intraepithelial lesion and progression to cervical cancer potentially occurs over 10 to 20 years or more. However, due to individual factors like a weakened immune system, the progression can be much faster and thus earlier development of cervical cancer.

Table 3: Rates of regression and progression of cytological abnormalities

CIN Category	Regression	Persistence	Progression to CIN 3 (HSIL)	Progression to Invasive cancer
CIN I (LSIL)	49%	35%	7 – 10%	1%
CIN II (HSIL)	50%	32%	18%	1.5%
CIN III (HSIL)	32-47%	56%	-	12%

Rates of regression and progression of cytological abnormalities (Bruno, 2021, Bruno 2022, ASCCP,2023)

Risk factors for cervical cancer

Without the presence of risk factors, singly or in combination, HPV infection is unlikely to progress to invasive cervical cancer. This is further implied by the fact that not all persistent HPV infections progress to cervical cancer (Mati, 1984, Berraho, 2017)

Risk factors for cervical cancer

- Early age at first sexual intercourse (<18 years*)
- Multiple sexual partners
- Having a sexual partner with multiple sexual partners
- Co-infection with other sexually transmitted infections e.g., Chlamydia trachomatis and herpes simplex virus type 2
- Multi-parity (3 or more children) **
- Immunosuppression due to HIV/AIDS infection
- Tobacco use

*Mekonnen, 2023 ** ACS, 2020 Tekalegn, 2022

The HPV vaccine has shown great efficacy in reduction of persistent HPV infection by boosting the immune response against HPV infection prior to its acquisition. (Lei, 2020) With the increasing availability of vaccines against high-risk HPV, there exists great potential to reduce the incidence of cervical and other anogenital cancers (ACCP 2004, WHO 2022, Lehtinen, 2021, Basu, 2021, Abbas, 2024). Kenya introduced the HPV vaccine in 2019, and is currently being given to girls age 10-14 years, as two doses six-months apart countrywide (however, vaccination stakeholders are currently considering giving an advisory for Kenya to adopt a single-dose strategy).

Rationale for cervical cancer screening

The ultimate objective is to expand the national cervical cancer screening program to achieve sufficient coverage, aiming to screen every woman aged 30-49 years nationwide at least twice (35 and 45 years), as recommended by the World Health Organization (WHO). Cervical cancer screening, at least twice, is recommended for every woman in the target age group, but this may be extended to women younger than age 30 if there is evidence of a high risk for CIN2+ and up to 65 years.

Who should be screened and when?

Table 4 Cervical cancer screening age group and frequency

In Kenya, for programmatic purposes, the target population for screening is every woman aged 25 – 49 years
Cervical cancer screening should be integrated with a clinical breast exam (CBE)*
HPV testing is the recommended primary screening method
Frequency of HPV testing is 5-yearly for HIV uninfected women but 3 yearly for HIV infected women

*See Breast Cancer Screening Guidelines

Cervical cancer screening rates are below expectations, with the lowest levels reported among individuals younger than 30 years. Given significant health equity concerns and the current suboptimal rates of cervical cancer screening and HPV vaccination, several guidelines (ACOG, ASCCP, SGO) recommend initiation of cervical cancer screening at age 21 years. HPV testing alone is recommended at 5-year intervals beginning at either age 25 or 30 years. (Perkins, 2020) Patients <29 years old have high spontaneous regression rates of HPV and a relatively low risk of developing cervical cancer. Therefore, an even more conservative management plan can be applied to this group given the risk of cervical intraepithelial neoplasia (CIN) 3+ is lower than in patients ≥30 years old.

HPV prevalence is expected to continue to decline with the introduction of vaccines targeting the most common cancer-causing HPV genotypes.

Women who have received the HPV vaccine should continue with cervical cancer screening as per the national guidelines.

Figure 5: HPV vaccination

Screening methods for cervical cancer

Table 5: Test Methods Available for Cervical Cancer Screening in Clinical and Research Setting

Molecular testing (NAAT[a], DNA methylation[b], Protein biomarkers[c]

- HPV testing is recommended as the primary screening method for women above 30 years of age

Visual Inspection with Acetic Acid[d]

- Where HPV testing is not yet available, or loss-to-follow-up is a risk, then Visual In spection with Acetic acid (VIA; Naked or Enhanced) is an acceptable primary screening method.

Cytologic[e]

- Pap smear is recommended as a primary screening method in the following situations:
- For women not eligible for VIA because of a type 3 transformation zone (see Fig.4) and HPV screening not accessible
- As a primary test in women between <30 years of age

a. Nucleic Acid Amplification Tests: Current tests for HPV; high risk HPV DNA genotyping recommended; mRNA no recommendation for WLHIV and must be physician-collected
b. HPV DNA methylation tests still being explored as a triage test
c. HPV antibodies and oncoproteins: high specificity but suboptimal sensitivity
d. Naked eye or magnified/enhanced by colposcope or camera; Automated visual evaluation of digital images
e. Conventional pap smear, Liquid-based cytology, Dual staining to identify p16 and Ki-67

NB: Routine co-testing with HPV and pap smear is not cost-effective nor is it more effective than hrHPV alone in predicting/prognosticating precancerous/invasive lesions thus is no longer recommended in routine screening (Arbyn, 2024, WHO, 2023)

Clinician algorithm for choice of screening test

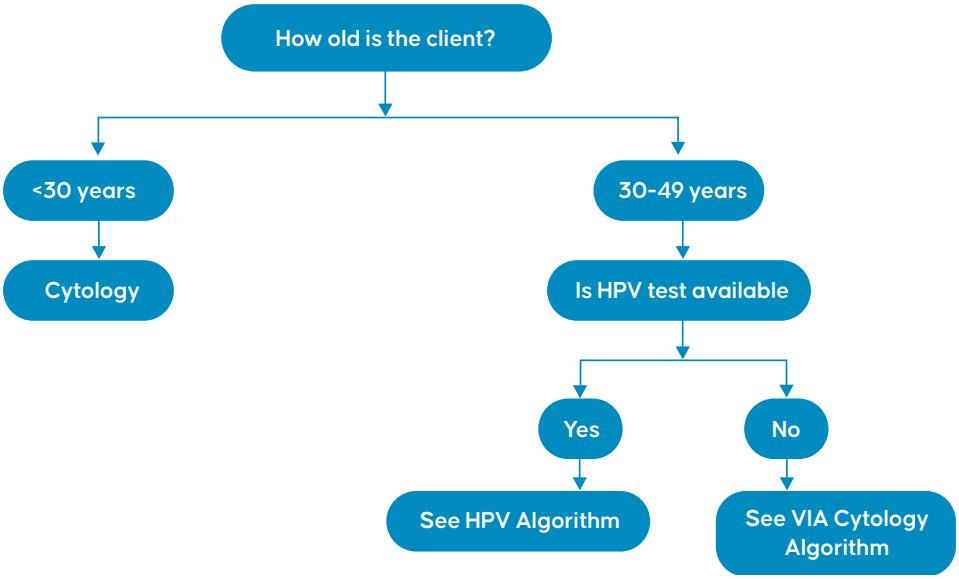
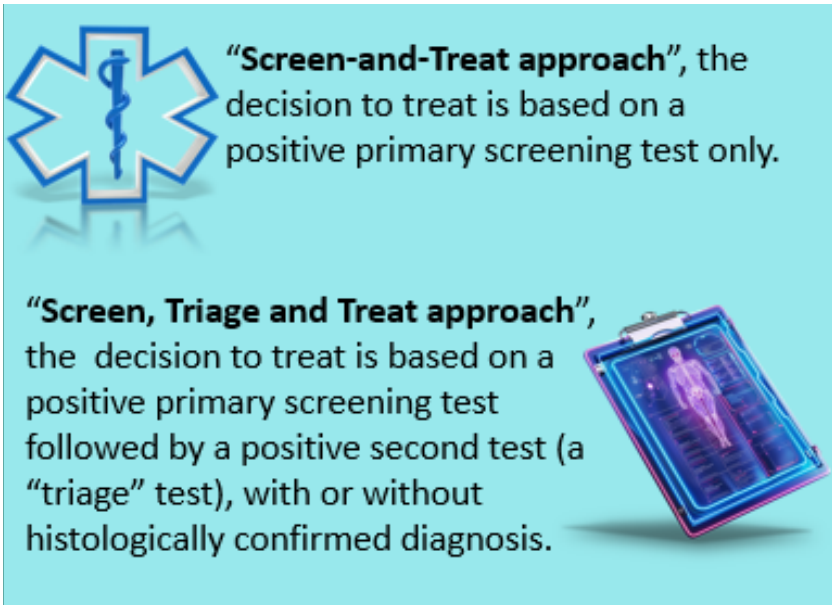


Fig 6: Flowchart for selection of screening method based on age

Human papilloma virus (HPV) test

Molecular testing detects high-risk HPV DNA in vaginal and/or cervical samples. Because persistent HPV infection is responsible for nearly all cervical cancer cases, a positive test result suggests that a woman may have an existing lesion or be at risk for developing pre-cancer or cancer in the future. Molecular HPV testing offers a significant advantage: heightened sensitivity in detecting severe dysplasia (CIN2+) and advanced dysplasia (CIN3+). Notably, it outperforms other methods in reliably identifying negative results. In clinical trials, HPV testing demonstrated a remarkable 30–40% improvement in sensitivity specifically for detecting CIN3+. Additionally, its negative predictive value provides substantial reassurance for women who receive negative test results. (Austin, 2018). In the HPV test **screen-and-treat strategy,** women who are HPV-negative are not treated, nor evaluated further. Women who are HPV-positive should all be treated but first eligibility for ablative treatment must be assessed through the application of acetic acid and visual evaluation using the naked eye or with a colposcope (or Automated visual evaluation/AVE where available). Those who are ineligible for ablative treatment should be referred for excisional treatment or further evaluation.

In the HPV test **screen, triage and treat strategy,** women who are HPV negative are not treated, nor evaluated further. Women who are HPV-positive undergo VIA as a triage test to determine whether they should be treated. Women who are HPV-positive and VIA-positive will be treated with ablation if adequate, or referred for excisional treatment or further evaluation, while women who are HPV-positive and VIA-negative will not be treated but followed-up as indicated in the algorithm (Fig 6). (WHO, 2021)



These guidelines recommend the screen, triage and treat approach, as depicted in the algorithm. Effort should be made to make this possible within the same visit.

Sample collection for HPV test

Provider collected sampling

A health-care provider can collect a sample with or without a speculum, by inserting the provided swab or other appropriate device high into the vagina, rotating 5 -10 times and then placing it in a container with a preservative solution or packaging provided.

Self-collection sampling

Self-collected samples provide women with a sample-collection kit and usage instructions, offering enhanced convenience and significantly reduced costs for the healthcare system. Self-collection can be done both in the facility and in community settings. Embracing self-care promotes privacy, independence, and convenience, empowering individuals to take responsibility for their health. This approach also fosters sustainability by lessening the burden on the healthcare system, improves health efficacy, and reduces overall healthcare burdens. Additionally, it expands the market

by allowing direct purchase from labs and boosts the uptake of screening services. (WHO, 2020).

Key messages for health care workers

- Clarify that an HPV test is not confirmation of cervical cancer; it is a test to identify women at risk
- HPV is sexually transmitted; however, a current positive test is not a confirmation of partner infidelity (male or female)
- To avoid test result misinterpretation, gender-based violence and proper adherence to post-treatment instructions (e.g., avoidance of coital activity after LEEP/Thermal ablation), encourage partner involvement and engagement in the screening & treatment process

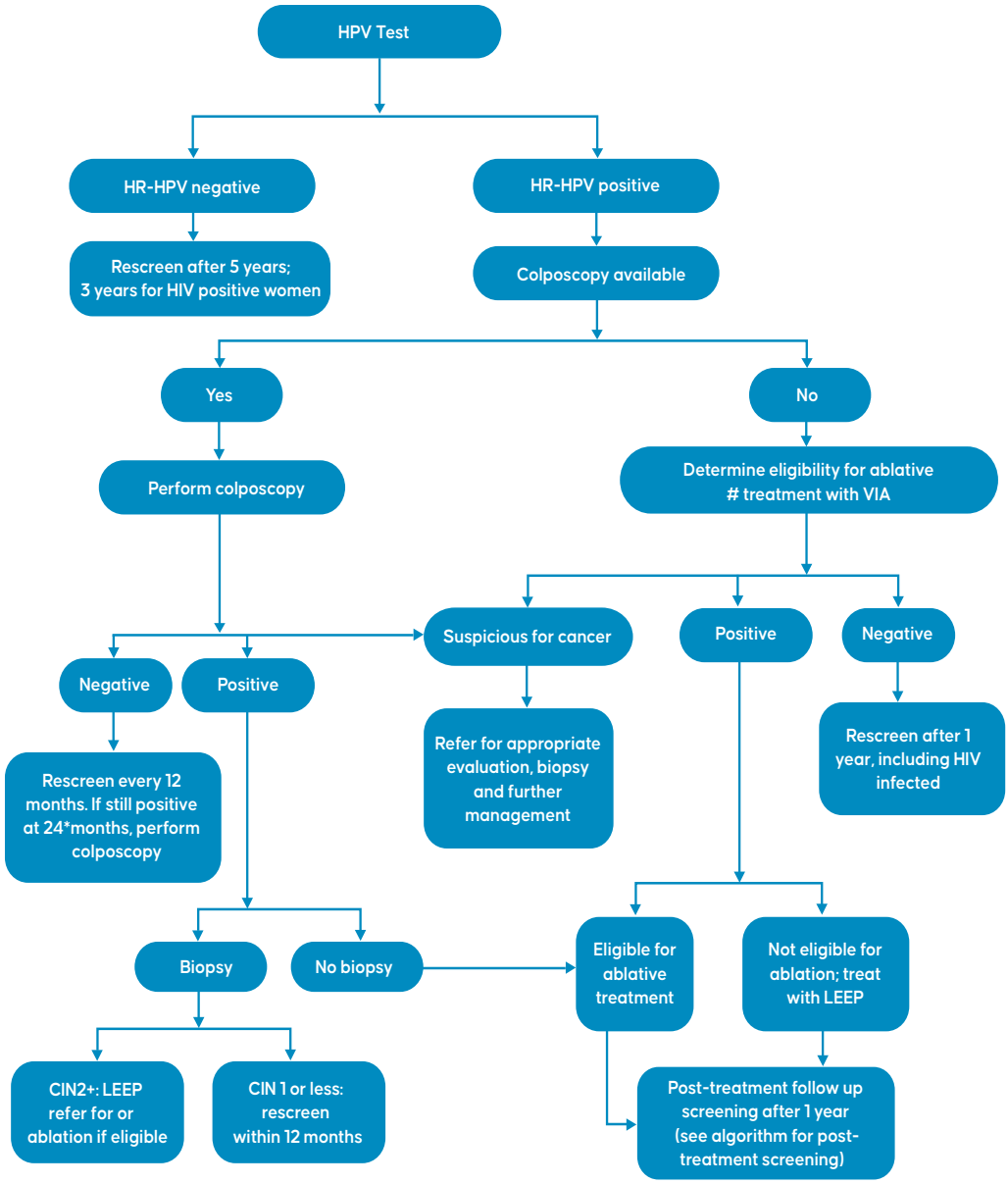


Fig 7: Algorithm for primary screening with HPV test Modified from WHO Guideline for Screening and Treatment of Precancerous Lesions for Cervical Cancer Prevention, 2023;

- *Women who test positive for HPV but have no lesion on colposcopy can be re-tested in 12-24 months with an HPV test for clearance and colposcopy repeated depending on resources available and to reduce overtreatment
- #Ablative treatment refers to thermal ablation or cryotherapy

Key Points to Note

- HPV test as the primary screening test when part of a screen-and-treat approach or a screen, triage and treat approach is strongly recommended
- Choice of approach should be made depending on context and in accordance to the feasibility, training and the resources needed for triage tests
- Women who test positive for hrHPV but have no lesion on colposcopy/VIA should re-test in 12 months; if still positive, repeat colposcopy
- Post-treatment, re-test with HPV after 12 months

Visual inspection methods

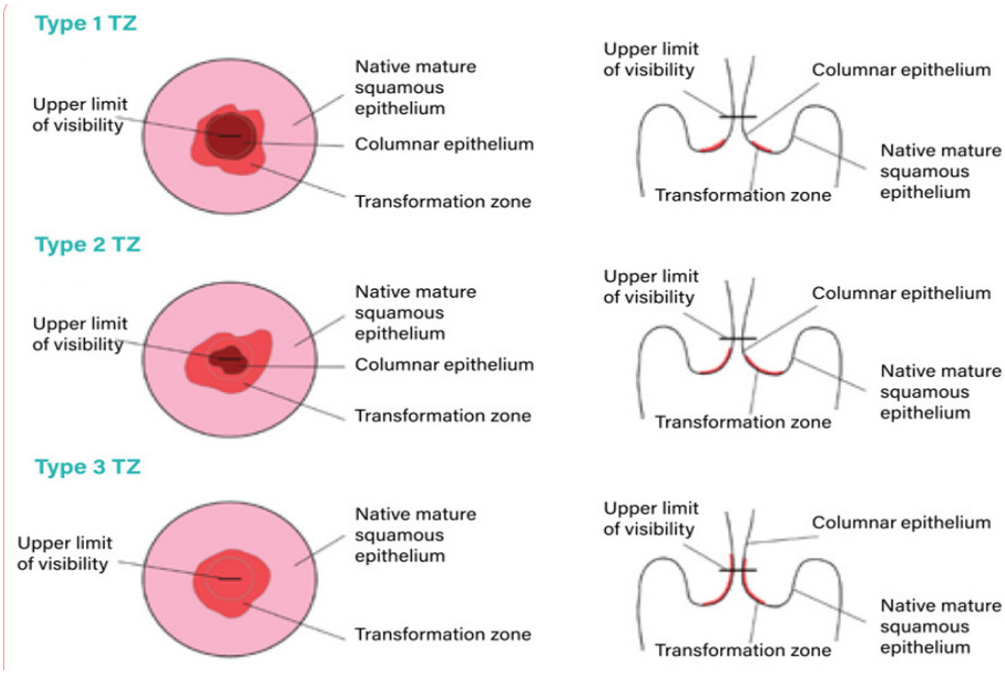
Visual inspection with acetic acid (VIA) is a method for detecting early cell changes that are visible when using a speculum to inspect the cervix with the naked eye after applying 5% acetic acid to it. It requires training and supervision of primary care providers, as well as ongoing quality control and quality assurance. It is quite inexpensive, utilizes locally sourced supplies (vinegar and cotton), and does not require laboratory services. It can be performed by trained providers, with adequate visual acuity, at any level of the health system.

We recommend preparing a 5% acetic acid solution using 99% glacial acetic acid mixed at a ratio of 5ml of glacial to 95ml of distilled water.

Anatomical Eligibility for VIA

VIA is appropriate to use in women whose squamocolumnar junction (SCJ) is visible, typically in those younger than 50.

This is because the SCJ gradually recedes into the endocervical canal when menopause occurs, making it possible to miss lesions when relying on visual inspection.



How to Perform VIA

1. Conducts a speculum examination following an assessment of the vulva and vagina.
2. During this examination, identify the squamocolumnar junction (SCJ) and meticulously inspect the cervix for any visual indications suggestive of cancer or abnormal lesion.
3. Apply a 3–5% acetic acid solution liberally to the cervix by spraying directly or applying a large cotton swab soaked in the acetic acid onto the cervix. If using a swab, wait for 60 seconds then remove the swab.
4. Inspect the cervix for any changes:
   Acetowhite changes on the cervix indicate likely cervical pre-cancer or cancer. If these changes are seen in the transformation zone and have well-defined borders, they are considered **a positive result.**
   If no persistent acetowhite changes are noted, then it is a **negative result.**
5. Document your findings

Note: The one-minute waiting time allows for any *areas that became faintly white due to inflammation or physiological cell changes (metaplasia) to recede.*

If the cervix shows any unusual signs or the provider suspects cancer, a punch biopsy should be collected or the patient can be referred for further diagnostic tests (colposcopy and biopsy).

VIA algorithm (Naked or Enhanced)

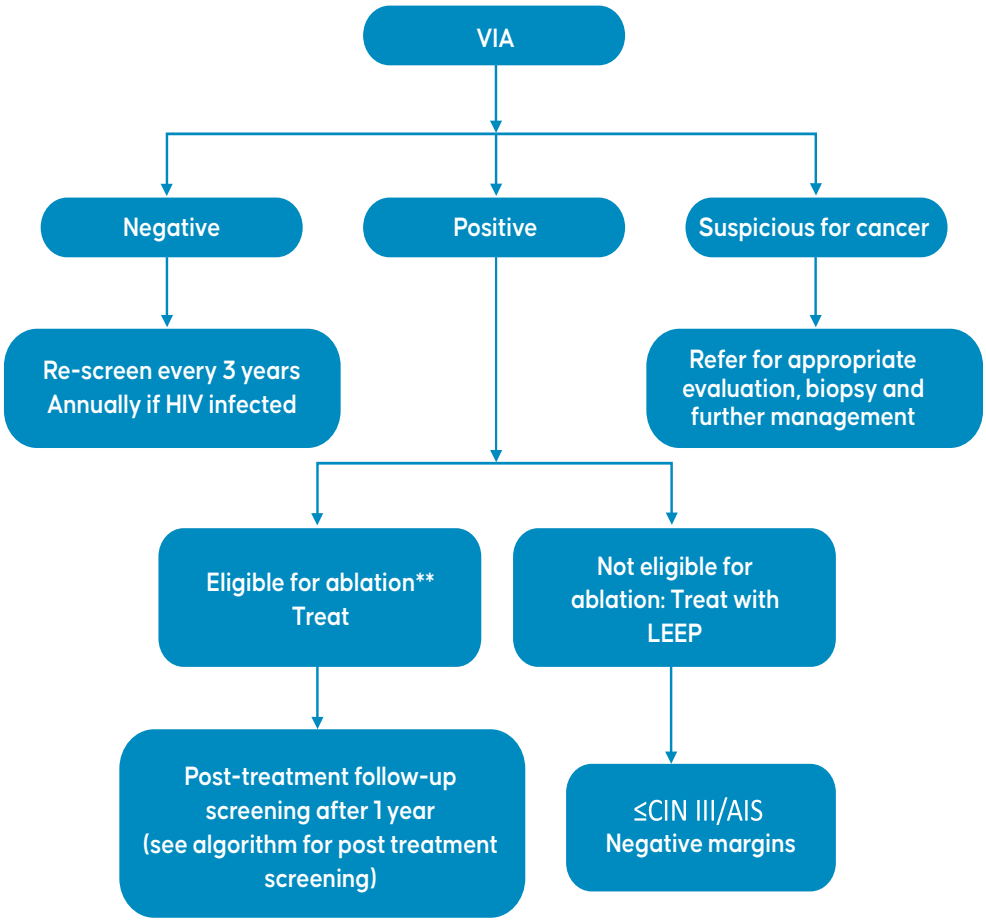


Fig 9: Algorithm for conducting visual inspection with acetic acid. Modified from WHO Guideline for Screening and Treatment of Precancerous Lesions for Cervical Cancer Prevention 2021 # Enhanced by Automated Visual Evaluation (AVE) algorithm with Artificial Intelligence capability with confirmation from an expert *Comprehensive Patient navigation structure with regional expert referral directorate is key to ensure minimizing loss to follow up **Ablation includes cryotherapy or thermal ablation

Exclusion Criteria For VIA

- Women who are very ill
- Women who are in 2nd and 3rd trimester of pregnancy
- Women less than 6 weeks after delivery
- Women with a mass suspicious for invasive disease (cauliflower-like growth or ulcer; fungating mass)
- Women with previous history of treatment of cancerous lesions
- Women with known allergy to acetic acid
- Women with a history of total hysterectomy

Cytology-based screening

Cytology-based screening involves taking a sample of cells from the entire transformation zone. The cells are either fixed on a slide at the facility (Pap smear) or placed in a transport medium (liquid-based cytology- LBC) and then sent to the laboratory for microscopic examination. Well-implemented cytology programs have successfully prevented cervical cancer in developed countries; however, they require highly skilled personnel and logistics which have been challenging in low-resource settings.

How to screen using cytology

Collection of a cytology sample requires a speculum and adequate lighting to visualize the entire surface of the cervix.

1. Collect the specimens from the face of the cervix and the endocervix using a spatula or brush and transfer the specimen to a slide (Pap smear) or a preservative solution (LBC).
2. Appropriately label and transport the sample to the laboratory
3. Cytotechnologists in the laboratory process and interpret it.

If abnormal cells are seen on microscopic examination, the extent of their abnormality is classified using the Bethesda System.

Cytology algorithm

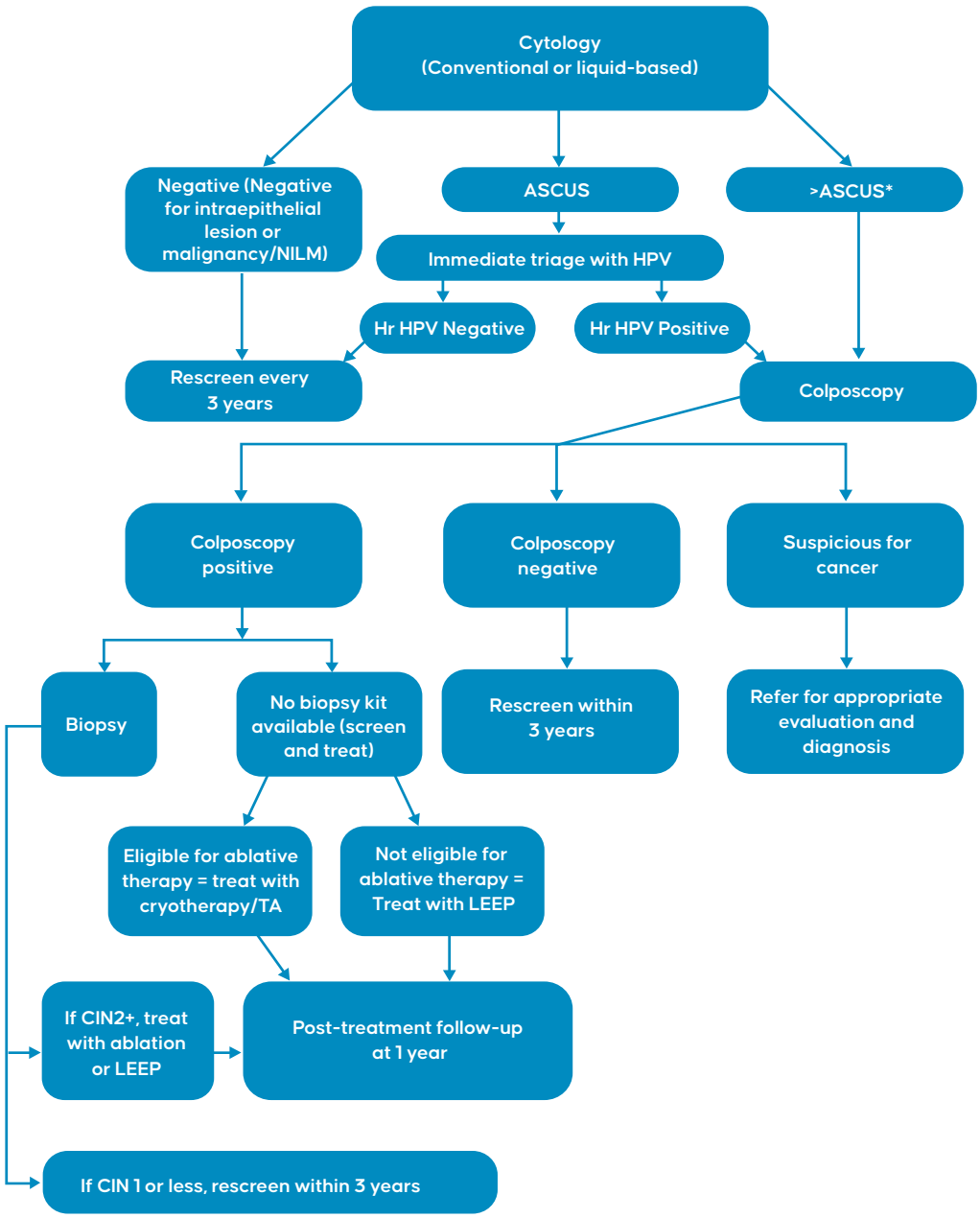


Fig 10: Algorithm for screening using cytology. Modified from WHO Guideline for Screening and Treatment of Precancerous Lesions for Cervical Cancer Prevention 2021 *Atypical Squamous Cells of Undetermined Significance or greater refers to squamous intraepithelial lesions, atypical glandular lesions or cancerous cells.

Recommendations for screening in special populations

Women Living with HIV

Women living with HIV (WLHIV) have higher risk of developing cervical cancer, hence the need for cervical cancer screen and treatment to be part of standard package of HIV care. Screening should start at age 25 years (regardless of when they first turned HIV positive), with HPV test as the primary screening method.

This means transitioning from high dependency on VIA-based screening to HPV-based screening in the country. In the absence of availability of HPV test, then the other tests may be employed. Women who turn screen positive, should be followed up with appropriate triaging strategy using either HPV16/18 genotyping, colposcopy, cytology, or VIA) to reduce the overall burden in this group (WHO, 2023). Screen and triage positive women should be treated with ablative or excisional methods. Those with suspected cancer should be referred appropriately.

HIV-infected women with CIN2+ have high rates of treatment at 1-year following ablative methods. Excision (LEEP or Cone Biopsy) is recommended to optimize cervical precancer treatment in this population.

When triage for HPV-positive WLHIV occurs during separate visits or at different clinics, there's a risk of loss to follow-up. To address this, we can leverage peer navigators and community-based models, such as HIV support groups. Additionally, aligning screening and triage visits with routine antiretroviral therapy (ART) dispensing and overall HIV care offers a systemic solution to improve continuity of care.

Table 6: Recommendations for Improving Service delivery for WLHIV

Strategy	Recommendation
Awareness creation on importance for early screening	Initiate discussions on the screening age of 25 years early, e.g. during HPV vaccination, through school health education programs, routine clinics, etc.
Primary test for screening	HPV-DNA
Mode of HPV test	Community and facility based self- or provider- collected options with well-defined collection and transportation of specimens

Age of Initiation of screening	25 years
Screening period	Lifetime
Screen interval	HPV -DNA: 5 yearly in HIV Negative VIA/ Cytology: Annually
HPV test positive management	Triage testing: Genotyping, Colposcopy evaluation where available, VIA, Cytology
Screen Triage Positive anagement	Treat with Thermal Ablation /LEEP
Post treatment follow up	Annually for lifetime Synchronize with other HIV services e.g., Viral load
Systems-based approach	Integrate Cervical cancer into HIV clinic Integrate HPV testing into HIV/TB platforms e.g., GeneXpert Expansion of number of the number and module capacity of GeneXpert equipment Dedicated testing days/hours /Personnel Capacity building for client navigators, CHPs, mentor mothers, peer educators, etc.

Women who are pregnant

- Screening can be done in the first trimester (up to the end of week 12)
- Treatment for precancerous lesion should NOT be performed during pregnancy, they should be re-evaluated 6 weeks post-delivery
- For suspicious lesions in pregnancy, a biopsy can be done at any trimester by a skilled health care provider noting that heavy bleeding could occur during the procedure

Post-partum women

- Cervical cancer screening should resume at 6 weeks after delivery

Women who have had a total hysterectomy

- Generally, they do not need to continue with cervical cancer screening if the hysterectomy was not performed for reasons related to cervical cancer or severe pre-cancerous lesion or dysplasia (HSIL)
- If the hysterectomy was performed due to high-grade cervical intraepithelial neoplasia (CIN) or cervical cancer, HPV testing or annual cytologic surveillance may be continued to screen for vaginal cancer or recurrence of the disease as there is a known risk factor for the development of secondary vaginal intraepithelial neoplasia (VAIN).

Women who have received HPV vaccination

- Women who have received the HPV vaccine should receive routine cervical cancer screening as per the national guidelines

Postmenopausal women

- Postmenopausal women should continue to undergo cervical cancer screening with HPV every five years, or cytology every three years, until the age of 65.

Women 65 years and above

- They should have had at least 2 negative HPV tests or 3 negative pap smears in the last 10 years for screening to be stopped.
- For women with a history of high-grade lesion or cervical cancer, screening will be lifelong and dependent on individual risks and history

Women Living with Disability

- Screening facilities must be accessible with adjustable examination tables and adequate space for mobility aids. The healthcare provider should communicate clearly and with appropriate tools to ensure understanding. Each case should be individualized and appropriate education, support and follow up care provided. Screening centres should also make arrangements to ensure effective communication with people with other disabilities, for example deaf women, who may need sign language interpreters.

Management of cervical pre-cancerous lesions

Treatment of precancerous lesions is a key consideration for the success of any cervical cancer prevention and screening program. A 'screen and treat' strategy is usually composed of two phases; the screening test followed by treatment of cervical intraepithelial lesions. Most screen-and-treat strategies to prevent cervical cancer will usually involve treatment with cryotherapy, thermal ablation or LEEP when a patient is not eligible for ablative procedures. Cold knife conization is a surgical procedure typically performed when there are indications of advanced cervical dysplasia that cannot be adequately evaluated through colposcopy and is used for both diagnostic and therapeutic purposes.

Points to note:

1. Screening and Eligibility:

ALL women who have screened positive, especially through HPV testing, should undergo colposcopy. In areas with no colposcopy, but with ablation methods, VIA should be done **to determine eligibility** for treatment with ablation or LEEP and rule out large cervical cancer lesions.

- **VIA Positive:** Women with positive VIA results should receive treatment.
- **VIA Negative:** Women with negative VIA results should not be treated.

2. Pre-Cancerous Lesions Treatment:
Women presenting for treatment of pre-cancerous lesions should be offered **HIV counseling and testing**. Immediate Referral: ALL women suspected to be having cancer should be referred immediately **for colposcopy with biopsy** and further management by a gynecologic oncologist.

3. Post-Treatment Follow-Up:
Women who have undergone treatment for precancerous lesions should receive post-treatment follow-up screening at one year after the treatment

Ablative procedures

Cryotherapy
This is an ablative form of treatment for precancerous lesions of the cervix which freezes cells using a cryoprobe with a tip made of highly conductive metal (usually silver and copper), that makes direct surface contact with the ectocervical lesion. Carbon dioxide or Nitrous oxide are usually the coolants of choice. Cells reduced to –20°C for one or more minutes will undergo cryonecrosis.
Cryotherapy is highly effective with cure rates of 85-90% for lesions occupying less than 75% of the cervix; however, for larger lesions the cure rate is reduced. When cryotherapy is indicated, only healthcare providers (including nurses or midwives) trained in cryotherapy should perform the procedure.

Thermal Ablation
The use of thermal ablation or thermocoagulation for the treatment of CIN is as effective as other methods, such as cryotherapy and LEEP, with the advantage of being rapid and is also associated with a low occurrence of side effects [Dolman, 2017]. It is a low-cost and simple treatment method comparable to cryotherapy. While cryotherapy is a highly effective intervention with a good cure rate, the low availability of refrigerant gas makes its use challenging in LMIC [Elit, 2011]. In this regard, thermal ablation represents an attractive alternative for the treatment of cervical precancerous lesions especially where electricity is available.

This method involves destruction of precancerous lesions in the transformation zone with temperatures between 100 - 120°C. It is a 20 second treatment procedure, followed by 20 seconds of waiting, followed by another 20 second treatment procedure. It requires electricity and overall takes about 1 minute to perform.

Table 7: Exclusion and Eligibility Criteria for Ablation

Exclusion Criteria for Ablation	Eligibility Criteria for Ablation
• Women with a history of prior treatment for precancer • Women with suspected cancer • Women with known pregnancy and until 6 weeks postpartum • Women with a lesion occupying more than 75% of the surface area of the cervix • The cryotherapy probe does not cover the lesion or leaves space of more than 2mm • The lesion extends more than 2mm into cervical canal or onto the vaginal wall	• Women with a positive test and an entirely visible lesion on the ectocervix, not extending to the vaginal wall or into the endocervix • The lesion can be adequately covered with a 2.5 cm cryotherapy probe • Women with no evidence of pelvic inflammatory diseases or cervicitis and with no polyps • Women who are not pregnant • Women who have given consent for treatment

Excisional methods

Loop electrosurgical excision procedure (LEEP)

LEEP, also referred to as Large Loop Excision of the Transformation Zone (LLETZ), is an excisional method of treatment for precancerous lesions. It is the treatment of choice for cervical lesions as it provides a histological sample that can be assessed for potential micro-invasion and margin status. It is recommended for lesions that do not meet the eligibility criteria for ablation. It involves removal of abnormal areas of the cervix by applying a low voltage high frequency alternating current to a thin wire loop electrode and slowly passing it through the cervix. The loop cuts and coagulates at the same time. LEEP is successful in eradicating pre-cancer in over 90% of cases. However, unlike ablative therapy, LEEP requires more highly skilled personnel, electricity and local anesthesia including colposcopy. Clients requiring LEEP should be referred to appropriately trained personnel. This guideline recommends that LEEP should be made available at all the Level 4, 5 and level 6 hospitals

Cone biopsy

Cone biopsy or Cold knife conization is the removal of a cone-shaped area from the cervix including the ectocervix and endocervix. It is usually done under general or regional anesthesia by gynecologists and gynecologic oncologists trained in the procedure and able to recognize and manage its complications, in an equipped surgical facility. Because of the possible side effects such as bleeding, cone biopsy should be reserved for cases that cannot be managed with ablation or LEEP excision. It can also be utilized as a second procedure post- LEEP where margins are positive and for confirmation of negative margins in patients who require less radical surgery for

early-stage low risk cervical cancer. The extent of conization depends on the size of the lesion; the woman's desire for fertility, and the likelihood of finding invasive cancer. The tissue removed is then subjected to histopathology.

Post-treatment follow-up

The first follow-up visit should be scheduled 1 year after treatment where re-testing is done preferably with HPV test to assess for clearance or cytology/VIA to check for a lesion if HPV is unavailable. If the initial follow-up test is negative, cytology/continued monitoring with HPV is recommended as per national guidelines for routine screening.

If the follow-up test is positive, further evaluation and possible re-treatment may be necessary. After treatment, retesting should occur 1 year later, as precancerous lesions can recur or persist despite treatment. Long-term surveillance is recommended, especially if the initial lesion was a high-grade lesion.

Algorithm for Post-treatment Follow-up for the General Population of Women

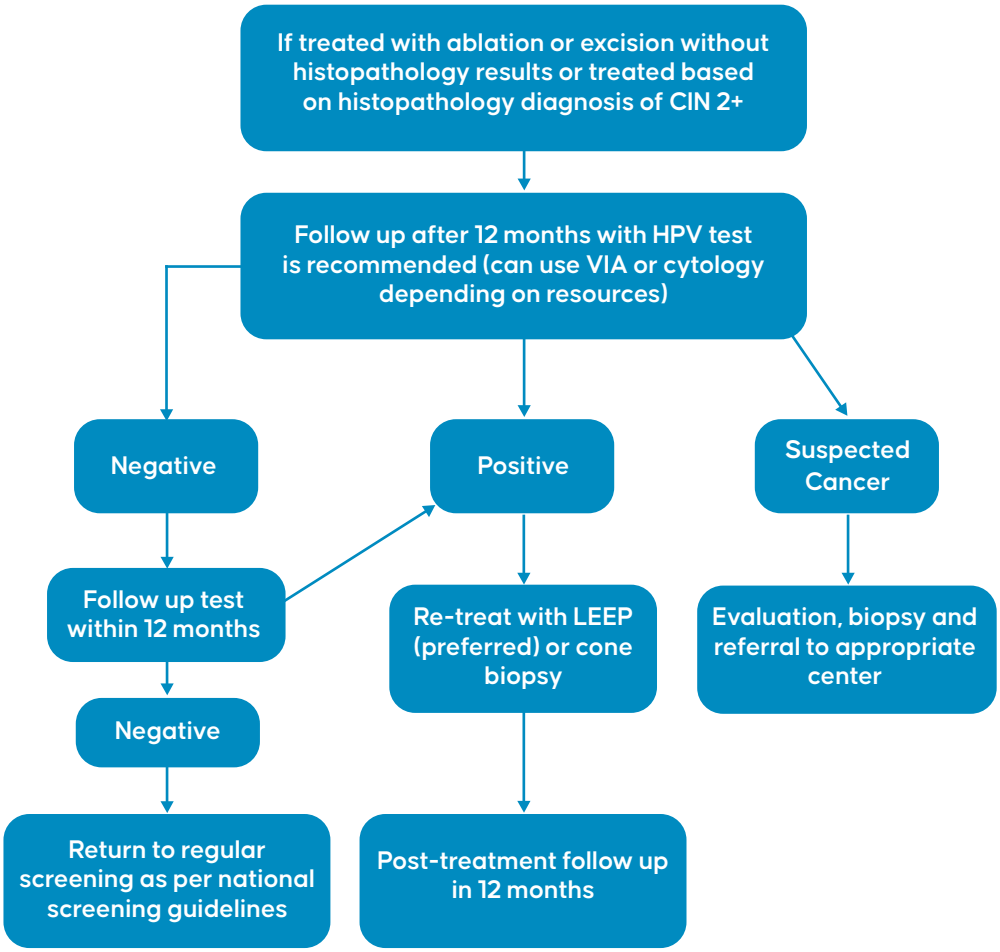


Fig 11: Post-treatment follow-up for women who were screen positive

Screening at various Healthcare Levels

Table 8: Screening at various healthcare levels

HEALTHCARE LEVEL & PERSONNEL	VIA	HPV	PAP SMEAR
Level 1		+ self-sample collection	
Level 2	+	+ sample collection	
Level 3	+	+ sample collection	
Level 4	+	+ sample collection, processing	+
Level 5	+	+ sample collection, processing	+
Level 6	+	+ sample collection, processing	+
Personnel required	Trained nurse, clinical officers, medical officers, gynaecologist	Sample collection: Client, Nurse, Clinical officer, medical officer Sample processing: Accredited lab by MOH	Trained nurse, clinical officers, medical officers, gynaecologist

References

1. A. B. Moscicki, S. Shiboski, N. K. Hills et al., "Regression of low-grade squamous intra-epithelial lesions in young women,"Lancet, vol. 364, no. 9446, pp. 1678–1683, 2004.
2. Abbas, K., Yoo, K. J., Prem, K., & Jit, M. (2024). Equity impact of HPV vaccination on lifetime projections of cervical cancer burden among cohorts in 84 countries by Global, regional, and income levels, 2010–22: A modelling study. eClinicalMedicine, 70, 102524. doi: 10.1016/j.eclinm.2024.102524
3. ACS, 2020 https://www.cancer.org/cancer/types/cervical-cancer/causes-risks-prevention/risk-factors.html#:~:text=Women%20who%20have%20had%203,HPV%20infection%20with%20sexual%20activity.
4. Alliance for Cervical Cancer Prevention (ACCP). Planning and Implementing Cervical Cancer Prevention and Control Programs: A Manual for Managers. Seattle: ACCP; 2004.
5. Arbyn M, Haelens A, Desomer A, Verdoodt F, Thiry N, Francart J, Hanquet G, Robays J. Cervical cancer screening program and Human Papillomavirus (HPV) testing, part II: Update on HPV primary screening. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). 2015. KCE Reports 238. D/2015/10.273/17.
6. Austin, R. M., Onisko, A. & Zhao, C. Enhanced detection of cervical cancer and precancer through use of imaged liquid-based cytology in routine cytology and HPV cotesting. Am J Clin Pathol 150, 385–392

(2018).
7. Basu P, Malvi SG, Joshi S, Bhatla N, Muwonge R, Lucas E, Verma Y, Esmy PO, Poli URR, Shah A, Zomawia E, Pimple S, Jayant K, Hingmire S, Chiwate A, Divate U, Vashist S, Mishra G, Jadhav R, Siddiqi M, Sankaran S, Prabhu PR, Kannan TPRA, Varghese R, Shastri SS, Anantharaman D, Gheit T, Tommasino M, Sauvaget C, Pillai MR, Sankaranarayanan R. Vaccine efficacy against persistent human papillomavirus (HPV) 16/18 infection at 10 years after one, two, and three doses of quadrivalent HPV vaccine in girls in India: a multicentre, prospective, cohort study. Lancet Oncol. 2021 Nov;22(11):1518-1529. doi: 10.1016/S1470-2045(21)00453-8. Epub 2021 Oct 8. Erratum in: Lancet Oncol. 2022 Jan;23(1): e16. doi: 10.1016/S1470-2045(21)00700-2. PMID: 34634254; PMCID: PMC8560643.
8. Berraho, M., Amarti-Riffi, A., El-Mzibri, M. et al. HPV and cofactors for invasive cervical cancer in Morocco: a multicentre case-control study. BMC Cancer 17, 435 (2017). https://doi.org/10.1186/s12885-017-3425-z
9. Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024; 74(3): 229-263. doi:10.3322/caac.21834
10. Bruni L, Albero G, Serrano B, Mena M, Collado JJ, Gómez D, Muñoz J, Bosch FX, de Sanjosé S. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in the World. Summary Report 10 March 2023.
11. Bruno, M.T., Cassaro, N., Mazza, G. et al. Spontaneous regression of cervical intraepithelial neoplasia 3 in women with a biopsy—cone interval of greater than 11 weeks. BMC Cancer 22, 1072 (2022). https://doi.org/10.1186/s12885-022-10179-1
12. Chesson HW, Dunne EF, Hariri S, Markowitz LE. The estimated lifetime probability of acquiring human papillomavirus in the nited States. Sex Transm Dis. 2014 Nov;41(11):660-4. doi: 10.1097/OLQ.0000000000000193. PMID: 25299412; PMCID: PMC6745688.
13. Comprehensive cervical cancer control: a guide to essential practice, second edition. Geneva: World Health Organization; 2014 (https://www.who.int/reproductivehealth/publications/cancers/ cervical-cancer-guide/en/).
14. Dolman L, Suvaget C, Muwonge R, et al. Meta-analysis of the efficacy of cold coagulation as a treatment method for cervical intraepithelial neoplasia: a systematic review. BJOG. 2014; 121:929–42.
15. Elit L, Jimenez w, McAlpine J, et al. Cervical cancer prevention in low-resource settings. J Obstet Gynaecol can. 2011;33(3):272–9.
16. https://www.asccp.org/guidelines.
17. Lehtinen M, Lagheden C, Luostarinen T, Eriksson T, Apter D, Bly A, Gray P, Harjula K, Heikkilä K, Hokkanen M, Karttunen H, Kuortti M, Nieminen P, Nummela M, Paavonen J, Palmroth J, Petäjä T, Pukkala E, Soderlund-Strand A, Veivo U, Dillner J. Human papillomavirus vaccine efficacy against invasive, HPV-positive cancers: population-based follow-up of a cluster-randomised trial. BMJ Open. 2021 Dec 30;11(12):e050669. doi: 10.1136/bmjopen-2021-050669. PMID: 35149535; PMCID: PMC8719207.
18. Lei J, Ploner A, Elfström KM, Wang J, Roth A, Fang F, Sundström K, Dillner J, Sparén P. HPV Vaccination and the Risk of Invasive Cervical Cancer. N Engl J Med. 2020 Oct 1;383(14):1340-1348. doi: 10.1056/NEJMoa1917338. PMID: 32997908
19. Maria Teresa Bruno, Nazario Cassaro, Francesca Bica, Sara Boemi, “Progression of CIN1/LSIL HPV Persistent of the Cervix: Actual Progression or CIN3 Coexistence”, Infectious Diseases in Obstetrics and Gynecology, vol. 2021, Article ID 6627531, 6 pages, 2021. https://doi.org/10.1155/2021/6627531
20. Mati JK, Mbugua S, Ndavi M. Control of cancer of the cervix: feasibility of screening for premalignant lesions in an African environment. IARC Sci Publ. 1984;(63):451-63. PMID: 6536618.

21. Mekonnen AG, Mittiku YM. Early-onset of sexual activity as a potential risk of cervical cancer in Africa: A review of literature. PLOS Glob Public Health. 2023 Mar 22;3(3):e0000941. doi: 10.1371/journal.pgph.0000941. PMID: 36962975; PMCID: PMC10032528
22. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. J Low Genit Tract Dis 2020; 24:102.
23. Stelzle D, Tanaka LF, Lee KK, Ibrahim Khalil A, Baussano I, Shah ASV, McAllister DA, Gottlieb SL, Klug SJ, Winkler AS, Bray F, Baggaley R, Clifford GM, Broutet N, Dalal S. Estimates of the global burden of cervical cancer associated with HIV. Lancet Glob Health. 2021 Feb;9(2):e161-e169. doi: 10.1016/S2214-109X(20)30459-9. Epub 2020 Nov 16. Erratum in: Lancet Glob Health. 2021 Feb;9(2):e119. doi: 10.1016/S2214-109X(20)30509-X. PMID: 33212031; PMCID: PMC7815633.
24. Tekalegn Y, Sahiledengle B, Woldeyohannes D, et al. High parity is associated with increased risk of cervical cancer: Systematic review and meta-analysis of case–control studies. Women's Health. 2022;18. doi:10.1177/17455065221075904
25. WHO 2024 https://www.who.int/news-room/fact-sheets/detail/cervical-cancer#:~:text=Key%20facts,-%20and%20middle-income%20countries.
26. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021.
27. WHO, 2022, https://www.who.int/news/item/20-12-2022-WHO-updates-recommendations-on-HPV-vaccination-schedule
28. WHO. (2020). WHO recommendations on self-care interventions. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/325480/9789241550550-eng.pdf?ua=1
29. Woodman, C., Collins, S. & Young, L. The natural history of cervical HPV infection: unresolved issues. Nat Rev Cancer 7, 11–22 (2007). https://doi.org/10.1038/nrc2050.
30. Singini MG, Singh E, Bradshaw D, Ramaliba T, Chen WC, Motlhale M, Kamiza AB, Babb de Villiers C, Muchengeti M, Mathew CG, Newton R, Bender N, Waterboer T, Sitas F. Usefulness of high-risk HPV early oncoprotein (E6 and E7) serological markers in the detection of cervical cancer: A systematic review and meta-analysis. J Med Virol. 2023 Jan;95(1):e27900. doi: 10.1002/jmv.27900. Epub 2022 Jun 9. PMID: 35641882; PMCID: PMC10952611.
31. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention: use of mRNA tests for human papillomavirus (HPV). Geneva: World Health Organization; 2021.
32. Clarke MA, Gradissimo A, Schiffman M, Lam J, Sollecito CC, Fetterman B, Lorey T, Poitras N, Raine-Bennett TR, Castle PE, Wentzensen N, Burk RD. Human Papillomavirus DNA Methylation as a Biomarker for Cervical Precancer: Consistency across 12 Genotypes and Potential Impact on Management of HPV-Positive Women. Clin Cancer Res. 2018 May 1;24(9):2194-2202. doi: 10.1158 / 1078-0432.CCR-17-3251. Epub 2018 Feb 2. PMID: 29420222; PMCID: PMC5932258.
33. Gilles, C., Velghe-lenelle, M., Manigart, Y. et al. Should the management of high grade cervical squamous intraepithelial lesion (HSIL) be different in HIV-positive women? AIDS Res Ther 18, 44 (2021). https://doi.org/10.1186/s12981-021-00371-x
34 Cuzick J, Cadman L, Mesher D, Austin J, Ashdown-Barr L, Ho L, Terry G, Liddle S, Wright C, Lyons D, Szarewski A. Comparing the performance of six human papillomavirus tests in a screening population. Br J Cancer. 2013 Mar 5;108(4):908-13. doi: 10.1038/bjc.2013.22. Epub 2013 Jan 31. PMID: 23370211; PMCID: PMC3590662.

BREAST CANCER SCREENING

BREAST CANCER SCREENING

Key messages

- Breast cancer epidemiology in Kenya starts peaking at age 40 years; therefore, an earlier screening age is recommended in these guidelines
- A risk-based early detection breast cancer program is recommended
- A CBE-driven program is proposed; which can aid in down-staging breast cancer diagnosis and reduce mortality
- Mammography is the recommended method of screening for women in the average risk population

Introduction

Globally, breast cancer is ranked 2nd in cancer incidence with 2 296 840 (accounting for 11.5% of all new cases), while it is 4th in mortality with 666 103 [6.8% of all cancer deaths] (GCO, 2022). In Kenya, breast cancer is ranked 1st in cancer incidence with 7 243 (accounting for 16.2 % of all new cases), while it is 2nd in mortality with 3 398 [11.6% of all cancer deaths] (GLOBOCAN, 2022).

In African women, the mean age for breast cancer at diagnosis ranges from 45.8 - 59.6 years, with the highest number of cases below 45 years, which is 10 –15 years earlier than peak incidence for western countries outside of the western Africa region (Amir et al,1994; Anyanwu,2000; Walburga et al 2019). Available data shows that between 50-70% of patients in Africa present at advanced stages (Stage III/IV) contributing to higher mortality and low overall survival (Ganiy et al 2012). In Kenya, 50.7% presented at Tumour, Node and Metastasis (TNM)stages III/IV (Abinya et al 2018).

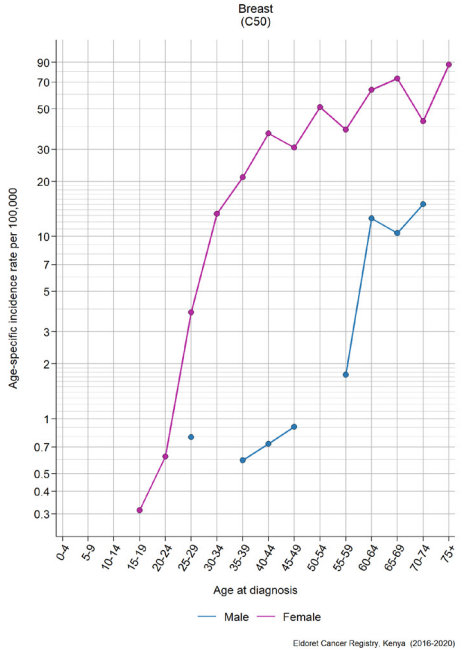


Figure 12: Epidemiology of breast cancer, Kenya, 2016-2020: Age-specific incidence rate per 100,000 (source: Eldoret/Uasin Gishu Population-Based Cancer Registry).

Rationale for early detection and screening

The initial guideline of 2018 indicated use of mammogram from level 4, while the Breast Cancer Action Plan recommended CBEs from level 2 facilities with referrals for screening mammograms in Level 5 and above facilities. Further, a baseline study performed by Ministry of Health/NCCP noted significant logistical and health system barriers to scale up of mammography screening, while it indicated availability of Clinical Breast Cancer (CBE) in 98.9% of the facilities.

In any screen-naïve population without a well-organized, mammography-based screening program, where late diagnosis in Stage 3 and 4 is prevalent, CBE is considered a reasonable approach to support early diagnosis of breast cancers. Furthermore, WHO and Breast Health Global Initiative (BHGI) supports early detection by use of CBE in low- and middle-income countries (LMICs) where roll-out of mammography would be expensive and logistically challenging.

This current guideline edition, therefore emphasizes the need for early diagnosis through CBE at all levels with appropriate referral to Level 4, 5 or 6 facilities for diagnostic mammogram.

The goal of these guidelines is to provide guidance on the appropriate use of clinical and screening tools for early detection of breast cancer and to help physicians, clinicians and women make informed decisions about screening for breast cancer.

Risk Factors for Breast Cancer

- Hereditary and family History
- Mutations (e.g., BRCA1, BRCA2)
- Previous abnormal biopsy
- Chest wall radiation
- High breast density

Hormonal factors -nulliparity, early menarche (less 11 years), late first delivery (more than 30), no breastfeeding history, late menopause, hormone replacement therapy (HRT)

Lifestyle–obesity, physical inactivity, tobacco & alcohol

Heredity and Family History

Having one or two affected first-degree relatives is associated with a higher risk of breast cancer, with a lifetime excess incidence of breast cancer of 5.5% and 13.3% respectively. The increase in risk is greater for younger women and when the relative was affected at a younger age (Collaborative Group, 2001).

Known Mutations

Women with hereditary BRCA1 and BRCA2 mutations have a cumulative lifetime risk of breast cancer of 57%. It is therefore important to assess cancer history from both the paternal and maternal side (Collaborative Study Group, 2000). Breast cancer and ovarian cancer may also occur in other genetic syndromes (e.g., PALB2, CHEK2). Assessment, counselling, and potential genetic testing for these syndromes will be considered by Medical Geneticists or Physicians.

Biopsy Proven Atypical Hyperplasia or Lobular Carcinoma in situ

Women with atypical hyperplasia or lobular carcinoma in situ in previous breast biopsies, have a four-fold increased risk of cancer which persists for at least 25 years (Hartman et al,2005).

Radiation

Women with a history of chest wall radiation as treatment for another cancer have up to a ten-fold increased risk for breast cancer (Terenziani M et al, 2013).

The risk of breast cancer due to radiation exposure during mammography is negligible compared with the expected mortality reduction that can be gained through screening (Yaffe, 2011).

Breast Density

Women with extremely dense breasts have about a two-fold increased risk compared to women with breasts of average density (Gierach, 2012).

Hormonal Influences

Women with earlier age of menarche and/or later age of menopause (Collaborative Group, 2012) have an increased risk of breast cancer, mediated in part by the increased number of menstrual cycles and the longer lifetime exposure to estrogen and progesterone.

Reproductive History

Nulliparity also increases a woman's risk of breast cancer, and every live birth reduces the relative risk by about 7%. Women 30 years or older at the time of their first live birth have a higher risk of breast cancer than women having their first child at a younger age (Nelson, 2012).

Breastfeeding

Breastfeeding can lower breast cancer risk, especially if a woman breastfeeds for longer than 1 year (Collaborative group, 2002).

Hormone Replacement Therapy

Prolonged use of combined estrogen-progesterone hormone replacement therapy (HRT) increases the breast cancer by 15% though this returns to baseline within about 2 years of stopping HRT. Estrogen therapy alone increases breast cancer risk as well, but the increased risk is lower than for combined therapy (Beral et al 2011).

Lifestyle risk factors

- **Obesity:** Obesity is associated with an increased risk of postmenopausal breast cancer, as is weight gain throughout adulthood. Obesity also negatively affects prognosis of early-stage breast cancer (Ligibel J, 2011).
- **Physical Activity:** Breast cancer risk is reduced by about 25% among physically active women compared to the least active women (Friedenreich CM, 2011).
- **Alcohol Consumption:** Regular consumption of as little as one drink per day elevates the risk of breast cancer by about 4%. (Mandelson et al, 2000). The risk increases steadily with increasing consumption regardless of the type of alcohol consumed (Seitz HK et al, 2012).
- **Tobacco Use:** Studies have demonstrated that there is a causal association between active smoking and second-hand tobacco smoke and breast cancer (Collishaw et al, 2009).

Early detection strategy

Clinical Breast Examination (CBE)

CBE should be considered as part of a physical examination and used as an opportunity to discuss and educate the woman on breast health. Studies indicate that a well-done CBE downgrades breast cancer and indirectly reduces mortality. It has sensitivity of 36-52%, specificity of 78-94%, and a positive predictive value of 1%. **While it should not be considered as a replacement for mammography in screening, it is valuable in early diagnosis and therefore is recommended for level 2, 3 and 4 of care.**

CBE positive findings include:

- Breast lump
- Breast pain
- Nipple discharge
- Skin changes - including peau d'orange,
- Axillary nodes

Ultrasound

Ultrasound, when available and if conducted by a competent clinician, should be considered as an adjunct to CBE in women below 39 years as complementary to mammography for those above 40 years. Ultrasound is not recommended for routine screening for the average risk population. It may be used to complement mammography in situations where patients have increased breast density.

Mammography

Mammography is the recommended method of screening for women in the average risk population.

(NCCN 2016).

Mammography is the only screening modality shown to reduce breast cancer mortality directly. Possible risks of mammography are listed in the table below.

Risks of Mammography

False negative results – this gives a false sense of security that may delay diagnosis.

False positive results - associated with anxiety and requiring extra unnecessary tests.

Breast Self-Examination (BSE) and Awareness

BSE is not recommended as a screening method.

However, women are encouraged to be aware and to report changes in their breasts, such as nipple discharge, rash on nipples, inversion, dimpling or new mass in the breast or axilla. The healthcare provider should discuss and educate the women about their breast health and promote breast awareness. (Textbox 12)

Key messages on breast self-examination and breast awareness:

- Knowledge of what is normal in your breast is important to maintain good breast health
- Discuss breast health and awareness with your healthcare provider
- Report any abnormality noted in your breast
- Self-breast examination and clinical breast examination are complementary but do not substitute mammography as screening tool
- Asymptomatic women above 40 years require a baseline mammography screening
- Breast cancer also occurs in men though rarely. They need to have breast awareness and not routine screening

Magnetic Resonance Imaging (MRI)

MRI is not recommended for routine screening the average risk population.

MRI may be used for screening in select high-risk populations or in specific circumstances as determined by a clinician such as previous lumpectomy, radiation, or trauma to breast.

Other Methods

Tomosynthesis, thermography, elastography and PET scans are not recommended for screening of breast cancer. Tomosynthesis may be used in specific circumstances to complement mammography as may be determined by a radiologist.

BSE, CBE, and Ultrasound are not screening modalities, but they aid in early detection of breast cancer.

Integration

Breast Cancer Screening should be integrated with Cervical Cancer Screening (see cervical cancer screening guidelines)

Target population

The target population for screening will depend on the risk of the patient, which could be defined as average risk or high risk as defined below (NCCN 2016).

Risk Assessment

An assessment of risk for breast cancer should be done for all women considering age, medical history, family history, and other associated risks in determining her breast cancer screening needs.

Assessment of risk stratifies women into two risk categories as follows:

- Average Risk Population-More than 80% of breast cancer occurs in women in the average risk population.
- High Risk Population
  - Women Requiring More Intensive Screening
  - Criteria for Referral to Medical Genetics

Average risk population

The average risk population is defined as that population of women who do not exhibit any of the risk factors that define the high-risk population. The clinician should discuss the benefits and risks of screening specific to each age group. (NCCN 2022).

Exclusions:

- Women with signs and symptoms suggestive of breast cancer
- Women with a previous diagnosis of ductal carcinoma in situ or invasive breast cancer
- Men

Table 9: Recommendations per age category for Women with average risk are provided below.

Age Group	Recommendation	Interval
25 - 34 years	CBE	Every 3 years
35 - 39 years	CBE and Ultrasound	Every 2 years
40 - 55 years	CBE + mammography	Annual
56 - 74 years	CBE + mammography	Every 2 years
75 years and older	Consider individual health factors and woman's preference to continue screening	Discuss with patient

Notes:
Clinical judgment may be used to adjust the frequency of screening considering individual differences.
Women who have had surgery for breast augmentation, breast reduction or sex-reassignment should follow the same recommendations below for mammographic screening as those in the average risk population. The clinician should clearly state presence of breast implants in the mammography requisition form.

High risk population

Women in the high-risk population require more intensive screening and/or genetic counselling. Women with the following characteristics are classified as high risk for breast cancer (Textbox 14).
Women who do not fulfil any of the five criteria should be classified in the average risk group.

High risk characteristics for breast cancer.

- Affected first degree relatives.
- Previous abnormal breast biopsy
- Previous chest wall radiation
- Previous breast cancer
- Genetic mutation known to increase risk of breast cancer

The screening recommendations for these are as follows:

1. Women with one or two first degree relatives with invasive breast cancer, but who do not meet the criteria for referral to Medical Genetics (See criteria below).
   - CBE-starting at age 21 years
   - Annual mammography starting 10 years younger than the youngest case in the family, but no earlier than age 25 and no later than age 40.
   - Complementary imaging like ultrasound and MRI in addition to the above where justified.
2. Women with a breast biopsy showing atypical hyperplasia or lobular carcinoma in situ and following surgical management to rule out invasive carcinoma:
   - CBE every 6-12 months
   - Annual mammography
3. Women with a history of chest wall radiation at age 30 or younger:
   - Annual mammography and MRI starting 5years after radiation given but starting no earlier than age 25 and no later than age 40.
   - Annual CBE

4. Women with previous breast cancer require screening of contralateral breast.
   - CBE every 6-12 months
   - Annual mammography

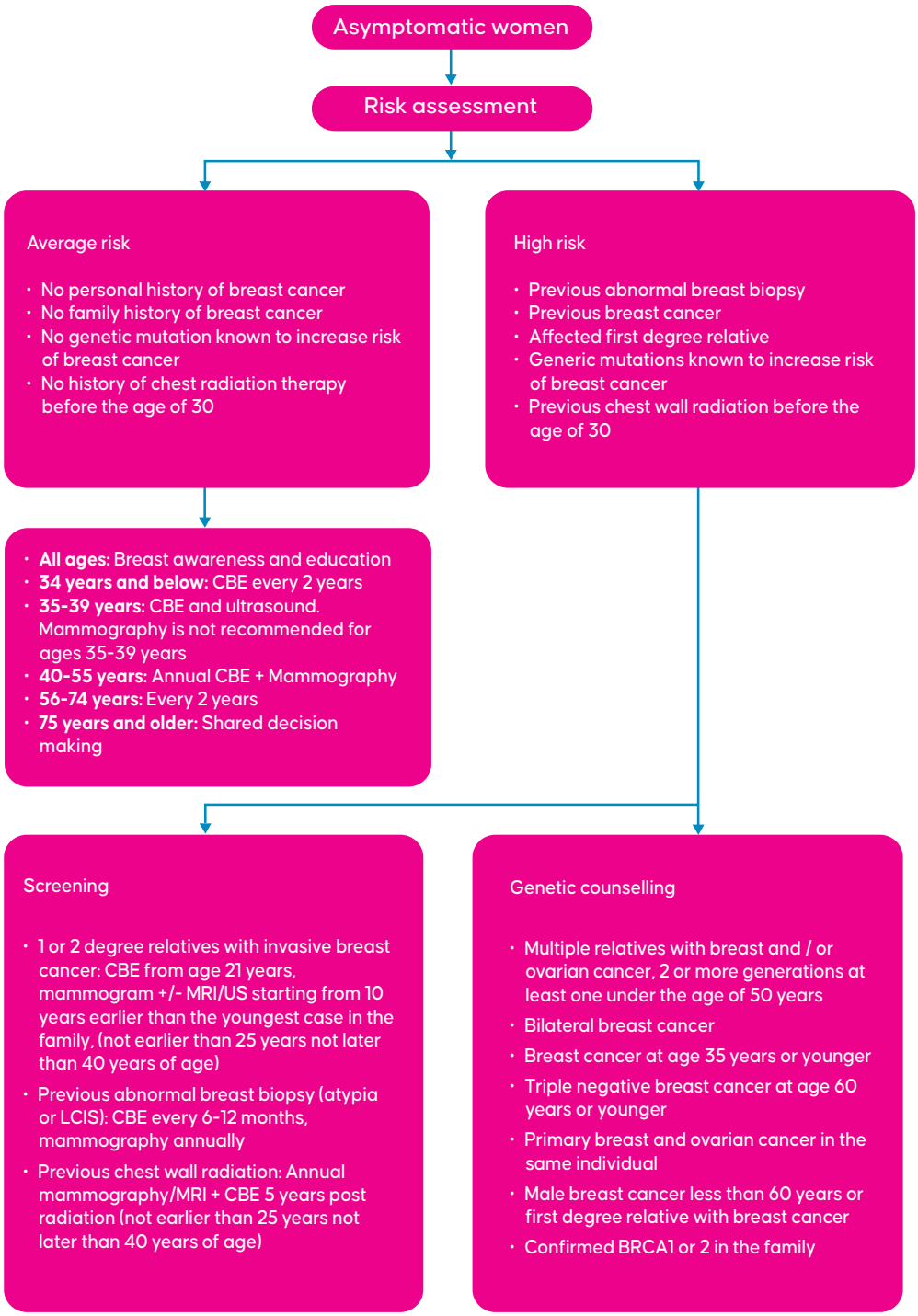
Criteria for referring high risk women for genetic counselling

Some women in the high-risk population will require referral for genetic testing and counselling.

These include the following:

1. An individual with several relatives with breast and/or ovarian cancer (e.g., three or more cases) in two or more generations, at least one case with onset under the age of 50)
2. Bilateral primary breast cancer
3. Breast cancer at age 35 or younger
4. Breast cancer that is hormone receptor negative and HER2 negative (triple negative), age 60 or younger
5. Primary breast and primary ovarian cancer in the same individual
6. Male breast cancer, age 65 or younger, or at any age if with close family history of breast cancer
7. Confirmed BRCA1 or BRCA2 mutation in the family.

Figure 13: Risk Assessment Algorithm for Breast Cancer:



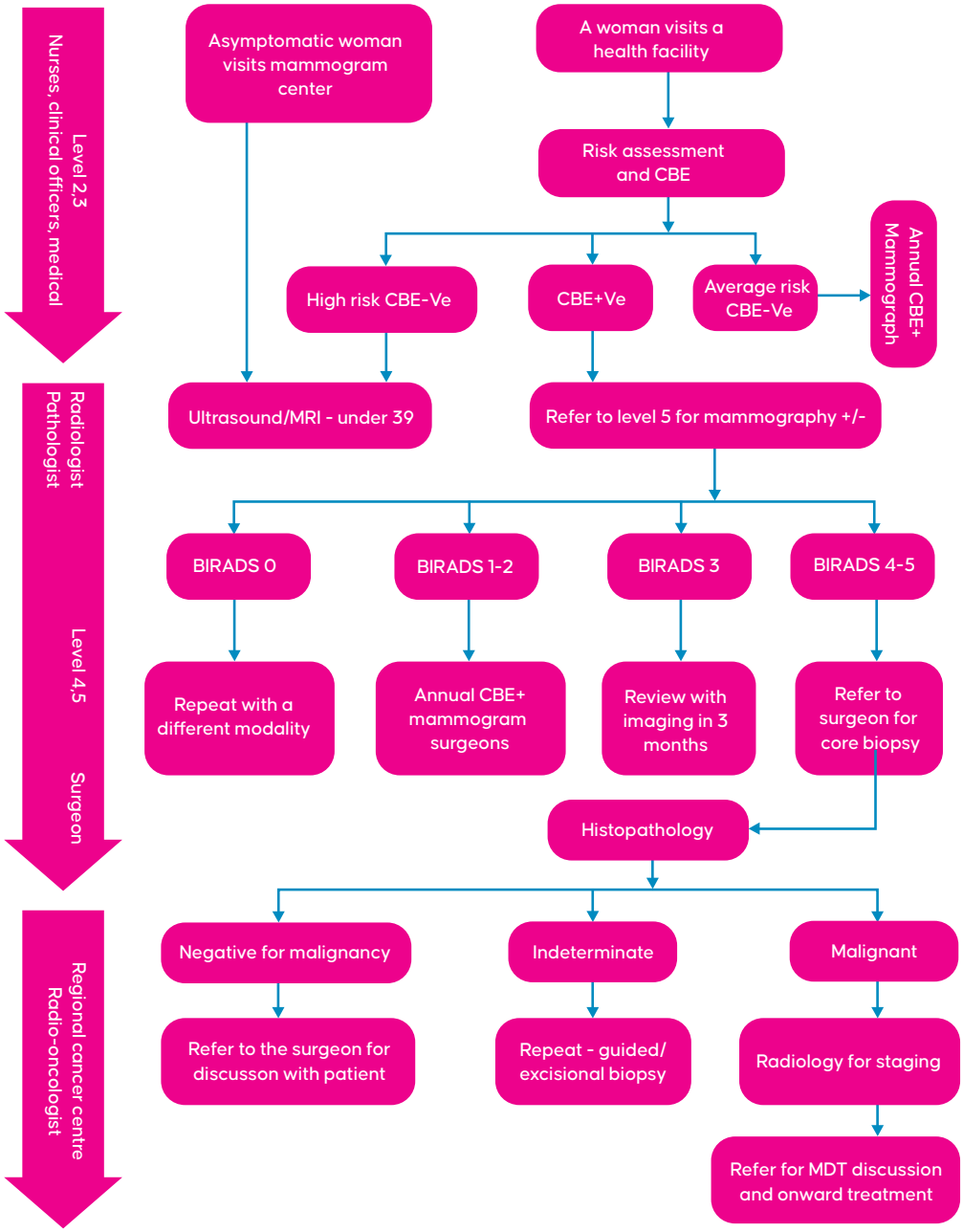
Screening at various Healthcare Levels

The table below shows the breast cancer screening activities to be performed at the various levels of service delivery of Kenya Essential Package for Health (KEPH):

Table 10: Breast Cancer Screening at various Health care Levels

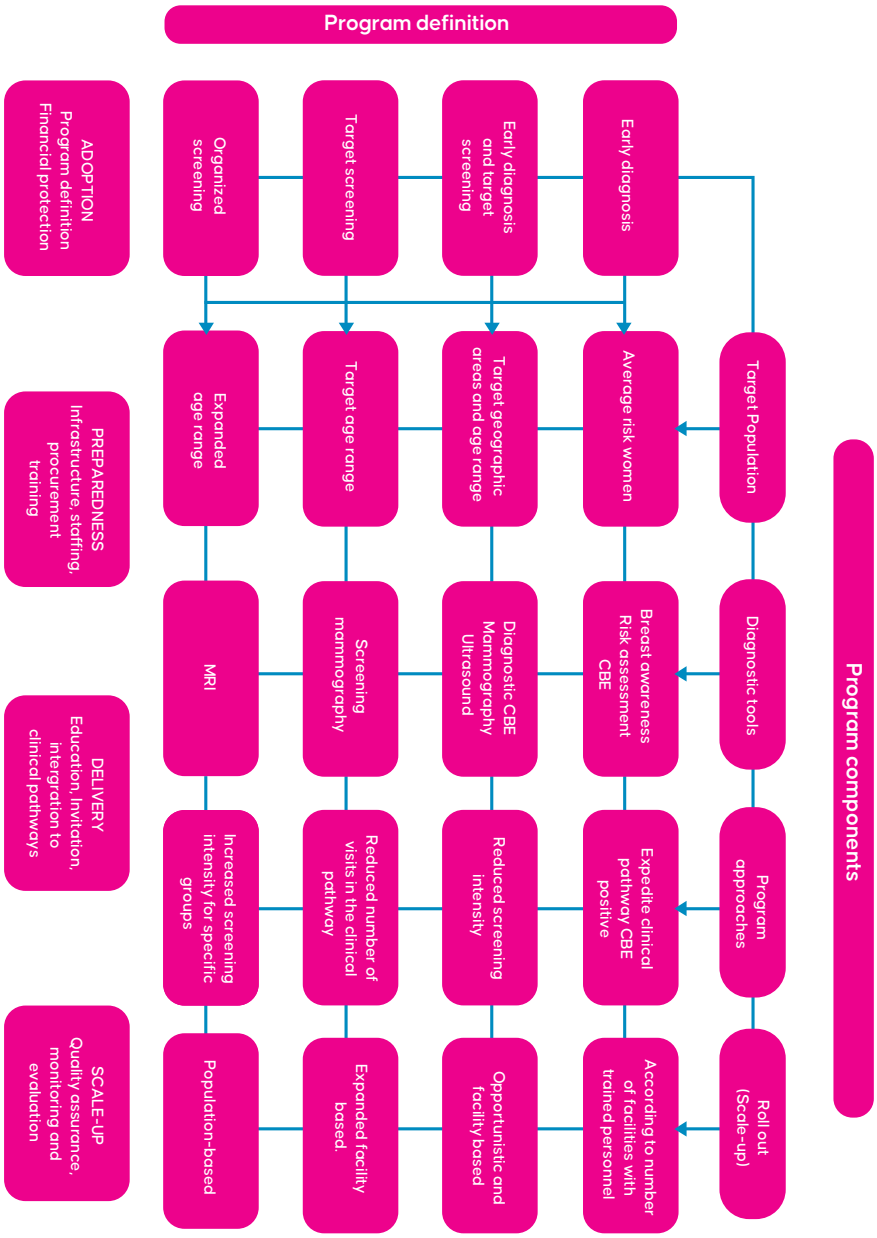
LEVEL	TYPE	CADRES	ACTIVITIES
1	Community	Community Health Assistant (CHAs)& Promoters (CHP)	Breast awareness Mobilization
2	Dispensary	Nurses	Breast awareness Mobilization CBE
3	Health Centres	Clinical officers Nurses	Breast awareness Mobilization CBE
4	Sub-county	Nurses Clinical officers Medical officers General surgeon Sonographers Radiographers Radiologist Pathologist	Breast awareness Mobilization CBE Ultrasound Mammogram
5	County/ Regional	Nurses Clinical officers Medical officers General surgeon Radiographers Sonographers Radiologist Pathologist Oncologist	Breast awareness Mobilization CBE CBE/ BSE/ Biopsy Mammogram Ultrasound CBE/BSE, Mammography CBE/ Biopsy Treatment
6	Referral	Nurses Clinical officers Medical officers Breast surgeon Radiographers Sonographer Radiologist Pathologist Oncologist	Breast awareness Mobilization/ Breast awareness/ CBE CBE/ Treatment CBE/Biopsy/ Surgery Mammogram Ultrasound CBE/BSE, Mammography CBE/Biopsy/ Reporting Treatment/ Monitoring

Figure 14: Breast Cancer Screening and Referral Algorithm



*This reprents women who may appear at imaging centers, with preference for undergoing imaging.

Figure 15: Breast cancer early detection program components



References

1. Anglian Breast Cancer Study Group. Prevalence and penetrance of BRCA1 and BRCA2 mutations in a population-based series of breast cancer cases. Anglian Breast Cancer Study Group. Br. J. Cancer. 2000 Nov;83(10):1301–8.
2. Amir H, Kitinya JN, Parkin DM. A comparative study of carcinoma of the breast in an African population. East Afr Med J. 1994; 71:2151994; 71:215–218.
3. Amir H, Makwaya CK, Aziz MR, Jessani S. Breast cancer and risk factors in an African population: a case referent study. East Afr Med J. 1998; 75:268–270.
4. Anyanwu SN. Breast cancer in eastern Nigeria: a ten-year review. West Afr J Med. 2000; 19:120 –125.
5. Beral V, Reeves G, Bull D, Green J. Breast cancer risk in relation to the interval between menopause and starting hormone therapy. J. Natl. Cancer Inst. 2011 Feb 16;103(4):296–305.
6. Breast Cancer Screening. Information available at: www.ScreeningforLife.ca/breastcancer
7. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and breastfeeding: collaborative reanalysis of individual data from 47 epidemiological studies in 30 countries, including 50302 women with breast cancer and 96973 women without the disease. Lancet. 2002 Jul 20;360(9328):187–95.
8. Collaborative Group on Hormonal Factors in Breast Cancer. Familial breast cancer: collaborative reanalysis of individual data from 52 epidemiological studies including 58,209 women with breast cancer and 101,986 women without the disease. Lancet. 2001 Oct 27;358(9291):1389–99.
9. Collaborative Group on Hormonal Factors in Breast Cancer. Menarche, menopause, and breast cancer risk: individual participant meta-analysis, including 118964 women with breast cancer from 117 epidemiological studies. Lancet Oncol. 2012 Nov;13(11):1141–51.
10. Collishaw NE, Boyd NF, Hammond SK, Johnson KC, Millar J, Palmer JR, et al.
11. Canadian Expert Panel on Tobacco Smoke and Breast Cancer Risk: full report [Internet]. Toronto, Canada: Ontario Tobacco Research Unit; 2009 Apr. Available from: http://otru.org/wp-content/uploads/2012/06/expert_panel_tobacco_ breast_cancer.pdf
12. Fregene, A., & Newman, L. A. (2005). Breast cancer in sub-Saharan Africa: How does it relate to breast cancer in African-American women? Cancer, 103(8), 1540-1550. doi: 10.1002/cncr.20978Fregene, Alero; Newman, Lisa A. (2005)."Breast cancer in sub-Saharan Africa: How does it relate to breast cancer in African-American women?"
13. Friedenreich CM. Physical activity and breast cancer: review of the epidemiologic evidence and biologic mechanisms. Recent Results Cancer Res. 2011; 188:125–39.
14. Gierach GL, Ichikawa L, Kerlikowske K, Brinton LA, Farhat GN, Vacek PM, et al. Relationship between mammographic density and breast cancer death in the Breast Cancer Surveillance Consortium. J. Natl. Cancer Inst. 2012 Aug 22;104(16):1218–27.
15. Globocan 2018
16. Hartmann LC, Sellers TA, Frost MH, Lingle WL, Degnim AC, Ghosh K, et al. Benign breast disease and the risk of breast cancer. N. Engl. J. Med. 2005 Jul 21;353(3):229–37.
17. Hassan I, Onukak EE, Mabogunje OA. Breast cancer in Zaria, Nigeria. J R Coll Surg Edinb. 1992; 37:159–161.
18. Ihekwaba FN. Breast cancer in Nigerian women. Br J Surg. 1992; 79:771–775.
19. Information-Booklet-Decision-Aid-For-Breast-Cancer-Screening-in-Canada-1.pdf Information on Mammography for Women Aged 40 and Older: A Decision Aid for Breast Cancer Screening in Canada, Public Health Agency of Canada, 2009. Available at: http://www.phac-aspc.gc.ca/cd-mc/mammography

mammographie-eng.php
20. Ligibel J. Obesity and breast cancer. Oncology (Williston Park, N.Y.). 2011 Oct;25(11):994–1000.
21. Muguti GI. Experience with breast cancer in Zimbabwe. J R Coll Surg Edinb. 1993; 38:75–78.
22. National Comprehensive Cancer Network. Genetic/Familial High-Risk Assessment: Breast and ovarian (Version2.2019).https://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf. Accessed October 25, 2018.
23. Nelson HD, Zakher B, Cantor A, Fu R, Griffin J, O'Meara ES, et al. Risk factors for breast cancer for women aged 40 to 49 years: a systematic review and meta-analysis. Ann. Intern. Med. 2012 May 1;156(9):635–48.
24. Othieno-Abinya, N. A., Musibi, A., Nyongesa, C., Omollo, R., Njihia, B., Nyawira, B., . . . Gachii, A. (2018). Report on breast cancer care (BRECC) registry at the Kenyatta National Hospital, Nairobi, Kenya. Journal of Clinical Oncology, 36(15_suppl). doi: 10.1200/jco.2018.36.15_suppl.e12546.
25. Seitz HK, Pelucchi C, Bagnardi V, Vecchia CL. Epidemiology and pathophysiology of alcohol and breast cancer: update 2012. Alcohol and Alcoholism. 2012 May 1;47(3):204–12.
26. Terenziani M, Casalini P, Scaperrotta G, Gandola L, Trecate G, Catania S, et al. Occurrence of breast cancer after chest wall irradiation for pediatric cancer, as detected by a multimodal screening program. Int. J. Radiat. Oncol. Biol. Phys. 2013 Jan 1;85(1):35–9
27. Yaffe M, Mainprize J. Risk of radiation-induced breast cancer from mammographic screening. Radiology. 2011 Jan;258(1):98–105.

COLORECTAL CANCER

COLORECTAL CANCER SCREENING

Key messages

- Screening to be initiated at 45 years for average-risk individuals
- Faecal Occult Blood Test (FOBT) is the preferred screening method for average-risk individuals
- Colonoscopy is recommended for individuals at increased risk and high-risk of colorectal cancer
- High-risk individuals should undergo more frequent screening, typically every 5 years.
- Genetic counselling and testing may be appropriate for individuals with a strong family history of colorectal cancer

Introduction

Colorectal cancer ranks as the third most common cancer and the second leading cause of cancer-related deaths worldwide, with 1,926,425 new cases and 904,019 deaths reported in 2022. In Kenya, it is the fifth most common cancer among both men and women, with an estimated 3,091 new cases and 2,116 deaths (GLOBOCAN, 2022). These numbers represent an increase in both incidence and mortality compared to previous data (GLOBOCAN, 2022; Saidi et al., 2011).

Colorectal cancer is largely preventable, as most cases develop from precancerous polyps that can be detected and removed early. It is also curable if diagnosed at an early stage. However, many people with colorectal cancer do not experience symptoms in the early stages of the disease. When symptoms do appear, they can vary depending on the size and location of the cancer within the large intestine. These symptoms are often non-specific and can mimic other conditions such as gastrointestinal infections and inflammatory diseases, necessitating a high index of suspicion for accurate diagnosis.

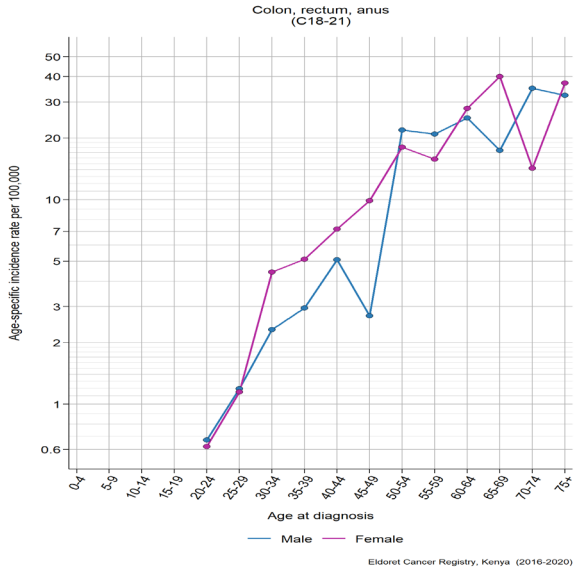


Figure 16: Epidemiology of cancer of the colon, rectum, anus, Kenya, 2016-2020: Age-specific incidence rate per 100,000 (source: Eldoret/ Uasin Gishu Population-Based Cancer Registry).

Presentation

- Change in bowel habits (diarrhoea or constipation)
- Rectal bleeding
- Persistent abdominal discomfort (cramps, bloating/flatulence, abdominal pain)
- Tenesmus (feeling of incomplete bowel emptying)
- Rectal mass on DRE
- Iron-deficiency anaemia - weakness or fatigue or unexplained weight loss
- Intestinal obstruction

Risk Factors

Non-modifaiable risk factors	Modifiable Risk Factors
• Older age greater than 45 years old	• Intake of red and processed meats
• Inflamatory bowel disease such as Crohn's disease or ulcerative colitis	• Physical inactivity
• A family history of colorectal cancer or colorectal polyps	• Low fruit and vegetable intake
• Presence of genetic syndromes like familial adenomatous polyposis (FAP) or hereditary non-polyposis colorectal cancer (Lynch Syndrome)	• A low fibre and high fat diet • Tobacco Use • Alcohol Intake • Obesity

Figure 17: Colorectal cancer risk factors

Rationale for screening

A significant proportion of colorectal cancer cases present at advanced stages, with 71% of patients with rectal lesions diagnosed at stage 3 or 4, compared to 78.6% for right-sided colon cancer (RCC) and 60% for left-sided colon cancer (LCC) (Saidi et al.).

Screening plays a crucial role in the early detection and removal of precancerous lesions, which can prevent or delay the onset of colorectal cancer. Furthermore, identifying the disease at an early stage allows for timely therapeutic intervention, leading to improved clinical outcomes.The primary goal of colorectal cancer screening is to detect precancerous lesions (adenomas and serrated polyps) and early-stage cancer. The majority of colorectal cancers develop from polyps, with the two main types of precancerous lesions being conventional adenomas and serrated polyps. Early detection and removal of these lesions significantly reduce the risk of progression to colorectal cancer.

Approaches to screening

There are various approaches that may be used for screening colorectal cancer. This guideline recommends using the risk-stratified approach.

Risk Based Screening

We recommend the clinical risk stratification to be utilized to assess the patient's risk for advanced adenoma and classify them as per risk status, either as high risk or low risk. We also recommend starting with FOBT and then guided screening for average-risk clients. For high-risk clients (refer to Table 1 for risk stratification), colonoscopy is the recommended modality for screening.

Multiple screening options

This is whereby the client is informed about all the available screening modalities (FOBT and colonoscopy) and they choose their preferred method. It is usually helpful in well-resourced settings.

Sequential approach

This involves a step-wise approach where the most effective screening modality is first recommended to the patient then a less preferred option is offered subsequently if the patient declines the initial method. This guideline recommends that for opportunistic screening, colonoscopy should be offered first and FOBT next. However, for the programmatic screening, FOBT should be offered first then colonoscopy.

Risk stratification

Individuals in the general population have varying risks of developing colorectal cancer and can be stratified into the following risk categories:

1. **Average Risk:** The lifetime risk of colorectal cancer is about 5%, increasing with age, especially after 50. This includes individuals with no family history or distant/late-onset family history.
2. **Increased Risk:** Includes individuals with one or more first-degree relatives with colorectal cancer, a personal history of colorectal cancer, or a history of inflammatory bowel disease.
3. **High Risk:** This category encompasses individuals with a strong genetic predisposition (familial adenomatous polyposis, etc.)

Eligibility Criteria

Table 11: Eligibility criteria for colorectal cancer screening

Risk	Recommendation	Interval
Average Risk	Screen between ages 45 – 75 years	FOBT (gFOBT or FIT) Annually
Increased Risk	Colonoscopy at 40 or 10 years before the youngest affected relative, whichever is earlier	Colonoscopy every 10 years
High Risk	Colonoscopy from 18 years for those with lynch syndrome Colonoscopy from 10 years for those with familial adenomatous polyposis	Colonoscopy every 10 years

* Decision to continue after age 75 should be individualized based on risk assessment and benefits

Risk Assessment Algorithm

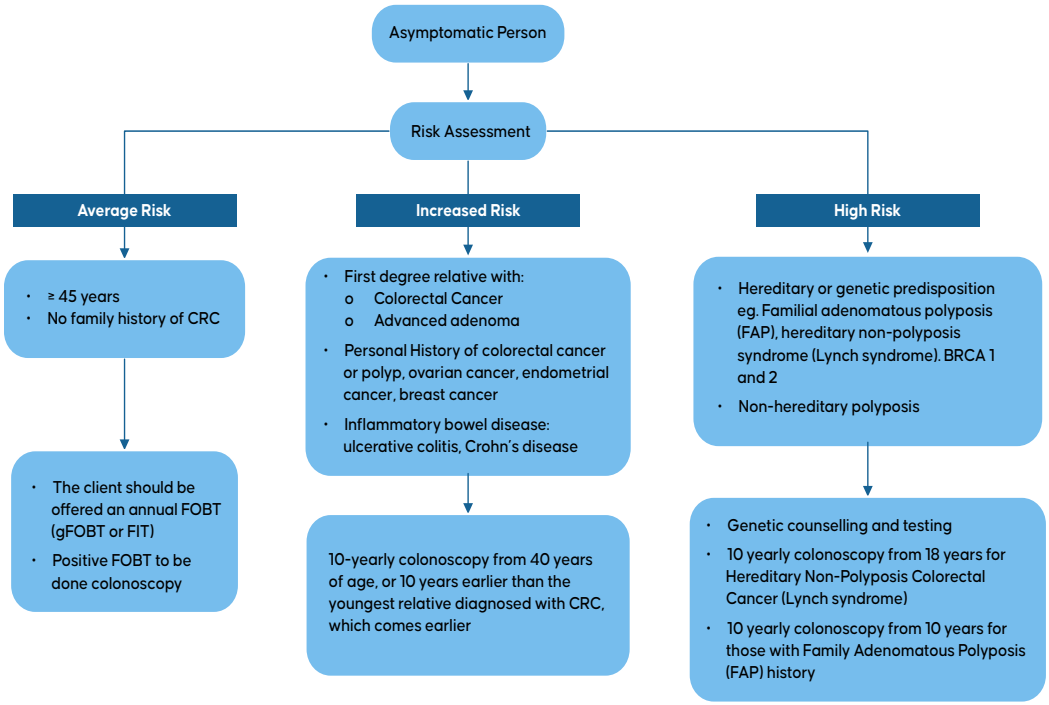


Figure 18: colorectal cancer screening algorithm

Screening modalities

Screening modalities for colorectal cancer (CRC) include various tests and procedures designed to detect early signs of cancer or precancerous conditions in the colon and rectum. These modalities can be broadly categorized into stool-based tests and direct visualization tests. Here are the commonly used screening modalities:

Stool-Based Tests

These non-invasive tests primarily focus on detecting faecal occult blood (FOBT), which can be a sign of CRC. While they may also identify some adenomas, their main goal is secondary prevention—finding early-stage cancer. These tests include faecal immunochemical test (FIT), guaiac-based faecal occult blood test (gFOBT), and the stool DNA test (FIT-DNA or Cologuard).

Table 12: stool-based screening tests

Screening Method	Fre-quency	Detection Method	Advantages	Disadvantages
Guaiac-Based Faecal Occult Blood Test (gFOBT)	Annually	Detect hidden blood in stool using guaiac to react with the haem component of blood	Non-invasive Widely available Low cost	Requires dietary restrictions lower sensitivity positive results require a follow-up colonoscopy
Faecal Immuno-chemical Test (FIT)	Annually	Detect hidden blood in stool using antibodies to detect human haemoglobin	Non-invasive No dietary restrictions Higher sensitivity for lower GI bleeding	Positive results require a follow-up colonoscopy

Stool DNA Test (FIT-DNA or Cologuard)	Every 3 years	Detects hidden blood by Combining FIT with molecular testing to identify DNA mutations and biomarkers associated with colorectal cancer sign	Non-invasive Higher sensitivity for detecting cancer and advanced adenomas	Higher cost Less widely available Positive results require a follow-up colonoscopy

As for stool-based tests, gFOBT and FIT are recognised as cost-effective, however:

- FIT is superior in terms of specificity and sensitivity compared with gFOBT in the detection of small amounts of haemoglobin in faeces (WHO/IARC; Parra-Blanco et al, 2010).
- In average-risk screening populations, FIT's sensitivity is higher than gFOBT's in detecting both CRC and advanced neoplasia.
- gFOBTs should be repeated on an annual or biennial basis or, at the very least, every three years if FIT is used
- Unlike gFOBT, FIT is not subject to false-negative results in the presence of high-dose vitamin C or E supplements, which block the peroxidase reaction.

Direct Visualization Tests

These procedures directly visualise the inner lining of the colon, allowing for the finding of cancer at an early stage (secondary prevention) and the removal of precancerous lesions (adenomatous polyp) in reducing the incidence of CRC (primary prevention). These tests include colonoscopy, flexible sigmoidoscopy, CT colonography (virtual colonoscopy), and capsule endoscopy

Table 13: Direct visualization tests

Screening Method	Frequency	Detection Method	Advantages	Disadvantages
Colonoscopy	Every 10 years*	Endoscopic examination of the entire colon and rectum	Comprehensive Allows for biopsy and polypectomy during the same procedure high sensitivity	Invasive Requires bowel preparation and sedation Higher risk of complications (e.g., perforation) ; higher cost
Flexible Sigmoidoscopy	Every 5 years (or every 10 years with annual FIT)	Endoscopic examination of the rectum and lower colon	Less invasive than colonoscopy Shorter procedure time can remove polyps and take biopsies	Does not examine the entire colon Requires bowel preparation Follow-up colonoscopy is needed if abnormalities are found
CT Colonography (Virtual Colonoscopy)	Every 5 years	CT imaging of the colon and rectum	Non-invasive No sedation is required Provides images of the entire colon	Requires bowel preparationIf polyps are detected Follow-up colonoscopy is necessary Radiation exposure

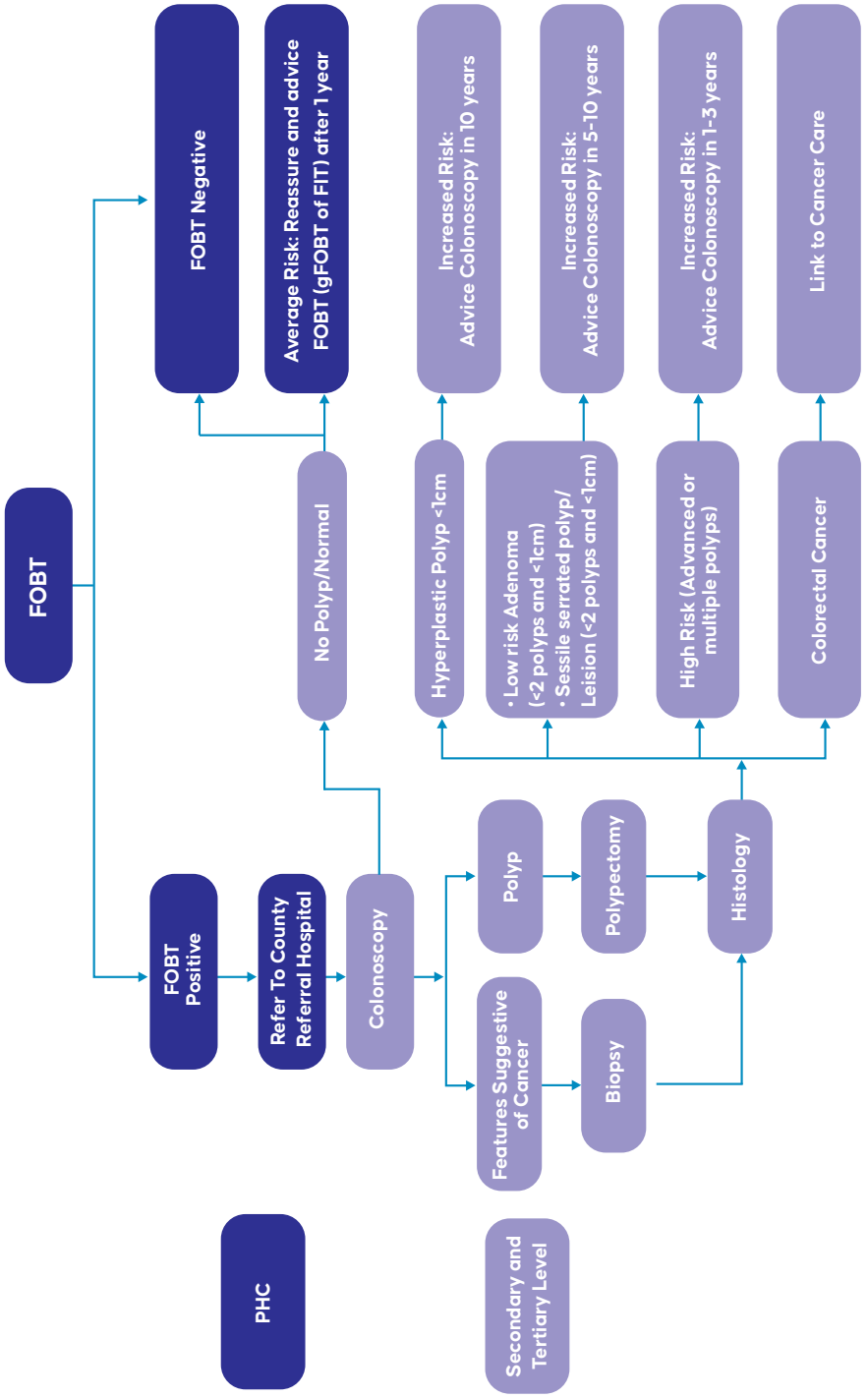
Capsule Endoscopy	As needed	Swallowed capsule with a camera	Non-invasive No sedation is required Can visualize the small intestine as well as the colon	Less effective for detecting small polyps Follow-up colonoscopy required for polyp removal Expensive Not for screening but can be used as an early diagnosis tool

*Screening frequency adjustable based on risk stratification. See Risk Assessment Algorithm and the Screening and Early Detection Algorithm below.

While colonoscopy is considered the "gold standard" for CRC screening, it may not always be the most practical option. Compared to colonoscopy, stool tests (gFOBT and FIT) have the following advantages:

1. **Higher participation rate:** It is easier and more convenient than colonoscopy hence can be scaled up more effectively.
2. **Cost-effective:** Annual FIT is cost-effective or cost-saving compared to a colonoscopy every 10 years (WHO/IARC; Zhang et al, 2020).
3. **Detection Rate:** FIT may be similar to 1-time colonoscopy in the detection rate of CRC, although it has lower detection rates of any adenoma and advanced adenoma than 1-time colonoscopy (WHO/IARC; Zhang et al, 2020).
4. **Requires no advanced training for administration:** This makes FOBT particularly accessible in settings with limited resources (IARC, 2019)

Figure 19: Colorectal Cancer Screening and Early Detection Algorithm



Colonoscopy

Colonoscopy is the screening gold standard for CRC because it allows for:
i. An examination of the complete colon
ii. Immediate removal of pre-cancerous polyps

Colonoscopy has five primary roles within the CRC screening process:
i. Primary screening;
ii. Follow-up of other abnormal screening tests (diagnosis);
iii. Removal of precancerous lesions (prevention);
iv. Removal of early cancers (treatment);
v. Long-term follow-up of patients who are at high risk because of previous neoplasms or increased individual risk (surveillance)

The goals of screening are to detect CRC (early detection) and to remove precancerous polyps (cancer prevention). Therefore, the performance of screening colonoscopy is the ability of the examination to detect CRC and remove precancerous polyps.

This guideline also recommends that colonoscopy procedures be performed by professionals who have the capability to collect biopsies and perform polypectomies. This ensures that any detected lesions can be appropriately sampled or removed during the procedure, enhancing diagnostic accuracy and patient outcomes.

This level of competence ensures that colonoscopists are well-equipped to handle the majority of cases encountered during colorectal cancer screening, thereby improving the effectiveness and safety of the screening process.

Specifically, this guideline recommends that colonoscopists achieve at least **Level 2 competency level**, which includes the ability to:

i. Remove polypoid and sessile lesions up to 25 mm in diameter.

ii. Perform biopsies on detected lesions to inform subsequent clinical decisions

Table 14: Competencies for colonoscopists

Competency level	Skills required	Comments
Level 0	Operator does not remove any lesions, but refers all patients with detected lesions; lesion biopsies can be performed, withpathological resultsl informing referral decisions.	Basic competency level for diagnostic sigmoidoscopy; not recommended for screening.
Level 1	Operator can remove lesions <10 mm in diameter at sigmoidoscopy. Larger lesions are removed at colonoscopy. Tissuebiopsy is required to decide whether colonoscopy is necessary.	People performing screening sigmoidosccopy should have this competency level.
Level 2	Operator can remove polypoid and sessile lesions <25 mmprovided the lesion is endoscopically accessible.	All colonoscopists should have this competency level.
Level 3	Operator can remove most smaller flat lesions (<20 mm), largersessile and polypoid lesions, and small lesions with difficultendoscopic access.	Any colonoscopists completing follow-up for positive screening results require this competency level.
Level 4	Operator can remove large flat lesions or challenging polypoidlesions that otherwise might require surgery. These lesions wouldnot be removed at the first colonoscopy, because of time constraintsor because of the need for discussion of surgical options.	This competency level is expected only among a small number of referral, regionally-based colonoscopists.
Adapted with permission from C Georg Thieme Verlag KG (Valori et al., 2012)		

Colonoscopy Quality Indicators

All endoscopists performing screening colonoscopy should measure their individual caecal intubation rates (CIRs), adenoma detection rates (ADR), and withdrawal times (WTs) as these have been shown to minimize the risk of interval CRC (Lund et al, 2019).

Caecal Intubation rate (CIR) – defined as the percentage of screening colonoscopies in which the colonoscopist has achieved caecal intubation. Caecal intubation is the introduction of the tip of the colonoscope into the caecal caput, which is necessary to visualize the entire colonic mucosa.

Adenoma detection rate (ADR) – defined as the percentage of screening colonoscopies in which at least one adenoma is identified and removed per colonoscopy

Withdrawal Time (WT) – defined as the time at which the caecum is reached until the withdrawal of the colonoscope from the patient. Withdrawal time is relevant only in the setting of negative screening colonoscopies (i.e., screening colonoscopies with no pathology detected)

Colonoscopists should

- Spend at least 6 minutes inspecting the mucosa during withdrawal
- Achieve a caecal intubation rate of at least 95% in screening subjects
- Achieve a minimum adenoma detection rate of 25%

Implementation considerations

Table 15: Services Per Level of Care

LEVEL	TYPE	CADRES	ACTIVITIES
1	Community	CHAs, CHPs	Awareness creation and mobilisation
2	Dispensaries	Nurses	Awareness creation and mobilisation
3	Health centres	Nurses clinical officer	Awareness creation, mobilisation, and FOBT
4	Sub county hospital	Medical officers Nurses Clinical officers General Surgeon Lab officer	Awareness creation, mobilisation, FOBT, colonoscopy and management
5	County Referral Hospital	Medical officers Nurses Clinical officers General Surgeon Lab officer	Awareness creation, mobilization, FOBT, and colonoscopy and management
6	National Referral Hospital	Medical officers Nurses Clinical officers General Surgeon Lab officer	Awareness creation, mobilization, FOBT, and colonoscopy and management

Strategies for Success

Given the accessibility of gFOBT, a phased approach to CRC screening should be considered for the average risk population:

1 **Initial Screening with gFOBT:** Due to its widespread availability and affordability, gFOBT can be used as the initial screening test for many individuals.
2. **Transition to FIT:** As resources allow and healthcare infrastructure strengthens, a gradual shift towards FIT can be implemented for its improved accuracy.
3. **Colonoscopy for Positive Tests:** Regardless of the stool test used (gFOBT or FIT), a positive result should always be followed by a colonoscopy for definitive diagnosis and potential polyp removal

FOBT Restrictions

When gFOBT is used to ensure accurate test results, it is essential to adhere to the following dietary and medication restrictions before undergoing a fecal occult blood test (FOBT):

1. Medication Restrictions

a. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): Avoid NSAIDs such as ibuprofen, naproxen, or aspirin for seven days prior to the test. These medications can cause bleeding, leading to a false-positive result.

Exception: Individuals taking NSAIDs daily for chronic conditions (e.g., heart disease) should consult their healthcare provider before discontinuing the medication for the test.

2. Dietary Restrictions

a. Vitamin C: Limit vitamin C intake to less than 250 mg daily from supplements or citrus fruits and juices for three to seven days before the test. Excessive vitamin C can interfere with the test chemicals, resulting in a false-negative result.

b. Red Meat: Avoid consuming red meat (beef, lamb, or liver) for three days prior to the test. Blood components in red meat can cause a false-positive result.

Referral System Development

- **Comprehensive Facility Mapping:** Conduct a thorough inventory of Level 4 to Level 6 hospitals equipped with colonoscopy equipment within the designated region.
- **Centralized Referral Directory:** Create and maintain a user-friendly, accessible directory listing these facilities, including contact information, capacity, and any specific requirements for referrals. Disseminate this directory to all relevant healthcare providers and patients.

- **Robust Referral Framework:** Establish clear guidelines and protocols for patient and biopsy referrals, including:
- **Referral Criteria:** Define specific indications for colonoscopy referrals based on screening results, symptoms, or other relevant factors.
- **Patient Information:** Outline the necessary patient information to be included in referral forms (e.g., demographics, medical history, test results).
- **Biopsy Handling:** Develop standardized procedures for collecting, transporting, and processing biopsy specimens.
- **Communication Channels:** Implement secure and efficient communication channels between referring and receiving facilities (e.g., electronic health records, dedicated referral lines).
- **Appointment Scheduling:** Facilitate timely appointment scheduling for referred patients.
- Follow-up: Establish a system for tracking referred patients and ensuring appropriate follow-up care.

Referral System Implementation and Optimization

- **Provider Education:** Conduct training sessions for healthcare providers on referral guidelines, the referral directory, and the importance of timely referrals.
- **Patient Education:** Develop patient-friendly materials explaining the referral process and the benefits of colonoscopy.
- **Performance Monitoring:** Regularly assess referral rates, wait times, and patient outcomes to identify areas for improvement.
- **Collaboration:** Foster collaboration between primary care providers, specialists, and hospitals to optimize the referral process.
- **Continuous Improvement:** Regularly review and update the referral system based on feedback and performance data.

Enhance public awareness of colorectal cancer by:

- **Disseminating information:** Develop and distribute educational materials (brochures, posters, social media campaigns) about CRC, including its symptoms, risk factors, prevention, and the importance of early detection.
- **Community engagement:** Conduct public awareness campaigns, health talks, and workshops in various community settings to reach diverse populations.
- **Media partnerships:** Collaborate with media outlets to promote CRC awareness through news articles, radio programs, and television spots.

Infrastructure

1. Colonoscopy screening services should be available from level 4 to level 6
- Equip all Level 4 and Level 5 facilities with colonoscopy equipment

References

1. *Colorectal Cancer Screening.* International Agency for Research on Cancer, World Health Organization; 2019.
2. Parra-Blanco A, Gimeno-García AZ, Quintero E, et al. Diagnostic accuracy of immunochemical versus guaiac faecal occult blood tests for colorectal cancer screening. *J Gastroenterol.* 2010;45(7):703-712. doi:10.1007/s00535-010-0214-8
3. Zhong GC, Sun WP, Wan L, Hu JJ, Hao FB. Efficacy and cost-effectiveness of fecal immunochemical test versus colonoscopy in colorectal cancer screening: a systematic review and meta-analysis. *Gastrointest Endosc.* 2020;91(3):684-697.e15. doi: 10.1016/j.gie.2019.11.035
4. Lund M, Trads M, Njor SH, Erichsen R, Andersen B. Quality indicators for screening colonoscopy and colonoscopist performance and the subsequent risk of interval colorectal cancer: a systematic review. *JBI Database Syst Rev Implement Rep.* 2019;17(11):2265-2300. doi:10.11124/JBISRIR-2017-003927
5. Adam E. Colorectal Cancer at Kenyatta National Hospital from 2014 to 2018: Clinicopathological Characteristics, Outcomes & Correlates. Thesis. University of Nairobi; 2020. Accessed July 15, 2024. http://erepository.uonbi.ac.ke/handle/11295/153736
6. Chloe Thomas, Olena Mandrik, Catherine L. Saunders, Deborah Thompson, Sophie Whyte, Simon Griffin, Juliet A. Usher-Smith; The Costs and Benefits of Risk Stratification for Colorectal Cancer Screening Based on Phenotypic and Genetic Risk: A Health Economic Analysis. *Cancer Prev Res (Phila)* 1 August 2021; 14 (8): 811–822. https://doi.org/10.1158/1940-6207. CAPR-20-0620

PROSTATE CANCER

Prostate Cancer

Key messages

- Prostate cancer is currently the leading cause of cancer deaths in Kenya
- Prostate cancer incidence in Kenya peaks from the sixth decade of life
- PSA-based screening is recommended, in an individualized approach
- Shared-decision-making should be offered to every eligible man before screening

Introduction

Prostate cancer is the fourth leading cancer in incidence globally, with higher mortality reported in less developed countries. In Kenya, prostate cancer is the commonest cancer in males with 3,582 new cases (21.9%) (GLOBOCAN, 2022) and the leading cause of death overall with 24.4 deaths per 100,000 (Age-Standardized Rate). (Figure 1).

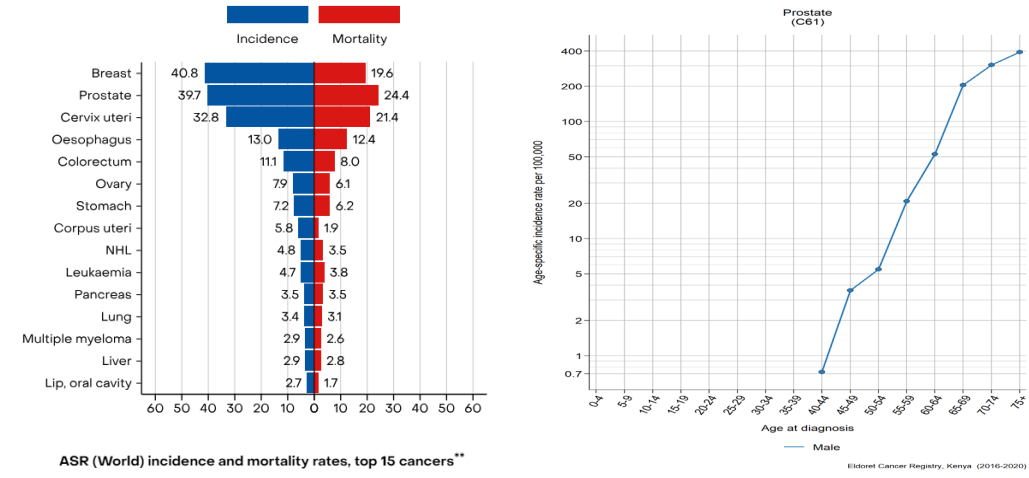


Figure 20: A) Age-Standardized Rate (Kenya) per 100 000, Incidence and Mortality (Source: Globocan 2022; B) Incidence by age group (Source: Eldoret/Uasin Gishu Population-Based Cancer Registry)

While the previous guidelines were recommending no population-level prostate cancer screening, this guideline proposes establishment of a national prostate cancer screening program, based on the principle of shared decision-making between the client and the healthcare provider.

Rationale for screening and early diagnosis of suspicious patients

Currently, there is high morbidity and mortality due to prostate cancer, early diagnosis can lead to improvement in survival. Healthcare providers should have a high index of suspicion and should be keen to screen eligible men presenting with any of the

following lower urinary tract symptoms for prostate cancer:

- Frequency and nocturia
- Difficulty in starting or stopping the urine flow
- Inability to urinate
- Weak, decreased, or interrupted urine stream
- A sense of incompletely emptying the bladder.
- Burning or pain during urination (dysuria)
- Post-micturition dribbling
- Urgency in urination
- Blood in the urine or semen

Risk adopted screening - Eligibility Criteria

- Age 40 years or more of african descent
- Family history of prostate cancer
- Family history of germline BRCA 1, BRCA2, CHECK2, and PALB2, etc. mutation carrier
- Family history of breast cancer, ovarian cancer, colorectal, pancreatic cancer, endometrial cancer
- If none of the above is present: initiate screening at age 55 years

These guidelines DO NOT recommend routine screening for the following groups:

- Men aged ≤40 years due to the low prevalence of the disease in these age groups.
- Men aged 70 years and above –Although they have a high prevalence of prostate cancer, they have a greater risk of dying from other life-threatening co-morbidities and over-diagnosis compared to younger men. However, for very fit patients without comorbidities, a shared decision-making should be made.
- Any man with a life expectancy of less than 10-15 years

Screening methods

The only evidence-based screening test for prostate cancer is quantitative Serum PSA.

- Multiparametric MRI and biopsy are not screening tests but further evaluation/ diagnostic tests, following abnormal PSA.
- While Digital Rectal Examination has no evidentially value as a screening modality for prostate cancer, it can inform part of the physical examination during the clinical evaluation of the patient, after an elevated PSA test.
- There is no role of qualitative PSA tests (rapid kits) for prostate cancer screening.

Prostatic Specific Antigen

The Prostate-Specific Antigen (PSA) is a blood test that measures the amount of a particular glycoprotein secreted by the prostate gland (the PSA) in serum. PSA is the standard screening method for early detection of prostate cancer for a targeted population.

Before starting or discontinuing prostate cancer screening, shared decision-making is recommended.

Shared decision making

Shared decision-making is strongly recommended before starting or discontinuing prostate cancer screening. The Implementation of Shared Decision Making in Urology should include the following features:

- Both the clinician and patient should be involved in the decision-making process.
- Information should be freely shared between the physician and the patient.
- Patient-centered care is provided to a well-informed patient with considerations on benefits, and risks of potential harm to reduce decision conflict.
- Personal values and preferences must be considered, along with the patient's ethics.
- The patient's preference for screening must be expressed and a clear demonstration of the procedures including the patient's anatomy.
- Consensus should be built through the free expression of preferences.

A well-informed patient understands the basic prostate anatomy, the benefits and risks of prostate cancer screening and the frequency of screening.

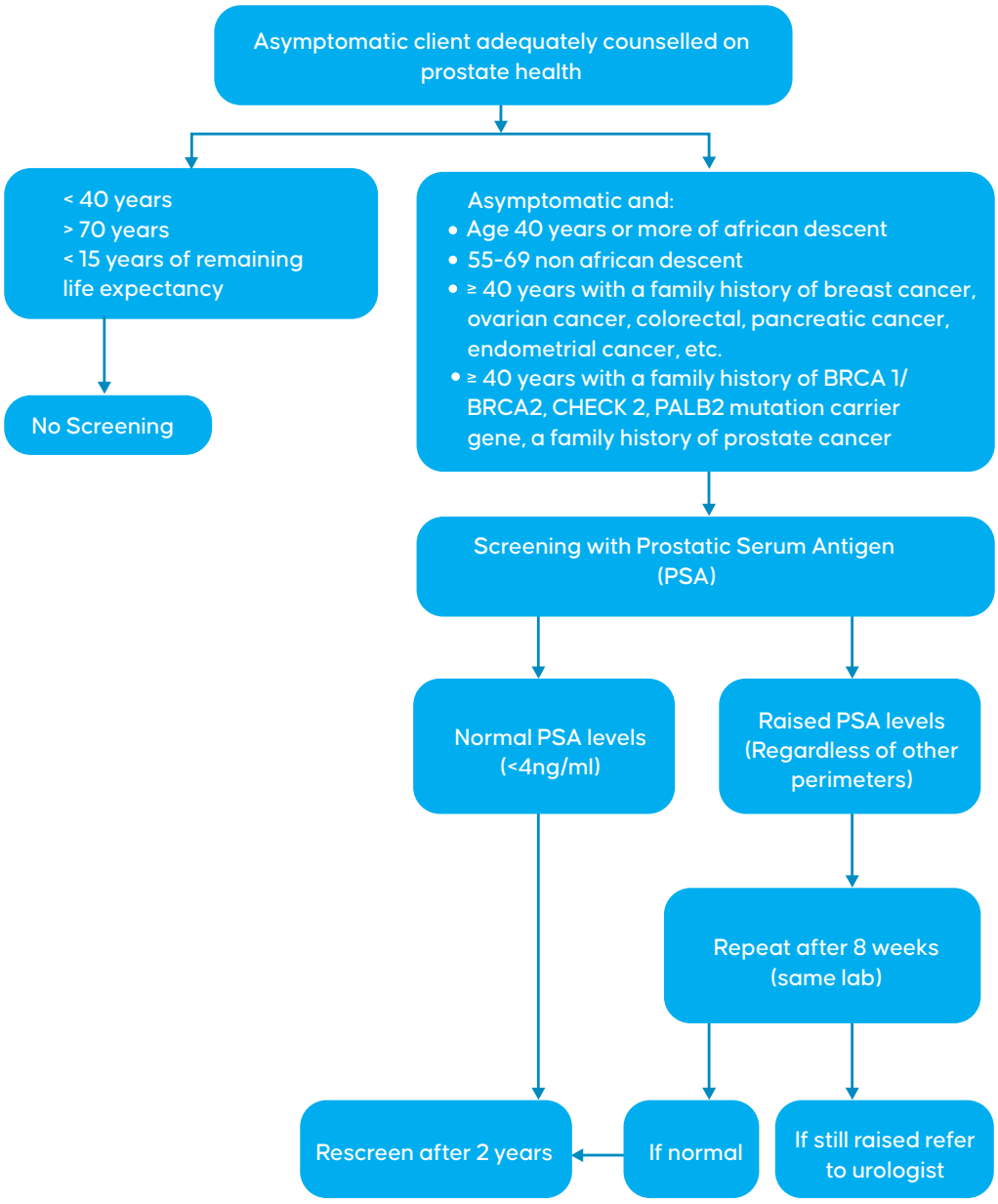
Multiparametric MRI

Integrating multi-parametric MRI in prostate cancer screening pathways is associated with a reduced number of unnecessary biopsies and over-diagnosis of insignificant prostate cancer while maintaining prostate cancer detection as compared with PSA-only screening.

Key Considerations

- There is no role for MASS screening for prostate cancer.
- Screening for prostate cancer is a highly individualized decision between a client and his caregiver: a well-informed client understands the ratio of benefit to harm of prostate cancer screening.
- High prostatic specific antigen (PSA) does not mean that one has prostate cancer.

Figure 21: Prostate Cancer Screening Algorithm



Who and where should the screening be conducted?

- Healthcare practitioners at **all levels** of the healthcare system should create awareness and refer eligible clients.
- A PSA test should be available from **Level 3 hospitals and above**, and at accredited private facilities.
- A general practitioner at level 3 and above can prescribe a PSA test to a **well-informed patient.**
- Patients with a PSA **>4ng/ml** regardless of other parameters should be referred to a urologist for further management.

Follow-up of PSA testing should ideally be in the same laboratory. A high PSA is re-confirmed in the same laboratory after **8 weeks.**

Table 16: Considerations for establishment of a national prostate cancer screening program

Action	Implementation Strategy
Assessment of need and feasibility	Assessing the need for screening in the population – This includes understanding the prevalence and impact of prostate cancer in the target population and the healthcare infrastructure's capacity to handle increased demand from screening and subsequent treatments. Mass screening should be highly discouraged.
Stakeholder engagement	Involving key stakeholders such as healthcare providers, policymakers, patient advocacy groups, and the target population is crucial. Providing insights into program design help address potential barriers, and assist in promoting the program to the community.
Education and Awareness	Messaging on prostate cancer and overall men's health should be integrated in health talks in medical camps and outreaches where men access services. Educating healthcare providers and the target population about the benefits, risks, and limitations of screening is essential.
Referrals and Treatment	Patients with elevated PSA are referred to urologists at level 4 and above facilities for further assessment. General surgeons at level 4 facilities should also be trained to reduce patients TAT.

Men wellness clinic	Support implementation of men wellness clinics to assess overall men health. Questionnaires will be provided to support informed decision making for prostate cancer screening.
Screening logistics	PSA screening will only be conducted in level 3 and above facilities with appropriate capacities, and only to the eligible population, ensuring their availability across screening locations, and setting up systems for follow-up diagnostic testing and treatment referrals for those with positive screening results. Telemedicine and teleconsultation can support the program in situations where a urologist is not available.
Quality control and Training	Ensuring high-quality screening procedures and consistent interpretation of screening results. This involves training for healthcare providers in conducting the tests and in the ethical issues related to screening and treatment. Note: these guidelines recommend quantitative PSA testing (expressed in ng/mL of blood; qualitative PSA tests (e.g., rapid diagnostic kits are not recommended).
Data collection and monitoring	Establishing systems for data collection and monitoring to track the progress and outcomes of the screening program. This data is crucial for evaluating the program's effectiveness and making necessary adjustments.
Evaluation and Adjustment	The program should be regularly evaluated based on collected data and research updates. This can involve adjusting guidelines, improving education materials, or changing logistical arrangements to meet the program's goals better.
Ethical Considerations	Addressing ethical concerns, such as informed consent and incidental findings management. Participants should clearly understand the potential outcomes of screening and their rights within the screening process.

References

1. Shared Decision Making Emphasized for Prostate Screening. Cancer Discov. 2018 Jul;8(7); doi: 10.1158/2159-8290.CD-NB2018-069. Epub 2018 May 24. PMID: 29794067.
2. Prostate Cancer Screening – For Providers: Information about talking to your patients about the PSA test. Available at https://www.mass.gov/info-details/prostate-cancer-screening-for-providers; accessed August 24, 2024.
3. Wei JT, Barocas D, Carlsson S, Coakley F, Eggener S, Etzioni R, Fine SW, Han M, Kim SK, Kirkby E, Konety BR, Miner M, Moses K, Nissenberg MG, Pinto PA, Salami SS, Souter L, Thompson IM, Lin DW. Early Detection of Prostate Cancer: AUA/SUO Guideline Part I: Prostate Cancer Screening. J Urol. 2023 Jul;210(1):46-53. [PubMed]
4. Lillie SE, Partin MR, Rice K, Fabbrini AE, Greer NL, Patel SS, MacDonald R, Rutks I, Wilt TJ. The Effects of Shared Decision Making on Cancer Screening – A Systematic Review [Internet]. Department of Veterans Affairs (US); Washington (DC): Sep, 2014. [PubMed]
5. James ND, Tannock I, N'Dow J, Feng F, Gillessen S, et al. The Lancet Commission on prostate cancer: planning for the surge in cases. Lancet. 2024 Apr 27;403(10437):1683-1722. doi:10.1016/S0140-6736(24)00651-2. Epub 2024 Apr 4. Erratum in: Lancet. 2024 Apr 27;403(10437):1634. PMID: 38583453.
6. Tobias P. Seraphin, Walburga Y. Joko-Fru, et al. Rising Prostate Cancer Incidence in Sub-Saharan Africa: A Trend Analysis of Data from the African Cancer Registry Network. Cancer Epidemiol Biomarkers Prev 1 January 2021; 30 (1): 158–165. https://doi.org/10.1158/1055-9965.EPI-20-1005
7. Van Poppel, H., Albreht, T., Basu, P. et al. Serum PSA-based early detection of prostate cancer in Europe and globally: past, present and future. Nat Rev Urol 19, 562–572 (2022). https://doi.org/10.1038/s41585-022-00638-6
8. Hugosson J, Roobol MJ, Månsson M, et al. A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer. Eur Urol. 2019 Jul;76(1):43-51. doi: 10.1016/j.eururo.2019.02.009. Epub 2019 Feb 26. PMID: 30824296; PMCID: PMC7513694.
9. Matsukawa A, Yanagisawa T, Bekku K, Kardoust Parizi M, Laukhtina E, Klemm J, Chiujdea S, Mori K, Kimura S, Fazekas T, Miszczyk M, Miki J, Kimura T, Karakiewicz PI, Rajwa P, Shariat SF. Comparing the Performance of Digital Rectal Examination and Prostate-specific Antigen as a Screening Test for Prostate Cancer: A Systematic Review and Meta-analysis. Eur Urol Oncol. 2024 Jan 4:S2588-9311(23)00292-4. doi: 10.1016/j.euo.2023.12.005. Epub ahead of print. PMID: 38182488
10. Mottet N, van den Bergh RCN, Briers E, et al. EAU-EANM-ESTRO-ESUR-SIOG Guidelines on Prostate Cancer-2020 Update. Part 1: Screening, Diagnosis, and Local Treatment with Curative Intent. Eur Urol. 2021 Feb;79(2):243-262. doi: 10.1016/j.eururo.2020.09.042. Epub 2020 Nov 7. PMID: 33172724.
11. Fazekas T, Shim SR, Basile G, et al. Magnetic Resonance Imaging in Prostate Cancer Screening: A Systematic Review and Meta-Analysis. JAMA Oncol. 2024 Apr 5: e240734. doi: 10.1001/jamaoncol.2024.0734. Epub ahead of print. PMID: 38576242; PMCID: PMC10998247.
12. Tu X, Liu Z, Chang T, Qiu S, Xu H, Bao Y, Yang L, Wei Q. Trans-perineal Magnetic Resonance Imaging-Targeted Biopsy May Perform Better Than Transrectal Route in the Detection of Clinically Significant Prostate Cancer: Systematic Review and Meta-analysis. Clin Genitourin Cancer. 2019 Oct;17(5):e860-e870. doi: 10.1016/j.clgc.2019.05.006. Epub 2019 May 21. PMID: 31281065.
13. Frequency of Screening by Age, Source: Mottet et al, 2017 and Conford et al., 2017 https://www.auajournals.org/doi/full/10.1097/ju.0000000000003491

ORAL CANCER

ORAL CANCER

Key messages

- An opportunistic, risk-based screening approach is proposed for oral cancer in Kenya
- The modified OraCLE criteria, which is based on age, sex, use of tobacco and alcohol, and presence or absence of Oral Potentially Malignant Disorders (OPMD) should guide the decision on whether to screen
- Screening can be conducted through two approaches: visual examination and/or exfoliative cytology
- All levels of the healthcare system should support an early diagnosis program for oral cancer through high index of suspicion and prompt referral to appropriate levels for diagnosis and management

Introduction

Oral cancer is by definition any malignancy arising from oral tissues, pharynx and salivary glands (Muller and Tilakaratne, 2022). The global incidence of these cancers is 758,022 cases where mortality attributed to this condition is 379,069 deaths per annum (GLOBOCAN, 2022). Despite the fact that early diagnoses and interventions result in survival rates of 80 – 90%, low public awareness and poor access to screening continues to adversely affect survival rates globally (Wang et al, 2023). In Kenya, the age standardized rate (ASR) of oral cancer is 6.6 per 100,000 population, almost twice as high as that of the WHO Africa Region.

Data from the Kenyan National Cancer Registry (Korir et al, 2008) shows that oral cancer accounted for 10.1% of malignancies while in females it contributed to 4.3%. Over 90% of oral cancers are squamous cell carcinomas (OSCC), with the remaining fraction consisting of varying percentages of lymphomas, melanomas, sarcomas and adenocarcinomas (Ibukunle et al, 2018; Idris et al 2016; Monteiro et al, 2016). It predominantly occurs in male patients in the fifth and sixth decades of life, though there has been a rise in the incidence among younger patients in the recent decades (Szewczyk et al, 2024).

The modifiable risk factors for oral cancer include habits such as consumption of tobacco, alcohol and betel nut, all of which are classified as Group 1 carcinogens by the International Agency for Research on Cancer (IARC/ WHO, 2024). Incidence varies regionally with the prevalence of these high-risk habits, with statistics as high as 40% in parts of Asia (Chuang et al, 2017). As an increasing percentage of youths and females are exposed to the modifiable risk factors, the socio-demographic patterns of oral cancers continue to evolve in different regions (Table 1).

Table 17. Risk factors for oral cancer

Non-modifiable	Genetics
	Age > 40 years
	Male gender
Modifiable	Tobacco (smoked, chewed and snuff types)
	Alcohol
	Immune suppression
	Ultra violet light
	Vitamin A, C & E deficiency
	Betel/ areca nut
	Khat (miraa/ muguka)

The synergistic carcinogenic effect of the combined use of tobacco and alcohol is well documented, with heavy consumption increasing the risk 40-fold (Barsouk et al, 2023). Oncogenic strains of the human papilloma virus (HPV) are aetiologically associated with oral cancer, particularly in younger populations (Timbang 2019, Irani, 2023). The incidence of oral cancer increases exponentially in patients infected with HIV (Khot et al, 2016). Potentially malignant mucosal diseases such as leukoplakia, erythroplakia, lichen planus and oral submucous fibrosis have variable capacities for progression into invasive oral cancer.

Table 18. Common symptoms of oral cancers

- Mouth ulcers that persist for more than three weeks.;
- Persistent pain in the mouth;
- A lump or thickening in the cheek;
- A white or red patch on the gums, tongue, tonsil, or lining of the mouth;
- Difficulty in moving the jaw or tongue;
- Bleeding or numbness of the tongue or other area of the mouth;
- Loosening of the teeth or pain around the teeth or jaw;
- Constant bad breath;
- Difficulty in talking or swallowing;
- Non-healing extraction socket

Rationale for screening

Conventional oral examination under direct light reduced oral cancer mortality by 26% advanced oral cancer cases by 19% screening in high-risk populations. Examination can be done by general dentist or doctor, other healthcare workers such as nurses or community health workers after appropriate training. Further, based on the risk-based selection of individuals for oral cancer screening would outperform age-based selection and provide greater sensitivity for oral cancer mortality (Cheung, 2021).

Taiwan scaled up to implement a nationwide program for tobacco and betel nut users incorporating over 2 million participants since 2004 (Chuang et al, 2017). This program resulted in a reduction in the number of patients presenting with TNM stages III and IV oral cancers and 24% reduction (95% CI, 3%-40%) in oral cancer mortality. As a result of similar evidence worldwide, the WHO guidelines recommend targeted screening for early detection of oral cancers (IARC/ WHO, 2024).

Longer diagnostic delay is a risk factor for later stage disease and increased mortality negatively impacts on disease, function and psychosocial treatment outcomes (Seoane et al, 2016; Schutte et al, 2020).

Who should be screened and when?

The most effective approach to ensure early diagnosis of oral cancers in a resource-limited setting is to offer opportunistic mass screening/targeted screening-, targeting all individuals at risk of developing the disease (NSC, UK, 2018). The criteria for annual screening is **any person, forty years and above, with history of consumption of tobacco and/ or exposure to any other risk factor for oral cancer.**

Table 19. Selection of oral cancer cases for targeted screening – medium or high scores on more than one risk factor (modified oracle criteria)

RISK FACTOR	LOW	MEDIUM	HIGH
Gender	Female	Male	
Age	<40 year	>40 years	
Alcohol usage	Never	<3 days/ week	>3 days/ week
Miraa usage	Never	<3 days/ week	>3 days/ week

SMOKED TOBACCO			
Age of initiation	Never	>25 years	<25 years
Duration of use	Never	< 10 years	>10 years
Frequency of usage	Never	<10 cigarettes/ day	>10 cigarettes/day
SMOKELESSS TOBACCO			
Age of initiation	Never	>20 years	<20 years
Duration of use	Never	< 5 years	>5 years
Frequency of usage	Never	<5 packs/ day	>5 packs/day
ORAL POTENTIALLY MALIGNANT DISORDERS (OPMD) (Warnakulasuriya et al, 2020)			
Leukoplakia			
Proliferative verrucous leukoplakia			
Erythroplakia			
Oral Submucous Fibrosis (OSF)			
Oral lichen planus			
Actinic Keratosis/Actinic Cheilitis			
Palatal lesions in reverse smokers			
Oral lupus erythematosus			
Dyskeratosis congenita			
Oral lichenoid Lesions (OLL)			
Oral graft versus host disease (OGVHD)			

Screening at various healthcare levels

Oral cancer screening is fairly straightforward because apart from the tumors extending into the pharynx, most lesions are easily accessible and those at risk can be easily identified (Chuang et al, 2017). Visual screening can be integrated into primary health care and serves as an entry point to diagnostic and treatment services. There is a need to develop a multi-sectoral approach that integrates tobacco and alcohol control as part of health education.

Table 20: Health facilities and staff cadres for oral cancer screening and further evaluation

LEVEL	TYPE	CADRE	ACTIVITIES
1	Community	Dental Assistant Community health promoter	Oral Health awareness and referral
2	Dispensary Private Dental Clinics	Nurses COHO	Oral Health awareness, education and referral
			Visual screening
			Appropriate referrals of oral cancer.
3	Health Centres	Nurses	Oral Health awareness and Visual screening Sample collection Referral Oral cancer screening outreach- assisted by COHO &CHP, screen for oral cancer.
		Clinical Officers	
		Community Oral Health Officer (COHO)	
4	Level 4	Nurses	Oral Health awareness Diagnosis Referral
		Clinical officers	
		Medical officers	
		Community Oral Health Officer	
		Pathologist	
		Dentists	

5.	Level 5	Nurses	Oral Health awareness Diagnosis Referral
		Clinical officers	
		Medical officers	
		Maxillofacial surgeon	
		Oral Pathologist	
		Dental officers	
6	Level 6	Nurses	Oral Health awareness. Diagnosis
		Clinical officers	
		Oral Pathologist	
		Medical officers	
		Dentists	
		Oral and maxillofacial surgeon	
		Oral and maxillofacial radiologist	

Screening tests to be done

The health care worker should conduct visual screening and refer appropriately for analytical screening and treatment in the sequence described in Figures 22 & 23 (Douglas, 2012; Huber et al, 2014): The target population should be all women and men aged 40-65 years.

Figure 22. Anatomy of the oral cavity and related structures.

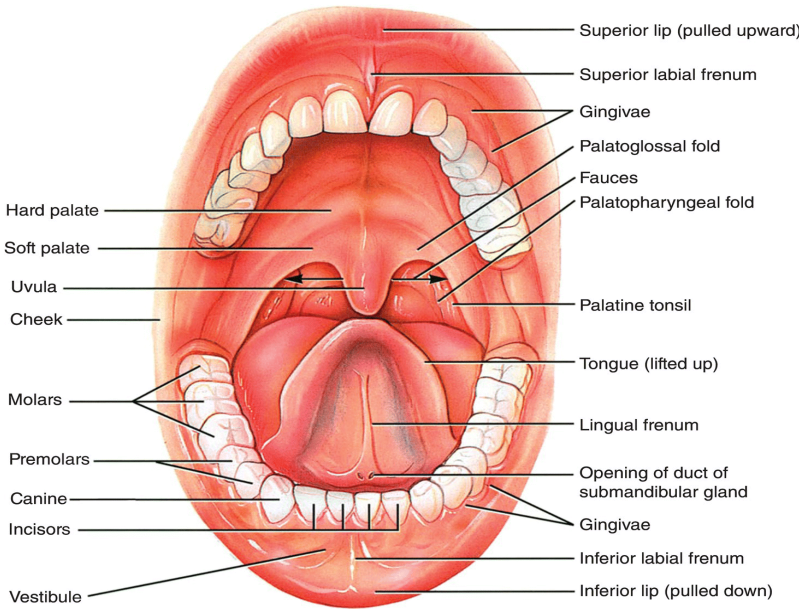
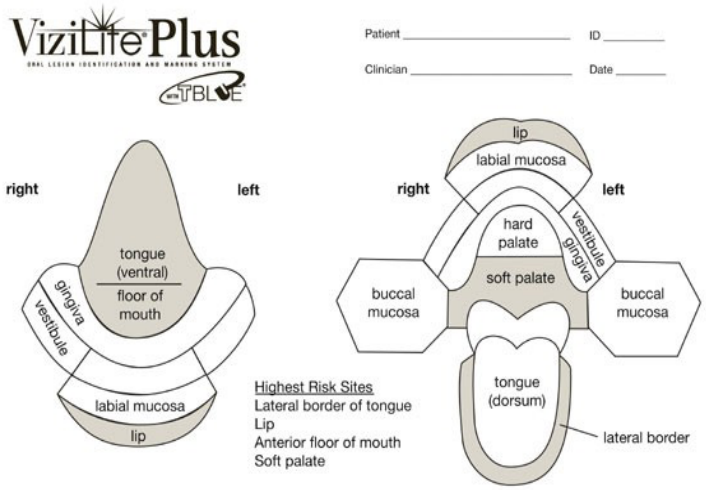


Figure 23. Steps for oral visual cancer examination



Optional screening adjuncts to be used in levels 4 – 6 hospitals

Adjunctive visual tools can enhance contrast between the clinical lesion and the adjacent normal oral tissue. Techniques include toluidine blue staining and direct fluorescence visualization. Mucosal changes stain positively with the application of toluidine blue dye or show loss of fluorescence in premalignant and malignant lesions. These methods, however, do not give a definitive diagnosis. Toluidine blue dye is itself mutagenic and, therefore, its use is restricted (Mills, 2022).

Direct fluorescence involves intraoral application of a hand-held device that emits a cone of blue light which excites various molecules within mucosal cells, causing them to absorb the light energy and re-emit it as visible fluorescence (Tiwari et al, 2020). Healthy oral tissue emits a pale green fluorescence while altered tissues which attenuate the passage of light appear dark brown or black (loss of fluorescence).

Diagnosis

Imaging

Imaging is used as an adjunct for diagnosis for patients with clinical lesions that have a high index of suspicion. Plain X-rays, CT scans and MRI are used to investigate the extent of the tumor, nodal involvement and metastasis. Visualization of soft tissue windows via either CT or MRI in addition to a chest X-ray or scan is essential for accurate tumour staging.

Diagnostic biopsy

Brush biopsy uses a round stiff bristle brush to collect cells from the surface layers of a lesion by vigorous abrasion. The cells collected are transferred to a microscope slide to identify abnormal cells. Cytological studies tend to be technique sensitive and require trained personnel for accurate interpretation.

Table 21: Screening and diagnostic sequence for early detection of oral cancer

Test Category	Type of Test	Personnel
Screening	Visual screening	Nurse, Clinical officer, Community oral health officer, Dentist, Medical Officer
	Exfoliative cytology	Sample collection: Nurse, clinical/ medical/ dental officers Analysis: Cytologist, pathologist
Diagnosis	Imaging	Radiographer, Radiologist,
	Incision biopsy	Sample collection: Dental officer, Maxillofacial surgeon Analysis: Pathologist

Recommendations

a. Early diagnosis of all craniofacial malignancies, through:
   - improving awareness and access to care
   - building diagnostic capacity and streamlining referral system
   - addressing barriers to timely access to treatment

b. All clinicians should screen all adults for tobacco/alcohol/betel nut/miraa use and OPMD, recommend against tobacco/alcohol/khat/betel nut use and provide tobacco cessation interventions for those who use tobacco products.

c. Adverse risk habits – smoking, alcohol, khat, tobacco and pan chewing – are highly prevalent, reinforcing the need to introduce risk habit cessation counselling along with screening to achieve long-term success in reducing oral cancer rates.

d. Using the existing infrastructure, such as primary health centers in rural areas, training primary health-care workers to conduct oral examinations with a triage system for those with detected lesions, engaging local village chiefs and community leaders to promote awareness about the adverse effects of tobacco, Khat, betel nut, alcohol consumption, can facilitate implementation of nation-wide screening programme.

e. Screening is not a "stand-alone" activity. It must be linked with accessible diagnosis and treatment for positive screened individuals, and with prevention and risk factor control to reduce the incidence of oral cancers.

f. Continuing clinical and operational research is needed to identify optimal screening intervention(s) simple, applicable in community settings, use by available health-care personnel with limited requirement for medical/dental specialists, acceptable to subjects (high compliance), and with established sensitivity and specificity to permit triage of subjects to achieve cost effective, high-throughput oral cancer screening and early detection in high-risk populations and limited resources.

Implementation framework and M/E

a. Training and human resource needs
   i. Providers-training and capacity building and mentorship of HCP on oral cancer screening and early diagnosis AND additional non-oral health providers, dentists' pathologists-oral pathologists and/or biomedical laboratory scientists to perform test and interpret results

b. Health system requirements: -
   i. Development of guidelines and SOPs for Screening.
   ii. Situation analysis – documentation of personnel and equipment.
   iii. Procurement of diagnostic equipment and consumables – cytology, radiology and histopathology.
   iv. Strengthening of National Cancer Registries.
   v. Enforce integrated cancer screening outreaches -ensure inclusion of oral cancer screening with Breast and Cervical Cancer Screening outreaches.
   vi. Procurement of toluidine and fluorescence reagents in specialist centers.

c. Public awareness: -
   i. Education on common cancer symptoms and risk factors.
   ii. Education on oral and NP cancer prevention (modifiable risk factors).
   iii. Screening-Attention to signs and symptoms of cancer AND participation in screening programme
   iv. Relevance of early detection (increased survival rates)

d. Health System and infrastructure development
   i. Invest in oral and nasopharyngeal cancer research development.
   ii. Adequate funding of oral and NPC cancer screening and diagnostics.
   iii. Inclusion of Oral cancer screening indicators and data sets in the National Cancer Screening tools.
   iv. Dissemination and implementation of oral cancer screening tool.

e. Leadership and governance-needs to be in place at all levels.

f. Behavior change communication: -

• Communication strategy for those suspected of oral cancer would be included to make them aware of the treatment options, levels of care, social protection schemes, support networks and existing programmes to address habits such as tobacco and alcohol; in addition to likely complications of their conditions. Effective interpersonal communication would be part of training programme for all providers.

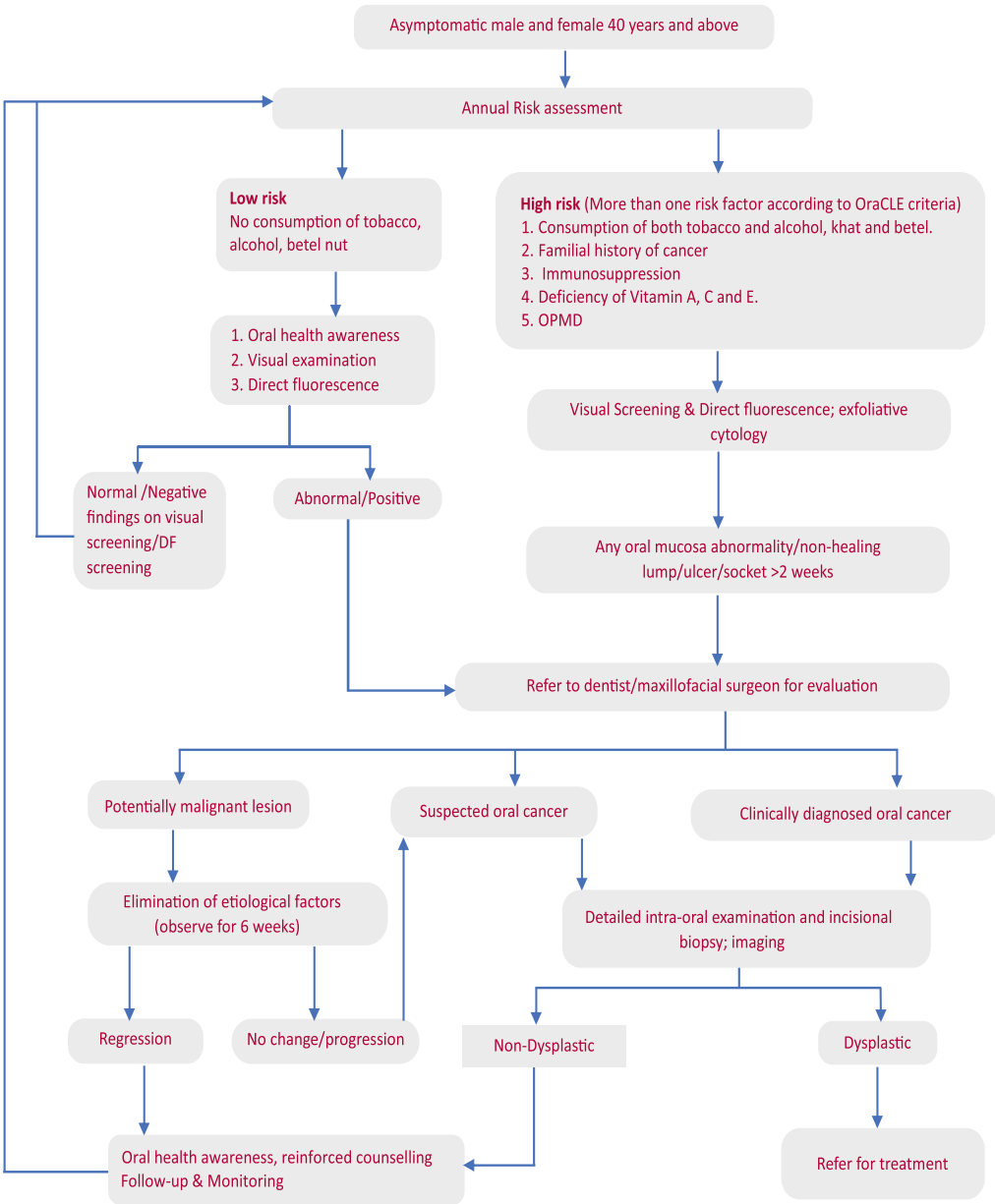
• IEC material at screening centres, person-person and group health education would be imparted for awareness and behavioral change

g. Monitoring and evaluation

i. Number of health workers trained on oral cancer screening.
ii. Total number of oral cancer patients screened per annum.
iii. Socio-demographics of the clients screened -Age, sex, location of residence of the clients screened.
iv. The risk factors screened-pattern of utilization of risk factors for Oral cancers.
v. The number of adjunct screening test offered to clients in Level 4,5, and 6
vi. Number of health facilities able to screen for oral cancer: -
    1. Percentage of health cancer education programs including elements of oral cancer.
    2. Percentage of level IV and above facilities availing screening services for high-risk groups.
    3. Percentage of level IV and above facilities can manage oral cancer cases
vii. Percentage of eligible patients screened for oral cancers.
viii. Oral cancer incidence (per 100,000).
ix. Number of patients referred for diagnosis and management.
x. The number of refereed clients with the following potentially malignant mucosal diseases: -
    1. Leukoplakia,
    2. Erythroplakia,
    3. lichen planus
    4. Oral submucous fibrosis have

ix. Percentage of patients diagnosed in early stages of oral cancer. Five-year survival rates for oral cancer patients.

Figure 24: Screening pathway for oral cancer



References

1. Muller, S., & Tilakaratne, W. M. (2022). Update from the 5th Edition of the World Health Organization Classification of Head and Neck Tumors: Tumours of the Oral Cavity and Mobile Tongue. Head and neck pathology, 16(1), 54–62. https://doi.org/10.1007/s12105-021-01402-9.
2. International agency for research on cancer, World health organization Dataviz, Cancer TODAY | IARC - https://gco.iarc.who.int Data version: Globocan 2022 (version 1.1) - 08.02.2024.
3. Wang et al. Current advances in noninvasive methods for the diagnosis of oral squamous cell carcinoma: a review. European Journal of Medical Research (2023) 28:53. https://doi.org/10.1186/s40001-022-00916-4.
4. Ibikunle AA, Taiwo AO, Braimah RO. A 5-year audit of major maxillofacial surgeries at Usmanu Danfodiyo university teaching hospital, Nigeria. BMC Health Serv Res. 2018 Jun 7;18(1):416. doi: 10.1186/s12913-018-3236-1. PubMed PMID: 29879975; PubMed Central PMCID: PMC5992770.
5. Idris A, Vani N, Saleh S, Tubaigy F, Alharbi F, Sharwani A, Tadrus N,Warnakulasuriya S. Relative Frequency of Oral Malignancies and Oral Precancer in the Biopsy Service of Jazan Province, 2009-2014. Asian Pac J Cancer Prev.2016;17(2):519-25. PubMed PMID: 26925637.
6. Monteiro LS, Albuquerque R, Paiva A, de la Peña-Moral J, Amaral JB, Lopes CA. A comparative analysis of oral and maxillofacial pathology over a 16-year period, in the north of Portugal. Int Dent J. 2017 Feb;67(1):38-45. doi:
7. Szewczyk M, Pazdrowski J, Golusin´ ski P, Wie¸ckowska B and Golusin´ ski W (2024) Oral cancer in young adults: should we approach these patients differently?. Front. Oncol. 14:1297752. doi: 10.3389/fonc.2024.1297752
8. Korir A, Okerosi N, Ronoh V, Mutuma G, Parkin M. Incidence of cancer in Nairobi, Kenya (2004–2008). International journal of cancer. 2015 Nov 1;137(9):2053-2059.
9. IARC/ WHO. 2024. IARC monographs on the identification of carcinogenic hazards to humans. https://monographs.iarc.who.int/list-of-classifications.
10. Chuang SL, Su WW, Chen SL, Yen AM, Wang CP, Fann JC, Chiu SY, Lee YC, Chiu HM,Chang DC, Jou YY, Wu CY, Chen HH, Chen MK, Chiou ST. Population-based screening program for reducing oral cancer mortality in 2,334,299 Taiwanese cigarette smokers and/or betel quid chewers. Cancer. 2017 May 1;123(9):1597-1609. doi: 10.1002/cncr.30517. Epub 2017 Jan 5. PubMed PMID: 28055109.
11. Seoane J, Alvarez-Novoa P, Gomez I, Takkouche B, Diz P, Warnakulasiruya S, Seoane-Romero JM, Varela-Centelles P. Early oral cancer diagnosis: The Aarhus statement perspective. A systematic review and meta-analysis. Head Neck. 2016 Apr;38 Suppl 1:E2182-9. doi: 10.1002/hed.24050. Epub 2015 Jul 20. PMID: 25783770.
12. Schutte HW, Heutink F, Wellenstein DJ, van den Broek GB, van den Hoogen FJA, Marres HAM, van Herpen CML, Kaanders JHAM, Merkx TMAW, Takes RP. Impact of Time to Diagnosis and Treatment in Head and Neck Cancer: A Systematic Review. Otolaryngol Head Neck Surg. 2020 Apr;162(4):446-457. doi: 10.1177/0194599820906387. Epub 2020 Feb 25. PMID: 32093572.
13. Timbang, M. R., Sim, M. W., Bewley, A. F., Farwell, D. G., Mantravadi, A., & Moore, M. G. (2019). HPV-related oropharyngeal cancer: a review on burden of the disease and opportunities for prevention and early detection. Human vaccines & immunotherapeutics, 15(7-8), 1920–1928. https://doi.org/10.1080/21645515.2019.1600985
14. Li C. Cheung, Kunnambath Ramadas, Richard Muwonge, Hormuzd A. Katki, Gigi Thomas, Barry I.

Graubard, Partha Basu, Rengaswamy Sankaranarayanan, Thara Somanathan, and Anil K. Chaturvedi. Risk-Based Selection of Individuals for Oral Cancer Screening. J Clin Oncol. 2021 Feb 20; 39(6): 663–674.

15. UK National Screening Committee (NSC): United Kingdom Cancer Screening Guidelines (2018). https://www.gov.uk/government/groups/uk-national-screening-committee-uk-nsc.
16. Devaraja K. OraCLE: A pre-screening tool for risk stratification of oral cancer that can aid in triaging individuals with high-risk profiles. September 2023. Cancer Research Statistics and Treatment 6(3):452-456. DOI:10.4103/crst.crst_249_23
17. Huber MA, Tantiwongkosi B. Oral and oropharyngeal cancer. Med Clin North Am. 2014 Nov; 98(6):1299-321. doi: 10.1016/j.mcna.2014.08.005. Epub 2014 Sep 20. Review. PubMed PMID: 25443678.
18. Mills S. (2022). How effective is toluidine blue for screening and diagnosis of oral cancer and premalignant lesions?. Evidence-based dentistry, 23(1), 34–35. https://doi.org/10.1038/s41432-022-0239-x
19. Tiwari, L., Kujan, O., & Farah, C. S. (2020). Optical fluorescence imaging in oral cancer and potentially malignant disorders: A systematic review. Oral diseases, 26(3), 491–510. https://doi.org/10.1111/odi.13071
20. Warnakulasuriya S, Kujan O, Aguirre-Urizar JM, Bagan JV, González-Moles MÁ, Kerr AR, Lodi G, Mello FW, Monteiro L, Ogden GR, Sloan P, Johnson NW. Oral potentially malignant disorders: A consensus report from an international seminar on nomenclature and classification, convened by the WHO Collaborating Centre for Oral Cancer. Oral Dis. 2021 Nov;27(8):1862-1880. doi: 10.1111/odi.13704. Epub 2020 Nov 26. PMID: 33128420.

RETINOBLASTOMA SCREENING

RETINOBLASTOMA SCREENING AND GENETIC COUNSELLING

Key messages

- Retinoblastoma is curable if detected and treated early; however, mortality in Kenya is greater than 60% due to late presentation
- An opportunistic screening program, based on family history is proposed, based on genetic counselling and testing, coupled with examination under anaesthesia
- Absence of genetic testing does not prevent screening from being offered; a pathway for such children has been proposed.
- Early diagnosis should be emphasized to all healthcare workers, through routine examination for white pupil or strabismus

Introduction

Retinoblastoma (RB) is the most common intraocular cancer of the eye affecting children less than 5 years of age with over 90% of cases being diagnosed by the third birthday. It is caused by mutation in RB1 tumor suppressor gene located on long arm of chromosome 13 at locus14 (13q14). Bilateral RB, found in 40% of cases, is hereditary and caused by germline mutation in the RB1 gene while unilateral in 60% is due to somatic mutation in the retinal cell. Positive family history of RB is reported in 10% of RB patients. Children with the germline mutation are also at risk of second non ocular cancers such as sarcomas and melanomas

The incidence of retinoblastoma is 1:15,000-20,000 live births and has a fairly uniform worldwide distribution with no sexual or racial predilection. In Kenya, it accounts for 4.8% of all childhood cancers and is estimated to have an incidence of 1 in 17,000 live births (Nyamori & Kimani, 2011). In the developed world most children treated for retinoblastoma survive, but in Africa most of them die from advanced disease. In Kenya the mortality of children diagnosed with retinoblastoma was found to be greater than 60% due to late presentation (Nyawira et al (2012). Retinoblastoma is curable if detected and treated early.

Screening recommendations

1. All infants and children in whom someone has observed a white pupil (either in person or in a photograph) have a full dilated-eye examination including red reflex test within 72 hours by an ophthalmologist.

2. Any child with **strabismus (Squint or Crossed eyes) or suspected strabismus** be referred for examination by a trained primary care health worker
    - Red reflex test should be applied to any child with strabismus (Squint or Crossed eyes) or suspected strabismus.

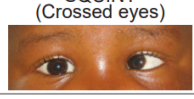
    - Urgent referral (within 72 hours) to an ophthalmologist of any child with strabismus / suspected strabismus and an abnormal red reflex.

3. If a parent/guardian report having noted any problem with a child's eye, the child should be referred to an ophthalmologist immediately even if no abnormality is observed by the health care worker.

4. A patient "at risk" is defined as a person with a family history of retinoblastoma in a parent, sibling, or first- or second-degree relative. At-risk family members found to carry the same RB1 mutation as the proband (patient with RB who is the starting point for genetic testing) benefit from early and intensive screening for RB.

5. The Kenya Mother and Child Health booklet should be consulted as necessary for information related to retinoblastoma screening.

I. Identification of early eye problems in an infant

EYE CARE ASSESSMENT (Tick on the appropriate unshaded boxes for age)		**AGE IN MONTHS**			
		At Birth	**At 6 months**	**At 9 months**	**At 18 months**
TETRACYCLINE EYE OINTMENT (TEO) GIVEN	TEO (ONLY at Birth)				
PUPIL 	Black				
	White (*If white refer urgently*)				
SIGHT	Following objects				
	Not following objects (*Refer to eye clinic*)				
SQUINT (Crossed eyes) 	Squint *(Refer to eye clinic)*				
	No Squint				
ANY other Problem	Yes (*Refer to eye clinic*)				
	No				

NB: *Some eye problems in children apart from causing visual impairment or blindness could also cause death of the child. Early identification and treatment for the problem is critical.*
Preterm infants on oxygen to have Retinopathy of Prematurity (ROP) examination.

Figure 25: Excerpt on retinoblastoma screening from the mother-child booklet

When and how often to screen

Screening tests to be done

- Molecular genetic testing of the RB1 gene, comprehensive genetic counselling must be done prior
- Screening through fundus dilated examination under anaesthesia for all children with positive family history / positive Test for RB1 gene mutation
- At community level, the health care provider should enquire about family history of retinoblastoma.
- All Neonates, infants and children should have red reflex examination at the health facility.

NB: We recommend that RB1 molecular genetic testing should be available in all level 4/County Referral Hospitals.

Genetic testing should be done for at-risk family members

- Children with a known RB1 mutation should have an eye examination every 3 to 6 weeks until 1 year, and then every 3 months until age 3 years, and then every 6 months until age 6 years. This examination should be carried out by an ophthalmologist and requires examination under anaesthesia (EUA)
- Those who test negative for a familial RB1 mutation, do not require ophthalmologic screening.

Screening where genetic testing is not available:

- In positive family history, examine the child soon after birth (or soonest afterwards) then monthly till 6 months, Then every 2 months till one year, Every 3 month till 3 years and every 6 months till 5 years
- Siblings of children with retinoblastoma should be screened at birth then after 1 month then 3 monthly for 1 year. If they still clear of the disease then screening can be stopped.

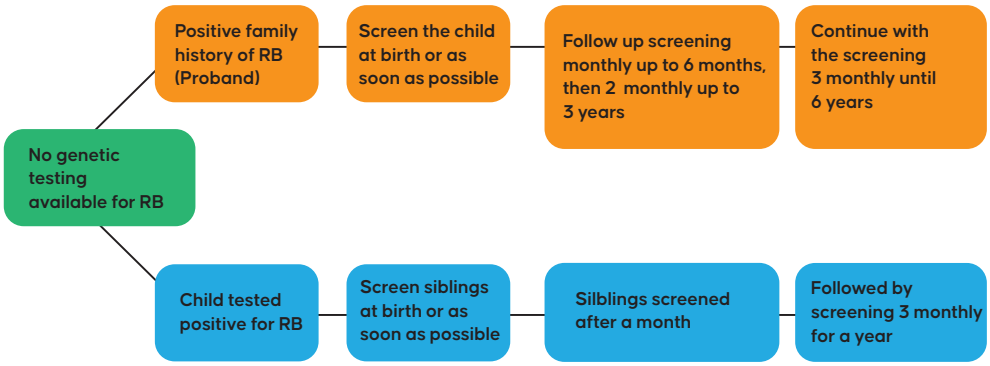


Figure 26: Flow diagram on RB screening in the absence of genetic testing

Table 22: counselling for genetic testing

Recommendation	Level of care
Expectant couples should undergo early prenatal counselling and their infants undergo perinatal management to facilitate the earliest possible treatment of tumours. Antenatal history includes a detailed family history of eye disease, and referral to an ophthalmologist when this history is positive.	Level 2
Each at-risk family member be screened as soon as possible after birth frequently until age 6 years, according to the empiric risk of developing retinoblastoma	Level 2
Creating awareness about the risk of other cancers in adult survivors and relatives.	Level 2
Surveillance be discontinued for relatives determined to be NOT at risk by genetic testing.	Level 2
Counselling for patients, parents and other relatives to discuss retinoblastoma, the risk and hereditary pattern of retinoblastoma, pregnancy options, post-delivery surveillance screening protocols to diagnose tumours early in infants at risk.	Level 3
Children with retinoblastoma should be offered repeated genetic counselling as they grow up, so that they completely understand their options and appropriate care for themselves and their children.	Level 4-6
RB1 gene mutation identification testing for the first affected person (proband) in each retinoblastoma patient family.	Level 4-6
When the RB1 gene mutation in a proband/family becomes known, genetic testing for all at-risk relatives.	Level 4-6

Table 23: vision screening guidelines for retinoblastoma

Age	Screening guideline
Newborn to 3 months	A complete examination of the skin and external eye structures including the conjunctiva, cornea, iris, and pupils. An accessment of the red reflex to rule out lenticular opacities or major posterior eye disease. Failure of visualization or abnormalities of the reflex are indications for an urgent referral to an ophthalmologist. High-risk newborns (at risk of retinopathy of prematurity and family histories of hereditary ocular diseases) should be examined by an Ophthalmologist
6 to 12 months	Conduct examination as above. Ocular alignment should again be observed to detect strabismus. The corneal light reflex should be central and the cover-uncover test for strabismus normal. Fixation and following a target are observed.
3 to 5 years	Conduct examination as above. Visual acuity testing should be completed with an age- appropriate tool.
6 to 18 years	Screen as above whenever routine health examinations are conducted. Examine whenever complaints occur.

Reference

1. Nyamori J, Kimani K, Njuguna M et al. The incidence and distribution of retinoblastoma in Kenya. Br J Ophthalmol 2011; doi:10.1136/bjophthalmol-2011-300739 (RB incidences in Kenya)
2. GLOBOCAN 2018 Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018 Sep 12. doi: 10.3322/caac.21492.
3. Retinoblastoma Best Practice Guidelines 2019, Kenya National Retinoblastoma Strategy
4. Mother and Child Health Handbook MOH 216 (2020)

SECTION C:
EARLY DIAGNOSIS

CHILDHOOD CANCERS

Key messages

- Cancer in children is treatable
- Causes of most childhood cancers are unknown
- Early detection/early diagnosis of childhood cancer results in better treatment outcomes
- Most of the signs and symptoms of childhood cancer are non-specific and require health care providers to have a high index of suspicion
- When the cancer diagnosis is highly likely, early direct referral to the comprehensive cancer centres is recommended

Burden of childhood cancers

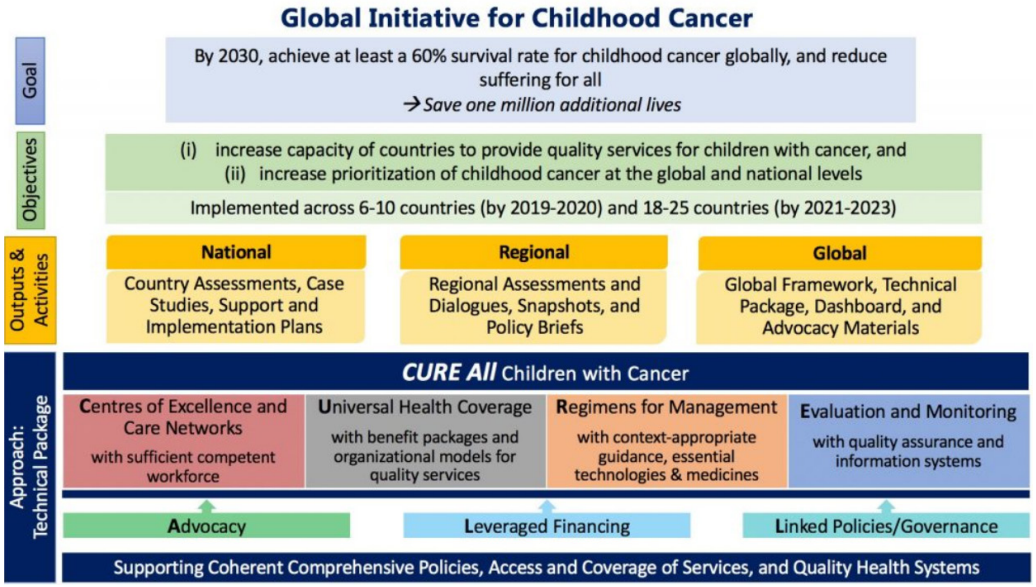
There are about 2,300 new cases of childhood cancer diagnosed in Kenya every year. Cancer in children is treatable.

According to the World Health Organization (WHO), a child is defined to be 19 years or younger. Globally, the annual incidence of cancer in children is estimated at 276,000 cases. Low- and middle-income countries (LMICs) account for almost half (42%) of childhood cancers. Survival rates are over 80% in high income countries but less than 30% in LMIC1

The WHO Global Initiative for Childhood Cancer (GICC), established in 2018, brings together stakeholders from around the world and across sectors with the joint goal of increasing the survival rate of children with cancer globally to at least 60% by 2030 while reducing their suffering and improving their quality of life. The WHO and partners are working to achieve this goal by increasing countries' capacity to provide quality services for children with cancer, and by increasing prioritization of childhood cancer at global, regional and national levels. Kenya is one of the focus countries engaged in the GICC, and is demonstrating advances in the Initiative's CureAll pillars. (https://www.who.int/initiatives/the-global-initiative-for-childhood-cancer).

The table below shows the Goal, Objectives, Outputs & Activities and Approach for the Global Initiative:

Figure 27: Global Initiative for Childhood Cancer



In Kenya, GLOBOCAN estimated that 2,300 new cancer cases were diagnosed in 2022 (Figure 1)

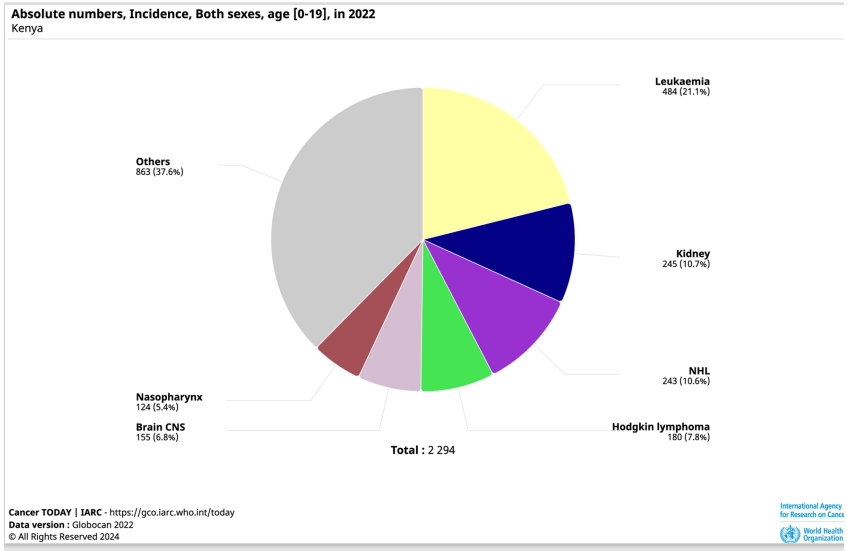


Figure 28: Estimated number of all childhood cancer cases in Kenya, 2022

Risk factors for childhood cancers

The causes for most childhood cancers are unknown; However, a few environmental and infectious agents have been implicated

Genetic factors, environmental factors such as exposure to ionizing radiation and chemicals have been implicated in the causation of childhood cancers, but there is insufficient data to make conclusive associations2 Infectious agents have also been linked to certain cancers; for example, Epstein Barr Virus (EBV) with Burkitt's lymphoma, Hodgkin's lymphoma and nasopharyngeal carcinoma; Human Immunodeficiency Virus (HIV) with Kaposi's sarcoma; malaria with Burkitt's lymphoma; Human Papillomavirus (HPV) with head & neck cancers; and Hepatitis B Virus (HBV) with hepatocellular carcinoma2.

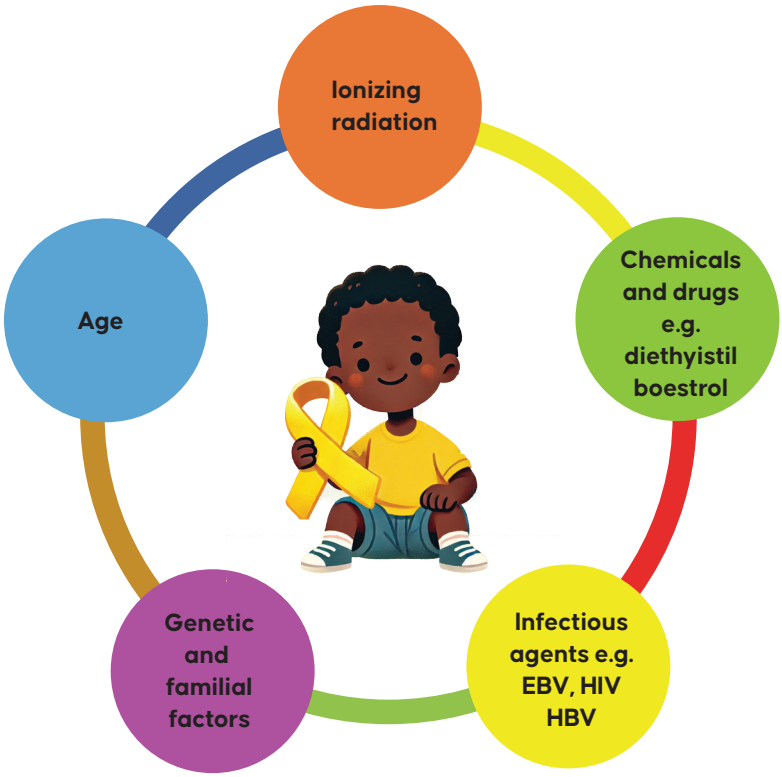


Figure 29: Risk factors associated with childhood cancer

Early detection/early diagnosis of childhood cancer results in better treatment outcomes.

Early detection/ diagnosis of childhood cancers

Early detection of childhood cancers through early diagnosis results in better treatment outcomes. This depends on recognition, mainly at the community level where enhanced awareness regarding childhood cancers by parents and community health workers is important[3]. Every contact of a healthcare provider (HCP) with a child should provide an opportunity for comprehensive evaluation for possible signs and symptoms of cancer. It is important for the HCP to understand that cancer in children may present with non-specific signs and symptoms. When a child is examined and these signs and symptoms are found, cancer must be suspected and action taken accordingly to prevent late diagnosis.

Common symptoms and signs of childhood cancer

Most of the signs and symptoms of childhood cancer are non-specific and require health care providers to have a high index of suspicion

The following are common symptoms and signs of childhood cancer:

C	-	Continued, unexplained weight loss
H	-	Headaches, with early morning vomiting.
I	- `	Increased swelling or persistent pain in your child's bones, joints, back or legs.
L	-	Lump or mass, especially in your child's belly (abdomen), neck, chest, pelvis or armpits.
D	-	Development of excessive bruising, bleeding or rash.
C	-	Constant, frequent or persistent infections.
A	-	A whitish color behind the pupil of your child's eye.
N	-	Nausea that persists, or vomiting without having nausea.
C	-	Constant tiredness (fatigue) noticeable paleness.
E	-	Eye or vision changes that occur suddenly and persist.
R	-	Recurring or persistent fevers of unknown origin, meaning your child has a fever that's not associated with the flu or other common illnesses

Symptoms of the commonest causes of childhood cancer are shown in the diagram below:

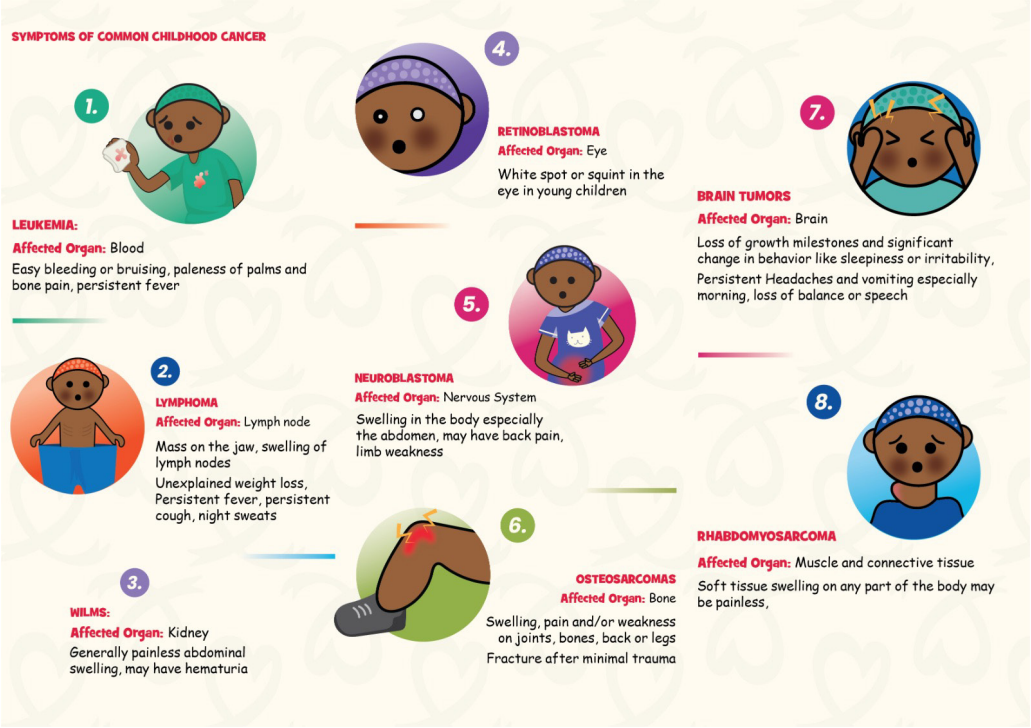


Figure 30: Symptoms and signs of childhood cancer

Implementation strategy of early detection of childhood cancers

Early detection of childhood cancers requires a high index of suspicion and appropriate referral systems to avoid late presentation and worse outcomes. Figure 4 below represents the referral system for such patients but early, direct referral to the comprehensive cancer centres is also recommended when the cancer diagnosis is highly likely in order to avoid delays and loss to follow up of patients.

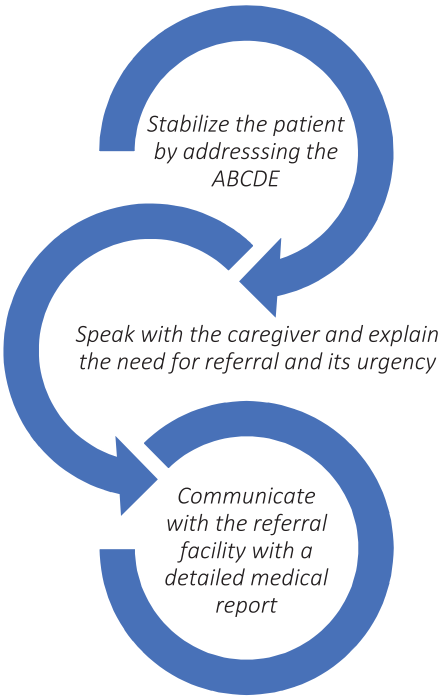
The following are the roles of healthcare providers at each level of care:

Table 24: Providers and services per level of care

Level of care	Healthcare providers	Roles/ Services
Community Level	Community health workers	Mobilise parents or guardians of children with symptoms to visit the nearest health facility
Level 2 and 3 (dispensaries and health centres)	Nurses, Clinical Officers	Evaluate the child using the table below, for early detection of cancer Generate comprehensive referral document and refer appropriately to higher levels of care*
Level 4 &5 (Sub-County and County Hospitals)	Nurses, Clinical Officers, Medical Officers, Paediatricians	Comprehensive physical examination and identification of plausible cancer cases Basic investigations e.g., TBC, UEC, LFT, X-rays, Ultrasounds Supportive care e.g., blood transfusions, treatment of infections, pain management Generate comprehensive referral document and refer appropriately to higher levels of care*
Level 5 and 6 (comprehensive cancer centre)	All above cadres and Paediatric Haematologists/ Oncologists	All the activities done at lower levels of care above Comprehensive management of cancer cases

*Consider direct referral to Comprehensive Cancer Centre when the cancer diagnosis is highly likely

The role of the healthcare provider at all levels of care can be summarized as follows:



Findings that may be associated with a cancer diagnosis in childhood

Symptoms and signs which require referral have been suggested in the table below. However, there are many occasions when it is instead a pattern of symptoms and signs that point towards a diagnosis of cancer. Individual features alone are too imprecise. Additionally, children often cannot express symptoms clearly, and for this reason, the level of suspicion must necessarily be kept high.

Telephone discussion with a paediatrician in cases where the need or timescale for referral is unclear is highly recommended.

AMBER: Concerning features - consider referral or discussion with a paediatrician.

RED: High-risk features - requires immediate referral to Comprehensive Cancer Centre

	CONSIDER REFERRAL	REQUIRES REFERRAL
Ear, Nose and Throat; and Oral	• Otorrhoea (persistent/ recurrent otitis externa) • Persistent/recurrent bloody/ purulent discharge from ear/ nose • Obstruction of ear/nose	• Swallowing difficulties (in absence of local cause) • Abnormal mass within the nasopharyngeal space Jaw mass
Endocrine	• Polyuria/polydipsia • Delayed/arrested puberty • Abnormal growth	• Precocious puberty • Galactorrhoea
Gastrointestinal	• Constipation not responsive to simple laxatives in appropriate dosage • Abdominal distension	• Persistent vomiting on awakening • Unexplained palpable abdominal mass • Unexplained hepatomegaly
Haematology	• Localised petechiae/ bruising (unexplained) • Bleeding (unexplained) • Pallor • Fatigue (persistent) • Infection (recurrent, persistent or unexplained) • Generalised lymphadenopathy • Generalised bone pain (All should be offered a very urgent FBC and referral to paediatrics considered. Some children with these symptoms will need immediate referral	• Splenomegaly - either in isolation or in association with night sweats, weight loss, pruritus or fever • Widespread petechiae/ bruising
Lymphadenopathy	• Widespread distribution (offer very urgent FBC) • Abnormal consistency (firm or hard) • Non-mobile • Absence of pain	• Persistent enlarged nodes >2cms for >2 weeks with no decrease in size •Supraclavicular site • Associated splenomegaly, night sweats, weight loss or pruritus • Symptoms/signs of mediastinal mass (facial swelling or edema, difficulty breathing, distended neck veins) • Associated bone pain

Musculoskeletal	• Night pain • Back pain • Pain limiting activities • Pain at rest • Unexplained or persistent generalised bone pain (offer very urgent FBC)	• Unexplained enlarging mass • Soft tissue mass with local lymphadenopathy • Localised unexplained bone pain (consider very urgent x-ray alongside referral) • Ultrasound scan of a mass suggests soft tissue sarcoma or is uncertain and clinical concern persists • X-ray suggests the possibility of bone sarcoma • Limp with fever • Painful scoliosis
Neurology	• Headache with vomiting • Behaviour or personality change • Reducing school performance	• Afebrile seizures • Increasing head circumference across centiles • Headache worse in the morning or waking from sleep • Persistent headache in a child <4years • Abnormal gait • Abnormal coordination • Confusion or disorientation occurring with headache • New bladder or bowel dysfunction • Development regression • Focal motor or sensory abnormalities • Abnormal head position, such as wry neck, head tilt, or stiff neck

Ophthalmology		• Absent red reflex • Proptosis • Abnormal eye movements • Blurred/double vision • Papilloedema • New onset paralytic (non-concomitant) squint
Renal		• Persistent unexplained microscopic haematuria • Hypertension (>95th centile, or for children aged 13 and over, >130/80) • Frank haematuria • Severe hypertension (>95th centile +12mmHg or >140/90)
Respiratory	• New/changed wheeze/ stridor in absence of typical history for asthma/viral induced wheeze	• New wheeze/stridor with orthopnoea • Difficulty breathing with facial swelling • Mediastinal widening on chest radiograph
Miscellaneous	• Genetic cancer predisposition syndromes • Strong family history of malignancy • Repeated presentation to health professionals • Severe or persistent cradle cap • Unexplained weight loss • Abnormal growth • Blood-stained vaginal discharge• Persistent parental/patient concern or anxiety about symptoms, even if the symptoms are most likely to have a benign cause	• Testicular mass

REFERENCES

1. CureAll framework: WHO global initiative for childhood cancer. Accessed May 16, 2024. https://www.who.int/publications-detail-redirect/9789240025271
2. Ricci AM, Emeny RT, Bagley PJ, et al. Causes of Childhood Cancer: A Review of the Recent Literature: Part I—Childhood Factors. Cancers. 2024;16(7):1297. doi:10.3390/cancers16071297
3. Njuguna F, Martijn H, Langat S, et al. Factors influencing time to diagnosis and treatment among pediatric oncology patients in Kenya. Pediatr Hematol Oncol. 2016;33(3):186-199. doi:10.3109/08880018.2016.1169566

OESOPHAGEAL CANCER

Key messages

- This is a high burden cancer in our setting
- There are no globally accepted, evidence-based screening approaches for oesophageal cancer; however, early diagnosis impacts treatment outcomes and reduces mortality
- A high index of suspicion and prompt linkage to diagnosis and treatment is necessary
- Early detection is primarily conducted through esophago-gastro-duodenoscopy (OGD)

Introduction

Oesophageal cancer is the 11th most common cancer and 7th most frequent cause of cancer mortality in the world, with estimates of 511,054 new cases and 445,391 deaths in 2022 (Global Cancer Observatory, 2022).

In Kenya it is one of the top five cancers in both men and women. In addition, cancer has been reported to be on the rise and in particular hot spots in the country. The main variant of oesophageal cancer seen in Kenya is oesophageal squamous cell carcinoma unlike in Europe and Asia.

Currently, international screening guidelines for oesophageal cancer do not exist. However, due to the high disease burden in Kenya (Globocan 2022), there is a need to provide guidance on how to improve early diagnosis of oesophageal cancer. This can lead to better treatment outcomes, better prognosis and will be a more cost-effective approach as compared to the current status whereby late diagnosis is most common.

Risk for oesophageal cancer
Identifying High-Risk Groups is the first entry to early detection, including:

- Long-standing gastroesophageal reflux disease (GERD)
- History of Barrett's oesophagus
- Smoking
- Heavy alcohol consumption
- Older age (usually above 50)

Symptoms and signs

- Progressive Dysphagia
- Odynophagia
- Unexplained Weight loss
- Heartburn not responsive to treatment

- Melena and /or symptoms of anaemia
- Hoarseness
- Cough not improving on medication.
- Generalized weakness.
- Epigastric pain.

Goals of early detection

Early detection makes it possible to detect precancerous lesions and early cancer lesions.

Implementation considerations for early diagnosis of oesophageal cancer in Kenya

The implementation strategy for early diagnosis of oesophageal cancer in Kenya involves multiple components aimed at raising awareness, conducting research, improving infrastructure, training healthcare workers, targeted screening, and establishing a robust patient navigation and referral system. Advocacy efforts will focus on educating the public about oesophageal cancer through various media channels and partnering with local leaders and organizations to promote early diagnosis initiatives. Research will include local studies to identify high-risk populations and the establishment of a cancer registry for tracking incidence and outcomes. Infrastructure development will ensure that diagnostic centres are equipped with necessary equipment, deploy mobile clinics to underserved areas, and enhance laboratory services.

Human resource recruitment and training are crucial, with specialized programs for healthcare workers on early detection and management, along with continuous education. A patient navigation system will support individuals through the diagnosis and treatment process, while a robust referral framework will ensure timely referrals. Monitoring and evaluation will include setting objectives, collecting data through health records and focus groups, and regular reporting and site visits. Evaluations will be conducted at various stages, and feedback mechanisms will help in continuous improvement.

Table 26: Implementation approaches for oesophageal cancer early diagnosis

Component	Key Activities
Advocacy and Communication	Raise awareness, engage stakeholders, use media channels
Research	Conduct local studies, support cancer registry, implement evidence-based practices
Infrastructure Development	Equip diagnostic centres, deploy mobile clinics, enhance laboratory services
Human Resource Recruitment	Develop training programs, increase recruitment, provide continuous education
Targeted Screening	Identify high-risk groups, establish regular monitoring
Patient Navigation and Referral	Develop patient navigation system, establish referral network, implement integrated care pathways
Monitoring and Evaluation	Set objectives, collect data, conduct routine reporting, site visits, evaluations, establish feedback mechanism

Early detection tests

1. White Light Endoscopy:

a. Advantages: Can be done in any endoscopy unit.
b. Disadvantage: Misses out on precursor lesions. Needs sedation as well as trained endoscopists.

2. Lugol's chromoendoscopy

a. Advantages: Shows precursor lesions. Lugol's iodine is cheap.
b. Disadvantages: Endoscopists need additional training. Allergic reaction to iodine can occur. Needs sedation and endoscopy.

Figure 32: Early detection flowchart for oesophageal cancer

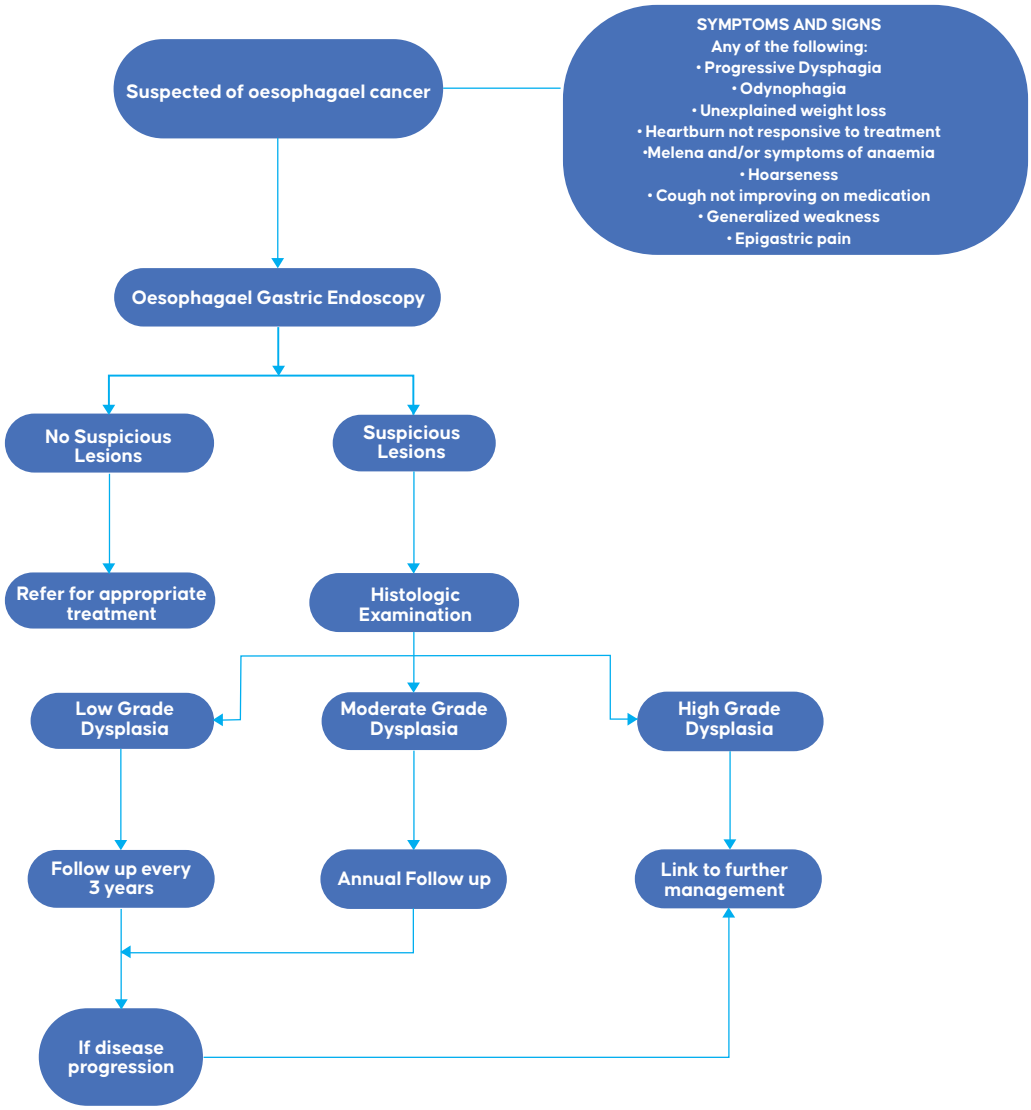
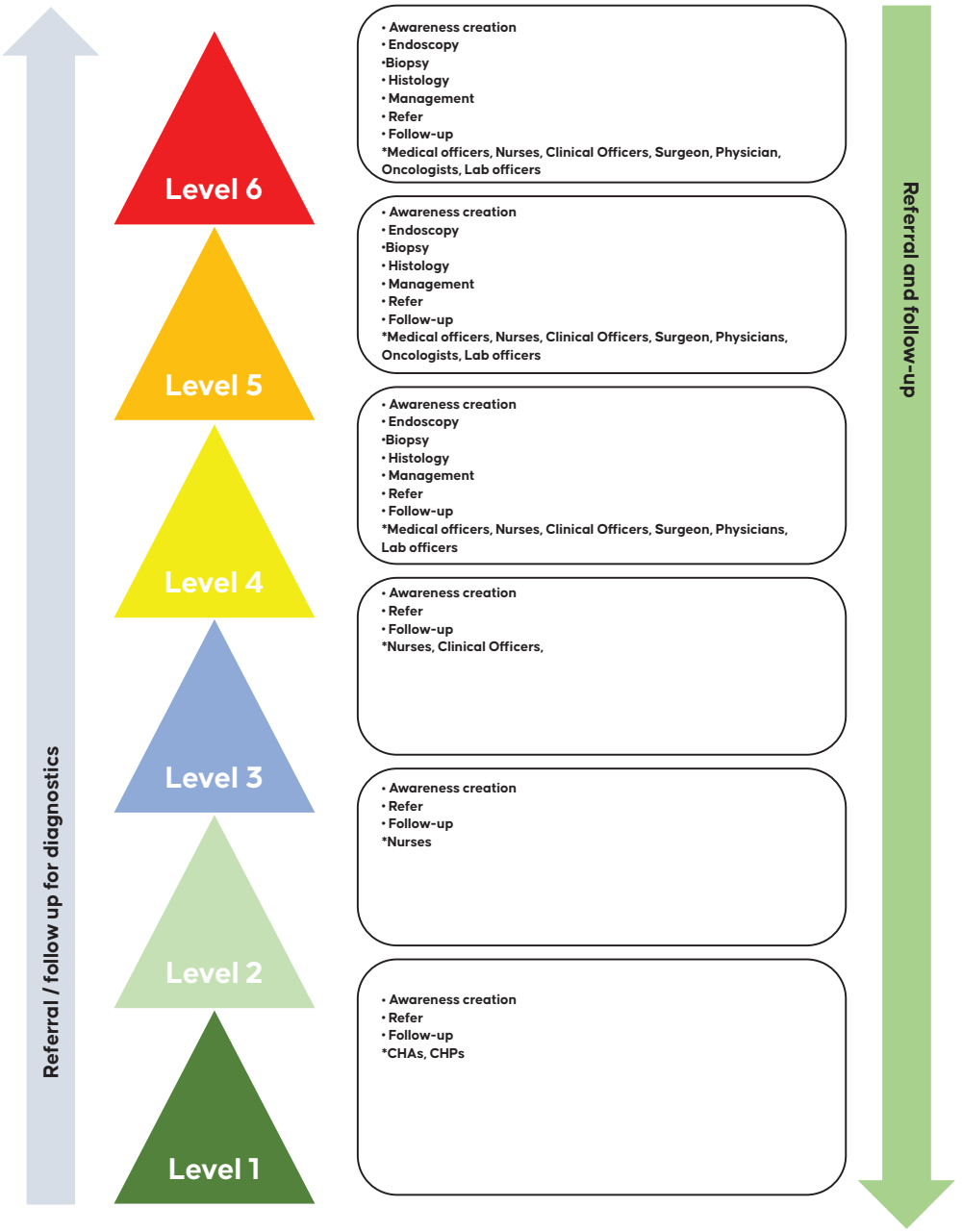


Figure 33: Implementation Strategies for Oesophageal Cancer Early Detection



References

1. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.who.int/today, accessed [22 May 2024].
2. Li H, Teng Y, Yan X, Cao M, Yang F, He S, Zhang S, Li Q, Xia C, Li K, Chen W. Profiles and Findings of Population-Based Esophageal Cancer Screening with Endoscopy in China: Systematic Review and Meta-analysis. JMIR Public Health Surveill. 2023 Jun 1;9: e45360. doi: 10.2196/45360. PMID: 37261899; PMCID: PMC10273033.
3. Stéphane Groulx, Heather Limburg, Marion Doull, Scott Klarenbach, Harminder Singh, Brenda J. Wilson, Brett Thombs. Guideline on screening for esophageal adenocarcinoma in patients with chronic gastroesophageal reflux disease. CMAJ Jul 2020, 192 (27) E768-E777; DOI: 10.1503/cmaj.190814

LUNG CANCER

Key messages

Although lung cancer is not among the most prevalent cancer types in Kenya, the burden may be an underestimate, due to misdiagnosis as tuberculosis or other chronic lung conditions. Lung cancer is amenable to screening through low-dose CT scan; however, due to programmatic and health system readiness, this guideline does not recommend a population-based lung cancer screening

A early diagnosis program, integrated within the national TB control structures is proposed for implementation in Kenya

Background

In 2022, lung cancer surpassed breast cancer to become the most common cancer globally, with 2.5 million new cases. It is also the leading cause of death with a record 1.8 million cases. In Kenya, lung cancer ranks number 11 in both incidence and mortality. New cases account for 2% (903) of our total new cases but have a higher mortality rate of 2.8% (822). However, these figures might not be showing the correct burden of the disease in the country; primarily due to misdiagnosis of lung cancer as other lung health conditions like tuberculosis, which have a similar clinical presentation. The local published data shows that there is male predominance of the lung cancer. The median age at diagnosis is 57-60 (29-84 years), in which 38% are aged <55 years. Majority (60-80%) of the patients present at stage IV with median survival rate of 18 months while the two-year survival rates is 60%.

Rationale for early detection

Lung cancer has a very high mortality rate if diagnosed at advanced stages. The directed lung cancer screening studies conducted in the UK, EU, and the USA have shown that lung cancer if detected early, greatly improves survival. In Kenya, most of the lung cancer patients are diagnosed at advanced stages resulting in poor survival rates. Moreover, many lung cancer patients have reported to have been treated for pulmonary tuberculosis (pTB) despite the TB test being negative; only later to be diagnosed with lung cancer. Thus, there is an unmet need for directed early diagnosis of lung cancer.

Signs of lung cancer

Individuals presenting with the following sign and symptoms should raise high index of suspicion of lung cancer

- A long-standing cough that is worsening after ruling out TB, COVID-19, and other causes
- Chest pain when breathing or coughing (pleurisy) which does not respond to conventional treatment
- Coughing blood (hemoptysis)
- Cough with unexplained weight loss
- Recurrent lung infections
- Persistent dyspnoea (shortness of breath) which is not associated with other

causes e.g heart disease
- Fatigue and lethargy

Early diagnosis in symptomatic individuals

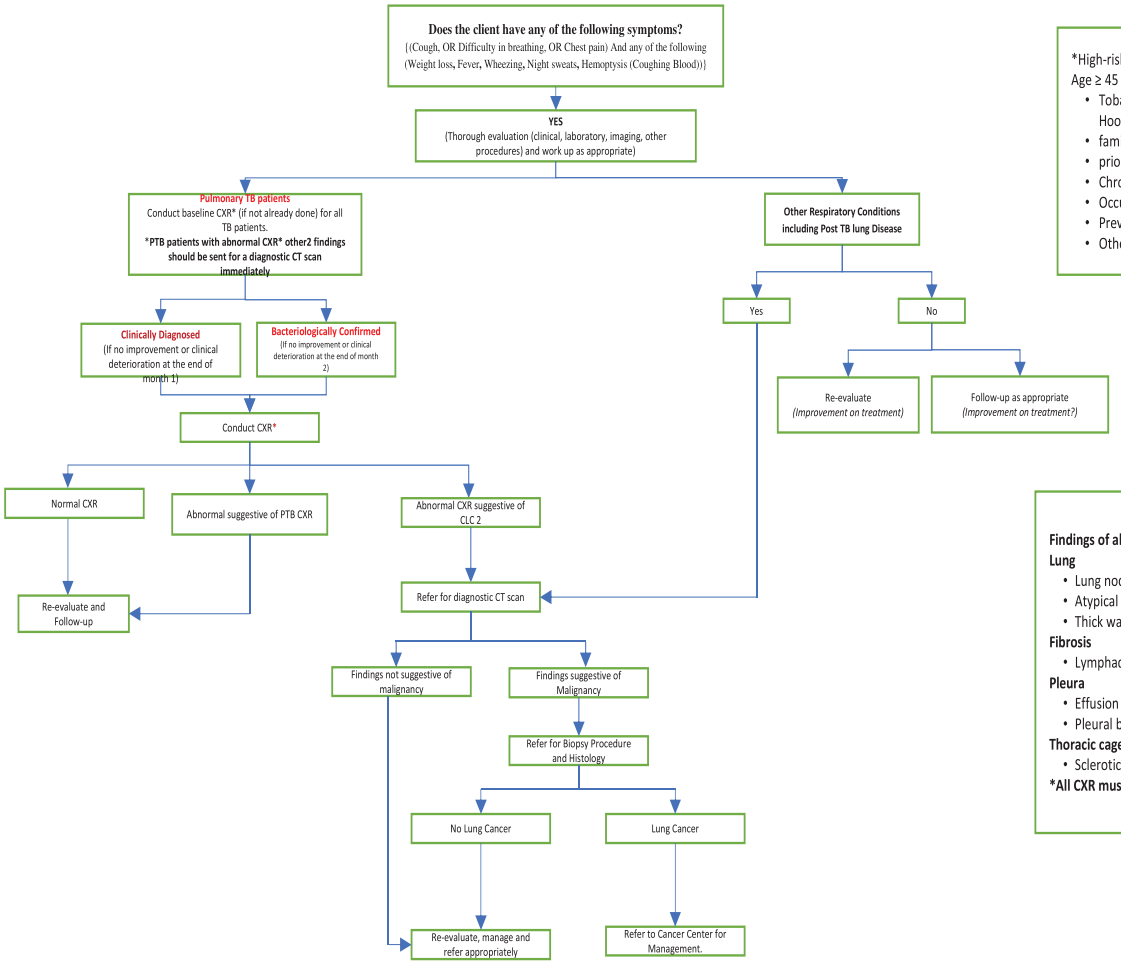
Screening is meant for individuals without symptoms. However, due to the misdiagnosis of lung cancer as TB and other chronic lung diseases, the following individuals should raise a high index of suspicion and should be screened for lung cancer. Remember, lung cancer if detected early is treatable with better survival outcomes. Thus, early diagnosis and prompt referral are critical.

- All patients with assumptive pTB (Gene Xpert negative)
- Patients treated for assumptive pTB without improvement
- Patients with confirmed pTB but not improving on anti-TB
- Patients with a lung lesion and or pleural effusion on chest X-ray
- Non-TB chronic cough not responding to treatment, with or without hemoptysis and weight loss
- Individuals with signs of lung cancer
- patients who have had previous radiotherapy to the chest including the chest wall

How to conduct lung cancer early diagnosis

- Individuals with suggestive symptoms should be screened to rule out lung cancer with a contrast-enhanced high-resolution chest CT (HRCT) scan as this could lead to early diagnosis. See the flow charts below

NB: Chest X-rays should not be used for lung cancer screening but suspicious chest X-rays should be reported by radiologists and confirmed by CT scan.



*High-risk factors Chronic Lung Conditions
Age ≥ 45 years with either of the following:

- Tobacco use both active and passive (sniffing/smoking/ Shisha/ Hookah)
- family history of lung cancer (first degree relative)
- prior history of cancer
- Chronic lung diseases such as TB and COPD
- Occupational exposure to cancer-causing agents
- Previous history of radiotherapy to the chest
- Others (specify).....

Findings of abnormal CXR* suggestive of Chronic Lung Conditions (CLC)

Lung

- Lung nodule or mass with malignant features
- Atypical consolidation/ground glass opacification
- Thick walled cavitating mass

Fibrosis

- Lymphadenopathy

Pleura

- Effusion
- Pleural based mass

Thoracic cage

- Sclerotic/lytic lesion with malignant features

***All CXR must be reported by a radiologist**

Implementation Strategies for Success:

The following are proposed solutions to possible challenges in implementation of the lung cancer early diagnosis guidelines:

- Ensure that there are sufficient personnel trained and certified to support the early diagnosis program (radiologists, pulmonologists, and other healthcare professionals).
- Conduct comprehensive patient education programs that emphasize the benefits of early detection.
- Provide clear and accurate information about the likelihood of false positives, treatment options, and survival rates with early detection to clear fear of lung cancer diagnosis.
- Foster trust through transparent communication encouraging open dialogue between healthcare providers and patients, ensuring that patient concerns are well addressed

References

1. Bray, F., Laversanne, M., Sung, H., Ferlay, J., Siegel, R. L., Soerjomataram, I., & Jemal, A. (2024). Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA: A Cancer Journal for Clinicians, 74(3), 229-263. https://doi.org/10.3322/caac.218341.
2. Incidences and Trends of Lung Cancer in Western Kenya for the Period Between 2012-2016 https://doi.org/10.1200/jgo.18.81400
3. P1.09-12 Lung Cancer in Kenya: Quantification of the Problem F. Asirwa, A. Kalebi, H. Kibet https://doi.org/10.1016/j.jtho.2019.08.2208
4. Said NS, Degu A. Assessment of survival outcomes among lung cancer patients at the National and Referral Hospital in Kenya. Cancer Med. 2023 Apr;12(8):9194-9201. doi: 10.1002/cam4.5658. Epub 2023 Jan 27. PMID: 36708066; PMCID: PMC10166906.
5. Lung cancer screening in England. https://www.lungcancerpolicynetwork.com/lung-cancer-screening-in-england/

EARLY DIAGNOSIS FOR OTHER CANCERS IN ADULTS

Key messages

- While screening is only applicable for just a few cancers, early diagnosis applies to all cancer types
- Early diagnosis ensures cancers are diagnosed in early stages, which makes treatment more successful, less toxic and cheaper
- Early diagnosis requires an informed public, trained health workforce and a health system that supports prompt diagnosis and treatment.

Introduction

Early diagnosis is defined as the **early identification** of cancer in **patients who have symptoms** of the disease, with the aim of identifying the disease at early stages, **link to diagnosis and treatment** and eventually **improving survival and quality of life.**

The three steps of early diagnosis

- Step 1: awareness of cancer symptoms, symptom appraisal and health-seeking behaviour
- Step 2: clinical evaluation, diagnosis and staging; and
- Step 3: accessing timely treatment, including pain relief.

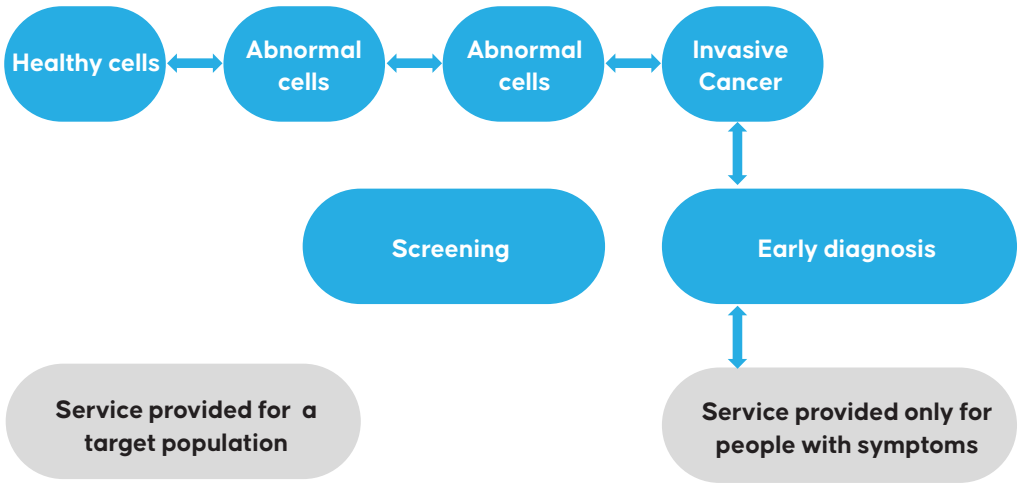


Figure 35: Differentiating cancer screening from early diagnosis (adapted from the Guide to cancer early diagnosis. Geneva: World Health Organization; 2017. Licence: CC-BY-NC-SA-3.0-IGO)

Common symptoms and signs that may be due to cancer

Cancer symptoms can be non-specific; however, any "red flag" symptoms should be recognized by providers and investigated further. The table below shows the commonest symptoms as per cancer type, and suggested action by HCWs at primary point of contact.

Table 27: Common cancer symptoms and signs, per organ system

Site of cancer	Common symptoms	Action for healthcare workers
Breast	Lump in the breast, asymmetry, skin retraction, recent nipple retraction, blood stained nipple discharge, eczematous changes in areola	Refer to a surgeon (who can then arrange imaging and biopsy in consultation with a radiologist)
Cervix	Abnormal vaginal bleeding and/or discharge, pelvic pain (Note: early cervical cancer has no symptoms)	Conduct speculum exam, biopsy and refer to gynaecologic oncologist (biopsy can be performed by a well-trained nurse, clinical officer, medical officer or higher).
Colon and rectum	Change in bowel habits, unexplained weight loss, anaemia, blood in the stool	Refer to the appropriate facility for colonoscopy
Oral cavity	White lesions (leukoplakia) or red lesions (erythroplakia), growth or ulceration in mouth; intraoral swellings	Refer to a dentist/ maxillofacial surgeon
Naso-pharynx	Nosebleed, permanent blocked nose, deafness, nodes in upper part of the neck	Refer to ENT specialist
Larynx	Persistent hoarseness of voice	Refer to ENT specialist
Stomach	Upper abdominal pain, recent onset of indigestion, weight loss	Evaluate and refer urgently for oesophageal-gastro-duodenoscopy (OGD)
Skin melanoma	Brown lesion that is growing with irregular borders or areas of patchy colouration that may itch or bleed	Refer to a dermatologist; or general surgeon if dermatologist is not available
Other skin cancers	Lesion or sore on skin that does not heal	
Urinary bladder	Pain, frequent and uneasy urination, blood in urine	Refer to a urologist
Prostate	Difficulty (long time) in urination, frequent nocturnal urination	
Testis	Swelling of one testicle (asymmetry)	

Referral Pathways/Mechanisms and Integrated Care

The success of cancer early diagnosis programs depends not only on prompt recognition of red-flag symptoms, but on referral and linkage to diagnosis and/or treatment. Various services that can support an efficient early diagnosis service, per level, is shown on table 27 below. The following recommendations are suggested to ensure an effective referral mechanism for cancer in Kenya:

- Coordinated, efficient referral systems that facilitate access, improve communication and reduce unnecessary visits
- Creation of a directory of available cancer diagnostic facilities per county
- Linking primary care and outpatient departments to advanced diagnostic and treatment services
- Effective communication between patients, families and providers, encouraging patient participation and shared decision making.
- A direct link between primary care facilities and higher levels of care by establishing criteria for referral and counter-referral and improving information transfer between providers
- A medical records system available at all levels of care, allowing providers to properly document diagnostic and staging information, management plans and status at each follow-up visit
- Integrate cancer early detection to all service provision areas, and utilizing existing infrastructure to support cancer early detection. For example; lung cancer early detection can be integrated with the TB diagnostic pathways across the country.
- Training and mentorship of health care workers, on having a high index of suspicion of various cancers, performing diagnostic tests as per level of care, referring and appropriately counselling patents to avoid care delays.

Table 28: Suggested organization of cancer early diagnosis interventions by level of care

Community Empowerment (level 1)	**Primary care level (level 2 and 3)**	**Secondary level (level 4 and 5)**	**Tertiary care level (level 6)**
Key interventions • Improve cancer awareness • Identify community leaders and cancer advocates • Reduce cancer stigma • Facilitate health-seeking behaviour • Engage public to identify barriers to accessing care	Diagnosis • Recognition of cancer signs and symptoms • Appropriate clinical evaluation • Early referral of suspicious cases Treatment • Basic procedures (e.g. cryotherapy) • Patient education and rehabilitation Additional functions • Health education, counselling • Coordinating services across facilities • Provide supportive, palliative and survivorship care	Diagnosis • Cytology, biopsy, routine histopathology • X-ray, ultrasound, endoscopy Treatment • Moderately complex surgery • Outpatient chemotherapy Additional functions • Coordinate with primary and tertiary care levels services • Provide supportive, palliative and survivorship care	Diagnosis • Cytology, biopsy, histopathology, prognostic markers, immunochemistry • X-ray, ultrasound, endoscopy, computerized tomography, endoscopy Treatment • Radiotherapy • Complex surgery and hemotherapy • Rehabilitation • Supportive services Additional functions • Communicate with primary and secondary care levels, counter-referrals • Provide supportive palliative and survivorship care as needed

Common barriers and potential solutions to early diagnosis

Various barriers may exist against cancer early diagnosis, on each of the three steps; these barriers result in delays in access (step 1), diagnosis (step 2) and treatment (step 3). Possible approaches to address these barriers in the Kenyan context are shown in the table below.

Table 28: Summary of common barriers and potential solutions to early diagnosis

Early diagnosis step		Common barrier s	Potential solutions	Examples in the Kenya context
Step 1: Awareness and Accessing care	Awareness of symptoms	Poor health literacy	Empower and engage people and community Improve health literacy Feedback from the community	CHPs Key personalities National/county first ladies NGAOS Religious institutions Huduma centres Local media houses Coordinated social media messaging Civil society
	Seeking and accessing care	Cancer stigma	Address and reduce Stigma Counselling on how and where to present for care	
		Limited access to primary care with cancer symptoms	Facilitate access to primary care Universal health coverage	SHIF

Step 2: Clinical evaluation, diagnosis and staging	Accurate clinical diagnosis	Inaccurate clinical assessment Delays in clinical diagnosis	Improve provider capacity at first contact point	MoH virtual academy NCD protocols Pre-service education Continuing professional development Diagnostic algorithms Investment in pathology
	Diagnostic testing and staging	Inaccessible diagnostic tests including pathology and staging	Strengthen diagnostic and pathology services	Leverage the chronic diseases fund Situational analysis/mapping of pathology, radiology services (infrastructure and workforce) Publicly available directory of cancer screening, diagnostic and treatment services
	Referral for treatment	Poor coordination of services	Develop referral mechanisms and integrated care	Direct link between primary care facilities and higher levels of care Avail diagnostic services within county facilities Improve coordination between providers and patients, through tumour boards, multi-disciplinary review or integrated electronic medical record system

		Loss to follow-up	Provide supportive counselling and people-centred care	Scheduled follow-ups, CHPs or patient navigators and/or mobile phones (e.g., text messaging, phone calls) Discussing cancer diagnosis and treatment plans with patient's social support system, such as relatives and friends, according to patient preferences. Effective counselling and strong media messaging on the value of cancer treatment to facilitate adherence to treatment Plans HCW training & mentorship to minimize need for referral Placement of treatment devices at lower levels of care Longitudinal patient tracking mechanisms Use of line-lists to track screen positive clients
Step 3: Access to treatment	Accessible, high quality treatment	Logistical, financial and geographic barriers	Increase treatment availability Address direct andindirect out-of-pocketcosts	Leverage the chronic diseases fund

		Sociocultural barriers	Improve communication through patient and family engagement	In-facility navigators Contacting patients with cancer at predesignated intervals.

SECTION D:
APPENDICES

APPENDICES

Appendix I: Planning for cervical cancer screening program

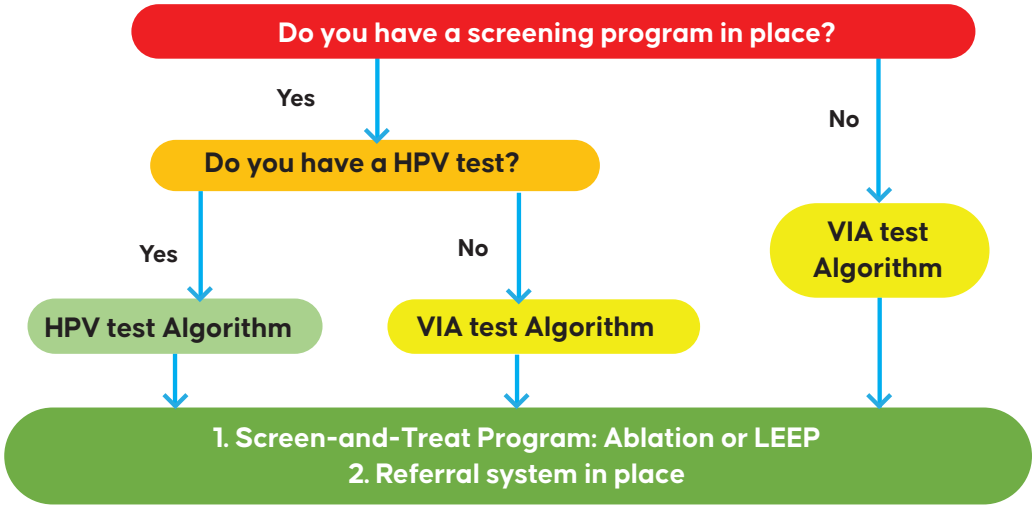


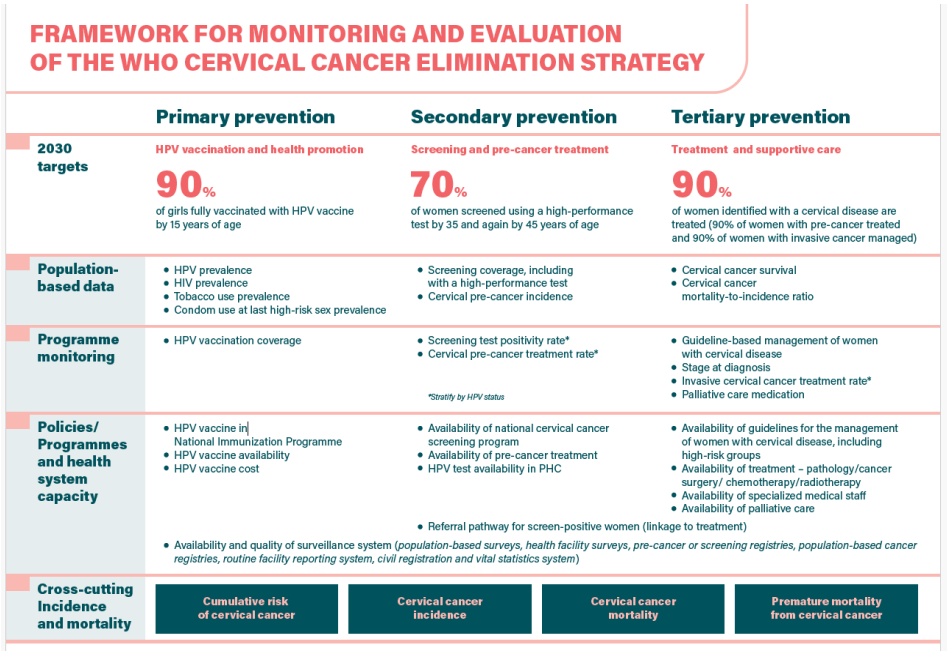
Fig 8: This decision-making flowchart has been developed to assist administrators/ managers at County & facility level to choose an appropriate screening strategy

Appendix II: Implementing a cervical cancer screening program

SWOT ANALYSIS

Appendix III: Global framework for monitoring and evaluation of the who cervical cancer elimination strategy

Framework for Monitoring the Implementation of the WHO Global Strategy to Accelerate the Elimination of Cervical Cancer: Indicator Metadata



FRAMEWORK FOR MONITORING AND EVALUATION OF THE WHO CERVICAL CANCER ELIMINATION STRATEGY

	Primary prevention	Secondary prevention	Tertiary prevention
2030 targets	HPV vaccination and health promotion **90%** of girls fully vaccinated with HPV vaccine by 15 years of age	Screening and pre-cancer treatment **70%** of women screened using a high-performance test by 35 and again by 45 years of age	Treatment and supportive care **90%** of women identified with a cervical disease are treated (90% of women with pre-cancer treated and 90% of women with invasive cancer managed)
Population-based data	• HPV prevalence • HIV prevalence • Tobacco use prevalence • Condom use at last high-risk sex prevalence	• Screening coverage, including with a high-performance test • Cervical pre-cancer incidence	• Cervical cancer survival • Cervical cancer mortality-to-incidence ratio
Programme monitoring	• HPV vaccination coverage	• Screening test positivity rate* • Cervical pre-cancer treatment rate* *Stratify by HPV status	• Guideline-based management of women with cervical disease • Stage at diagnosis • Invasive cervical cancer treatment rate* • Palliative care medication
Policies/ Programmes and health system capacity	• HPV vaccine in National Immunization Programme • HPV vaccine availability • HPV vaccine cost	• Availability of national cervical cancer screening program • Availability of pre-cancer treatment • HPV test availability in PHC • Referral pathway for screen-positive women (linkage to treatment)	• Availability of guidelines for the management of women with cervical disease, including high-risk groups • Availability of treatment – pathology/cancer surgery/ chemotherapy/radiotherapy • Availability of specialized medical staff • Availability of palliative care
	• Availability and quality of surveillance system (*population-based surveys, health facility surveys, pre-cancer or screening registries, population-based cancer registries, routine facility reporting system, civil registration and vital statistics system*)		
Cross-cutting Incidence and mortality	Cumulative risk of cervical cancer	Cervical cancer incidence	Cervical cancer mortality	Premature mortality from cervical cancer

Appendix IV: Tracking the cervical cancer program at the national and sub-national level

Main indicators;

- Monthly screening performance - % of screening target reached
- Screening tests positivity rates
- Target age screening rates
- Pre-cancer treatment rates
- Counties/facilities monthly screening rates
- Data consumption at facility level

Example of a cervical cancer screening score-card

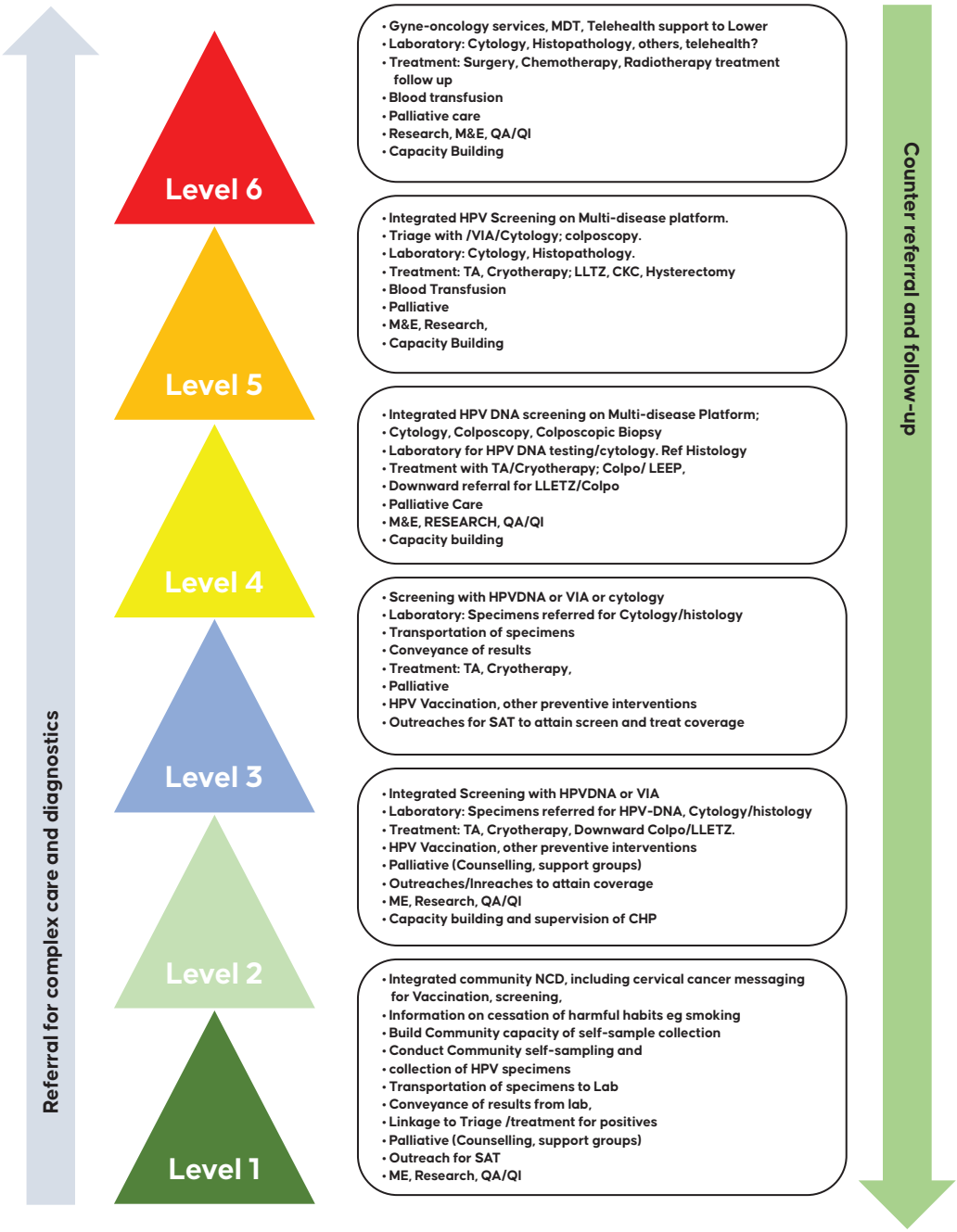
Percentage of screening target reached for the last quarter

≥ 85%	Good
75 - 84	Caution and continue to monitor
> 75%	Immediale action needed

Percentage of first-time screened women aged 25–49 years with a positive screening test result

VIA: 5-10% HPV: 5-25% Cytology: 1-5% HSIL	Good
VIA: 4-4%: 10-19%	Caution and continue to monitor
VIA: <3% or >19%	Immediale action needed

APPENDIX V: Recommended Cervical cancer services by levels of Care



APPENDIX VI: Performance of HPV tests used for cervical cancer screening

All HPV tests rolled-out in the country should be based on validated assays, to maintain the quality assurance of the screening program. All stakeholders (public and private facilities, health managers, program teams, funders and development partners) should make reference to and be guided by the list of WHO-prequalified In Vitro Diagnostic products; available on the link below:

https://extranet.who.int/prequal/vitro-diagnostics/prequalified-vitro-diagnostics

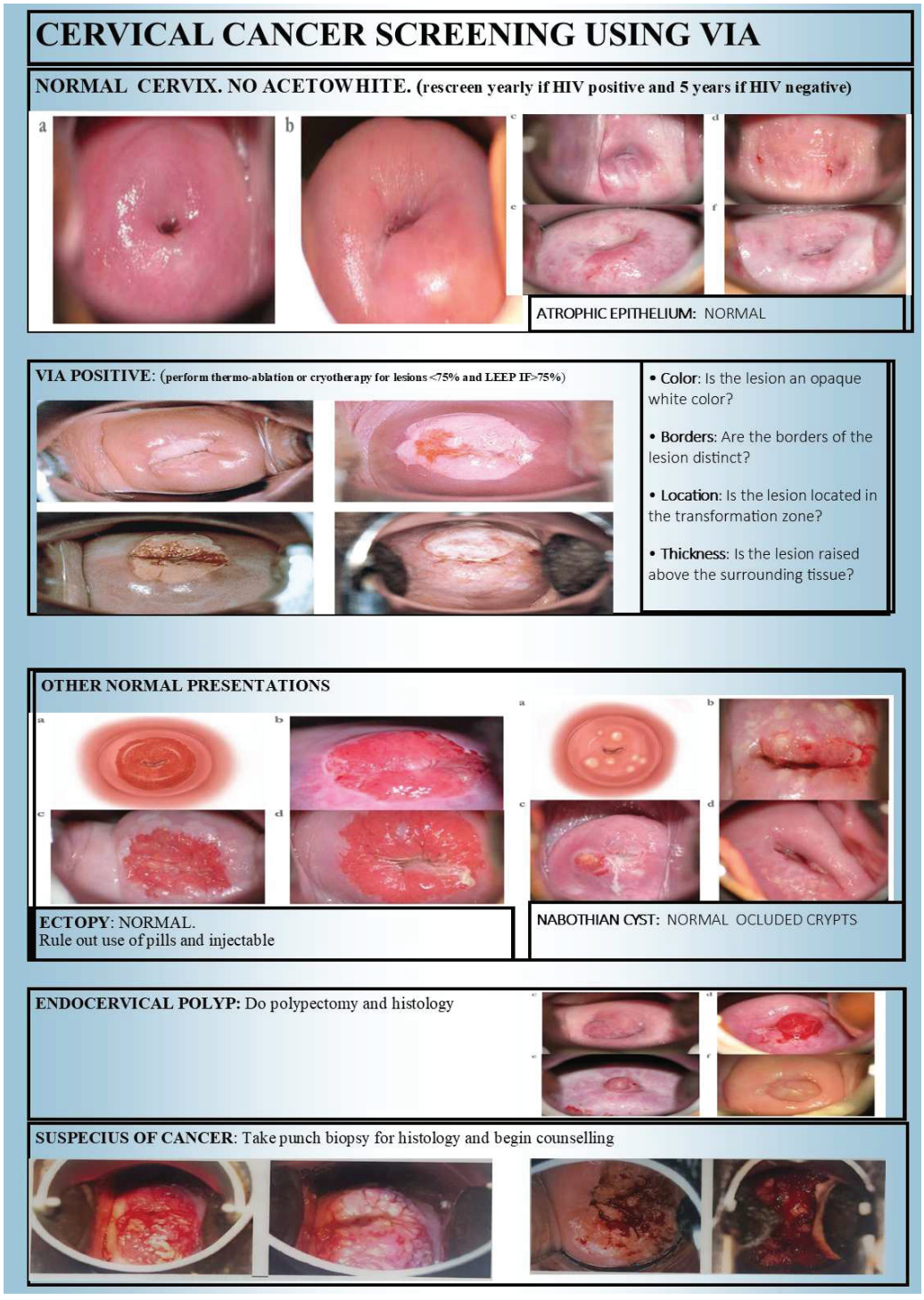
Selection of the HPV test for the cervical cancer screening program

Once the decision has been made to introduce HPV testing into the screening program, the most suitable

HPV test can be chosen from the options available on the market. The selection needs to be based on clinical validation of the test, operational and logistical aspects, and the test's costs and benefits. Consider the following:

- What HPV types are detected by the test?
- How are the results presented: by HPV type or as HPV positive/negative?
- Are the tests clinically validated?
- What are the manufacturer requirements and costs of the HPV test, equipment and supplies?
- What is the appropriate lot size to process samples?
- How long does specimen processing take?
- What type of training is needed to process the tests?
- What in-country support is available for equipment installation and maintenance?
- How is the quality of the test result controlled?
- Can self-sampling be used with the HPV test?
- What are the requirements for storage, expiration dates, and other supply chain management issues?
- With the local distributor of the HPV test, are there any conditions, arrangements and additional costs to consider?

Appendix VII: Findings on VIA and Colposcopy



Appendix VIII: equipment needed for screening and treatment

HPV DNA screening
Collection kit
Sample collection system (to the lab)
Testing equipment (vary from facility- GeneXpert, Cobas, BD viper)
Testing reagents for each specific equipment
personnel
LIMS (Laboratory Information Management System)
Where the testing facility doesn't have enough capacity to process the specimen, they should refer to the guidelines on 1) integrated sample referral system, 2) diagnostic optimization network guidelines,
Cervical Cytology (if done)
Cervical Brush / cervix brush or Ayre's spatula
Glass slides
Fixative solution
Sample collection system (to the lab)
Testing reagents
Processors (automated stainers)
Personnel (histo/Cytotec)
microscopes
LIMS (Laboratory Information Management System)
Where the testing facility doesn't have enough capacity to process the specimen, they should refer to the guidelines on 1) integrated sample referral system, 2) diagnostic optimization network guidelines
Histology for uterine cervical biopsy specimen
Punch biopsy gun e.g., Tischler-Kevorkian punch biopsy
Fixative (10% formalin)
Specimen container (enough to accommodate the specimen and fixative). The five should be three times the volume of the specimen
Sample collection system (to the lab)
Testing reagents
Processors (automated tissue processor), among other listed equipment/machines (refer to laboratory manual)
Personnel (pathologist, histology/Cytotec)
microscopes
LIMS (Laboratory Information Management System)

Where the testing facility doesn't have enough capacity to process the specimen, they should refer to the guidelines on 1) integrated sample referral system, 2) diagnostic optimization network guidelines
Cryotherapy procedure- supplies in addition to VIA supplies
Gas cylinder (NO2 or CO2) -15 -25kg Average 15-18 treatments per 15Kg cylinder Average 22 -26 treatments per 25KG cylinder Estimate initial VIA/VILI positive rate of 10 -15% Estimate 85% of VIA/VILI positive eligible for cryotherapy (13/100)
Appropriate cryotherapy unit with cryotips
Adjustable spanner
Gas cylinder adaptor
Monsel's paste or silver nitrate sticks
Glutaraldehyde (cidex)
Thermal Ablation
Same as VIA including a thermal ablator e.g., Liger, WiSAP or MedGyn
COLPOSCOPY
Same as VIA including a colposcope with magnification and green light
Light source (phone torch not recommended)
LEEP Supplies in addition to VIA supplies for sites providing LEEP
LEEP units
Loops (can vary with manufacturer) • 15mm x12mm x11cm shaft • 10mm x 10mm x11cm shaft • 2.0mmx1.8mmx11cm shaft • 2.0mmx1.5mmx12cm shaft • Roller Balls (can vary with manufacturer) • 5mm ball, 12cm shaft • 3mm ball, 12cm shaft
Electro surgery pens
Dispersive pads
Dispersive pad adapter (ES -3160C)
Coated Speculum
Smoke evacuator and filters
Speculum tubing
Internal Filter (replace annually)
1 -2% lidocaine with 1:100 000 epinephrine
Spinal needles 22 -25 gauge, 3.5 inches long
Syringes – 10cc

Needles 18 – 20 gauge
Wooden spatulas
Long needle holder
Long mayo scissors -straight
Suture- Vicryl no O on a taper cut needle
Long tissue forceps
Sterile surgical gloves (6.5 – 8.5 depending on provider)
Large Cotton swabs (Ob /Gyn or Proctology)
Sterile gauze- Raytec
Specimen containers with lid and labels
Monsel's paste
Gluteraldehyde 2 -4 %)
Formalin
Pathology forms

Appendix IX: Frequently asked questions for cervical cancer screening

What is Human papilloma virus?

The Human Papilloma Virus (HPV) is an extremely common virus, the virus easily spread by skin-to-skin contact during sexual activity with another infected person, HPV is the main cause of cervical cancer. Cervical Cancer is preventable through the **HPV Vaccine** to young girls before they are exposed to the HPV virus, and early screening of women of reproductive age to identify the cancer

What is cervical screening?

Cervical screening is a test to detect early abnormal changes in the cervix to prevent cervical cancer. Common screening tests include Pap smear and HPV test.

Which cervical screening test should I receive?

Women of age of 25years are required to undergo cervical cytology as the screening modality. For women aged between 30 and 64, HPV testing as the primary screening method for cervical cancer.

Is it possible to get screened by a female clinician instead of a male one?

Communicate that clients' privacy and confidentiality is of utmost importance and there is a possibility to get a female clinician to screen them. However, both male and female clinician are well trained to screen and are tasked to respect every client no matter your background.

How can I address my intention to go but never actually getting around to it?
The health worker will assist in making an appointment and offer to accompany you to the appointment

How can I manage my fear of pain?
Offer to explain what happens during an exam and encourage the woman to speak up if there is pain during the exam or procedure as there may be ways to make it less painful; encourage the woman to be relaxed during the procedure.

How can I address my worry about the outcomes?
Ask questions about what worries you
Ask how she's handled worrisome experiences in the past

At what Age should I get screened since I do not feel at risk/ older women may not think they still need screening?
Ask about her ideas of risk
Ask about who they know who has had cancer; create connections that cancer affects women of all ages

Where can I get information about cervical cancer screening?
Share information about cancer services, the need for screening, and how early screening is effective
For more information contact health worker in the health facility near you

How can I handle stigma around cancer?
Share information about survivor support groups
Share information about cancer survivorship and how early screening is effective at finding cancer early

What will happen if people in my village or my partner knows that I have cervical cancer?
Not being accepted by one's spouse if found to have cervical cancer can be quite difficult to deal with. We recommend that there is partner involvement during screening. However, cervical cancer diagnosis is not a death sentence and it can be treated if detected early.

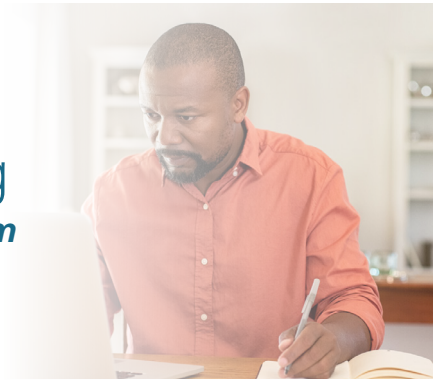
Governance	**Screening Tools**	**Protocol**	**Professional Training**
National breast TWG County breast TWG	CBE + history taking Mammogram Ultrasound MRI	Short protocol for every level Distribute to every level	National TWG to train County TWG as TOT County TWG to train all the county health personnel in every locality on CBE and History taking for breast
Policy	**Target Population**	**Diagnosis**	**Information and Education**
National Guidelines on screening Review Breast Cancer Action Plan	Average risk, start with 40-55, then expand to 25-39, 56-74 High risk-CBE from 25 years	Develop protocols and SOPs for mammogram reporting Develop protocol for histopathology reporting tool	Develop simple brochures for use in clinics- public and private, schools, churches Patient education in radios, TV
Resources	**Advocacy**	**Treatment**	**Quality Assurance**
SHIF Personnel Infrastructure	Involve stake holders in training and patient education NCCP, KESHO, SSK, KABS, Civil societies, Survivor groups, KOGs, KACP, KAR, NOC-K	Develop treatment protocols Develop patient navigation tools	Develop Matrix for Monitoring and evaluation Meet stakeholder for annual feedback

Appendix XI: Prostate health assessment tool

PROSTATE CANCER

Prostate Cancer Screening

Talking to Your Health Care Team Assessment Tool



This fact sheet is meant for all people with a prostate gland. It is of great value to know that all people who are born genetically male have a prostate and thus should be aware of prostate cancer.

Why Talking with Your Health Care Team May Help

Understanding more about your symptoms may help you take control. A visit to your health care provider is the right time to ask questions. Read the questions on both pages and answer them based on the last month. Share your completed assessment with your health care provider. Your answers on this assessment may help you measure your symptoms and how much they may bother you. There may be great value in talking about how results could impact you and your family.

Do you have any symptoms (problems when peeing)?

❑ I have some urinary symptoms (problems when peeing). See next page to identify and score your symptoms.
We recommend that you talk with a health care team about your symptoms.

Are you more likely to benefit from prostate cancer screening?

❑ I have a **family history** of prostate cancer and am **40-69 years old**. My (circle all that apply) father, brother, uncle, grandfather, son had prostate cancer. Age when family member's prostate cancer was found, if known: _____

❑ I am **African-American** and am **40-69 years old**.

❑ I am **45-69 years old**.

❑ I am over 70

If you checked ANY of the boxes above and you have NOT had a prostate cancer test within the past two years, the American Urological Association recommends you talk with a health care provider to see if prostate cancer testing is right for you.

Are you less likely to benefit from prostate cancer screening?

If you answered no to all of the questions in the boxes above, the American Urological Association does not recommend you get routine prostate cancer screening at this time. But you may still want to talk with your health care provider about prostate cancer screening or any other questions or symptoms you may have.

Would you like to talk to a health care provider?

❑ I have decided NOT to talk to a health care provider. *(You are done.)*

❑ I have decided to talk to a health care provider about prostate cancer screening or other prostate health issues.

If you have already been seen by a health care provider, what have you decided to do?

After talking with a health care provider about the risks and benefits of prostate cancer screening, I have decided:

❑ Not to be tested for prostate cancer.

❑ To be tested for prostate cancer.

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Appendix XII: Prostate health symptoms score

Prostate Cancer Screening

Talking to Your Health Care Team

Assessment Tool

American Urological Association (AUA) Symptom Score

Have you noticed any of the following when you have gone to the bathroom to pass urine over the past month? Circle the correct answer for you and write your score in the right hand column. **Talk with a health care provider if your total score on the first seven questions is 8 or greater or if you are bothered at all.**

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score
Incomplete emptying — It does not feel like I empty my bladder all the way.	0	1	2	3	4	5	
Frequency — I have to go again less than two hours after I finish urinating.	0	1	2	3	4	5	
Intermittency — I stop and start again several times when I urinate.	0	1	2	3	4	5	
Urgency — It is hard to wait when I have to urinate.	0	1	2	3	4	5	
Weak stream — I have a weak urine stream.	0	1	2	3	4	5	
Straining — I have to push or strain to begin urination.	0	1	2	3	4	5	
	None	**1 time**	**2 times**	**3 times**	**4 times**	**5 times or more**	**Your score**
Nocturia — I get up to urinate after I go to bed until the time I get up in the morning.	0	1	2	3	4	5	
						Total AUA Symptom Score	
							Total score: 0–7 mildly symptomatic; 8–19 moderately symptomatic; 20-35 severely symptomatic.

Quality of life due to urinary symptoms	**Delighted**	**Pleased**	**Mostly satisfied**	**Mixed: about equally satisfied and dissatisfied**	**Mostly dissatisfied**	**Unhappy**	**Terrible**
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

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Appendix XIII: psychosocial counselling of parents/children living with retinoblastoma

Children with eye cancer and their siblings can be quickly overwhelmed by intense emotions. They have less experience and fewer coping skills than adults, and need extra support to navigate traumatic experience.

The affected child, brothers and sisters experience similar emotions to parents. During the course of the cancer journey, they may feel anger, sadness, fear, guilt or jealousy, and great concern for one another and their parents.

The child with cancer may feel violated and betrayed by procedures and therapy. Enucleation and chemotherapy can amplify distress as the body is changed by loss of an eye or hair.

Siblings often experience very strong emotions. They may feel abandoned as all attention is focused on their brother or sister who has cancer.

If children do not have safe, effective ways of coping, strong emotions bubble over into difficult behaviours. They can also be suppressed, causing depression, even in very young children.

Good communication and compassionate discipline are essential in supporting children under stress. Regular conversation and play help identify difficult feelings and develop coping skills. Discipline sets boundaries and helps children grow beyond their experience of cancer to be happy, responsible people.

Children Learn from You

You are your children's teacher. How you respond to the cancer impacts how they cope. Consistent love, honesty and fairness are essential.

Sibling Responses to Childhood Cancer

Brothers and sisters are often forgotten victims, unintended casualties of the war against the unseen monster threatening their family._Difficult behaviours sometimes occur as a result of the enormous stress siblings feel, but there is much you can do to help them.

Communicate With Your Children

Talking with and listening to your children – both your child who has cancer and unaffected siblings – Is vital during treatment and beyond.

Reduce Stress

Children need compassion and understanding, and someone to teach them healthy ways to cope with their very strong emotions.

Tantrums in Children Affected by Cancer

Tantrums are normal behaviour for young children under stress. They should be expected and understood, but try to avoid them by diffusing stress early.

Discipline for Children Affected by Cancer

Children thrive in an environment with structure and routine. You can do much to maintain constructive discipline, even through the crisis of cancer.

Appendix XIV: Summary of International Lung Cancer Screening Guidelines

Organization	Recommendation	Year
American Association of Thoracic Surgery	Recommends annual low-dose CT scan screening for high-risk individuals (ages 55 to 79 years with ≥30 pack-year history of smoking and current smoker or quit within past 15 years; ages 50 to 79 years with ≥20 pack-year history and cumulative risk >5% over next 5 years; or lung cancer survivors with no incidence of disease for ≥4 years).	2012
American Cancer Society	Recommends annual low-dose CT scan screening for high-risk individuals (ages 50 to 80 years with ≥20 pack-year history of smoking or current smoker).	2023
American College of Chest Physicians	Recommends annual low-dose CT scan screening for high-risk individuals (ages 55 to 77 years with ≥30 pack-year history of smoking and current smoker or quit within past 15 years).	2018
American Society of Clinical Oncology	Recommends annual low-dose CT scan screening for high-risk individuals (ages 55 to 74 years with ≥30 pack-year history of smoking and current smoker or quit within past 15 years).	2019
Canadian Task Force on the Periodic Health Examination	Recommends screening asymptomatic adults aged 55 to 74 years with at least a 30-pack-year smoking history who smoked or quit smoking <15 years ago with low-dose CT every year for 3 consecutive years.	2016

National Comprehensive Cancer Network	Recommends annual low-dose CT scan screening for high-risk individuals (age 50 years or greater with ≥20 pack-year history of smoking). Screening is not recommended for individuals with functional status or comorbidity that would prohibit curative-intent therapy.	2022
US Preventive Services Task Force	Recommends annual low-dose CT scan screening for high-risk individuals (ages 50 to 80 years with a 20-pack-year history of smoking and current smoker or quit within the past 15 years). Discontinue when the person has not smoked for 15 years or if limited life expectancy.	2021
Centers for Medicare and Medicaid Services	Recommends annual low-dose CT scan screening after completion of a shared decision-making visit for high-risk individuals (ages 50 to 77 years with ≥20 pack-year history of smoking and current smoker or quit within the past 15 years).	2022
American Academy of Family Physicians	Supports the United States Preventive Services Task Force recommendation for annual screening for lung cancer with low-dose CT in adults (ages 50 to 80 years who have a 20-pack-year smoking history and currently smoke or have quit within the past 15 years).	2021

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