NATIONAL GUIDELINES FOR PREVENTION AND MANAGEMENT OF CERVICAL, BREAST AND PROSTATE CANCERS

January 2012
FOREWORD

Cervical, breast and prostate cancers are a major public health concern in Kenya. They are however easily prevented and controlled through behaviour change, vaccination, screening, early detection and treatment of pre-cancerous lesions and/or at early stage disease thereby leading to better management and outcomes for these diseases.

The Kenyan health sector through the National Reproductive Health Policy (2007) and the National Reproductive Health Strategy 2009-2015 provide the policy framework, with cancers of the reproductive organs being priority components. Despite the favourable policy environment, the number of reported advanced cases of cancer is increasing. This high burden of advanced cancers of the reproductive organs and subsequent mortality is due mainly to inadequate access to prevention (including screening services), and delay in seeking health care. These are further compounded by limited access to health care and inadequate capacity of health workers to manage advanced disease.

In an effort to reduce the incidence, morbidity and mortality associated with these cancers, the Kenya government is placing greater emphasis on the need to strengthen the capacity of health facilities to provide screening, detection, diagnosis and appropriate management of pre-cancer and cancers. To facilitate this, it is critical therefore, to streamline and standardize screening, diagnosis and treatment practices at all levels of health care.

These national guidelines for prevention and management of cervical, breast and prostate cancers are intended to contribute to making quality services available in the country by guiding health care providers at all levels of health care to provide prevention and management services of the three most common cancers of the reproductive organs.

The aim of these guidelines is to set standards for comprehensive Reproductive Tract (RT) cancer prevention and management services while promoting rational use of existing resources. These guidelines provide all health care workers with a practical reference source for service delivery. These guidelines will be available in all health facilities. We therefore urge all health care providers at all levels to embrace and consistently use these guidelines so as to achieve universal access to cancer prevention and control and reduce the incidence, morbidity and mortality associated with these cancers.

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January 2012
Extensive consultations among various stakeholders marked the development process of these Guidelines for Prevention and Management of Cervical, Breast and Prostate Cancers. The process was organized through stakeholder workshops with technical guidance from the Reproductive Organs Cancers Technical Working Group, chaired by the Division of Reproductive Health, and provided with structured inputs from experts. The stakeholders involved in several workshops were drawn from:

- Division of Reproductive Health - Ministry of Public Health and Sanitation
- Division of Obstetrics and Gynaecology - Ministry of Medical Services
- Division of Non Communicable Diseases – Ministry of Medical Services
- Jhpiego Kenya – ACCESS Uzima, APHIALPLUS Kamili and Tupange programs
- Jhpiego – Baltimore USA
- USAID/Capacity Kenya Project
- Family Health International
- Programme for Appropriate Technology in Health (PATH)
- Department of Obstetrics and Gynaecology, University of Nairobi
- Department of Surgery, University of Nairobi
- Kenyatta National Hospital (Department of Obstetrics and Gynaecology)
- National AIDS and Sexually Transmitted Infections Control Program (NASCOP)
- Kenya Breast Health Program
- Kenya Medical Research Institute (KEMRI)
- Kenya Obstetrical and Gynaecological Society (KOGS)
- World Health Organization (WHO) - Kenya office

The former and current Head of the Department of Family Health, Dr. Josephine Kibaru and Dr. Annah Wamae, respectively, provided overall leadership during development of these guidelines. Coordination was provided by Dr. Janet Wasiche, Dr. Bashir Issak and Dr. Shiphrah Kuria in their roles as Head of the Division of Reproductive Health in the Ministry of Public Health and Sanitation at various times, together with Dr. Simon Mueke, the Head of Obstetrics and Gynaecology in the Ministry of Medical Services. Dr. Lucy Musyoka and Dr. Aisha Mohamed, as Program Managers in the Division of Reproductive Health were instrumental in coordinating the relevant activities of the technical working group that led the process of finalising these guidelines.

During the process of finalizing these guidelines, there were significant contributions and technical input from various experts during meetings and through electronic discussion forums that demonstrated their commitments to the prevention, management and control of Reproductive organ cancers. Their
collective opinions and wisdom, based on an extensive evidence-based literature review, contributed greatly to the quality and updated contents of the guidelines.

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<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>AGUS</td>
<td>Atypical glandular cells of undetermined significance</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>ASC-H</td>
<td>Atypical squamous cells-high grade lesion cannot be ruled out</td>
</tr>
<tr>
<td>ASCUS</td>
<td>Atypical squamous cells of undetermined significance</td>
</tr>
<tr>
<td>BRCA</td>
<td>Breast cancer gene</td>
</tr>
<tr>
<td>BSE</td>
<td>Breast self examination</td>
</tr>
<tr>
<td>CAF</td>
<td>Cyclophosphomide, Adriamycin (Doxorubicin), Fluorouracil</td>
</tr>
<tr>
<td>CBE</td>
<td>Clinical breast examination</td>
</tr>
<tr>
<td>CCC</td>
<td>Comprehensive Care Centre</td>
</tr>
<tr>
<td>CEF</td>
<td>Cyclophosphomide, Epirubicin, Fluorouracil</td>
</tr>
<tr>
<td>CHEW</td>
<td>Community Health Extension Worker</td>
</tr>
<tr>
<td>CHW</td>
<td>Community Health Worker</td>
</tr>
<tr>
<td>CIN</td>
<td>Cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>CIS</td>
<td>Carcinoma in situ</td>
</tr>
<tr>
<td>CLO</td>
<td>Complete local excision</td>
</tr>
<tr>
<td>CMF</td>
<td>Cyclophosphomide, Methotrexate, Fluorouracil</td>
</tr>
<tr>
<td>CO</td>
<td>Clinical Officer</td>
</tr>
<tr>
<td>CT</td>
<td>Computerised tomography</td>
</tr>
<tr>
<td>DRE</td>
<td>Digital rectal examination</td>
</tr>
<tr>
<td>DRH</td>
<td>Division of Reproductive Health</td>
</tr>
<tr>
<td>ECC</td>
<td>Endocervical curettage</td>
</tr>
<tr>
<td>ER+</td>
<td>Oestrogen receptor positive</td>
</tr>
<tr>
<td>EUA</td>
<td>Examination under anaesthesia</td>
</tr>
<tr>
<td>FNA</td>
<td>Fine needle aspiration</td>
</tr>
<tr>
<td>HMIS</td>
<td>Health Management Information System</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>HPV</td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td>HSIL</td>
<td>High-grade squamous intraepithelial lesion</td>
</tr>
<tr>
<td>IEC</td>
<td>Information, education and communication</td>
</tr>
<tr>
<td>KEPH</td>
<td>Kenya Essential Package for Health</td>
</tr>
<tr>
<td>LEEP</td>
<td>Loop electrosurgical excision procedure</td>
</tr>
<tr>
<td>LLETZ</td>
<td>Large loop excision of the transformation zone</td>
</tr>
<tr>
<td>LSIL</td>
<td>Low-grade squamous intraepithelial lesions</td>
</tr>
<tr>
<td>LHRH</td>
<td>Luteinizing hormone releasing hormone</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MRI</td>
<td>Magnetic resonance imaging</td>
</tr>
<tr>
<td>OPD</td>
<td>Outpatient Department</td>
</tr>
<tr>
<td>PR+</td>
<td>Progesterone receptor positive</td>
</tr>
<tr>
<td>PSA</td>
<td>Prostate specific antigen</td>
</tr>
<tr>
<td>RT</td>
<td>Reproductive Tract</td>
</tr>
<tr>
<td>SDP</td>
<td>Service delivery point</td>
</tr>
<tr>
<td>TNM</td>
<td>Tumour-node-metastasis</td>
</tr>
<tr>
<td>TRUS</td>
<td>Trans-rectal ultrasonography</td>
</tr>
<tr>
<td>VIA</td>
<td>Visual inspection with acetic acid</td>
</tr>
<tr>
<td>VILI</td>
<td>Visual inspection with Lugol’s iodine</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</tbody>
</table>
PART ONE

INTRODUCTION AND OVERVIEW OF

CERVICAL, BREAST AND PROSTATE CANCERS
CHAPTER 1: INTRODUCTION

Cancer is characterized by uncontrolled growth and proliferation of abnormal cells resulting from internal and external risk factors working together and/or in sequence to trigger the process. People may be exposed to risk factors or cancer-causing agents in their environment and/or from their lifestyles. These cancer-causing agents play a larger role in the aetiology of cancer than inherited genetic factors. Cancer risk factors are highest in groups with the least education and lowest social status; these same groups also have poorer survival rates than higher socio-economic status groups.

Cancer is a leading cause of death worldwide and accounted for 7.6 million deaths (around 13% of all deaths) in 2008 (Globocan 2008, IARC 2011). More than 70% of all cancer deaths occurred in low- and middle-income countries. In these countries resources available for prevention, diagnosis and treatment of cancer are limited or nonexistent. Deaths from cancer worldwide are projected to continue to rise to over 11 million in 2030. The good news is that cancer is one of the most preventable non-communicable chronic diseases. More than 30% of cancer deaths can be prevented and with adequate investments in prevention and control strategies, the morbidity and mortality rates attributable to cancers can be significantly reduced (WHO fact sheet no 297, Feb 2011).

The table below shows the leading 6 causes of cancer in men and women globally as compared to the Africa region. The data has not changed much since 2004.

<table>
<thead>
<tr>
<th></th>
<th>Global</th>
<th>Africa</th>
<th></th>
<th>Global</th>
<th>Africa</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>1</td>
<td>5</td>
<td>Breast</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Stomach</td>
<td>2</td>
<td>6</td>
<td>Lung</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Liver</td>
<td>3</td>
<td>2</td>
<td>Stomach</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Colorectal</td>
<td>4</td>
<td>8</td>
<td>Colorectal</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Oesophagus</td>
<td>5</td>
<td>3</td>
<td>Cervix</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Prostate</td>
<td>6</td>
<td>1</td>
<td>Liver</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>

(Source: Globocan 2008; IARC 2010)

Globally, the leading causes of cancer deaths among males are cancers of the lung, colon and prostate, while among women these are cancers of the breast, colon and lung. In Africa, although data is limited, the leading causes of cancer deaths appear to be liver cancer in males, and cervical cancer in females respectively. Viral infection plays a critical role in the aetiology of both liver and cervical cancer and is especially apparent with HPV in cervical cancer.

In Kenya, there is scanty literature on the incidence of cancers in general. However, it has been noted that cancers of the head and neck are the most common. Oesophagus and prostate cancers lead in frequency among male adults. It has also been noted that cancers of the breast and cervix represent a large proportion (43.3%) of all reported cancers. Incidence and prevalence of breast cancer seem to be increasing.
According to the Nairobi cancer registry, the most common reproductive organ cancers in women are of the cervix and breast, while in men prostate cancer is the most common, followed by breast cancer. Breast cancer contributed 23% of all female cancers, cervical cancer 20%, and cancer of the ovary contributed 3%. Cancers of the uterus, vagina, vulva, penis and testis are rare. Between 2004 and 2006, the prevalence of prostate cancer by histology of prostatectomy and needle biopsy specimens has been reported to be 24% in two hospitals in Nairobi.

The Government of Kenya, through the Ministry of Public Health and Sanitation and the Ministry of Medical Services, recognizes the importance of addressing the cancers of the reproductive organs, and emphasizes the need to strengthen screening and early detection, diagnosis and appropriate management of these cancers at all levels of health care. (Towards this, the Ministry of Finance has made a budgetary allocation through the Ministry of Public Health and Sanitation for equipment for cervical and breast cancer screening). Various policies and strategies exist to address prevention, treatment and control of cancers of the reproductive organs to reduce the burden of disease from these cancers thereby improving the wellbeing of Kenyans towards achievement of MDGs and Vision 2030. These documents include the National Cancer Control Strategy 2010-2015, the National Reproductive Health Policy, 2007, and the National Reproductive Health Strategy 2009-2015 among others.

As part of the control programme for Reproductive tract cancers, a clearly laid out community mobilization and implementation plan is important. To reach as many people as possible, the general population- (both men and women, particularly the young) must be targeted. Messages to reduce stigma against those who have been diagnosed with cancer are important as they influence utilisation of screening services. For a comprehensive and effective control programme, screening must always be linked to treatment and follow up.

The National Guidelines for Prevention and Management of Cervical, Breast and Prostate Cancers are designed for use by all cadres of health care workers (doctors, nurses and clinical officers –among others) across the KEPH levels of the health care system. Strengthening of the referral systems is important to ensure optimal services to the clients.

These guidelines are divided into three parts. The first part provides detailed guidelines on the screening, diagnosis and management of the three Reproductive organ cancers of public health significance; that is cancers of the cervix, breast and prostate.

The second part details cross-cutting programmatic considerations for the three types of cancer. These include health education; community mobilization; effective networking and collaboration between providers and different levels of the health care system; quality improvement; monitoring and evaluation; advocacy and resource mobilization.
The third and final part is composed of guidelines on palliative care as well as appendices.

For the RT cancer program to have impact, all key components have to be implemented in a coordinated manner (that is: community mobilisation, screening, diagnosis, treatment and follow up). There is need to focus national actions in controlling these three RT cancers (cervix, breast and prostate) as this will significantly reduce the morbidity and mortality associated with them; thereby saving national resources and contributing to attainment of Vision 2030.
CHAPTER 2: CERVICAL CANCER

OVERVIEW

Globally, cervical cancer kills one woman every 2 minutes. Cancer of the cervix is the fifth most common cancer among women worldwide. The incidence of cervical cancer is highest in Central America followed by East and Southern Africa. In 2008, it was estimated that 529,409 new cases occurred globally. During the same period 274,883 of the women died. Of the total new cases each year, about 86% occur in developing countries, where 80-90% of deaths occur. It is therefore the leading cause of cancer deaths in developing countries as well as the top cancer affecting women in Africa. With the peak age being 35-45 years of age, in these regions cervical cancer claims the lives of women in the prime of their life when they may be raising children, caring for the family, and contributing to the social and economic development of their community.11, 12

Data from hospital-based registries in Kenya indicate that cancer of the cervix accounted for 70-80% of all cancers of the genital tract and 8-20% of all cancer cases for the 10-year period of 1981 to 1990. It has been reported that there are 10 to 15 new cases of cervical cancer in Nairobi each week.5 According to the Nairobi Cancer Registry 2003-2006, cervical cancer is the second most common cancer after breast cancer at 19.3% and 20% of all reported cancers in Kenya, respectively [KEMRI, 2010]. However cervical cancer is the most common cause of cancer related deaths in Kenya. The incidence of cervical cancer in Kenya is estimated to be 2,454 women per year with annual number of deaths estimated at 1,676 women. In the absence of accelerated interventions for screening, detection and early treatment, the incidence of cervical cancer is projected to rise to 4,261 resulting in 2955 deaths in 2025.

Opportunities to prevent, cure and relieve suffering from cervical cancer exist through primary prevention of HPV infection, secondary prevention by screening, treatment of precancerous disease and early stages of cancer as well as tertiary care for women with invasive cancer.

Cancer of the cervix is easily detectable and curable in its early stages. Unfortunately, only about 5% of women in developing countries undergo screening for cervical cancer as compared to over 40% in developed countries, and 70% or higher in countries that have shown marked reduction in incidence and prevalence of cervical cancer.3,13 In Kenya, it is estimated that only 3.2% of women aged 18-69 years have been screened in any 3 year period.11

It is therefore not surprising that in Africa, where screening rates are low or nonexistent, the majority of women present with advanced disease. This is compounded by unavailability of treatment facilities and adequate personnel to manage invasive disease. The cost of treatment of invasive cancer is enormous and many developing countries are therefore unable to provide the systems necessary for this service, and where these are available they are few and far in between hence not accessible to the majority of
those who need them. Investment in preventive services for cervical cancer therefore translates to cost savings for the individuals, families, communities and the country at large.

CAUSE OF CERVICAL CANCER

Human papillomavirus (HPV) is responsible for approximately 5% of all cancers globally, making it the single most common cause of cancer that is attributable to a virus. HPV is one of the commonest sexually transmitted infections. Infection with one or more of the 15 high-risk oncogenic types usually results in invasive cervical cancer after 10-20 years. HPV is the primary cause of 99.7% of all cervical cancers. Globally, about 70% of all cases of cervical cancer are caused by HPV types 16 and 18. With vaccines against these two types of HPV, being now available, there exists great potential to reduce the incidence of cervical and other anogenital cancers.\textsuperscript{16, 17}

The lifetime risk for HPV infection among sexually active women is 50-70%. By the age of 50 years, at least 80% of women will have acquired genital HPV infection. Fortunately, most HPV infections clear due to the natural cell-mediated immunity hence the majority of women who get infected with high risk oncogenic HPV types do not develop cervical cancer. Even in those with persistent high risk HPV infection, not all of them progress to cervical cancer. This implies that the presence of additional cofactors is necessary for the HPV infection to progress to invasive cervical cancer.\textsuperscript{18}

HPV Types

There are over 100 types of HPV. More than 40 of these infect the anogenital area of women and men. Although not all of them have been reported to induce cancer of the cervix,\textsuperscript{22, 23, 24} some types have strongly been associated with occurrence of cervical cancer and are referred to as high-risk (oncogenic) types. Approximately 15 of these types (types 16, 18, 31, 33, 35, 39, 41, 51, 52, 56, 58, 59, 66, 67 and 68) have been identified in cervical cancer and its precursor lesions. Types 16 and 18 are responsible for approximately 70% of cases of invasive cervical cancer and the precursor high-grade squamous intraepithelial lesions.\textsuperscript{25, 26}

Globally, data show that at any given point in time, 10.4% of women with normal cervical cytology are infected with HPV. HPV is more prevalent in the less developed world (13.4%), than in more developed regions (8.4%). African women have the higher prevalence rates (22.1%) than women living in South-Eastern Asia (6.2%). For some unclear reasons, women living in East Africa have the highest HPV prevalence rates (31.6%) in the world.\textsuperscript{27}

It is estimated that 38.8% of women in Kenya have cervical HPV infection at any given time. Approximately 61-69% of invasive cervical cancers in Kenya are attributed to HPV types 16 and 18. Infection with multiple high risk types is commoner in women who are co-infected with HIV compared to HIV-negative women. In a study at Kenyatta National Hospital (KNH), HPV 16 and 18 were the most common types found in women with invasive cervical cancer. The prevalence among HIV-negative
women was 69.1%- with 57.7% being type 16 and 11.4% type 18. Concurrently 68.7% of HIV-positive women had HPV types 16 and 18 of which 46.1% were type 16 and 22.6% were type 18.\textsuperscript{28}

Pathophysiology

Over 80% of HPV infections are transient, asymptomatic and resolve spontaneously in 2-3 years. Of the 20% of infections that persist, the HPV viral gene is incorporated into the DNA of cervical cells stimulating abnormal cell division. This may cause mild cytological abnormalities and/or mild cervical intraepithelial neoplasia (CIN 1), which usually clears spontaneously in about 60% of women in 2-3 years. In about 40% of women, the abnormalities progress to high grade squamous intraepithelial lesions (HSIL) or CIN 2/3 and carcinoma-in-situ (CIS) that subsequently progress to invasive cancer. About 40% and 30% of CIN 2 and CIN 3, respectively spontaneously regress to normal.

Figure 1:

![Natural History of HPV Infection](image)

High grade SIL is much less common than LGSIL. Normally it progresses from LGSIL but it has been known to progress directly from HPV infection. High grade SIL should be treated because it has a higher tendency to progress to invasive cancer. Conversely, low grade SIL should be monitored as most lesions regress spontaneously or do not progress.

Factors that increase likelihood of HPV progression to invasive cervical cancer

HPV infection is necessary for development of cervical cancer. Factors that promote acquisition of HPV include: early initiation of sexual intercourse; having multiple sexual partners; having a sexual partner with multiple sexual partners, co-infection with other sexually transmitted infections such as Chlamydia trachomatis, and herpes simplex virus type 2 and high parity; However, other cofactors are necessary
for of progression HPV infection to cancer. These include immunosuppression like in HIV/ AIDS infection, and tobacco smoking.

PREVENTION STRATEGIES

Primary Prevention

The main aim of primary prevention is to prevent infection with HPV and with cofactors that increase the risk of HPV acquisition and expression. This includes education and awareness to reduce high risk sexual behavior, and discouragement of tobacco use/ cigarette smoking – a known risk factor for cervical cancer.

The following strategies are recommended for primary prevention in Kenya:
- Promote Abstinence or delayed sexual debut for adolescents (A)
- Promote faithfulness to one partner for those in relationships, (B)
- Promote Condom use - C
- Promote HPV Vaccination
- Promote male circumcision – (This has been associated with a reduced risk of penile HPV infection, and in the case of men with a history of multiple sexual partners, a reduced risk of cervical cancer in their current sexual partner. Note also that male circumcision is associated with 60% reduction in transmissibility of HIV hence conferring a double benefit to the female partner)

- Reduction of high-risk sexual behaviour:
  Abstinence, delay in age of sexual debut, limiting the number of sexual partners, male circumcision, and correct and consistent use of condoms are all effective measures for reducing the risk of cervical cancer.
  **Condom use:** Even though condoms only offer partial protection against HPV transmission due to the fact that the virus can be transmitted through body surfaces not covered by the condom (such as the perianal area and anus in men and women; the vulva and perineum in women, and the scrotum in men), consistent and correct condom use has been shown to provide important benefits that include:
  - Allowing faster HPV clearance in both men and women;
  - Increased regression of cervical lesions; reduced risk of genital warts; Reduced risk of cervical precancer and cancer;
  - Protection against other STIs (including Chlamydia and Herpes Simplex Virus-2), which are possible cofactors for cervical cancer;
  - Protection against HIV infection, a known facilitator of both high-risk HPV infection and progression to high-grade lesions and cancer; and
  - Protection against unplanned pregnancy.

Condoms also reduce the risk of developing HPV-related diseases by decreasing the amount of HPV transmitted or by reducing the likelihood of re-exposure.
HPV Vaccine:
Human papilloma virus (HPV) is the primary cause of 99.7% of all cervical cancers. Globally, about 70% of all cases of cervical cancer are caused by HPV types 16 and 18. Infection with one or more of the high-risk oncogenic types of HPV usually leads to invasive cervical cancer after 10-20 years. HPV vaccine has shown more than 90% efficacy to prevent precancerous lesions in females naïve to vaccine-specific HPV types who complete all three doses. At present, two types of HPV vaccines are licensed for use in Kenya: a quadrivalent type - ‘Gardasil’ (manufactured by Merck) that protects against the high risk HPV types 16 and 18 as well as low risk types 6 and 11 that are responsible for genital warts and a bivalent type, ‘Cervarix’ (manufactured by GlaxoSmithKline) which protects against HPV types 16 and 18. HPV vaccine is effective for 7-8 years. It is not known whether booster shots will be needed.

The risks of HPV vaccine are minimal and similar to other vaccines. The most common reported side effects are: redness and soreness where the shot is given, fever, and headaches.

Recommendations for HIV vaccination in Kenya are as follows:
- The target for vaccination will be Pre and young adolescent girls before first coitus. The recommended age group is 9-13 years. Antibody response is high in this age group and vaccine efficacy is highest in those who are naïve to vaccine-specific oncogenic HPV types. Hence the greatest impact of HPV vaccination on cervical cancer is through broad participation of young adolescent girls rather than older girls or women. In line with the country vision of universal free primary education, the best approach would be a school based program targeting upper primary classes 4 to 8.
- Either bivalent or quadrivalent type of vaccine will be used
- Out of school population will be targeted through targeted in reach and outreach approaches
- Catch up vaccination will be provided for non-sexually active older girls; however, modeling studies suggest diminishing protection when age of vaccination is increased
- Booster doses are not recommended until additional data is available

The focus of the programme is females. This is because there are presently no studies indicating that HPV vaccination of males will result in less sexual transmission of vaccine-specific HPV infection from males to females thereby reducing cervical cancer. Note that HPV vaccines are not intended to treat women with past or current HPV infection.

**Administration of Vaccine:** *(source WHO 2007)*

<table>
<thead>
<tr>
<th></th>
<th>Quadrivalent type - Gardasil</th>
<th>Bivalent type - Cervarix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Merck</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>HPV types covered</td>
<td>6, 11, 16, 18</td>
<td>16, 18</td>
</tr>
<tr>
<td>Dosage Schedule (3 doses)</td>
<td>0, 2, &amp; 6 months</td>
<td>0, 1 &amp; 6 months</td>
</tr>
<tr>
<td>Recommended age of 1st dose</td>
<td>9 – 15yrs</td>
<td>10 – 14 yrs</td>
</tr>
</tbody>
</table>
Both vaccines are given in a series of three 0.5 ml intramuscular injections within six months, and require storage and transport in a cold chain system. If the strategy is for use in the school health system, the timing may be adjusted to fit in with the school term dates. For instance, for Cervarix administration would be: end of Term 1 for 1st dose; beginning of Term 2 for 2nd dose, beginning of 3rd term for 3rd dose.

**HPV Vaccine Introduction**

HPV vaccination programmes may be cost-effective in countries where high-quality screening is not widespread, vaccination coverage is high (> 70%), and the cost of a three-dose course is low (< US$10-25). If used, HPV vaccination should be a part of a coordinated strategy, including community education and mobilization with appropriately targeted messages to different audiences, and should not undermine or divert funding from effective screening programmes. Even if all these measures are met, the impact of a fully implemented HPV vaccination programme would not be felt for decades, and high-quality screening would need to continue.

**Logistics**

For Kenya, the HPV vaccination will be coordinated by the Division of Vaccines and Immunization (DVI), which is responsible for all vaccination activities in the country. DVI will be responsible for all HPV vaccine procurement, cold chain management, training, monitoring and evaluation. It is recommended that HPV vaccines are stored between 20 to 80 Centigrade. HPV vaccine management protocols should be developed and followed to minimize vaccine wastage. Since this vaccine will be administered as part of the school health program, there is need for collaboration between the Department of Family Health (DRH, DCAH and DVI) and the Ministry of Education to ensure success of this program.

**Monitoring and Evaluation of HPV vaccination:**

The monitoring and evaluation will be conducted routinely through the existing DVI Vaccination monitoring system; however, this will be linked to the overall monitoring of the National Cervical Cancer Prevention and Control Program and the cancer registry. The possible indicators for HPV vaccination will include, but are not limited to:

- **HPV vaccination coverage** *(Number of girls fully or partially vaccinated, age distribution of vaccinated girls)*
- **HPV incidence in vaccinated population**
- **Rates of cervical precancerous lesions**
Why Secondary Prevention is needed even with HPV Vaccines

HPV vaccine has been listed in the priority vaccines to be introduced in Kenya. However even with introduction of HPV vaccine, secondary prevention through screening for pre-cancer will still be imperative. This is because:

- There will still be a large cohort of women who will not benefit from the HPV vaccine
- Reaching target population of young girls and women is challenging due to low levels of women empowerment in many of the target countries
- Kenya like many developing countries still experiences early age of sexual debut and hence earlier exposure to HPV infection
- There is the potential for inadequate vaccination due to poor compliance on return visits for 3 doses
- Even if vaccination was successfully carried out, the impact on prevalence will not be felt for a long time and screening will therefore still be necessary

SECONDARY PREVENTION

Secondary prevention aims to prevent invasive cervical cancer by detecting and treating precancerous lesions of the cervix before they progress to cancer. Cervical cancer has a long precancerous period, usually taking more than 10 years to progress from precancerous lesions to invasive cancer. As a result, it is rare for cervical cancer to develop in a woman less than 30 years of age (WHO 2006). This long precancerous stage provides an excellent opportunity for effective intervention measures

Continuum of Care for HPV Infection to Cervical Cancer

![Continuum of Care Diagram]
Screening for cervical cancer aims to detect precancerous lesions that are then treated to prevent progression to invasive cancer. This can be carried out in several ways including, cervical cytology (Pap smear test), and visual inspection of the cervix with acetic acid [VIA] or HPV testing. [UNFPA Feb 2011]: Other screening methods such as visual inspection with Lugol’s iodine (VILI) can also be used in research and training settings.

A good screening test is one that is acceptable to women and providers, accurate, reproducible, safe, practical, affordable and available. To screen effectively in the Kenyan rural setting, we need an approach that will meet the stated characteristics and ensure at least 70% coverage of the eligible population.

**Screening Methods**

The following screening methods are recommended for the Kenya program:

- Visual Inspection with Acetic Acid (VIA)
- Visual Inspection with Lugol’s iodine
- Cytology using Conventional Pap smear
- HPV testing

The comparison between the different screening Methods is shown below:

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Conventional Cytology</th>
<th>HPV DNA tests</th>
<th>Visual inspection with acetic acid (VIA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>47 – 62%</td>
<td>66 – 100%</td>
<td>67 -79%</td>
</tr>
<tr>
<td>Specificity</td>
<td>60 –95%</td>
<td>62 – 96%</td>
<td>49 – 86%</td>
</tr>
<tr>
<td>No. Of visits required for screening and treatment</td>
<td>2 or more</td>
<td>2 or more</td>
<td>1 or 2</td>
</tr>
<tr>
<td>Health Systems requirements</td>
<td>Requires highly trained cytotechnicians and cytopathologists; microscope, stains, slides, transport systems, system for informing and tracking positive cases</td>
<td>Required trained lab workers, electricity, kits, reader, transport system</td>
<td>Requires training and regular supervision, no equipment, few supplies</td>
</tr>
<tr>
<td>Comments</td>
<td>Assessed over the last 50 yrs in a wide range of settings in both developed and developing countries Test must be repeated every few years due to low sensitivity</td>
<td>Assessed over the last decade in many developed countries and some developing countries Due to high sensitivity, screening may be done with less frequency</td>
<td>Assessed over the last decade in many developing countries with good results</td>
</tr>
</tbody>
</table>

(Source: Comprehensive Cervical Cancer Prevention and Control: Programme Guidance for Countries February 2011)
**State of Science:**

In developing countries, cytology based screening has been able to make little impact on cervical cancer. Cytology screening has a lower sensitivity, but cytology-based screening programmes for cervical cancer compensate for this through frequent, regular screening. These programmes have been successful in developed countries as they are able to ensure compliance, coverage and quality. However, developing countries suffer from major obstacles:

- Lack of infrastructure (laboratories, cytotechnicians), lack of quality control for laboratories and cytology reporting, and poor treatment facilities.
- Poor compliance and lack of follow up. As a result, women with abnormal tests do not receive treatment and costs are incurred without benefits, thereby decreasing cost-effectiveness.

These problems may be addressed in certain settings by visual inspection with acetic acid (VIA) followed by cryotherapy of positive cases at the same sitting (a single visit strategy).

**Visual Inspection with Acetic Acid:**

Although not new, this approach has been validated and revitalized by a number of studies between 1996 and 2004, which establish that VIA is an alternative option to screening cervical precancer. These studies show the relatively high sensitivity of VIA but a specificity that is slightly lower than cytology.

VIA uses instrument sets and equipment usually available at healthcare centers. It does not require a laboratory and provides an immediate result, allowing the use of "screen and treat" methodology. Nurses and midwives can be trained, and have demonstrated that they can perform as well as any similarly trained physicians. The ability to utilize mid-level providers is important as it extends accessibility to cervical cancer screening in regions where physician time and resources are scarce. Healthcare providers are encouraged to initiate counselling and screening for eligible women at all points of contact.

The procedure involves applying 3-5% freshly prepared acetic acid to the cervix and observing after one minute. Acetic acid dehydrates cells and reversibly coagulates the nuclear proteins. Thus, areas of increased nuclear activity and DNA content exhibit the most dramatic colour change to white. Acetowhite staining is not specific for CIN and may also occur to some extent in areas of squamous metaplasia and inflammation. The VIA results are generally categorized into three subsets: suspicious for cancer, VIA negative and VIA positive. A VIA test positive or positive cervix is defined by the International Agency for Research on Cancer (IARC) as a raised, thickened, well defined, white plaque or acetowhite epithelium at or close to the squamocolumnar junction (SCJ).

The following recommendations should be considered when using VIA as a screening method:

- Women between 25-49 years of age will be the primary target for screening
- Women under 25 years of age should be screened only if they are at high risk for disease. (Women at high risk for cervical abnormalities are those who have had early sexual exposure, multiple partners, previous abnormal screening results or CIN, or are HIV positive).
- VIA is not appropriate for women over 50 years. These women should be screened at five-year intervals using cytology or HPV testing.
- Annual screening is not recommended for the HIV negative population.
Timing of VIA:
- For the general population, it is recommended that HIV negative women be screened for cervical cancer every 5 years. The screening cycle for HIV positive women is outlined below.
- Screening can be done at any point in the menstrual cycle including during menses (it may be difficult to see, if menstrual blood flow is heavy—in such cases, you may need to reexamine), during pregnancy, and at the post partum or post abortion care check up. It can also be performed in a woman suspected to have an STI or HIV/ AIDS
- Recent sexual intercourse does not affect VIA.

Since VIA is known to have a lower specificity than other methods, there is a potential for over treatment if inspection is not carefully and consistently supervised. The ability of those performing VIA to identify a normal cervix correctly (specificity) seems to improve with practice. Effective training and quality assurance programs are therefore critical to ensuring the effectiveness of VIA. The detailed procedure for VIA can be found in Annex 1.

Visual Inspection with Lugol’s Iodine:
Visual inspection with Lugol’s iodine (VILI) - also known as Schiller’s test, uses Lugol’s iodine instead of acetic acid. VILI can be done with the naked eye or direct visual inspection, [DVI]), or with low magnification (also called gynoscopy, aided VI, or VIAM). VILI is a simple, easy-to-learn approach that is minimally reliant upon infrastructure. It has low start-up and sustaining costs; many types of health care providers can perform the procedure; VILI has a sensitivity and specificity of about 92% and 85%, respectively; Test results are available immediately and this results in decreased loss to follow-up.

VILI involves looking at the cervix after swabbing it with Lugol’s iodine. Squamous epithelium contains glycogen, whereas precancerous lesions and invasive cancer contain little or no glycogen. Iodine is glycophilic and is taken up by the squamous epithelium, staining it mahogany brown or black. Columnar epithelium does not change color, as it has no glycogen. Immature metaplasia and inflammatory lesions are at most only partially glycogenated and, when stained, appear as scattered, ill defined uptake areas. Precancerous lesions and invasive cancer do not take up iodine (as they lack glycogen) and appear as well-defined, thick, mustard or saffron yellow areas.

Moderate specificity may result in over-referral and over-treatment in a single-visit approach. There is a need for developing standard training methods and quality assurance measures. More research is needed to establish the most appropriate and feasible approach to reducing false positives and over-treatment (when offered as part of a single-visit, “test-and-treat” approach). VILI is still relatively new as compared to the other methods; therefore properly designed studies on VILI are essential to evaluating the effectiveness in reducing cervical cancer incidence and mortality. Recommendations and timings of VIA outlined above also apply to VILI.
Flow diagram for cervical cancer screening with VIA/VILI

CYTOLOGY

Cervical cytology testing by Pap smear is one of the oldest methods of screening. It has resulted in successful and significant reduction in incidence of invasive cancer in countries where it is consistently practiced and provided in an organized manner. Lack of infrastructure in low resource areas has prevented similar programmes from being successfully implemented.

The procedure for Pap smear is outlined below:
- A Cusco’s or Grave’s Speculum inserted and cervix is visualized.
- A cytology collection tool (see below) is used to “scrape” cells from the cervix (the transformation zone; TZ).
  - If using a spatula turn it 360 degrees while pressed against the cervix.
  - If using an endocervical brush- turn it only 90 degrees
  - If using a plastic/ cervix brush, turn it $360^0$ five times
**Cytology collection tools**

<table>
<thead>
<tr>
<th>Tool</th>
<th><strong>Advantages</strong></th>
<th><strong>Disadvantages</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocervical brush</td>
<td>Provides high yield of endocervical material.</td>
<td>May cause minor bleeding. Should not be used on pregnant women.</td>
</tr>
<tr>
<td>Spatula—wood or plastic</td>
<td>Usually does not cause bleeding. Specimen adheres to wood.</td>
<td>May miss the TZ; may fail to collect endocervical cells.</td>
</tr>
<tr>
<td>Plastic brush/broom</td>
<td>Ectocervix and endocervical canal are sampled at the same time.</td>
<td>May cause some bleeding.</td>
</tr>
</tbody>
</table>

- The cells are then placed on the glass slide and “fixed” in absolute alcohol.
- The slide is then treated with Pap stains to color the cells.
- Note that the slide serves as a permanent record.
- Thereafter, the slide is read by a specially trained cytotechnologist and/or pathologist for signs of cellular changes.

Reporting of Pap results using Bethesda system and the correlation with other reporting systems is shown below. Note that dysplasia and Bethesda systems comprise cytology reporting while CIN is a histology reporting done of evaluation of biopsy.

**Correlation between Dysplasia, CIN and Bethesda system**

<table>
<thead>
<tr>
<th>Dysplasia terminology</th>
<th>Original CIN terminology</th>
<th>Modified CIN terminology</th>
<th>Bethesda system (SIL) terminology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Normal</td>
<td>Normal</td>
<td>Within normal limits, Benign cellular changes (infection or repair)</td>
</tr>
<tr>
<td>Atypia</td>
<td>Koilocytic atypia, flat condylomata without epithelial changes</td>
<td>Low grade CIN</td>
<td>ASCUS / AGUS / LSIL</td>
</tr>
<tr>
<td>Mild dysplasia or mild dyskaryosis</td>
<td>CIN1</td>
<td>Low grade CIN</td>
<td>LSIL</td>
</tr>
<tr>
<td>Moderate dysplasia or moderate dyskaryosis</td>
<td>CIN2</td>
<td>High grade CIN</td>
<td>HSIL</td>
</tr>
<tr>
<td>Severe dysplasia or severe dyskaryosis</td>
<td>CIN 3</td>
<td>High grade CIN</td>
<td>HSIL</td>
</tr>
<tr>
<td>Carcinoma in situ</td>
<td>CIN 3</td>
<td>High grade CIN</td>
<td>HSIL</td>
</tr>
<tr>
<td>Invasive carcinoma</td>
<td>Invasive carcinoma</td>
<td>Invasive carcinoma</td>
<td>Invasive carcinoma</td>
</tr>
</tbody>
</table>

Timing of Pap smear
The Pap smear is best taken around mid cycle. It should be postponed in case of cervicitis until after treatment; otherwise the pus cells obscure clarity of the smear and affect interpretation. The pap smear should also not be taken during menses since the red blood cells also obscure the picture and affect interpretation. In perimenopausal or postmenopausal clients, the yield of cells may be improved by using the endocervical brush or use of hormone therapy prior to taking the smear

Limitations of Pap smear
- It requires microscopes, laboratory, trained technicians, pathologists, transport of specimens, reporting, and supplies.
- Immediate results are not possible therefore SVA is not possible.
- Multiple visits in poor resource areas lead not only to increased costs but also to higher loss to follow up.
- It has a lower sensitivity than the other methods and lower reproducibility during reporting.
- Lesions may be missed if:
  - They are not exfoliating.
  - There is a barrier to exfoliation.
  - Cells are not sampled properly from the squamocolumnar junction and transformation zone.
  - Abnormal cells are not transferred to the slide.
  - The slide cannot be read effectively because it is obscured by blood or pus.
  - The technician misses the precancerous cells.
- It generally costs more than the other screening methods. It can however be cost effective if screening targets the population at highest risk for disease, and the infrastructure is in place.

Benefits of Pap smear:
- It is trusted, proven over 50 years.
- Given adequate resources and a screening program, it can be practical, affordable, and accurate.
- The slide serves as a permanent record.
- There are no medical conditions that should exclude patients from receiving appropriate screening, including pregnancy.
- It has very high specificity
- It is an appropriate screening method for women over 50 years of age.
Management of abnormal Cytology results

HPV Testing

HPV testing- though more recent- is an effective and objective method for screening. Women who do not have persistent high risk HPV types are very unlikely to develop cervical cancer. For those who test positive for oncogenic HPV types, additional screening becomes important. HPV testing is therefore a very useful triage tool that allows visual or cytological testing for women with high risk HPV types.

HPV testing of self-collected vaginal samples provide high sensitivity and this may be useful in certain cultures. As well as relieving pressure on clinicians time, Self-sampling also provides an option for women to access cervical cancer screening, even if they are resistant to a pelvic examination. A rapid, low-cost, portable HPV test (Fast HPV) designed for rural developing country settings is being tested. This test is designed to allow for HPV testing within the screen and treat approach as test results are available within hours.

The following considerations are important in determining the target groups and frequency of screening:

- Though HPV infection is very common in young women, most infections are transient and clear spontaneously within 1-2 years
- Only a small percentage of all HPV infections will lead to invasive cancer
- Cervical cancer usually develops slowly, taking 10–20 years from early precancer to invasive disease
• Cervical cancer is rare before the age of 30 years. Screening younger women will detect many lesions that will never develop into cancer; This will lead to considerable overtreatment, and is therefore not cost-effective
• Treatment should not be initiated on the basis of HPV testing alone

Flow chart for HPV DNA testing

There are several diagnostic tests for detection of oncogenic genotypes of Human papillomavirus (HPV); some detect HPV-DNA and others target HPV-RNA. Recent research indicates that HPV testing is the most sensitive screening tool available at this time for the detection of CIN 3 and cervical cancer. The HPV test is highly sensitive, although less specific, in primary screening of precancerous lesions of the cervix (CIN 2 and CIN 3).

Meta-analyses of studies have shown that the mean sensitivity of HPV-DNA testing for detection of CIN 2/3 is over 90% although reports from studies performed in developing countries obtained lower sensitivities. Specificity of HPV-DNA testing for cross-sectional CIN 2/3 ranged from 85-90%. This sub-optimal specificity is one of the limitations of the test since a considerable number of women with positive results may be unnecessarily referred for additional evaluation. This is an especially important consideration in areas where treatment resources are limited and unnecessary follow up treatment presents a worrisome burden to the health system.

One of the advantages of HPV-DNA testing is the high negative predictive value. It has been demonstrated that the risk of developing CIN 3 after a negative HPV-DNA test is almost zero within 6 and 10 years respectively. This characteristic of HPV-DNA testing could permit longer inter screening periods and fewer overall screenings during a woman’s lifetime.
Recommendations for HPV testing
HPV testing is widely recommended for women above the age of 30 up to 55-65 years of age. In low resource settings, a once or twice in a lifetime screening at age 35 and 45, with triage of HPV positive women to cytology or VIA, may be optimal. The screening interval is currently recommended at 3-5 years but longer intervals are being investigated.

At this time, HPV testing is recommended for use with existing screening methods or as a triage test. The replacement of current screening approaches with a sole HPV test has not been recommended. It is still impossible to determine by using a single-time test which women will clear the virus and which women will become chronically infected and progress to cancer. Hence treatment should never be given on the basis of HPV test alone.

Target group for Cervical Cancer screening
The focus of the Kenya CECAP programme will be women aged 25-49. However women outside this age group who request or for whom screening is recommended will not be denied services.

Screening cycle
The recommended screening cycle in HIV negative women regardless of screening test is once every five years if the initial result is negative/normal. If screening has been normal, it can be stopped when a woman reaches 65 years of age. If a woman can be screened only once in her lifetime, the best age is between 35 and 45 years. If results have been abnormal or the client has undergone treatment, rescreening should be provided in a year. If follow up screening is normal, she should return for screening every five years.

Screening for HIV infected Women
Squamous cell carcinoma of the cervix is now an AIDS-defining illness. HPV is detected more frequently and resolves more slowly in HIV-infected women. In these women, HPV-associated disease is also more difficult to treat, recurrence rates are higher and progression from HPV to cancer is faster. Although antiretroviral treatments improve the quality of life for HIV-infected persons, it is still not known if they have any effect on progression to pre-cancer or cancer. Women presenting for cervical cancer screening should also receive HIV counseling and testing.

All HIV positive women with history of sexual activity 18-65 years old should be screened for cervical cancer. For these women, start screening at the time of diagnosis of HIV or on first contact. Screen every 6 months for the first year then annually thereafter. Note that in HIV positive women lesions on VIA/VILI tend to be larger and therefore may not be amenable to cryotherapy.

Following treatment with cryotherapy or LEEP, the client should be made aware of the risk of increased viral shedding and therefore advised on condom use until the cervix is completely healed.
Screening during pregnancy

Screening for cervical cancer should be provided to eligible clients as part of routine preconception care. Though screening for cervical cancer is not provided routinely as part of focused antenatal care, pregnancy does not preclude screening for cervical cancer and it can be performed up to 20 weeks of gestation to avoid missed opportunity. Furthermore, speculum examination should be part of routine ANC evaluation to rule out gross cervical abnormalities. When taking a pap smear during pregnancy, it is advisable to use the plastic brush /broom to minimise trauma to the cervix.

However, it is important to recognize that pregnancy causes changes in the cervix that make interpretation of screening results more difficult than in non-pregnant clients. At VIA/VILI, lesions may look larger than they actually are while interpretation of Pap smear may be more difficult. For clients who are likely to return, they should be advised to come for re-screening 6-12 weeks after delivery. This is because most lesions shrink or regress spontaneously after delivery. Such clients should be advised to complete the recommended postnatal care visits including a screening visit at 6-12 weeks. For clients who present with symptoms that may suggest invasive cervical cancer such as abnormal vaginal discharge or bleeding, speculum examination should be performed to rule out gross lesions.

Some arguments against performing routine screening for cervical cancer during pregnancy include the fact that most pregnant women are young; precancerous lesions tend to regress spontaneously after childbirth; treatment of precancerous lesions is contraindicated during pregnancy; taking biopsy should be avoided unless invasive cancer is suspected; and some women may find speculum examination unacceptable thereby potentially affecting utilization of FANC services negatively. For those ineligible for screening during pregnancy as outlined above, they should be advised to go for screening at 6 weeks postpartum. Such clients should also be advised to encourage other eligible women to seek screening services.

Should a screening be abnormal or a lesion detected at speculum examination, the patient should be immediately referred to a specialist for colposcopy. Due to the risk of significant bleeding the colposcopist should defer taking a biopsy until at 12 weeks after delivery unless there is suspicion of invasive cancer. Treatment for precancerous lesions by cryotherapy, LEEP or cold knife conisation is contraindicated in pregnancy or within 12 weeks postpartum. Unless invasive cancer is suspected, any intervention should be delayed until after 12 weeks postpartum when she should be re-evaluated and appropriate treatment provided then, if still indicated.
DIAGNOSIS

The standard method for diagnosis of cervical precancerous lesions is histopathological examination of tissue obtained through colposcopy directed biopsy. The screen and treat approach however involves providing treatment on the basis of a positive screen test without further diagnostic training.

A colposcope is a low-power, stereoscopic, binocular field microscope with a powerful light source used for magnified visual examination of the uterine cervix to help in the diagnosis of cervical neoplasia. It provides illumination and magnification 6X to 40X. Colposcopy allows the cellular patterns in the epithelium and surrounding blood vessels to be examined, the extent of abnormal lesions to be defined and abnormal areas biopsied. Colposcopy has a high sensitivity (around 85%) and a specificity of about 70% for the detection of precancer. Colposcopy is not recommended for use as a screening tool!

Indications for colposcopy:
The most common reason for referral of women for colposcopy is abnormal cervical cytology. This is usually discovered as a result of cytological screening / Pap smear. Other indications of colposcopy include:

- Suspicious-looking cervix
- Invasive carcinoma on cytology
- CIN 1, CIN 2 or CIN 3 on cytology
- Persisting (for more than 12-18 months) low-grade (CIN 1) abnormalities on cytology
- Persistently unsatisfactory quality on cytology
- HPV positive test in women above 30 years of age
- VIA or VILI positivity
- To map abnormalities before cryotherapy or LEEP

The key ingredient of colposcopic practice is the examination of the features of the cervical epithelium after application of saline, 3-5% dilute acetic acid and Lugol's iodine solution in successive steps. The study of the vascular pattern of the cervix may prove difficult after application of acetic acid and iodine solutions. Hence the application of physiological saline before acetic acid and iodine application is useful in studying the sub epithelial vascular architecture in great detail. It is advisable to use a green filter to see the vessels more clearly.

Special Considerations:
1. The entire transformation zone is not visible. This indicates an unsatisfactory colposcopy and endocervical curettage should be done
2. The woman is pregnant. Taking biopsies in pregnancy is associated with significant bleeding. If there is no colposcopic indication of invasive cancer, re-evaluate at 12 weeks post partum and take a biopsy at that time if indicated
3. The woman is postmenopausal. The transformation zone may not be visible. One may therefore have to use and endocervical sperculum or perform as endocervical curettage
4. HIV positive women. Colposcopy and biopsy should not be modified on the basis of HIV status alone. However counselling should be done on the risk of increased viral shedding or increased risk of additional viral load if re-exposed after biopsy.

**Indications for Endocervical curettage:**
1. Patient with positive pap smear but no abnormality is seen on colposcopy
2. Pap smear reveals a glandular lesion
3. Unsatisfactory colposcopy

NB Colposcopy, biopsy and endocervical curettage DO NOT require any anaesthesia since they are associated with minimal discomfort
Ensure that the patients return as per appointment for the results of biopsy and advice on treatment. *(Mechanisms should be in place to trace patients who do not return for results or treatment)*

**MANAGEMENT OF PRE-CANCEROUS LESIONS**
The elements of a comprehensive cervical cancer prevention programme include a treatment arm. In most cases precancerous lesions can be treated on an outpatient basis using relatively non invasive procedures. These treatment methods may be ablative (destroying abnormal tissue by heating or freezing) or excisional (surgically removing abnormal tissues). The choice of treatment depends on:
- The training and experience of the provider
- The location and extent of the lesion
- The advantages and disadvantages of each method
- The cost
Cryotherapy and LEEP are the recommended treatment options for most cases of pre cancer. Women should be offered the same treatment options irrespective of HIV status.

**Methods for treatment of precancerous lesions of the cervix**

**Cryotherapy**
Cryotherapy is an ablative form of treatment for precancerous lesions of the cervix. The cryotherapy technique uses a cryoprobe with a tip made of highly conductive metal (usually silver and copper), that makes direct surface contact with the ectocervical lesion. A substantial drop in temperature is achieved when a compressed refrigerant gas is allowed to expand through a small aperture in the cryoprobe. Nitrous oxide (N\textsubscript{2}O) or carbon dioxide (CO\textsubscript{2}) are the refrigerants of choice, as both provide excellent thermal transfer when circulating in the probe tip. If excellent contact between the cryoprobe tip and the ectocervix is achieved, N\textsubscript{2}O-based cryotherapy will achieve $-89^\circ$C and CO\textsubscript{2}-based system will achieve $-68^\circ$C at the core of the ice ball and temperatures around $-20^\circ$C at the edges. Cells reduced to $-20^\circ$C for one or more minutes will undergo cryonecrosis.
Cryotherapy is the easiest and least costly treatment method for pre cancer. 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 <80%. In developing countries, cryotherapy is being recommended for use in the single visit approach (SVA) to reduce the number of clinic visits by women and thereby avoid loss to follow up and treatment.

Because the area of the cervix that is frozen has very few nerve endings, cryotherapy can be done without anesthesia since in results in very minimal discomfort

**Eligibility criteria for cryotherapy**
- The screening test for cervical precancer is positive
- There is no evidence of invasive cancer
- The endocervical canal is normal and there is no suggestion of glandular dysplasia
- The entire lesion is located in the ectocervix without extension to the vagina and/or endocervix
- The lesion is visible in its entire extent and does not extend more than 2 to 3 mm into the canal
- The lesion can be adequately covered by the largest available cryotherapy probe (preferably the 19mm probe);
- The lesion extends less than 2 mm beyond the cryotherapy probe
- The woman is not pregnant
- If the woman has recently delivered, she is at least three months post-partum
- There is no evidence of pelvic inflammatory disease
- The woman has given informed written consent to have the treatment

**Procedure:**
1. The service provider should explain the treatment procedure to the woman and reassure her. This is important to help the woman to relax during the procedure.
2. After ensuring she has emptied her bladder, she should be placed in a modified lithotomy position and the cervix should be exposed with the largest speculum that can be introduced comfortably.
3. The secretions are removed with a cotton swab soaked in saline. Then VIA/ VILI is performed to delineate the limits of the lesion.
4. The cryoprobe surface is wiped with saline to ensure adequate thermal contact with the cervix and optimal lowering of the tissue temperature.
5. The cryotherapy probe tip is then firmly applied, with the centre of the tip on the os. It is obligatory to ensure that the vaginal walls are not in contact with the cryoprobe tip.
6. The timer is then set and the gas trigger in the cryogun is released or squeezed to cool the cryoprobe in contact with the cervix. The gas escapes through the pressure gauge with a hissing noise. One should be able to observe ice being formed on the tip of the cryoprobe and on the cervix as freezing progresses.
7. The cryoprobe is applied to the cervix twice for three minutes each time with a five minute thaw in between (double freeze technique). Adequate freezing has been achieved when the margin
of the ice ball extends 4-5 mm past the outer edge of the cryotip. This will ensure that cryonecrosis occurs down to at least 5 mm depth.

8. Once the second freeze for 3 minutes is completed, allow time for adequate thawing before removing the probe from the cervix.

9. When thawing is completed, the ice formation on the cryoprobe tip is totally cleared and the probe is removed by gently rotating on the cervix. Do not attempt to remove the probe tip from the cervix until complete thawing has occurred.

10. After removing the probe, examine the cervix for any bleeding. The vagina should not be packed with gauze or cotton after cryotherapy to allow the secretions to escape. Women may be provided with a supply of sanitary pads to prevent the secretions staining their clothes.

Side effects
The main side effect associated with this procedure is profuse watery vaginal discharge starting a few days after treatment when sloughing of the “necrotic areas” occurs. The discharge may go on for four to six weeks until the healing process is completed.

Long term sequelae are rare. Cervical stenosis occurs in less than 1% of women; reduced mucus production occurs in 5-10% of women. Cryotherapy has no known adverse effect on fertility and pregnancy.

Post-treatment Instructions
- Women should be informed that they may experience some mild cramps and a clear or lightly blood-stained watery discharge for up to 4-6 weeks after treatment.
- Women should be advised not to use a vaginal douche or tampons or to have sexual intercourse for one month after treatment. If it is not possible to abstain, condoms may be used 2 weeks post treatment to reduce disturbance to the cervix and facilitate healing.
- They should be instructed to report if they have any one of the following symptoms in the six weeks after treatment: fever for more than two days, severe lower abdominal pain, foul-smelling pus colored discharge, bleeding with clots or bleeding for over two days.
- It is preferable to give written instructions on the above aspects and on follow-up.

Follow up
Appointments should be made for a follow-up visit 9-12 months after treatment. During the follow-up, cytology and/or VIA should be performed, followed by colposcopy and directed biopsy depending upon the colposcopy findings, to assess the regression or persistence of lesions. Retreatment is carried out if lesions persist.

Women who are negative for neoplasia may be referred back to a screening programme.

Special considerations
- The effect of cryotherapy on the potential transmissibility of human immunodeficiency virus (HIV) infection (to or from women) during the healing phase is not known. HIV-1 shedding in the vaginal secretions after treatment of CIN in HIV positive women has been demonstrated.
Therefore women should be informed that cryotherapy may increase the transmissibility of HIV and advised to use condoms as an effective means of prevention.

- If the woman is suffering from cervicitis, trichomoniasis or bacterial vaginosis, she may be offered a choice of having either cryotherapy immediately with simultaneous antimicrobial treatment, or taking treatment and returning two to three weeks later for cryotherapy.
- If there is evidence of pelvic inflammatory disease (PID), it is advisable to delay cryotherapy until the infection has been treated and resolved.
- If there is marked atrophy due to estrogen deficiency in an older woman and staining of the outer margin of a lesion is indistinct, cryotherapy may be carried out after a course of topical estrogen treatment and colposcopic reassessment preferably at a higher level of care.

Care and maintenance of equipment
The cry probes /cryotips should be decontaminated using standard procedure, cleaned and then subjected to High level disinfection or autoclaving
The cryogun, regulator and gas cylinder should be wiped after use with 60-90% ethyl, isopropyl alcohol

Loop Electro Surgical Excision Procedure (LEEP)
LEEP - also referred to as Large Loop Excision of the Transformation Zone (LLETZ), is an excisional method of pre cancer treatment. It is the treatment of choice for cervical lesions that are large for the cryoprobe, when the lesion involves the endocervical canal or when a histological specimen is needed.
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 cryotherapy, LEEP requires more highly skilled personnel, electricity, local anaesthesia and is therefore more expensive. Although LEEP is a relatively simple surgical procedure, it is best performed in higher level facilities where potential problems can be easily managed. LEEP is also best performed under colposcopic guidance.

Eligibility criteria for LEEP
- A positive diagnostic test for pre-cancer (when possible, CIN is confirmed by cervical biopsy)
- If the lesion involves or extends into the endocervical canal, the distal or cranial limit of the lesion should be seen; the furthest (distal) extent should be no more than 1 cm in depth
- There is no evidence of invasive cancer or glandular dysplasia
- There is no evidence of pelvic inflammatory disease (PID), cervicitis, vaginal trichomoniasis, bacterial vaginosis or anogenital ulcer
- The woman should not be pregnant. If the woman has recently delivered, she should be at least three months postpartum
- Women with hypertension should have their blood pressure well controlled
- There should be no history or evidence of bleeding disorder
- The woman must give written informed consent to have the treatment
LEEP procedure
1. Explain the procedure, obtain informed consent and prepare the patient for a gynecological examination.
2. Prepare all the necessary equipment and supplies and attach a return electrode to the inner thigh.
3. Insert a non-conducting speculum with an electrically insulating coating, or a speculum covered with a latex condom.
4. Examine the cervix, and note any abnormalities; if there is no evidence of infection, proceed. If you note signs of infection, suspend the procedure and treat the patient and her partner completely before making a second attempt.
5. Perform colposcopy to determine the location and extent of the lesion.
6. Inject 3–5 ml of local anesthetic (1% or 2% lidocaine with adrenaline (to control bleeding)), using a long 27-gauge needle, just beneath the cervical epithelium at the 12 o’clock, 3 o’clock, 6 o’clock and 9 o’clock positions (in patients with cardiac problems, use lidocaine without epinephrine).
7. Select the appropriate electrode to remove the entire abnormal area in a single pass: for small low-grade lesions in nulliparous women, use an electrode 1.5 cm wide by 0.5 cm deep; for larger lesions and multiparous women use one 2.0 cm wide by 0.8 cm deep.
8. Turn on the vacuum suction on and activate the generator.
9. Excise the lesion: push the electrode perpendicularly into the tissue to a depth of 4–5 mm and draw it laterally across the cervix to the other side, producing a dome-shaped circle of tissue with the canal in the centre. Do not insert the electrode deeper than 5 mm at the 3 o’clock and 9 o’clock positions, because this can damage the uterine arteries. Additional passes with the loop can be made to excise residual tissue.
10. Pick up all excised tissues with the forceps, and place in a labeled bottle with formalin to send to the histopathology laboratory.
11. Perform endocervical curettage and place the tissue in a separate bottle with formalin.
12. Fulgurate any bleeding tissue in the crater base using a ball electrode and coagulation current.
13. Apply Monsel’s paste to the crater base to prevent further bleeding and remove the speculum.
14. Provide a sanitary pad.

Side effects:
- Severe and moderate postoperative bleeding occurs in a few women. This usually occurs 4-6 days after treatment and often from the posterior lip of cervix. This bleeding can usually be controlled by fulguration, applying Monsel’s paste, or using a silver nitrate applicator stick. Rarely, placement of a suture at the bleeding site is necessary.
- Few women complain of post-operative pain. If this occurs, it usually is similar to cramps; women should be instructed to use oral analgesics such as acetaminophen or ibuprofen, if necessary.
• The risk of post-operative infection is very small and can probably be reduced even more by delaying surgical treatment until any woman with a likely diagnosis of PID, cervicitis, or vaginitis has been adequately treated and recovered.
• Women should be warned that cervical stenosis, partial or complete may occur. This is however more common in menopausal women.

Post Treatment instructions:

a. Instruct the patient to abstain from sexual intercourse for a minimum of 4 weeks, and until the bleeding stops completely. This is to avoid infection and heavy bleeding.

b. Provide condoms for use if she cannot abstain as instructed. Teach her how to use them.

c. Tell her she may have some mild to moderate pain for a couple of days; she can take ibuprofen or paracetamol.

d. Explain that she may have very light bleeding and that she will notice blood-tinged discharge for one month or more. She can use sanitary pads but not tampons for this.

e. Advise her how to take care of herself when she goes home: She should rest and avoid heavy work for several days; she should not put anything in the vagina.

f. Inform her of possible complications and ask her to return immediately if she notices:
   a. fever with temperature higher than 38 °C or shaking chills;
   b. severe lower abdominal pain;
   c. foul-smelling or pus-like discharge;
   d. Heavy bleeding or bleeding with clots.

Follow up
At 2-6 weeks post op, the patient should return to the health centre to be checked for healing and to receive the laboratory report.
All women, regardless of whether or not the pathology report states that the excisional margins are clear, should be followed up at 9 - 12 months from treatment to evaluate regression or persistence of lesions and complications. At this visit, it is advisable to biopsy all persistent lesions to rule out the presence of unsuspected invasive carcinoma. Retreatment is carried out if lesions persist.
Women who are negative for neoplasia require annual screening for 5 years after which she may be referred back to the routine screening programme.

Special Considerations:
The effect of LEEP treatment on the potential transmissibility of HIV (to or from women) during the healing phase is not known. HIV-1 shedding in the vaginal secretions after treatment of CIN in HIV-positive women has been demonstrated. Therefore women should be advised that that LEEP treatment may increase the transmissibility of HIV and that using condoms is an effective means of prevention. Condoms should be used for period of 6-8 weeks. Ideally, a supply of condoms should be available, free of charge, at colposcopy clinics in settings where HIV infection is endemic.
Women presenting for pre-cancer treatment should be offered HIV counseling and testing as an opt out, as part of the RH /HIV integration strategy.
**Cold Knife Conisation:**
Cold knife conisation is the removal of a cone shaped area from the cervix including the ectocervix and endocervix. It is usually done under general or regional anaesthesia, by gynaecologists or surgeons trained in the procedure and able to recognise and manage its complications, in an equipped surgical facility. Because of the possible side effects, cold knife conisation should be reserved for cases that cannot be managed with cryotherapy or LEEP excision. The extent of conisation depends on the size of the lesion; the woman’s desire to have more children, and the likelihood of finding invasive cancer. The tissue removed is then subjected to histopathology to ensure that the abnormal tissue has been completely excised.

**Eligibility criteria for Cold knife conisation:**

a. The lesion extends into the endocervical canal and it is not possible to confirm the exact extent.

b. The lesion extends into the canal and the farthest extent exceeds the excisional capability of the LEEP technique (maximum excisional depth of 1.5 cm).

c. The lesion extends into the canal and the farthest extent exceeds the excisional capability of the colposcopist.

d. The cytology is repeatedly abnormal, suggesting neoplasia, but there is no corresponding colposcopic abnormality of the cervix or vagina on which to perform biopsy.

e. Cytology suggests a much more serious lesion than that which is seen and confirmed on biopsy.

f. Cytology shows atypical glandular cells that suggest the possibility of glandular dysplasia or adenocarcinoma.

g. Colposcopy suggests the possibility of glandular dysplasia or adenocarcinoma.

h. Endocervical curettage reveals abnormal histology.

i. The woman is not pregnant; if she has delivered, she should be at least 12 weeks post partum or less than

j. There should be no evidence of cervicitis or PID

k. There should be no obvious invasive cancer

**Procedure of Cold Knife conisation**
This is outlined in standard gynecologic surgery manuals

**Side effects**
The most common complication is bleeding. This may be immediate (primary bleeding) or up to 14 days after the procedure (secondary bleeding). Infection of the surgical site may also sometimes occur. Women should be warned that cervical stenosis may occur. In some women due to destruction of the internal OS, cervical incompetence may result.
Post treatment instructions
These are similar to those for LEEP

a. Before she leaves hospital, the woman should be given counseling on how to take care of herself, and what symptoms of complications to look for.
b. If gauze packing was left in the vagina, it must be removed within 6-12 hours to avoid infection.
c. Relative rest for a few days is recommended. The patient should avoid heavy work for the first three weeks. Normal daily activities can be performed, such as light housework, bathing, showering, and eating.
d. Tell her she may have some mild to moderate pain for a couple of days; she can take ibuprofen or paracetamol.
e. She will have a hidden wound in the vagina, which needs at least 4–6 weeks to heal. To prevent infection and allow proper healing, she should not put anything into the vagina for that time, including fingers or tampons, and she should not douche or have sexual intercourse. If she is unable to abstain from intercourse, provide condoms and teach her (and her partner) how to use them.
f. Make sure she knows the symptoms of complications and instruct her to go to the health centre or hospital immediately if any of them occur.

Follow up
The patient should be given an appointment for a check-up in 2–6 weeks to discuss the results of the tissue examination and to be examined by the surgeon.

All women, regardless of whether or not the pathology report states that the excisional margins are clear, should be followed up at 6 months and at 12 months from treatment to evaluate regression or persistence of lesions and complications. At these visits, it is advisable to rescreen and then biopsy all persistent lesions to rule out the presence of unsuspected invasive carcinoma. The patient should then be managed accordingly.

INVASIVE CANCER:

Patients with invasive cancer should be referred without delay! Details of management of overt cancers are beyond the scope of these guidelines. However the ability to recognise invasive cancer and be familiar with the management is imperative for any service provider involved in a cervical cancer prevention programme.

Health care providers at all levels should know the common symptoms and signs of cervical cancer. If a woman presents with such symptoms, her cervix should be examined visually to determine whether further testing is needed. Furthermore any woman presenting with a foul smelling discharge should have a speculum examination in order to rule out the possibility of invasive cervical cancer. (This is also known as down staging). The stage of the cancer is a measure of how far it has advanced. This
determines how it can be treated, and the likely outcome. Invasive cervical cancer should be treated by specialists at central-level facilities. Treatment is by surgery or radiation therapy, with or without chemotherapy. Access to treatment greatly improves prognosis and survival rates.

**Diagnosis**

**Symptoms and signs of Invasive cervical cancer**

Micro invasive cancers are usually asymptomatic, and may be detected only on cytology or histological evaluation of a biopsy specimen. On the other hand, most cases of frankly invasive cervical cancer are diagnosed once they become symptomatic. In women who are not sexually active, the disease may remain asymptomatic until it is well advanced. The clinical presentation is determined by the patterns of growth and spread. Eliciting patients' symptoms is important for optimal patient management and for pain control.

The table below shows the common symptoms and signs of Invasive Cervical cancer

<table>
<thead>
<tr>
<th>Early</th>
<th>Late</th>
<th>Very late</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Vaginal discharge, sometimes foul smelling</td>
<td>• Urinary frequency and urgency</td>
<td>• Severe back pain</td>
</tr>
<tr>
<td>• Irregular bleeding in WRA</td>
<td>• Backache</td>
<td>• Weight loss</td>
</tr>
<tr>
<td>• Post coital bleeding in women of any age</td>
<td>• Lower abdominal pain</td>
<td>• Oliguria (due to ureteric obstruction or renal failure)</td>
</tr>
<tr>
<td>• Post menopausal bleeding (especially that which does not respond to appropriate treatment)</td>
<td></td>
<td>• Urinary/fecal incontinence</td>
</tr>
</tbody>
</table>

Any woman presenting with any of the above symptoms should have a speculum examination to visualize the cervix, and any visible lesions should be biopsied. If the woman is pregnant, she should be referred to a specialist for biopsy and follow-up. The definitive diagnosis of cancer is confirmed by histopathological examination of the biopsy specimen and is mandatory before any therapies, or even extensive investigations, are started.

**Cervical cancer Staging**

Once a histological diagnosis of cervical cancer has been made, the next step is to formulate the most effective therapy for the individual concerned. In order to manage a cervical cancer patient properly, it is essential to understand the extent or “stage” of her disease at the time of diagnosis. This is what is referred to as staging.
The classification of the International Federation of Gynecology and Obstetrics (FIGO), which is based on tumor size and the extent of spread of disease in the pelvis and distant organs, is recommended for staging invasive cervical cancer. The extent of growth of the cancer is assessed clinically, supplemented by a limited number of relatively unsophisticated investigations. An exception to the above is staging of micro invasive cervical cancers, which are staged according to pathological criteria of the depth and width of the invasive lesion in relation to the epithelium of origin (which may be either squamous or glandular epithelium).

In many low-resource settings, speculum, vaginal and rectal examinations are the only feasible approaches to staging; these will often provide sufficient information when performed by experienced clinicians. Attention should be paid to the size of the tumor and possible involvement of the vaginal fornices, the parametria (transverse cervical and uterosacral ligaments), the pelvic walls, the bladder and the rectum. This assessment can be done without anesthesia. However, general anesthesia is recommended if there is any doubt about the diagnosis or if the patient is too tense or in pain. Other imaging modalities, such as computerized tomographic (CT) scan and magnetic resonance imaging (MRI) of the abdomen and pelvis, are optional and not needed for diagnostic and staging purposes.

### Overview of FIGO Staging

<table>
<thead>
<tr>
<th>Stage 0</th>
<th>Carcinoma in situ, cervical intraepithelial neoplasia Grade III. This is not considered invasive cancer, since the lesion has not gone beyond the basement membrane.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage I</td>
<td>Carcinoma strictly confined to the cervix. <em>Extension to the uterus is disregarded.</em></td>
</tr>
<tr>
<td>IA</td>
<td>Micro invasive carcinoma strictly confined to the cervix. Can only be diagnosed by microscopy; it is not clinically visible. <em>Please note that absence of a visible lesion does not mean absence of malignancy!</em></td>
</tr>
<tr>
<td>IB</td>
<td>Carcinoma strictly confined to the cervix and clinically visible</td>
</tr>
<tr>
<td>Stage II</td>
<td>Cancer extends beyond the cervix but has not reached the pelvic wall and/or carcinoma involves the upper part of the vagina but not the lower third.</td>
</tr>
<tr>
<td>IIA</td>
<td>Spread beyond the cervix, including upper two-thirds of the vagina, but not to tissues around the uterus (parametria)</td>
</tr>
<tr>
<td>IIB</td>
<td>Spread beyond the cervix, with parametrial invasion, but not as far as the pelvic wall or the lower third of the vagina</td>
</tr>
<tr>
<td>Stage III</td>
<td>Carcinoma has extended to the pelvic wall. On rectal examination, there is no cancer-free space between the tumour and the pelvic wall. The tumour also involves the lower third of the vagina. Clients may also have hydro-nephrosis or non-functioning kidneys.</td>
</tr>
<tr>
<td>IIIA</td>
<td>Invasion of the lower third of the vagina, with no extension to the pelvic wall</td>
</tr>
<tr>
<td>IIIB</td>
<td>Extension to the pelvic wall, or hydronephrosis or nonfunctioning kidney</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Carcinoma extended beyond the true pelvis or clinically involves mucosa of the bladder or rectum.</td>
</tr>
<tr>
<td>IVA</td>
<td>Spread to involve the mucosa of the bladder or rectum.</td>
</tr>
<tr>
<td>IVB</td>
<td>Spread to distant organs, such as extra pelvic lymph nodes, kidneys, bones, lungs, liver and brain</td>
</tr>
</tbody>
</table>
MANAGEMENT OF INVASIVE CANCER

Details of treatment are beyond the scope of these guidelines. They are adequately covered in standard gynaecology and oncology textbooks. Treatment options are pegged to the stage of invasive cancer and comprise of either surgery, radiotherapy or chemotherapy. Consideration should be given to the best interest of the client, the overall assessment of the patient, the availability and quality of surgery, radiotherapy and oncology services, and the other support systems available to the patient. Women should be given all the information about the procedure (including the benefits, risks, potential side effects, recovery time, cost, chances of success, 5 year survival rates etc) before it is performed.

With timely diagnosis and optimal treatment, the following are the five (5) year survival rates by stage of cancer:

- Stage 1A – 95-98%
- Stage 1B - 75 - 85%
- Stage 1II - 65 - 75%
- Stage 1III – 30%
- Stage IV – 5 -10%

Follow-up

All patients who have undergone treatment for invasive cancer require follow up. Clients who are diagnosed in early stages of disease and have had treatment require less frequent follow-up than those with advanced disease. However, every individual client’s needs should be addressed appropriately.

Feedback mechanisms should be established and strengthened to and from the referring centres and to all levels of health care. Proper records including those of referral should be maintained. Those who are found to be out of danger after the recommended duration of follow-up should be discharged with recommendation and continuation with routine screening.

Follow-up for women treated with surgery alone

Women who have been treated with surgery alone should have **three-monthly follow-up consultations for a period of 2 years**, with careful recording of symptoms, particularly bleeding, discharge or pelvic pain. During the consultations, the following examinations should be performed:

- Speculum examination and visualization of the vaginal vault;
- Cytological smear of the vaginal vault and of any abnormality noted on examination;
- Bimanual vaginal and rectal examination to palpate for recurrence of disease;
- Other investigations depending on the clinical findings and resources available.

Recurrent disease in these women can be treated with radiation.
Follow-up for women treated with radiation
For women who have been treated primarily with radiation, follow-up should be the same as for those who have had surgery, but clinical evaluation is more difficult because of radiation-induced fibrosis.

One of the reasons for regular follow-up is to look for sequelae of radiotherapy, which may be mistaken for recurrence of cancer. Treatment options for women with recurrence after primary radiation are limited, as no further radiation can be given.

Salvage hysterectomy may be considered where surgical expertise and facilities exist; this approach is unlikely to alter the survival rate, but is associated with a longer disease free interval and possibly a better quality of life. Chemotherapy is also an option in case of recurrence after radiation.

Finally, radiation can be used to treat non-pelvic or distant metastases, e.g. in the bones, lung or other organs.

Management of invasive cancer in pregnancy
Diagnosis of invasive cervical cancer during pregnancy is rare but poses serious dilemma to the pregnant women and her family. Management should be individualized, taking into consideration her concerns and health and the impact on the outcome of the pregnancy.

The patient should be counseled on all available options and allowed to make an informed consent. As for non-pregnant women, management by surgery or by radiotherapy depends on the stage of the cancer. However, it also related to the gestational age of the pregnancy. Skilled counseling is necessary to assist the woman and her family to come to terms with the diagnosis and arrive at a decision about management.

In early pregnancy, radiotherapy is appropriate for management and should begin with pelvic irradiation to cause fetal death and abortion followed by uterine evacuation and brachytherapy. An ultrasound scan must be done to verify that the fetus is no longer viable.

In the third trimester, definitive treatment is usually delayed until the fetus is mature to survive outside the uterus, upon which the baby is delivered by classical Caesarean section followed immediately by surgery or radiation as determined by the stage of the cancer. For radiotherapy, it must be begin after involution of the uterus.

Management of Invasive Cervical Cancer in HIV positive women:
HIV positive women with CD4 counts <200/mm³ are at risk of complications irrespective of treatment methods. Where possible, surgery is preferable. Treatment with radiotherapy and chemotherapy should be tailored to the individual.
CHAPTER 3: BREAST CANCER

OVERVIEW

Breast cancer is the most common form of cancer in women worldwide. It is marked by geographical variation in incidence in different countries and regions. The incidence is highest in Europe and North America and lowest in Asia and Africa. These differences are attributed in part to diet and lifestyle, and in part to better reporting of cases. Breast cancer also affects men, though to a lesser extent. In the year 2000, there were 1,050,346 cases of breast cancer reported worldwide with 372,969 deaths. Most of these were in developed countries. It has also been observed that the disease is more aggressive in the black population than in Caucasians.

Breast cancer in Kenyan women occurs more commonly in younger women (aged 40 to 49 years) compared to the West where the peak prevalence is between 50 and 59 years. In addition, most patients in Kenya present at late stages of the disease. When screening and detection are regularly and correctly performed, and timely treatment is provided, breast cancer is associated with a good prognosis. Unfortunately when diagnosis is made late, breast cancer is associated with poor outcome.

One of the contributing factors to late presentation is lack of awareness about early detection of breast cancer. The community needs to be sensitised and educated on how to detect breast lumps early. The breast is quite accessible because of its anatomical location on the external surface of the chest. It is therefore easy to detect changes early through simple observation and manual breast examination.

These simple procedures that can be performed by individuals on their own breasts or by a health care provider at any level of health facility help pick up lumps when they are still small. Other advanced screening procedures such as mammography and fine needle aspiration and cytology (FNAC) are carried out in higher levels of health care.

RISK FACTORS

The specific cause of breast cancer is unknown. Most of the risk factors (approximately 90%) are thought to be modifiable and are mainly environmental and life-style related; while the rest (5% to 10%) are genetic. Women who inherit a mutated breast cancer gene (BRCA-gene) from either parent have 85%-90% chance of developing breast cancer. The major risk factors include:

- Female sex
- Age
- Family history of breast cancer
- Prolonged exposure to oestrogens
Other related factors include: hormone replacement therapy, ionizing radiation, high-fat diet, lack of physical exercise, obesity, alcohol and family history of other cancers such as ovarian, prostate, colorectal and endometrial.

The following health behaviours may reduce the risk of developing breast cancer:

- Prolonged lactation
- Regular physical activity
- Avoidance of obesity
- Avoidance of alcohol consumption
- Avoidance of excess exposure to radiation
- Avoidance of prolonged use of exogenous hormones

PATHOPHYSIOLOGY

In most cases, cancer of the breast arises from the epithelium lining the lactiferous ducts. When breast cancer spreads, it commonly occurs locally, invading the breast stroma through the lymphatic ducts to the lymph nodes in the armpit and neck, or through the blood stream to other parts of the body. The common sites of distant metastases include bone, liver, lungs and brain. This may result in the abnormal function of these organs and death. All lumps in the breast must be regarded as possible cancer until proved otherwise.

PREVENTION AND SCREENING

Primary prevention measures to prevent breast cancer include practicing a healthier lifestyle and avoidance of risk factors such as: high-fat diet, lack of physical exercise, obesity and alcohol consumption.

Secondary prevention includes early detection and treatment. Screening for early detection and appropriate treatment are the most effective way of avoiding advanced disease, since lesions treated in the early stages have a high cure rate. Screening for breast cancer involves breast self examination (BSE), clinical breast examination (CBE) and breast imaging (mammography and/or ultrasound scanning). All of these forms of screening aim to detect breast lesions in their early stages.

Breast Self Examination (BSE)

This is a simple, quick examination done by the client herself, that improves breast self-awareness and allows individuals who detect breast lumps early enough to present themselves to clinicians in good time for treatment when chance of complete cure is greater. Regular and correct technique of breast examination is important

Timing

BSE can be done at any time: - when lying down, when taking a shower or when bathing. Women should examine their breasts at least once every month. Since breasts change in shape and feel different at different stages of a menstrual cycle, BSE should be performed at the same time during each menstrual cycle. The best time is immediately after menses. For women on oral contraceptive pills, the
best day is the day they start a new packet. For those who have reached menopause, are on injectable progesterone-only contraceptive method or implants and for those with irregular menses, the examination should be done on the first day of each calendar month.

Men, too, should examine their breasts regularly, at least once every calendar month. The best time is the first day of each calendar month.

**Technique of BSE**

A variety of methods and patterns are used in breast self-exams.

1. Most methods suggest that the woman stand in front of a mirror with the torso exposed to view. She looks in the mirror for visual signs of dimpling, swelling, or redness on or near the breasts. This is usually repeated in several positions, such as while having hands on the hips, and then again with arms held overhead.

2. The woman then palpates her breasts with the pads of her fingers to feel for lumps (either superficial or deeper in tissue) or soreness. There are several common patterns, which are designed to ensure complete coverage. The vertical strip pattern involves moving the fingers up and down over the breast. The pie-wedge pattern starts at the nipple and moves outward. The circular pattern involves moving the fingers in concentric circles from the nipple outward. Some guidelines suggest mentally dividing the breast into four quadrants and checking each quadrant separately. The palpation process covers the entire breast, including the "axillary tail" of each breast that extends toward the axilla (armpit). This is usually done once while standing in front of the mirror and again while lying down.

3. Finally, women that are not breastfeeding gently squeeze each nipple to check for any discharge.

(A pictorial example of breast self-examination in six steps. Steps 1-3 involve inspection of the breast with the arms hanging next to the body, behind the head and in the side. Step 4 is palpation of the breast. Step 5 is palpation of the nipple. Step 6 is palpation of the breast while lying down)
Clinical Breast Examination (CBE)

CBE is performed by a trained and skilled health care provider. It can be done at any KEPH level; and includes taking a detailed history and conducting a physical examination. All breast quadrants must be examined in detail. During CBE, the provider inspects the skin for changes and swellings, for tethering of the breast on the chest wall, palpates for lumps, checks for nipple discharge and advises clients on the next steps.
A suspicious lump or bloody nipple discharge requires additional evaluation by mammography or ultrasonography as well as fine needle aspiration and cytology.

Timing:
Annual CBE should be provided by a skilled health care provider to individuals aged 40 years or more. Individuals who are younger than 40 years should have CBE every 2 years, beginning from the age of 18 years. Women presenting for breast cancer screening should be offered cervical cancer screening and vice versa.

Mammography
A mammogram is a low-dose x-ray of the breast. It is used for screening and diagnosis of breast cancer. Mammography is the test of choice for screening of early breast cancer when the lumps are not palpable by the patient or the doctor. However, although relatively fast and accurate, it is a highly-technological test that requires highly-trained personnel and elaborate equipment.

Breast Ultrasound
Ultrasound alone is not used as a screening test, but is useful as an additional tool in characterizing palpable tumours and taking of image-directed biopsies. In some instances, it has been used as a screening tool in lactating women, small-breasted women and in males.

DIAGNOSIS

Fine Needle Aspiration (FNA) and Cytology
Following detection of breast lumps or abnormalities from CBE and mammography, FNA of the abnormal area is performed. The specimen is taken for cytology to confirm or rule out breast cancer. If the results of clinical assessment, mammography, FNA and cytology are combined, the accuracy of diagnosis approaches 100%. The use of these three tools is referred to as a “triple test assessment.”

Histological Diagnosis
Larger breast specimens can be taken from suspicious lesions (excision biopsy) and evaluated histologically for malignancy as well as for their receptor status. About two-thirds of postmenopausal breast cancers are oestrogen receptor positive and progesterone receptor positive. Receptor status informs the treatment options (e.g. only oestrogen receptor positive tumours are sensitive to hormonal therapy).
Clinical Presentation of Breast Cancer

During early stages the following symptoms and signs may be present:
- A painless lump in the breast (in majority of patients)
- nipple retraction
- skin changes such as darkening and dimpling (appearance like the skin of an orange)
- nipple discharge that may be bloody

In late stages, common presentations include:
- ulceration
- enlarged lymph nodes in the armpit and neck
- uniform breast enlargement
- signs and symptoms of distant metastasis such as un-resolving cough, bone pains and pathological fractures

*Pain is usually a late symptom.*

*Note:* Breast cancer can also occur or be diagnosed in pregnancy.

Staging of Breast Cancer

Breast cancer is staged according to the Tumour-Node-Metastasis (TNM) system. Prognosis is closely linked to the results of staging. More importantly, the TNM staging system is used to decide the appropriate treatment method and regimen for the patients. This staging is based on clinical findings and results from imaging (e.g. chest x-ray, ultrasound and Computerised Tomography or CT scans).

The following is a summary of the stages of breast cancer using TNM system:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>Carcinoma in situ (CIS)</td>
</tr>
<tr>
<td>Stage I</td>
<td>Invasive breast cancer with tumour up to 2 cm, and no axillary lymph nodes involved</td>
</tr>
</tbody>
</table>
| Stage II | Invasive breast cancer with one of the following:  
- Tumour < 2 cm with spread to axillary lymph nodes;  
- No tumour in the breast but cancer cells in axillary lymph nodes;  
- Tumour 2 to 5 cm with spread to axillary lymph nodes; or  
- Tumour > 5 cm without spread to axillary lymph nodes |
| Stage III | Tumour has spread to axillary nodes which are clumped together, has spread locally to the chest wall or the skin of the breast or to infra and supra-clavicular nodes |
| Stage IV | Distant metastasis (M) |

*Note:* Histological staging or classification is used more as prognostic factor.
TREATMENT

Treatment modalities include surgery, adjuvant hormonal therapy, chemotherapy and/or radiotherapy. When done in the early stages of the disease, prognosis is very good in more than 90% of patients. Most of these patients are considered for breast reconstruction after treatment. Radiotherapy is often used for local disease control in the early stages. Treatment of late or advanced breast cancer is geared towards control of symptoms and prevention of progression. Details of treatment modalities including regimens and dosages may be found in standard oncology manuals/texts

**Surgery** is the mainstay treatment for breast cancer. The aim of surgery is to eradicate the primary tumour and any local extension in the hope of achieving total control of the disease. Surgical treatment of primary breast cancer has devolved into the following two basic procedures: 1) complete local excision (CLE) with axillary dissection, and 2) total mastectomy with axillary dissection.

This is followed by **radiotherapy and adjuvant hormonal** therapy. It is very important to determine if the tumour is oestrogen and/or progesterone receptor positive, and whether the client is pre- or postmenopausal, as this will determine the kind of hormonal treatment to be given. The addition of **chemotherapy** has an added advantage in terms of delaying tumour recurrence. Duration of treatment and adequate doses are key to remission of disease.

The type of surgery and treatment is determined by the physician and the patient after assessment and weighing pros and cons of each treatment taking into consideration the individual client’s choices and needs.

**Neo-adjuvant hormonal** and chemotherapy are given to clients with advanced cancer. In this case, it is given before surgery is done.

**Prognosis**

Early disease has excellent prognosis with 90% of patients being cancer free at five years and 80% at 10 years. Advanced breast cancer with distant metastasis, however, has poor prognosis, with less than a 30% five-year survival rate.
KEY MESSAGES

1. Cancer of the breast affects both men & women
2. It is more common in women
3. It is one of the most common cancers & very fatal if discovered late
4. It rarely occurs before 25 yrs of age but it is more common in clients 30 - 40s yrs of age with a peak at 40-50 yrs in our communities
5. Family history of ca breast is a strong etiological factor.
6. Early detection and prompt treatment of cancer saves lives
7. Early detection is by: Breast self examination (BSE) & clinical breast examination (CBE; followed by mammography & ultrasound
8. The main presenting symptom for breast cancer is a palpable mass/ lump
9. A definitive diagnosis is made through a simple outpatient procedure - Fine Needle Aspirate (FNA) and cytology
10. Treatment: Surgery is the mainstay of treatment & has excellent prognosis when done in early stages; Radiotherapy & chemotherapy are given for advanced disease
11. Adherence to treatment & follow up schedules is critical to prognosis
CHAPTER 4: PROSTATE CANCER

OVERVIEW

The prostate gland is a male reproductive gland located at the base of the bladder. Prostate cancer occurs when cells of the prostate gland multiply abnormally and in an uncontrolled manner. It mainly affects men 40 years and older. Some prostate cancers are fast growing while others are very slow growing and without symptoms. By the age of 70 years, 80% of men will have developed prostate cancer but a big proportion of these cancers will have gone undetected clinically due to their slow growth.\(^{35}\)

Prostate cancer is the most common cancer in men in Africa and the third cause of cancer deaths in men after age 55 worldwide. Rates of prostate cancer vary widely. For example, according to the American Cancer Society, it is more common among the black population. In the year 2000, the reported incidence of prostate cancer worldwide was 543,000 new cases, with 416,000 of these being in the developed countries\(^{20}\) where screening is regularly done. These figures are similar to those for cervical cancer.

According to the Nairobi cancer registry report, prostate cancer represented 73% of all cancers of the reproductive system in males between 2000 and 2002.\(^{3, 21}\) although these figures are low, they were reported by just a few hospitals in Nairobi, and the indication is that prostate cancer is much more common than these figures indicate.

Anatomy of the Prostate Gland

The prostate weighs only a few grams at birth. At puberty, it undergoes androgen mediated growth and reaches adult size by age 20. It remains stable in size for another 25 years, after which it starts the second growth phase that continues until the age of 90 years. This growth is termed prostatic hypertrophy, the most common cause of obstruction to urine outflow in men.

The prostate gland surrounds the proximal part of the urethra at the neck of the bladder. The ejaculatory ducts also traverse through the gland and open into the prostatic urethra. Posterior and adjacent to the prostate gland is the rectum. The prostate gland is well palpable during Digital Rectal Examination (DRE). The gland is small, conical in shape with the apex at the bottom. It has two lateral lobes with a furrow in between that is felt during DRE. The figure below illustrates the anatomical position of the prostate gland.

Histologically, the prostate gland is divided into three zones: the peripheral zone, internal zone and innermost zone. Cancer almost exclusively affects the peripheral zone, which is mainly glandular, while the internal zone is prone to benign hypertrophy. The internal zone is immediately next to the urethra. When benign hypertrophy occurs, urethral constriction may follow, resulting in urine flow obstruction. Urine obstruction in most cases is due to benign prostatic hypertrophy rather than to prostate cancer.
RISK FACTORS

The specific cause of prostate cancer is unknown. However, there is some evidence that several factors play an important role in its occurrence. These factors include:

- **Age:** This is the strongest risk factor for prostate cancer. The disease is rare before age 40, but the risk rises rapidly after age 50. About two out of three prostate cancers are found in men over the age of 65.37
- **Race:** The disease appears to be more common among blacks.
- **Diet:** Inadequate intake of micronutrients such as zinc, selenium and vitamin E has been shown to predispose to prostate cancer.
- **High testosterone levels:** The glandular tissue of the prostate responds to testosterone levels. Thus it has been postulated that onset of prostate cancer is related to high testosterone levels.
- **Infections:** Chronic prostatitis and frequent sexually transmitted illnesses are risk factors.
- **Family history:** The risk is higher for men with an affected brother than those with an affected father.
PATHOPHYSIOLOGY
Initially, the disease is localized but later spreads locally, through the lymphatics and via the bloodstream to organs such as the pelvic bone, lumbar vertebrae, rectum and other distant tissues such as the lungs and liver.

CLINICAL PRESENTATION
Early prostate cancer is usually asymptomatic. When symptoms occur, the patient may present with a decrease in the force of urine stream, intermittency, frequency, urgency, dysuria, pain on ejaculation, haematuria, dribbling of urine, difficulty in achieving an erection and finally distended bladder with urinary retention. These symptoms may also occur in other urinary system conditions; therefore thorough investigation prior to diagnosis is imperative.

In advanced prostate cancer, the patient may present with backache or bone pains, fractures, paralysis, abdominal swellings and general ill health. Presence of scrotal and lower extremity lymphoedema indicates that the disease is advanced and extensive.

PREVENTION
Measures to prevent prostate cancer include creating and increasing awareness of prostate cancer among the general population, educating them on the risk factors and encouraging them to improve their diet with reference to micronutrients and vitamins.
Locally available foodstuffs that contain micronutrients that protect against prostate cancer include green leafy vegetables, tomatoes, pumpkins and water melons, particularly the seeds. Clients should be encouraged to eat them routinely. In addition, there are screening methods described below that can detect early cases when they are still curable.

Screening and Detection Methods of Prostate Cancer
Prostatic cancer screening options include:

- **Digital Rectal Examination (DRE):** Prostate cancer is screened for and is usually detected through routine DRE. With the patient lying on their left side in knee chest position, the doctor or nurse inserts a lubricated, gloved finger into the rectum and firmly presses against the prostate gland. Pressing on the prostate gland does not hurt, although it may make one feel like urinating. A healthy prostate gland should feel soft, smooth and even. The presence of abnormal lumps or hard irregular areas, on the prostate indicates pathology, e.g. prostate cancer. Tenderness of the prostate may indicate prostatitis. Note that tumors which are small and located only within the prostate are often not detected during a DRE.
- **Prostate Specific Antigen (PSA):** PSA is an enzyme produced by the prostate gland and facilitates sperm motility. Since this enzyme is produced in large amounts when there is inflammation and in cases of prostate cancer, it is an important tumour marker for prostate cancer. Normal levels of PSA are up to 4ng/ml; levels higher than 4ng/ml indicate over secretion of the enzyme due to a prostatic pathology.
- **Trans-rectal Ultra-sonography (TRUS):** TRUS involves scanning the prostate gland through ultrasound and creating a picture of the gland using sound waves. Ultra-sonography is most
useful for directing taking of needle biopsy and ensuring uniform sampling of the prostate lesions. It also helps to document degree of spread to the bladder and the seminal vesicles if any.

The combined use of DRE, PSA and TRUS enhances the sensitivity and hence early detection of prostate cancer.

**DIAGNOSIS**

**Tru-cut biopsy**, which is used for diagnosis, is the removal of a small piece of prostate for microscopic examination. It is used in combination with TRUS. Biopsy is essential for establishing a definitive diagnosis.

**Investigations for Staging**

The following additional investigations are done as part of staging:

- **X-rays**: X-rays of the pelvic, lumbar and sacral areas.
- **Cystoscopy**: Cystoscopy entails viewing the prostate gland from inside the bladder using a small camera inserted down the bladder. It helps in detecting if the cancer has spread to the bladder. This method can be done at Level V of health care and above.
- **Magnetic Resonance Imaging and CT scan**: Magnetic Resonance Imaging (MRI) and CT scan can also be used to define the extent of the tumour. These are available in tertiary health care levels.

The figure below illustrates some of the diagnostic steps in prostate cancer. To make a confirmatory diagnosis, biopsy and histology report are mandatory.

**Diagnostic steps of prostate cancer** *(Source: Harrison’s Principles of Internal Medicine. 14th Edition).*

From 45 years – annual DRE and PSA determination

- **Negative DRE**
  - PSA ≤ 4 ng/ml
  - Annual follow-up

- **Positive DRE**
  - Any PSA levels
  - If normal

- **PSA > 10 ng/ml**
  - Negative DRE
  - PSA 4.1–10 ng/ml
  - TRUS Biopsy

- **Negative DRE**
  - PSA 4.1–10 ng/ml
  - TRUS Biopsy or Biopsy if TRUS is abnormal or PSA refinement to determine need for biopsy

- **If abnormal**
  - TRUS Biopsy

- **Treatment**
Staging of Prostate Cancer

To help guide treatment and offer information about chance of cure, prostate cancer is divided into four different stages. This staging is done in a limited fashion before surgery is performed. It takes into account the clinical findings on DRE and the results of any imaging tests. These stages are:

<table>
<thead>
<tr>
<th>Stage 1</th>
<th>Tumour cannot be felt during a DRE; it was detected by an elevated PSA blood test or found incidentally during another prostate procedure for a benign condition.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1I</td>
<td>Tumour can be felt during a DRE, but it has not spread beyond the prostate, or to lymph nodes or other organs.</td>
</tr>
<tr>
<td>Stage 1II</td>
<td>Tumour extends outside the prostate and can be in the seminal vesicles, but has no distant metastasis.</td>
</tr>
<tr>
<td>Stage 1IV</td>
<td>Tumour has spread to other organs or lymph nodes.</td>
</tr>
</tbody>
</table>

Another method of staging is the TNM system of staging. In the TNM system, the most important distinction is whether or not the cancer is confined to the prostate. Clinical stage T1 and T2 cancers are usually confined to the prostate, while T3 and T4 have spread elsewhere.

TREATMENT

The choice of treatment is determined by several factors such as stage of the disease, the Gleason score and the PSA level. Other important factors are the man’s age, his general health and his feelings about potential treatments and their possible side effects. Because all treatments can have significant side effects, such as erectile dysfunction and urinary incontinence, treatment discussions often focus on balancing the goals of therapy with the risks of lifestyle alterations.

Treatment modalities include surgery, radiotherapy, chemotherapy and/or hormonal therapy.

Surgery: Surgery is a common form of treatment for prostate cancer. It attempts to remove all of the prostate cancer from the body especially in early stages of the disease. However, surgery is also done to relieve symptoms in advanced stage.

Radiation: Prostate cancer is commonly treated with radiation therapy during the early stages of the disease and is preferred in those clients who are too ill or too old and may not withstand anaesthesia. It has fewer side effects than surgery.

Hormonal: Both normal tissue and cancer tissue of the prostate gland depend on male sex hormones (androgens) to grow and replicate. Therefore one of the ways of treating prostate cancer is to remove the androgens from the body. This makes cancer shrink or grow very slowly. This is the preferred and the most common method of treatment. There are different ways of removing androgens, such as using anti-oestrogens, LHRH agonists or removing the testicles or orchidectomy. Hormonal therapy is also ideal for metastatic disease.
**Chemotherapy:** Chemotherapy is reserved for very advanced cancers that are no longer responsive to hormonal therapy. Docetaxel and prednisone are given to patients with metastatic disease (usually for a minimum of six cycles).

**Watchful waiting:** Watchful waiting is an option for clients whose cancer is slow growing and who desire to avoid side effects that come with surgery, radiotherapy or hormonal therapy. It is appropriate for older men with low-grade tumour, slowly rising PSAs and other medical problems.

Options for management of advanced disease (Stages III and IV) include:

- Radiotherapy with or without initial (neo-adjuvant) or adjuvant androgen deprivation. The latter may mean orchidectomy.
- Hormonal treatment alone. Administration of Luteinising Hormone Releasing Hormone (LHRH) agonists (buserelin, goserelin or leuprolide) or anti-androgens such as flutamide.
- Chemotherapy, commonly docetaxel and prednisone.
- Hormonal treatment with combination of surgery or radiotherapy.
- Watch-and-wait active surveillance.

**Prognosis**

Early detection and radical treatment have a good prognosis although some patients may develop complications related to treatment. Advanced prostate cancer with distant metastasis has a poor prognosis.

**KEY MESSAGES:**

1. Cancer of the prostate is a common problem among men over 40 yrs of age
2. The risk rises rapidly in men over 50 years of age
3. In early stages prostate cancer is usually asymptomatic
4. When symptoms occur, this usually indicates advanced disease
5. Screening, early diagnosis & early initiation of treatment are very important
6. Early detection is through:
   - Routine digital rectal examination (DRE)
   - Estimating prostatic specific antigen (PSA) in blood
7. If managed while in early stage, the prognosis/outcome is usually good.
8. Late diagnosis is associated with poor prognosis
9. Treatment includes surgery, hormonal therapy & chemotherapy
PART TWO

CROSS-CUTTING PROGRAM CONSIDERATIONS
CHAPTER 5: HEALTH PROMOTION FOR CANCER PREVENTION

Cancers of the cervix, breast and prostate are the most common reproductive organ cancers in Kenya. The prevalence and incidence of these diseases can be reduced through primary prevention, early detection and early treatment. A clearly laid out community mobilization plan is important. To reach as many people as possible, the general community must be targeted and educated on the importance of prevention, early diagnosis and treatment. They must be made aware that when diagnosed and treated early, these cancers are treatable and clients can continue leading normal and productive lives. For an effective cancer control program, there is a need to screen at least 75% of eligible clients. Screening should be linked to appropriate treatment of detected precancerous and cancerous lesions.

The MOH recommends that information and education strategies should be directed towards persons who have never been screened before, and towards their partners and family members who can encourage them to solicit screening and comply with follow-up instructions. Health care providers should pass on clear and consistent messages in a language that is understood by audience.

The following three basic types of informational and educational strategies are recommended:

- Facility-based: One-on-one and/or group education to inform patients who are attending health facilities
- Community-based (outreach): One-on-one and/or group education to inform people in the home and community settings
- Media-based: Using radio, television and print media to convey messages to a larger and more dispersed audience

To increase awareness of cancer prevention the following advocacy strategies are recommended:

- Conduct advocacy meetings at different levels, such as women groups, policymakers, politicians, development partners, religious leaders and community champions.
- Promote advocacy campaigns at national, regional, district, village and community levels.

HEALTH PROMOTION MESSAGES

The following are key evidence-based messages that can be used to promote cancer prevention.

An effective cervical cancer prevention health educator and advocate should:

- Have accurate, up-to-date knowledge about cancer.
- Possess good communication skills.
- Provide consistent messages about cancer, tailored to the educational and cultural background of the audience.
- Be comfortable and non-judgmental when talking about sexuality and behavior that increases the risk of HPV infection.
- Be comfortable explaining how to use male and female condoms.
- Provide messages that are in line with national policy and appropriate to the local situation.
Key cervical cancer prevention messages for adolescents, women and men:

Key take home messages are in Bold

- Cancer of the cervix is the second most common cause of cancer-related death in women worldwide, and is the second most common cancer amongst women in Kenya
- Cervical cancer is the leading cause of cancer deaths in women in their 40s, 50s and 60s in developing countries.
- **Cervical cancer is preventable—a healthy lifestyle, screening of women 25 years of age and older, and vaccination of young girls are key prevention measures.**
- Cervical cancer is caused by infection with HPV, a very common STI. This infection frequently occurs in young men and women.
- HPV has been demonstrated to be the cause of more than 99% of cases of cervical cancer and is involved in other cancers and diseases.
- Most HPV infections have no signs or symptoms. Most infected people are unaware that they are infected; yet, they can transmit the virus to a sex partner.
- Condom use offers partial protection from HPV and may lower the risk of developing HPV related diseases, such as genital warts and cervical cancer.
- HPV vaccine offers protection against the types of HPV that cause the majority of cervical cancers worldwide. If the vaccine is administered to girls before sexual debut, it is expected to prevent up to 70% of cervical cancer cases in this group.
- Most HPV infections do not persist and do not cause cancer. The few HPV infections that do persist may lead to precancerous lesions; if not diagnosed and treated early, these precancerous lesions may progress to cancer.
- It usually takes 10-15 years for HPV infection to cause precancerous lesions and years longer for these lesions to progress to cancer.
- **Screening can detect precancerous lesions. Most abnormal conditions found during screening can be treated. Early detection and immediate treatment can save lives.**
- Women aged 30 years and older are more likely than younger women to have cervical precancerous lesions. Women should be screened every three years from age 30. All women should have screening at least once in a lifetime after age 35.
In the designing key messages for cervical cancer prevention and control, different areas of focus will apply depending on the target populations. These are highlighted below:

<table>
<thead>
<tr>
<th>TARGET GROUP</th>
<th>AREAS OF FOCUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Makers/</td>
<td>Highlight cervical cancer as: a human rights and development issue and a Public health concern,</td>
</tr>
<tr>
<td>governors / senator</td>
<td>Highlight the Cost effectiveness of prevention as opposed to treatment</td>
</tr>
<tr>
<td></td>
<td>Model cost savings of vaccination/ screening vs treatment</td>
</tr>
<tr>
<td></td>
<td>Develop Champions to pass messages to populace</td>
</tr>
<tr>
<td>Parliamentarians</td>
<td>Lobby for Legislation of appropriate policies</td>
</tr>
<tr>
<td></td>
<td>Link Cervical cancer prevention and control to constitutional rights</td>
</tr>
<tr>
<td></td>
<td>Garner their support in increasing Budget for cervical cancer</td>
</tr>
<tr>
<td></td>
<td>Link impact of cervical cancer programme to persons that directly impact on them e.g. their mother, child, sister, voter</td>
</tr>
<tr>
<td></td>
<td>Link cervical cancer programme to popularity and voter base</td>
</tr>
<tr>
<td>Men</td>
<td>Refer to MOH outreach guide page 9</td>
</tr>
<tr>
<td></td>
<td>Consider “value-benefit messages especially cost savings and economic benefits</td>
</tr>
<tr>
<td></td>
<td>Promote benefits of primary prevention e.g. Abstinence/ postponement of sexual debut, Condoms and Male Circumcision, Vaccines,</td>
</tr>
<tr>
<td></td>
<td>Pass messages that Promote a healthy lifestyle and reduction of risk behaviour for acquisition of HPV e.g. smoking, multiple partners</td>
</tr>
<tr>
<td></td>
<td>Create awareness on signs and symptoms of cervical cancer e.g. post coital bleeding</td>
</tr>
<tr>
<td>Women</td>
<td>Pass messages on promotion of healthy lifestyle and reduction of high risk behaviour</td>
</tr>
<tr>
<td></td>
<td>Promote benefits of primary prevention</td>
</tr>
<tr>
<td></td>
<td>Create awareness on the Signs and symptoms (emphasise that lack of symptoms does not rule out cervical cancer)</td>
</tr>
<tr>
<td></td>
<td>Key messages should emphasize that “Early detection can lead to cure and prevent progression to cancer”</td>
</tr>
<tr>
<td></td>
<td>Pass information on Sexuality and sexual health</td>
</tr>
<tr>
<td></td>
<td>Include messages on: Where to get the services (which/ where/ when/ cost)</td>
</tr>
<tr>
<td>Teachers, Matrons and</td>
<td>Focus on primary prevention and avoidance of risk factors</td>
</tr>
<tr>
<td>Masters; PTAs, BOGs</td>
<td>Messages on Sexuality and sexual health</td>
</tr>
<tr>
<td></td>
<td>Information on services and availability Services</td>
</tr>
<tr>
<td>School children /</td>
<td>Basic focus on Life Saving Skills -LSS</td>
</tr>
<tr>
<td>youth</td>
<td>Messages on primary prevention especially postponement of sexual debut, avoid early marriage, avoid high risk sexual behaviour and Vaccines</td>
</tr>
<tr>
<td></td>
<td>Utilise Child-to-parent messaging to promote screening</td>
</tr>
<tr>
<td></td>
<td>Messages on promoting a healthy lifestyle e.g. avoid Substance abuse</td>
</tr>
<tr>
<td></td>
<td>Information on sexuality and sexual health</td>
</tr>
<tr>
<td></td>
<td>Address myths and misconceptions</td>
</tr>
<tr>
<td>Religious leaders</td>
<td>Use entry point for promotion healthy lifestyles and life saving skills</td>
</tr>
<tr>
<td></td>
<td>Promote primary prevention and avoidance of high risk behaviour including substance abuse</td>
</tr>
<tr>
<td></td>
<td>Use platform to dispel myths and misconceptions on CECAP</td>
</tr>
<tr>
<td></td>
<td>Pass information on Sexuality and sexual health</td>
</tr>
<tr>
<td></td>
<td>Pass information on services (which/ where/ when /cost)</td>
</tr>
<tr>
<td>CSOs</td>
<td>Use their platforms for: Advocacy for resources, lobbying for standards, lobbying for</td>
</tr>
<tr>
<td><strong>Corporate world</strong>&lt;br&gt;<strong>Insurance companies</strong></td>
<td>Present CECAP as a Public health concern, and a development issue,&lt;br&gt;Invoke corporate social responsibility&lt;br&gt;Resource mobilisation&lt;br&gt;Lobby HMOs to provide insurance cover for cancers</td>
</tr>
<tr>
<td><strong>Celebrities</strong></td>
<td>Recruit and Develop them as Champions</td>
</tr>
<tr>
<td><strong>Community leaders</strong></td>
<td>Same as for religious leaders,&lt;br&gt;Elicit support to identify community role models/ champions</td>
</tr>
<tr>
<td><strong>Affected women and families</strong></td>
<td>Information on services (Which / when /where / cost of services / treatment options/&lt;br&gt;post treatment care &amp;palliative care )&lt;br&gt;Information on support services (nutrition, healthy living etc)&lt;br&gt;Information on family support and psychosocial support groups</td>
</tr>
</tbody>
</table>
CHAPTER 6: COMMUNITY MOBILIZATION

A clearly laid out community mobilization plan is key to creating and sustaining demand for screening and early management of RT cancers. Strategies used must also be cost-effective and include key stakeholders. Community mobilization activities should reach the highest peak during the cancer screening awareness month when publicity is at its maximum. Different stakeholders have specific roles in community mobilisation. In Kenya, Community mobilization for cancer prevention and control will be mainstreamed within the community strategy.

ROLE OF COMMUNITY LEADERS AND COMMUNITY HEALTH WORKERS

Many settings have used community leaders and community health workers to mobilize and disseminate health messages. In Kenya, the community strategy recognizes community leaders and community health workers as an essential part of the community, who should play a key role in promoting acceptability of cancer prevention services. It is important to provide them with the correct information about cancer prevention programs. The roles of community health workers and leaders will include:

- Advocating for and providing information about cancer prevention services.
- Identifying the persons eligible for screening in a given coverage area
- Encouraging eligible persons to seek for cancer prevention services.

The use of cancer survivors (persons who have been successfully treated for cancer) in education and advocacy for cancer prevention should also be considered. This is because they have first-hand knowledge of the importance of early detection, and can provide powerful messages based on their experience.

ROLE OF HEALTH FACILITIES

Health facilities are responsible for the implementation and design of appropriate communication and advocacy strategies to increase the utilization of cancer prevention services. A good communication strategy at this level requires the following:

1. Well-trained staff to provide education and counseling to clients.
   a. Health workers need clarity on the “silent nature” of cervical, breast and prostate cancers—the fact that symptoms are not present until the cancer is at an advanced stage.
   b. Health care workers should help patients understand the enormous advantages offered by the various cancer prevention services, as well as their limitations.
2. Appropriate key informational and educational messages for clients.
   a. The cervical, breast and prostate cancer prevention information guide should be tailored to specific key audiences.
   b. Educational materials that are culturally appropriate, and contain consistent and accurate information should be disseminated.
3. Identified settings for delivery of information.
The MOH recommends integration of cervical and breast cancer prevention services in the following settings: MCH/FP clinics, gynecology clinics, outpatient clinics, and comprehensive care clinics (CCCs). Mobile/outreach clinics are also encouraged to provide screening and treatment services. Health providers should integrate the promotion and prevention messages into health education talks in these service areas.

**Channels of Communication**

Every opportunity should be taken to create awareness. These messages should also be incorporated in the teaching curriculum and school health programs. Depending on the target group, age, education status, residence, cultural norms and practices - etc, different communication channels can be explored. They include:

- Chief’s barazas, Community dialogue days, religious and cultural meetings, at market places, cinema halls, social gathering points, football matches and smoking zones (since smoking is one of the risk factors)
- Electronic media, print media, ICT e.g. M4RH, internet, etc
- Pamphlets, Brochures, murals, fliers, Posters, banners, billboards, caravan, Road shows, T-shirts, ‘Khangas’/ ‘Lessos’, caps, car stickers, Chalk Board and other modalities that are used in awareness campaigns - culturally acceptable
- Referral directories
- Use of artists, comedians and celebrities / community theatre

International / National health days, Cancer month, Integrated outreaches etc

**COUNSELLING:**

Counseling before, during and after all services, using appropriate tools and in a language the client understands is considered a basic standard of care. Men should be encouraged to take part in the counseling.

Clients being screened for cancers of the reproductive organs need accurate information about the disease, the tests and the treatment procedures. They also need counseling to help them make informed decision about what to do in case of a positive or negative result. In addition, clients should know that a test may detect cancer at a stage where curative treatment cannot be offered. It should also be communicated that in some cancers, some tests can fail to detect early tumours.

Health care providers therefore need to deliver appropriate counselling to clients at the following three stages: pre-screening, post-screening and follow-up.

**PRE-SCREENING INFORMATION**

Pre-test counselling will minimize delays in initiating treatment and/or referral where needed. The information to be provided includes:

- Accurate information about the disease, the tests, process of arriving at a diagnosis and

<table>
<thead>
<tr>
<th>Pre-screening Information for Clients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervical Cancer:</strong> Information on VIA, VILI and Pap smear tests, and treatment information for precancerous lesions.</td>
</tr>
<tr>
<td><strong>Breast Cancer:</strong> Information and demonstration on BSE, CBE, imaging (mammogram and ultrasound) and FNA.</td>
</tr>
<tr>
<td><strong>Prostate Cancer:</strong> Information on DRE and PSA.</td>
</tr>
</tbody>
</table>
the treatment procedures for each disease (See text box.)

- Availability and accessibility of the tests and the types of treatment available for precancerous and cancerous lesions
- Side effects associated with treatment procedures
- Importance of adherence to treatment and follow-up
- Anticipated time lines for receiving the results of the tests they undergo, i.e., which results are available and when
- Complications associated in case of delayed diagnosis or management of overt cancers

Health care providers need to build confidence and honest relationships with the clients they counsel. They should therefore know and be able to use basic counselling techniques.

In addition to being made available through counselling, this information should be made available in the form of leaflets, pamphlets and brochures in the clinic. This is particularly important when patients are considering multiple treatment options.

POST-SCREENING INFORMATION
When test results are available, they are disclosed to the client clearly and as soon as possible. Health care providers use counselling skills to deliver the following post-screening information as appropriate in a supportive, confidential and nonjudgmental manner:

- specific diagnosis, including the extent of the disease
- treatment options (including benefits, side effects, cost and time frame for treatment)
- consent for the treatment and need for referral to a higher treatment centre
- a detailed follow-up schedule and tests that will need to be done

FOLLOW-UP
All clients who have been screened for cancer, irrespective of the stage, will require follow-up. Various factors can contribute to non compliance to follow up. These should be probed for and addressed during the counselling session.

Special effort should be made to ensure that clients referred for treatment present themselves at the referral points and receive the recommended treatment. To ensure this, the screening site should maintain a record of the contact of the screened patient in its database and whenever a client has a positive lesion the contact of the next of kin. Furthermore contact and rapport between the referring /management centres, and the client /family should be maintained. Every individual client’s needs should be addressed appropriately.

Follow-up includes relevant tests, counselling, support, and assessment and management of any complications. Close follow-up in clients with the early stage of the disease is important so that in cases of recurrence or complications, additional treatment can be offered. Palliative care is also an important aspect of follow-up and is discussed in the appendices.
A feedback mechanism should be established and implemented. For clients who are found to be out of danger after the recommended duration of follow-up, routine screening is recommended.

Family members need to be involved in the counselling sessions so that they are able to offer support and avail resources for the care of the patient. They will also be the ones to ensure that the patients attend clinics and ensure adherence to follow up
Some misconceptions and facts about cervical cancer

While interacting with clients, one will come across many myths and misconceptions about cervical cancer screening. These will vary by population and set up. A selection relating to cervical cancer is outlined below countered by the corresponding facts

<table>
<thead>
<tr>
<th>Myth / Misconception</th>
<th>Fact</th>
</tr>
</thead>
<tbody>
<tr>
<td>In screening, part of your body is removed</td>
<td>Cervical cancer screening using VIA/ VILI does not involve removal of any part of your body. Pap smear involves gentle collection of cells from the cervix. No pieces of tissue are removed</td>
</tr>
<tr>
<td>Cervical cancer screening is painful</td>
<td>Cervical cancer screening is painless. There may be mild discomfort during insertion of the speculum if the woman is tense</td>
</tr>
<tr>
<td>Cervical cancer screening is a disguise for HIV testing</td>
<td>The two tests are very different. However patients presenting for cervical cancer screening are advised to also have HIV testing as this informs the follow up schedule</td>
</tr>
<tr>
<td>Screening is like a vaccine; once you have it you cannot get cancer</td>
<td>Screening does not protect one against cervical cancer. It enables the early diagnosis and treatment of pre cancer thereby preventing the development of overt cancer</td>
</tr>
<tr>
<td>There is no point in going for cervical cancer screening since it only tells a woman that she has a fatal condition and nothing can be done about it</td>
<td>Screening can detect precancerous lesions which can be treated as an outpatient. Screening also enables early detection of cancer which can then be treated</td>
</tr>
<tr>
<td>Cervical cancer is seen in women with poor hygiene practices</td>
<td>There is no evidence linking cervical cancer to hygiene</td>
</tr>
<tr>
<td>Use of modern Family planning methods causes cervical cancer</td>
<td>Cervical cancer is caused by an infection with Human Papillomavirus. Smoking and having multiple sexual partners increases the risk of getting the virus</td>
</tr>
<tr>
<td>Supplements can be used to treat cervical cancer</td>
<td>Supplements are not used for treatment of cancer or pre-cancer. One must have surgery or radiotherapy depending on the stage of cancer</td>
</tr>
<tr>
<td>Use of tampons and herbs can cause cancer of the cervix</td>
<td>Tampons and herbs have not been associated with development of cancer of the cervix</td>
</tr>
<tr>
<td>The same instruments are used for different women during cervical cancer screening and this is not safe</td>
<td>This practice is never done during screening. If available one may use disposable speculum which are discarded after a single use. In case these are not available, the re useable speculums are subjected to stringent infection prevention protocol and sterilisation before being reused</td>
</tr>
</tbody>
</table>

More myths and misconceptions exist in different parts of the world. The health worker should always explore the myths and misconceptions and address them before they affect adversely the implementation of the screening programme
CHAPTER 7: ESTABLISHING AN EFFECTIVE NETWORK

In order for screening and prevention to have an impact on the incidence of cancers of the reproductive organs, there is a need to effectively screen as many people as possible. It is therefore recommended that 75% of the targeted population be reached and screened within the screening cycle. The screening program must also be linked to treatment of the detected lesions. An effective network is vital to ensure that health care providers at all levels work in a concerted manner providing standardised health care services. Regions/ counties need to have a readily available referral directory so that health workers and the community know where and when to refer patients and which treatments are available and accessible to them.

NETWORKING AND COLLABORATION

Inter-professional networking through scientific meetings such as tumour boards will enhance networking, bring out implementation problems and seek solutions. Such interactions should be extended to professional association meetings of various cadres of health care providers such as clinical officers (COs), nursing officers, doctors, physiotherapists, radiotherapists, community health workers and community health extension workers, among others. Facilities need to be linked in order to minimize delays and strengthen linkages. The MOH will also reinforce continuous communication with training institutions.

The private sector involvement needs to be increased through capacity building, standardisation, quality assurance and ensuring that screening is covered under health insurance, just to name a few. Inter-sectoral collaboration will reduce the incidence of cancers and increase the uptake of services. Some examples of other sectors that influence the health seeking behaviour and accessibility to health services include Ministry of Education, Agriculture, Finance, Public works, Roads, Gender, Culture and Social services, Information and Technology etc. Their role in cancer prevention and control needs to be emphasized in multisectoral forums and strategic priority actions for cancer control be implemented per sector.

Partnerships, collaboration and formation of networks are also encouraged through conferences /workshops, medical camps, publications, newsletters, Web sites/Internet and outreach services. All levels of the health care system have important roles to play within a functioning network for screening, prevention and control of cancers of the reproductive organs. In addition, at all levels program managers, health care providers and beneficiaries need to contribute to advocacy efforts to ensure the long-term success and sustainability of the program.
CHAPTER 8: QUALITY IMPROVEMENT, MONITORING AND EVALUATION, ADVOCACY AND RESOURCE MOBILIZATION

Every health facility that conducts screening for cancers of the reproductive organs should be actively involved in quality improvement, and monitoring and evaluation of the screening program. Cancer prevention and control needs resources- monetary, human, supplies and equipment. Since the cancers of the reproductive organs are generally silent especially in pre-cancer stage, advocacy for allocation of necessary resources must be actively conducted to ensure implementation of prevention programmes.

QUALITY IMPROVEMENT

To ensure high quality and standardisation of cancer services across the country, there is a need for development of standards for cancer prevention and control. Thereafter intensive training of service providers on the importance and benefits of standards and quality improvement efforts must be undertaken. As new approaches are adapted regular updates/continuing education will be key. Skill-based training is conducted by trainers developed at national and provincial levels who then cascade the training to the districts and health facilities. Note that for example - the specificity of VIA/VILI improves with practice. A support supervisor needs to be well versed with the relevant skills. Mentors are best utilized for on-the-job training. It is recommended that providers conduct at least 10 VIAs per week to maintain quality.

Establishing and strengthening institutional quality improvement teams is required at all levels. Quality improvement committees or teams facilitate the quality improvement activities which include setting standards and targets, assessing compliance and providing the means to measure performance at the individual health facilities. Minimum standards that are the same across board are monitored and regulated by a national-level team. To motivate staff and institutions, and ensure standards are maintained, a system of recognition such as issuing of certificates or rewarding in some way the health facility and staff will be put in place and go hand-in-hand with support supervision.

Continuous education and professional development support the quality improvement efforts described above. They can be ensured through:

- Institutionalisation of the Reproductive Tract Cancer Guidelines in pre-service and in-service training
- Regular updates to service providers including: workshops, short courses, support supervision, on-the-job training/ mentorship and continuing medical education
- Operational research and other research
MONITORING AND EVALUATION

An effective Health Information System (HIS) is an essential tool for tracking clients and monitoring the cervical cancer programme performance. The monitoring and evaluation system will be guided by:

- Clearly-defined valid and measurable indicators;
- Standard data collection tools and methodologies;
- Clear procedures for filling out the forms; and
- Clear guidelines and protocols for data management including validity and consistency checks.

The National Cervical Cancer Prevention Program will have standardized national forms that have been approved by the MOH and are linked to the current HMIS system. The Cervical Cancer Prevention and Control Program monitoring and evaluation protocol will follow the existing integrated HMIS in Kenya, which is operational from the facility to the central level. At the facility level, it is paper-based (registers and client cards) and is computerized at district, regional and national levels.

Basic tools for data collection at all levels include:

- **Client’s Card:** The client card is completed with the client’s name and identification number with the regional and the centre code. The service delivery point (SDP) number can be used as the centre code. Other details to be included are: date tested, test results, management given, referral information as appropriate and follow-up.

- **The Cervical Cancer screening form:** This will capture detailed information on all clients screened. It will be retained in the facility for quality assurance and will be used in filling out of the register. In case of VIA or VILI it will have the map to show schematically the kind of lesion seen, the position and the coverage of the cervix. The screening form will be signed by the clinician conducting the procedure.

- **Health Facility Register:** The health facility register includes the date, name of the client, identification number with all the codes, age, telephone number, test and test result, treatment given and the date, referral to higher centre and HIV status of client if known. The register will be completed daily based on information from the screening map. The Health Management Information System (HMIS) staff will disaggregate cancer information at district level.

- **Reporting Tool:** This will capture summary information from the service delivery points registers that will be forwarded to the DRH and HMIS on monthly basis to inform policy and decision making.

- **National Cancer Register:** This office will be located at the MOH headquarters.

Information on breast and prostate cancer screening will be captured in the routing data capturing tools in the designated service areas. E.G. the revised family panning first and revisit cards have provision for capturing data on screening of breast and prostate cancers.
ADVOCACY AND RESOURCE MOBILIZATION

Advocacy to policy makers, development partners and all other stakeholders on the magnitude, impact, cost-effectiveness of prevention and early management of cancers of the reproductive organs is paramount to the success and sustainability of the program. This advocacy is essential for maintaining of RT cancer prevention and control as a priority area in the country’s health and development agenda, resource mobilization (to include- human resources, finances, commodities and supplies etc), and demand creation at all levels.

In addition, there is an integral need to identify and strengthen community mobilization systems with necessary information and other supportive resources for cancers of the reproductive organs.
CHAPTER 9: PALLIATIVE CARE FOR CANCER PATIENTS

INTRODUCTION
Active, supportive care of cancer patients from the time of diagnosis until the end of life is a realistic, humane approach to their management. Support that aims at improving “quality of life” of cancer patients will be necessary until totally effective measures of prevention, early diagnosis, curative treatment, sufficient health facilities and trained health care workers are universally available.

Quality of Life
Enhancing of quality of life in a patient with cancer involves the reduction of suffering (the feeling of “ill-being”) and an increase in positive feeling and happiness (“well-being”). It is not the length of survival as is frequently misunderstood.

Nature of Pain
Most cancer patients experience complex pain in the course of their illness, as depicted in Figure D-1. It is important to remember that every cancer patient has a right to access pain therapy.

Figure D-1: Factors that influence patients’ perception of pain

Adapted from: Cancer Pain Relief and Palliative Care; Report of WHO Expert Committee. 1990.

The complex nature of cancer pain means that some patients will continue to experience intolerable pain even when given increasing amounts of analgesic medication. Often, unrelieved severe pain is associated with other symptoms like disturbed sleep, reduced appetite, impaired concentration, irritability and
depression. Freedom from pain is central to comprehensive palliative care which encompasses the physical, psychological, social and spiritual aspects of suffering.

**PALLIATIVE CARE**
Palliative care is the active total care that improves the quality of life of patients and their families facing problems associated with life limiting illness. The goal is to achieve the best possible quality of life for patients and their families through control of pain, other physical symptoms and by addressing psychological, social and spiritual problems. It:

- affirms life and regards dying as a normal process
- neither hastens nor postpones death
- provides relief from pain and other distressing symptoms
- integrates the psychological and spiritual aspects of patient care
- offers a support system to help patients live as actively as possible until death
- helps families cope during patient illnesses and during their own bereavement

The “unit of care” is the family and thus family members should be encouraged to ask questions about the illness and to participate actively in the care of the patient.

Health care providers should understand how cancers of the cervix, breast and prostate develop and attack the body and, besides being familiar with the screening, diagnostic tests and treatment regimens, including their limitations, as these issues are likely to come up in discussions with clients and their families in the course of care.

**Teamwork Approach**
Palliative care requires a multi-disciplinary team approach, and all health care workers and caregivers have roles to play. Confidentiality remains paramount and sensitive personal information should not be shared outside the team unless there are compelling reasons for doing so, or the patient gives specific permission for information to be passed on.

**Nurses as Front Runners**
Nurses assume a central role in palliative care and are well placed to provide information, counselling and education to patients and their families, besides facilitating continuity of care between home and hospital. They monitor and evaluate pain and symptom control; hence they must have the authority to adjust drug doses within prescribed ranges to meet the needs of patients at any given time.

**ORGANISATION OF PALLIATIVE CARE**

**Public Education**
The primary setting for palliative care is at home and in the community, with institutions merely backing up. The main burden thus falls on the family and the community, with care givers needing support, guidance and reassurance in their effort to keep the sick as comfortable as possible. Everyone needs to
be aware that care is there and proper palliative care will improve the quality of life. However, proper pain and symptom control requires expertise and does not result in psychological dependency.

**Tips on Providing Palliative Care**

Health care workers trained in palliative care can teach family members and caregivers how to provide supportive care to the patient as follows:

- Helping them plan care for the sick and share tasks with others.
- Demonstrating good communication skills for effective social, emotional and spiritual support.
  - Offering warm greetings and shaking hands when they get to the patient.
  - Talking about general topics before getting into personal issues of the patient.
  - Asking open-ended questions and following up the answers with further questions.
  - Listening carefully and patiently to give the patient time to speak.
  - Summarizing important issues that the patient makes, to show understanding.
  - Assuring the patient that the information will be kept private.
  - Using simple medical terms that the patient will understand.
- Guiding them to select and prepare suitable meals for the patient.
- Training them on general hygiene in relation to patient management.
- Training them how to administer analgesics and other necessary drugs at home.
  - Explain what each medication is for, how it should be taken and for how long. Give written instructions in the local language for each recommended medication if possible.
- Showing how to deal with other specific medical problems such as paraplegia and incontinence.
- Ensuring carers make time for themselves so they can relax for specified periods of time. This will help renew their energy and avoid quick burn-out.
  - Encouraging them to talk about their feelings and assure them that such feelings are normal. Help them find a trusted friend or counsellor to continuously support them.
- Ensuring they can seek and reach for further medical help and information when needed.
- Establishment and linking affected patients with cancer support groups

**Follow-up on Professional Care**

The palliative care team should ensure regular home visits to the affected families. As & where necessary volunteer carers should be recruited, including from amongst neighbours. It is essential to ensure all health care workers are aware of and adequately conversant with principles of palliative care.

**MANAGEMENT OF COMMON SYMPTOMS OF CANCER PATIENTS**

Symptoms commonly experienced by patients with advanced cancer include pain, dehydration, nausea and vomiting, diarrhoea or constipation, fever, poor appetite and wasting, weakness and fatigue,
swelling or lymphoedema, bed sores, systemic and wound infections, coughing and difficulty breathing, and incontinence. These are often distressing to both the patient and family, hence the importance of ensuring they are effectively controlled. The following measures go a long way to improve or maintain quality of life for patients.

PAIN MANAGEMENT

Pain relief is a right for every patient. Pain can arise from diverse causes and in most cancer patients pain will be progressive, meaning that the patient will require stronger analgesics and at higher doses as the disease progresses or gets complicated. Correct determination of its cause enables selection of the most appropriate effective analgesic, while adequate doses at correct intervals are essential. Care givers should be made aware of the following key points for the control of chronic pain:

- **Oral Dosing.** Analgesics given by mouth in the form of tablets, capsules and syrups work just as well as injections and easier to administer.

- **Regular Administration.** Analgesics should be given at regular intervals, relying on a watch, clock or radio, or using some other regular local event(s) to prevent “break through” of the pain.

- **Bedtime Dose.** Rather than waking the patient and the caregiver, the bedtime dose of the drug can be increased or doubled to prevent breakthrough pain and avoid sleep disturbance.

- **Helper Drugs.** These are analgesic drugs that relieve nerve or bone pain that frequently occurs among cancer patients and may not be stopped by opioid analgesics alone. **Amitriptyline** (commonly used for depression) can help stop nerve pain. Similarly, an anti-inflammatory drug such as ibuprofen reduces swelling within the bone and thereby relieves the pain.

- **Monitoring and Adjustments of Drugs.** Analgesics should be given based on the patient’s need. If a medication no longer stops the pain, the nurse should be informed to advise on one of three actions to be taken: 1) increase the dose, 2) add another drug, or 3) switch to a new drug.39

- **The dose should be repeated if the patient vomits immediately after taking the drug.** However, for vomiting that occurs much late, only repeat of the tablet was seen in the vomit.

Health care providers should watch and listen to the patient so they can identify the type of medication and the amount that relieves pain. A form indicating the degree of pain relief (by the patient) after taking a particular dose can be filled out by the provider.39 See Appendix for a sample of this form.

**Common Analgesics for Mild to Moderate Pain**

The most common analgesics are paracetamol and ibuprofen, given orally for mild to moderate pain:

- **Paracetamol** relieves mild to moderate cancer pain in doses of 325 mg to 650 mg every four hours. It is also used to reduce fever. If nausea, vomiting and pain in the stomach occur, reduce the dosage and give lots of water to drink.

  **Caution:** Paracetamol should not be administered to patients with liver or kidney failure, because it is eliminated from the body by these two organs.

| Paracetamol | Dose: 325 mg to 650 mg every four hours |

---
• Ibuprofen can similarly be used to reduce fever and relieve moderate pain in doses of 400 mg to 600 mg every six hours. It also reduces swelling and inflammation and is effective in pain caused by cancer that has spread to the bone. Ibuprofen should not be given to patients who have stomach ulcers.

Opioid Analgesics for Moderate to Severe Pain
Opioid medication is used when non-opioid drugs by themselves no longer control cancer pain. These have to be prescribed by a registered doctor and it is important to adhere to the instructions exactly as prescribed and to give appropriate dosages to avoid overdosing. Codeine dihydrocodeine (DF 118) and morphine are examples of these drugs. Since the goal of treatment is continuous round-the-clock pain relief, quite often the dosage will gradually need to be increased. However, there is little risk of addiction or dependency since the dose is titrated against the patient’s pain threshold. Various preparations are available for oral, rectal or parenteral administration.

- Codeine and Dihydrocodeine (DF118): are mild opioid analgesics for us to control moderate pain. They often cause constipation, while drowsiness, nausea, vomiting, itching and headaches are other possible side effects.

- Morphine: is the strongest opioid analgesic available locally and is reserved for situations where other medications are no longer effective. Because it is so effective, every effort should be made to ensure morphine is available to patients with terminal cancer who have severe. Like other analgesics, morphine should be taken regularly and not just when the patient complains of pain.

Since opioids usually causes constipation, patients on them should also be taking laxatives appropriately and drink lots of liquid as practical. Nausea and vomiting while on opioids often reflect constipation and may lessen after a few days.

Helper Analgesics
Helper drugs such as ibuprofen and amitriptyline are useful adjuncts for controlling bone pain and neuropathic pain. Ordinary doses are used as follows:

- Amitriptyline
  Dose: 10 mg to 25 mg at bedtime. Gradually increase dose up to 150 mg or until pain is relieved

- Ibuprofen
  Dose: 400 mg to 600 mg every six hours
  To be taken after food or with a glass of milk
Ibuprofen for Bone Pain: ibuprofen helps by reducing swelling and inflammation.

Amitriptyline for Neuropathic Pain: Amitriptyline (Elavil®) is commonly available for treating depression. It helps relieve reduce unpleasant neuropathic pain.

Dehydration
Dehydration in cancer patients results from diarrhoea, vomiting, high fever and poor appetite resulting from intake of little food and drink. Signs of dehydration include thirst, dry mouth, sunken or dry eyes, inelastic skin and reduced urine output.

The following types of liquids may be used to hydrate the patient:

- Oral rehydration salt or a hydration solution
- Watery cereal, light porridge, tea, soup or clean boiled water that has been cooled.
- Homemade drinks, especially cereal drinks made from locally available cereals such as finely powdered rice, maize, wheat flour, sorghum or cooked and mashed potatoes.

Patients who are not feeding normally should keep taking small sips of liquids frequently to prevent dehydration. It is important to note that most patients are more likely to tolerate small frequent drinks than large ones.

Nausea and Vomiting
Nausea and vomiting may be a complication of the disease itself or a side effect of opioid analgesics, radiation or chemotherapy treatment. It is important to establish the cause of nausea and vomiting so as select the most appropriate management. This usually will be a combination of hydration and medication.

Hydration
Hydration drinks mentioned above are ideal in nausea and vomiting. In addition, ginger tea, ginger ale and cola drinks—which are well-tolerated when a patient has nausea and vomiting—can also be tried. Small sips should be taken every five to 10 minutes. When the vomiting subsides, small amounts of light porridge, cooked bananas, dry bread and un-spiced food may be eaten.

Antiemetics
Two of the most commonly used antiemetics are prochlorperazine and metoclopramide.

- Metoclopramide is preferred where the cause is general illness or gastric stasis (delayed emptying of the stomach) as a side effect of opioid use.
- If the cause of nausea is renal failure, prochlorperazine (Stemetil®) is recommended.

<table>
<thead>
<tr>
<th>Metoclopramide</th>
<th>Dose: 10 mg to 20 mg every six hours taken before meals and at bed time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prochlorperazine (Stemetil®)</td>
<td>Dose: 5 mg to 10 mg every six hours</td>
</tr>
</tbody>
</table>
• If the cause is chemotherapy, prochlorperazine (Stemetil®) started at least 24 hours before administration of chemotherapy works best.

• Where severe vomiting and diarrhoea make oral medication inappropriate, parenteral metoclopramide or prochlorperazine together with intravenous fluids are indicated. Metoclopramide 20 mg or prochlorperazine 10 mg rectal suppositories are also effective.

Diarrhoea
The following instructions have been found to be useful:

Feeding
• Let the patient eat whatever he/she prefers, though fatty and spiced food is likely to worsen diarrhoea and should therefore be avoided.
• Maintain regular food intake and frequent oral rehydration, particularly if there is concurrent nausea and vomiting.
• Loperamide (Imodium®) 2 mg tablets is useful.
• If the patient has a fever for more than 24 hours and bowel infection is suspected, the patient may be started on Cotrimoxazole.

Toileting and General Hygiene
• If the patient can manage, let him/her use the toilet to relieve him/herself.
• If he/she needs help, give appropriate help, using clean, disposable gloves.
• Wash your hands well with soap and water after helping to clean the patient.
• Beddings and clothing should be changed regularly.
• Encourage household caregivers to always glove when cleaning up after diarrhoea.

Constipation
Constipation in cancer patients may result from stasis, intestinal obstruction or the use of opioids.

Stasis
A considered practical, feed the patient on fruits, green vegetables and other foods with natural fibre, such as cassava, carrots, ground nuts, simsim (sesame seeds) and pumpkin will prevent constipation. As far as is possible cancer patients should be ambulated.

Side effect of Use of Opioid Analgesics
Proactively use stool softeners (1-3 tablespoons of liquid paraffin at bed time) plus one of the following:
• Senekot® (two to four tablets at bedtime)
• Dulcolax® (one to two tablets at bedtime)
• Milk of magnesia (one to two tablespoons at bedtime)
• Castor oil (one to four tablespoons at bedtime)
Faecal Impaction
Perform rectal examination and digital dis-impaction. Where this fails, use an enema (either soap & water, or any of the several preparations available locally)

Fever
Respond to the determined cause of the fever. In addition consider Paracetamol, 650 mg tablets by mouth every four hours until the temperature settles.

Loss of Appetite and Wasting
Wasting often denotes advanced or late stage cancer disease. Appetite may be boosted by:
- Considering food presentation when serving meals to the patient.
- Limit exposing the patient to the smell from cooking food
- Give the patient foods that he/she usually enjoys and accepts.
- Serve fresh foods, fruit juices and juices, particularly oranges and watermelon
- Corticosteroids (prednisone or dexamethasone) may be helpful in stimulating appetite.
- Educate the family on weight loss over time, irrespective of the use of corticosteroids.

Weakness and Fatigue
Asthenia (weakness) and fatigue may set in following radiation or chemotherapy, or as the disease advances if the patient is not feeding enough, is anxious, has not rested enough, is anaemic, or if other vital organs have been affected. Encourage small frequent feeds, ensure the patient gets adequate rest and assist them to move about, or to stretch, as practical. Corticosteroids, correctly used, may boost the feeling of well-being.

Body Swelling
Lymphoedema, usually from swollen glands obstructing the flow of lymph fluid, can cause a great deal of discomfort to the patient with advanced cancer. The lower limbs commonly affected in cases of cervical cancer or prostate cancer, while breast cancer often results in swelling of the upper limbs—particularly on the side of the affected breast.

There is no fully successful treatment for lymphoedema, but the following measures provide relief:
- Skilled massaging of the limb, wrapping it in elastic stocking and elevating it on a pillow so that it is a little higher than the rest of the body.
- In some cases a brief course of external beam radiotherapy directed at the obstructed lymph nodes may help reduce the swelling for a short while.
- Regular inspection for infection (redness, warm & tenderness) and appropriate antibiotic treatment (Erythromycin 500mg, or Penicillin V 500mg, by mouth four times a day).

**Bed Sores**

Bed sores, also known as pressure sores, develop on weight bearing parts when a person spends much time in one position with little movement, thereby impairing blood circulation to the skin & adjacent tissues and resulting in necrosis. They commonly affect the buttocks, back, shoulders, elbow and the heel of the feet or the ankles. The wounds must be well cared for to prevent infection setting in. The best strategy is prevention, through frequent turning and position changes, use of well-selected and appropriately placed cushions and supports, plus hygiene measures including regular bathing, gentle massaging with oil and frequent change of bedding and prompt clean-up after toileting or vomiting. Once bed sores develop, they take a long time to heal.

Care of established bed sores:

- Regular change in position but ensuring the patient does not lie directly on any sores.
- Twice daily wound cleaning with dilute hydrogen peroxide (2% solution), or mild soap or povidone iodine/betadine solution (Wokadine®).
- Gentle debridement without peeling off any skin & dressing with clean bandages.
- An antibiotic powder (gramicidin, bacitracin, neomycin mixture) or metronidazole powder (crushed 200 mg tablets of metronidazole) sprinkled into the cleaned wound controls the smell and assists in healing the infection.
- If bedsores have pus and the patient is febrile, add an oral antibiotic (cloxacillin).

**Infections**

**Wound Infection**

Wound infection is common in breast cancer following ulceration of the tumour. Clean and dress the wound at least twice daily and use antibiotics as necessary.

**Infection of Cervix and Lower Genital System**

Bacterial infection of the cervical cancer wound is a common problem that results in foul-smelling vaginal discharge. This is a distressing condition as relatives and friends keep away, leaving the patient withdrawn.

Proper hygiene, regular vaginal douches with vinegar or metronidazole in clean lukewarm water and frequent changing of the sanitary wear, decrease the smell and help to keep the patient dry. Applying zinc oxide cream or petroleum jelly on the peri-anal skin prevents damage due to wetness either from discharge or from urine incontinence.
Cough or Breathing Difficulties

Coughing can signify possible infection or spread of the cancer to the lungs, while shortness of breath may be a sign of anaemia, chest infection or heart failure. Ensure the following measure:

- Determine and treat the cause
- Prop the patient up to reduce breathing difficulties
- Codeine (tablet or syrup) may relieve a severe dry cough that interferes with sleep
- Initiate antibiotics and avoid codeine, if infection is suspected
- Psychological support is important if the dyspnoea results in undue anxiety in the patient
- For end stage cancer that has spread to the lungs, make the patient as comfortable as possible.

Specialised attention should be sought:
- If the patient has constant dyspnoea increasing in severity or lasting longer than two weeks.
- If the patient coughs up blood or foul-smelling sputum, a chest infection is likely.
- If the patient loses weight, has a persistent fever and chest pain, a chronic chest infection such as tuberculosis may be the cause.
- If both legs are swollen and orthopnoea develops, congestive heart failure should be ruled out

Incontinence

Urine incontinence is common in patients with cervical and prostate cancer. In cervical cancer, it may result from a vesicle-vaginal fistula due to tumour invasion of the vagina and bladder or following radiotherapy. In prostate cancer it mostly follows prostatectomy but can also occur due to tissue destruction around the prostatic tumour. Faecal incontinence can follow invasion of the tumour into the rectum. Incontinence is extremely distressing. Unfortunately, the main treatment is hygiene support.

MANAGEMENT OF CHEMOTHERAPY SIDE EFFECTS

Chemotherapy will have some deleterious side effects on normal tissues and many complications can be anticipated, prevented and/or managed. The most common side effects include: nausea and vomiting, myelo-suppression, stomatitis (inflammation and ulceration of oral mucosa), anaemia and alopecia. Control measures are described below.
Nausea and Vomiting Due to Chemotherapy

Prevention is recommended, beginning the anti-emetic at least 24 hours prior to chemotherapy then continuing on a regular schedule. The antiemetic agents and doses should be selected according to the chemotherapy regimen's emetogenic (power to induce nausea and vomiting) potential. Chlorpromazine and Prochlorperazine oral are each effective for mildly emetogenic drugs such as fluorouracil.

Parenteral metoclopramide (Stemetil) is effective against the more emetogenic chemotherapeutic drugs and should be used with an antihistamine such as lorazepam to prevent extra-pyramidal side effects. High doses of dexamethazone in combination with Metoclopramide may be used for brief intervals.

Myelo-suppression / Anemia

Myelo-suppression manifests as anaemia and thrombocytopenia following chemotherapy. Blood counts reach their nadir between 10 to 14 days after treatment, with recovery noted by the 21st day and return to normal by the 28th day after treatment. Thus most regimens are administered in cycles of 21 to 28 days. Some agents such as nitrosoureas involve a longer recovery period and are therefore given every six weeks. Some degree of anaemia is anticipated with every round of chemotherapy. Look out for anaemia with neutropenia which increases chances of infection.

Severe thrombocytopenia (below 50 x 100^9/L) increases the risk of haemorrhage. In most cases, unless intense chemotherapy is being given, patients may be allowed to recover rather than transfusing them. However every patient is assessed and managed as an individual.

Stomatitis

Stomatitis, or inflammation of oral mucosa, is an important complication of chemotherapy. Starting as erythema and oedema, it may end up with painful ulceration which lasts up to two weeks and results in dehydration and malnutrition due to poor food intake. Meticulous oral hygiene is critical to avoid oral infection that may severely complicate issues.

Virtually all chemotherapeutic agents cause stomatitis. Treatment with topical oral anaesthetics such as viscous xylocaine can relieve pain and help maintain food intake.

Alopecia

Chemotherapy-induced hair loss follows the cytotoxic effects of anti-neoplastic agents on hair follicles and is a highly distressing aspect of cancer treatment for many patients. The patchy hair loss tends to be
more severe on the scalp, and appears a week or two after initiating chemotherapy. Chemotherapeutic agents such as cyclophosphamide, vincristine, dactinomycin, doxorubicin and paclitaxel are most notorious and patients should be reassured that hair will gradually return to pre-treatment levels although it may be different in texture and colour.

**SOCIAL, EMOTIONAL AND PSYCHOLOGICAL SYMPTOMS**

Apart from taking care of physical symptoms of patients with advanced cancer, palliative care should also address the social, psychological and spiritual problems experienced by the patient and the family unit as these factors affect the quality of life for the patient.

**Social Symptoms**
The reality of an incurable illness changes the way a sick person, family members and close friends treat one another. As there is no right or wrong way of coping with terminal illness, it is important that people are able to talk to each other and that they get help when needed.

**Family Stress**
The person suffering from cervical, breast or prostate cancer will quite often have been independent and most likely a breadwinner. Becoming suddenly dependent on family members or friends for care and support shifts relationships within the family as other members take on new responsibilities. This shift can be difficult since people may not know how to do it or may be afraid of taking new roles. Supporting the family and discussing these issues with them will help ease the transition.

Young children are key members of the social unit who also need help in order to cope. They should therefore receive emotional support and their questions and concerns should be practically addressed.

**Stigma and Avoidance**
Some family members and friends may avoid seeing or being with a very sick person out of fear. These need counselling to lessen their anxiety about visiting or caring for the ill person.

**Economic Strain**
The sick person may have been a breadwinner. When he/she falls ill, the family’s income goes down while expenses, particularly on medication and special medical care, go up. Family and Community support will be necessary and it is important to discuss palliative care with the family and key community members.

**Depression and Sexuality**
Depression is common when dealing with death, whether it is one’s own impending death or that of a person one cares about. The cervix, breast and prostate are reproductive organs and their illness or surgical removal alters an individual’s self-identity, changing how one feels and affecting one’s sexuality and relationship with the spouse. This should be discussed and appropriate counselling ensured.
Emotional Symptoms

Most people experience various emotions (shock, denial, depression, anger, guilt, fear and anxiety) when informed that they have cancer and that the disease is advanced. If the emotional problems are severe, professional help should be sought and the patient referred appropriately.

**Depression**
Depression is often anticipated and frequently a socially acceptable reaction. The patient and care unit should be assessed for this and appropriate professional counselling ensured. It is essential to keep monitoring the situation for persistence and deterioration. Symptoms of clinical depression include:

- feeling that life is not worthwhile and nothing is enjoyable any more
- feeling very sad and with a tendency to cry on most days
- being withdrawn, usually quiet and not interested in activities that previously were enjoyable
- feeling tired, slow and without energy
- changed eating patterns resulting in changes in weight
- difficulties falling asleep and/or waking up early and not getting back to sleep
- having difficulties concentrating or making decisions
- neglecting personal hygiene
- having thoughts of committing suicide or being preoccupied with thoughts of wanting to die

A person who has two or more of these symptoms and has been depressed for longer than expected requires professional review and may benefit from antidepressant medication (e.g. amitriptyline starting with 25 mg and increasing gradually up to 150 mg). He/she should be closely and regularly monitored.

**Anger**
When people lose control over their own lives or when they feel powerless, they become angry with themselves or with other people. They may calm down after letting it out. However, if it persists, they require support from an understanding close family member, a friend or a counsellor, rather than confrontation.

**Fear and Anxiety**
Fear and anxiety often accompany the uncertainties of the changing family roles and positions, altered relationships with family members and friends, loss of control over everyday life, inadequate income, persistent suffering, pain, thoughts regarding death and fear of the unknown. Talking with the patient about their feelings can allay much of the anxiety and fear by identifying ways of resolving it.

**Guilt**
Patients may feel guilty, particularly when they associate the cause of their illness with something they did or did not do. It may also be a result of patients’ feeling that they are a financial, social and emotional burden to other people. Guilt often also arises out of pending ‘unfinished business’ with
family members, close friends or associates. Understanding, reassurance and support are needed to prevent patients from being overwhelmed by feelings of guilt.

**Spiritual Needs**

Spiritual beliefs and religion can be very comforting to people who are ill as well as those taking care of them. In some cases however, they can be a source of questions and doubt. In either case, it is important to be respectful and responsive to the spiritual and religious beliefs of a patient and her/his family. They should be allowed and helped to find spiritual peace as this helps them accept death.

Sometimes there may be an already-identified religious leader who can help support the patient. Since religious and spiritual matters are personal in nature, the patient or family member in need of support should identify the religious leader to whom they wish to turn for help.

**Bereavement Support**

People often need extra support to help them cope with their bereavement, both when death is impending and when it has occurred. Spiritual leaders, who may double as counsellors, as well as health care workers and volunteers, should be identified to provide appropriate bereavement support.

Palliative care is an important and complex undertaking that results in adding life to the days of patients with terminal cancers. It is best provided with the help of a conversant multi-disciplinary team. A list of hospices around the country with reliable contacts of key focal persons is included in the appendix.
PART THREE

ANNEXES
Annex 1: VIA /VILI learning guide

Rate the performance of each step or task observed using the following rating scale:

1. **Needs Improvement**: Step or task not performed correctly, out of sequence (if necessary), or is omitted.
2. **Competently Performed**: Step or task performed correctly in proper sequence (if necessary), but participant does not yet proceed efficiently between steps.
3. **Proficiently Performed**: Step or task efficiently and precisely performed in the proper sequence (if necessary).

<table>
<thead>
<tr>
<th>STEP/TASK</th>
<th>CASES</th>
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<tr>
<td><strong>CLIENT ASSESSMENT</strong></td>
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<tr>
<td>1. Greet the woman respectfully and with kindness.</td>
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<td>2. Establish why the VIA / VILI test is being done and describe the procedure.</td>
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<td>3. Tell her what the findings might be and what follow-up or treatment might be necessary.</td>
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| 4. Take a reproductive health history for VIA / VILI or, if medical record is available, confirm the following information:  
  - Parity  
  - Currently pregnant  
  - Age at first intercourse  
  - Current contraceptive method  
  - LMP and menstrual interval (days)  
  - Bleeding pattern  
  - History of STDs, including HIV/AIDS  
  - History of abnormal Pap smear |       |
| **GETTING READY**          |       |
| 1. Check that speculum, gloves and other supplies are available. |       |
| 2. Ensure that light source and dilute acetic acid (for VIA) and/or Lugol’s iodine (for VILI) are ready to use. |       |
| 3. Tell the woman what is going to be done and encourage her to ask questions. |       |
| 4. Check that the woman has emptied her bladder. |       |
| 5. Ask her to undress from the waist down. |       |
| 6. Help her onto the examining table. |       |
| 7. Wash hands thoroughly with soap and water and dry them appropriately. |       |
| 8. Place a drape over the woman for pelvic examination. |       |
| 9. Put new examination or high-level disinfected surgical gloves on both hands. |       |
| 10. Arrange instruments and supplies on high-level disinfected tray or container. |       |
### VIA /VILI PROCEDURE

1. Inspect external genitalia and check urethral opening for discharge.
2. Insert vaginal speculum and adjust the speculum and light source so that the entire cervix can be seen.
3. Fix the speculum blades in the open position so that the speculum will remain in place with the cervix in view.
4. Examine the cervix for cervicitis, ectropion, tumours, Nabothian cysts or ulcers.
5. Use a clean vaginal swab to remove any discharge, blood or mucus from the cervix.
6. Identify the external cervical OS, the transformation zone and the squamocolumnar junction.
7. Soak a clean swab in dilute acetic acid and apply thoroughly to the cervix if VIA is being done first.
8. Wait 1 minute for the acetic acid to be absorbed and any acetowhite reaction to appear.
9. Inspect the transformation zone carefully and look for any acetowhite change.
   - Check if there is any overt Cervical cancer
   - Check to be sure the entire SCJ and T-zone can be seen.
   - Check for any VIA positive lesion and note density, area & extent
   - If a positive lesion is seen, determine suitability for Cryotherapy
   - As needed, reapply acetic acid or swab the cervix with a clean swab to remove mucus, blood or debris.
   - Proceed to VILI
10. Apply Lugol’s iodine solution to the cervix using a clean swab and inspect the transformation zone carefully and record any iodine negative areas.
    - Check for any overt cervical cancer
    - Check to be sure the entire SCJ and T-zone can be seen.
    - Check for any VILI positive lesions and determine if suitable for cryotherapy
11. When VIA /VILI has been completed, use a fresh swab to remove any remaining solution from the cervix and vaginal fornix.
12. Alert the woman that she may have a brown, iodine discharge that stains her undergarments but that it can be easily removed by washing.
13. Remove the speculum and place in 0.5% chlorine solution for 10 minutes for decontamination.
14. Have the woman sit up, get dressed and get down from the table.

### POST-VIA /VILI TASKS

1. Before removing gloves, dispose of used swabs by placing in a leak proof container or plastic bag.
2. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out.
   - Dispose the gloves in a leak proof container
3. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
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<tr>
<td><strong>4.</strong> Wipe down and dry examining table surface and light source with 0.5% chlorine solution after each use.</td>
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</table>
| **5.** Record findings on the cervical cancer screening form  
  - Remember to draw a schematic representation on the screening map |   |
| **6.** Discuss the VILI (or VIA) results with the woman and answer any questions.  
  - If result is normal, reassure the woman that test was negative.  
  - If result is abnormal or cancer is suspected, discuss recommended next steps.  
  - After counselling, provide treatment or refer. |   |
Annex 11 Answers to questions frequently asked by women

Why should I get screened today when I am feeling healthy? Cervical cancer is a serious health problem for many older women. It is a major cause of death of women aged 40 to 60. But before the cancer starts, there are some early changes in your cervix that can be seen. Screening today can identify problems in your cervix years before they might turn into cancer. These problems can be easily treated. Women cannot tell if they have these early problems—they feel fine. By examining the cervix before you have any symptoms (meaning when you feel healthy and fine), we can find any abnormality and provide effective treatment provided to prevent cancer.

Am I being tested for HIV/AIDS? No. You are not being tested for anything except for early problems with your cervix that could lead to cancer.

Does this test treat sexually transmitted infections? No. This is a screening test to see whether you have abnormal areas on your cervix. If we see that you have an STI during the examination, we will offer you treatment if you want it.

I am embarrassed. Do I really need this exam? Yes. You have made a wise decision to protect your health. Even if you are embarrassed or ashamed, you should feel proud of taking steps to make sure you are healthy. Some women feel embarrassed if a male clinician is examining them. Remember, it is a required procedure to have a female clinician in the room to accompany you during the examination.

If I have an abnormality does this mean I have cancer? Probably not but if you do have an abnormal area that is not treated, it could turn into cancer. To prevent this from happening, treatment can be provided that is almost completely effective in getting rid of the pre cancerous changes.

Will you remove my uterus (womb) during the exam? No. The purpose of the exam is to make sure that you do not have problems on your cervix.

Will the vinegar hurt my uterus? The vinegar might sting a little when it is first applied. This is normal and does not mean that anything is wrong or that the vinegar is harming your cervix.

What is the brown solution? The brown solution is iodine similar to that used on cuts or wounds. It allows the provider to see any abnormal spots on your cervix.

Will the brown solution stain my underwear? The brown solution may leave a brownish spot on your underwear. This spot should wash out without permanently staining your underwear.

Will this examination hurt? Aside from a mild stinging that you might feel from the vinegar, the rest of the examination may be a little uncomfortable but will not be painful.

Can I go home and think about it and then come back another time to be screened? Yes. (Clinicians, be sure to clearly explain times/locations where she can return for screening.)

Are the instruments clean? Yes. They have been sterilized (cleaned) so that there is no danger of infection.

Have they been used on other women? Yes. But they have been sterilized (cleaned) after every use; they are completely clean and free of germs for every woman coming in for screening.
**Will I have privacy during the examination?** Yes. Your clinician and his or her assistant(s) will be the only ones in the enclosed area with you. The door to the exam room will be closed and no one will interrupt you during the exam.

**Why should I come back in 5 years if my cervix is healthy?** You do not have any abnormalities on your cervix right now, but these signs could develop over the next five years. For this reason, you should return to be screened.

**Where should I go in 5 years?** You can return to this facility. If services are not offered here at that time, then someone here can tell you where to go for screening.

**Should I keep my card?** Yes. It is a good record of your exam results and a reminder to come again in five years.

**Does a negative test result mean that I don’t have cervical cancer?** Yes. This means that your cervix looks normal and we are fairly sure that you do not have cervical cancer or the abnormal signs that come before developing cancer.

**Does a positive result mean that I have cancer?** Not always. A positive result means that you may have a precancerous lesion that, if not treated, might turn into cancer over several years. To prevent this from happening, treatment can be provided that is almost completely effective in getting rid of the precancer.

**If they find that I have a precancerous area, what is the treatment?** Treatment involves freezing the abnormal cervical tissue using a simple procedure called cryotherapy. To do cryotherapy, an instrument that becomes very cold is put on the cervix, and the affected area is destroyed by freezing. Your clinician will explain the process to you in detail if he or she thinks you should have it done.

**Will treatment hurt?** During the treatment you may feel some mild cramping in the lower abdomen. The cramping usually disappears quickly over 15 to 30 minutes. You may have some mild cramping over the following couple of days. Your clinician will explain the process to you in detail if he or she thinks you should have cryotherapy.

**Will treatment affect my daily life?** After treatment, there are certain things you will need to do to make sure that your cervix heals properly. You will need to avoid heavy lifting for several days, take medicines, not place anything in the vagina, and abstain from sexual intercourse for 4 weeks. If abstaining will not be possible for you, you will be given a supply of condoms for use during every act of intercourse.

**How much will the examination and treatment cost?** Health workers should find out how much screening and treatment costs in that facility and be able to provide women with accurate cost information.

**What if my husband won’t support my being screened or treated? What can I do?** If you explain why the visit is important to protect your health and he still does not want you to go, and then ask him to come with you to this facility so that our clinician can explain it to him. We will explain the examination and treatment to him and why he should be supportive of your obtaining the services. We will also tell him about the qualifications of the clinicians, and encourage him to join you on the visit if he is interested.
Annex III: Observation guide for counseling activities

Facility Name: _______________________________________

Name of provider being observed: ______________________ Date: ___/___/_______

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<tr>
<th>TASK/ACTIVITY</th>
<th>Cases</th>
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<tr>
<td>ORIENTATION AND COUNSELING</td>
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First step: Establish a cordial relationship.

1.1 Greets client in a kind and respectful manner.

1.2 Assures confidentiality and privacy.

1.3 Determines the purpose of the consultation.

Second step: Identify the client’s needs.

2.1 Asks questions in a clear and appropriate manner.

2.2 Inquires about the client’s health. Asks the client how she feels.

2.3 Maintains an attentive posture.

2.4 Does not criticize or give opinions about the client’s comments.

2.5 Clarifies and repeats the information that the client gives, when appropriate.

2.6 Asks about client’s partner’s opinion.

Third step: Respond to the client’s needs.

3.1 Offers general information about screening to prevent cervical cancer and VIA/VILI.

3.2 Describes the process and possible side-effects (if applicable).

3.3 Describes the cases in which the client should return to the facility.

3.4 Responds with clarity to the client’s questions.

3.5 Speaks with simple language.

3.6 Uses support material during the counseling (if it is not used, provide written comments explaining why it was not used).
### Fourth step: Verify the client’s understanding.

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<td><strong>4.1</strong></td>
<td>Verifies that the client understood everything, asking in an appropriate manner.</td>
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<td><strong>4.2</strong></td>
<td>Does not ask leading questions.</td>
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<td><strong>4.3</strong></td>
<td>Clarifies information and any doubts.</td>
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<tr>
<td><strong>4.4</strong></td>
<td>Asks the client if she would like to participate in VIA/VILI screening exam.</td>
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<tr>
<td><strong>4.5</strong></td>
<td>Makes sure that the client is making an informed choice to participate in the study.</td>
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<tr>
<td><strong>4.6</strong></td>
<td>Tests for comprehension by asking the client to explain what informed choice is and what will happen to her during the exam.</td>
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### Fifth step: Maintain a cordial relationship.

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<tr>
<td><strong>5.1</strong></td>
<td>Maintains an approachable posture with the client.</td>
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| **5.2** | If the result of the VIA/VILI is negative: instructs the client to return to the clinic in 5 years to be examined again.  
If the result of the VIA/VILI is positive: counsels for cryotherapy or referral as appropriate |
| **5.3** | Asks client whether she has any remaining questions or concerns. |
Annex IV: Preparation of Lugol’s iodine, and Monsel’s paste

Lugol’s iodine solution

Ingredients / Quantity
1. Potassium iodide 10 g
2. Distilled water 100 ml
3. Iodine crystals 5 g

Preparation
a. Dissolve 10 g potassium iodide in 100 ml of distilled water.
b. Slowly add 5 g iodine crystals, while shaking.
c. Filter and store in a tightly stoppered brown bottle.

Storage:
1 month

Label:
Lugol’s iodine solution
Remember to include “Use by” date

Monsel’s paste

Ingredients Quantity
1. Ferric sulfate base 15 g
2. Ferrous sulfate powder a few grains
3. Sterile water for mixing 10 ml
4. Glycerol starch (see preparation on next page) 12 g

Preparation: Take care: The reaction is exothermic (emits heat).
  a. Add a few grains of ferrous sulfate powder to 10 ml of sterile water in a glass beaker. Shake.
  b. Dissolve the ferric sulfate base in the solution by stirring with a glass stick. The solution should become crystal clear.
  c. Weigh the glycerol starch in a glass mortar. Mix well.
  d. Slowly add ferric sulfate solution to glycerol starch, constantly mixing to get a homogeneous mixture.
  e. Place in a 25 ml brown glass bottle.

For clinical use, most clinics prefer to allow enough evaporation to give the solution a sticky paste-like consistency that looks like mustard. This may take 2 to 3 weeks, depending on the environment. The top of the container can then be secured for storage. If necessary, sterile water can be added to the paste to thin it.

Note: This preparation contains 15% elementary iron.

Storage: 6 months

Label:
Monsel’s solution; Shake well; External use only; Use by (date)
Glycerol starch (an ingredient in Monsel’s paste)

Ingredients Quantity
1. Starch 30 g
2. Sterile water for mixing 30 ml
3. Glycerin 390 g

Preparation
a. In a china crucible, dissolve the starch in the sterile water. Shake well.
b. Add the glycerin. Shake well.
c. Heat the crucible and its contents over a Bunsen burner. Mix constantly with a spatula until the mass takes on a thick, swelling consistency. Take care not to overheat so as not to let it turn yellow.

Storage: 1 year

Label:
Glycerol starch; for external use only
Store in a cool place; Use by (date)

Note: Do not overheat; otherwise the mixture will turn yellow.
Annex V: Cryotherapy job Aid- Wallach unit

First Use of the Day

1. With master cylinder valve in closed position, tightly attach regulator of cryotherapy unit (cryogun /probe) to CO2 cylinder.
2. While holding cryogun pointed towards ceiling, slowly turn master cylinder valve to open position.
3. Check pressure on pressure gauge:
   a. Green: approximately 40–70 kg/cm2. Appropriate pressure to operate.
   b. Yellow: below 40 kg/cm2. Replace gas cylinder (see below).
   c. Red: above 70 kg/cm2. Unsafe to operate (see below).
4. Confirm pressure in “green zone.”
5. Point cryogun to ceiling. Press freeze (left) trigger to check freeze function for 1 second, then press defrost (right) trigger for 1 second.
6. Screw high-level disinfected (HLD) cryotip with sleeve onto end of probe.
7. Double-freeze (3-5-3) technique: Freeze 3 minutes—defrost 5 minutes—freeze 3 minutes using “freeze-clear-freeze” technique described below.
8. Set timer for 3 minutes. Apply cryotip to cervix and press freeze (left) trigger. After first 15 seconds, briefly press defrost (right) trigger for 1 second or less and then immediately press freeze (left) trigger again to continue freezing process.
9. Repeat this “freeze-clear-freeze” technique every 15 seconds during the entire 3 minutes of freezing. Watch as ice ball develops and freeze for 3 minutes. (Three minutes is a guideline. Most importantly, look for a 3–5 mm ice ball beyond the cryotip edges. Depending on gas pressure in cylinder, and other factors, freeze time may be more or less than 3 minutes.
10. After the freeze step, press defrost (right) trigger to defrost. Wait for the cryotip to detach from the cervix.
11. Repeat steps 7 and 8 if using double-freeze technique.
12. Inspect cervix to ensure ice ball is present, covers appropriate area of cervix, and no injury to surrounding tissues.
13. Remove cryoprobe and tip from vagina and either hand to assistant or place on clean tray.
14. After caring for the patient, turn master cylinder valve to closed position, release pressure by pressing freeze followed by defrost triggers.
15. Wipe the cryogun, probe, sleeve and tip with alcohol. Unscrew cryotip from end of probe, place stopper in opening of the tip, clean tip and sleeve with soapy water, rinse in clean water and soak in 2–4% glutaraldehyde (Cidex) or 70–90% isopropyl or ethyl alcohol for 20 minutes for HLD; or sterilize by using autoclave where feasible.
16. Place protective cover over end of cryoprobe.
17. At end of HLD, rinse cryotip and sleeve thoroughly in clean water (if using cidex, no need to rinse if using alcohol), and air dry in HLD container.
Repeat Use during Clinic Session
1. Screw HLD cryotip with sleeve onto end of probe.
2. Turn master cylinder valve to open position.
3. Proceed with steps 7–15 as above.

At End of the Day
1. Assuming steps 13–15 have been done, unscrew regulator of cryotherapy unit from CO2 cylinder and store in box with cryotips. Alternately, can leave unit attached with cover over the end of the cryoprobe and store unit and cylinder in secure area in clinic.
2. Ensure that CO2 cylinder is in safe, cool place for storage.

Gauge in “Red Zone”
1. Do not operate—could ruin cryotherapy unit or rupture hose and cause injury. Turn master cylinder valve to closed position, release pressure by pressing freeze (left) trigger.
2. Unscrew regulator of cryotherapy unit from CO2 cylinder.
3. In well-ventilated area, ensure all is clear from tank. Turn master cylinder valve to slightly open position and vent large cylinder for 30 seconds, small cylinder for 15 seconds. Recheck pressure—if still red, repeat steps. If green, ready to operate. If still red after repeated venting, do not use cylinder—return to manufacturer or Gas Company for further evaluation.
4. Note: If cylinder is warm to touch, do not use. Store in cool place or wrap in cool wet cloths to reduce temperature.

Gauge in “Yellow Zone”
1. Replace cylinder. Turn master cylinder valve to closed position, release pressure by pressing freeze trigger. When pressure reads zero, press defrost trigger.
2. Unscrew regulator of cryotherapy unit from CO2 cylinder.
3. Proceed with steps as outlined under “First use of the day.”
Annex V1: Screening and treatment modalities for breast cancer at various levels of service provision

<table>
<thead>
<tr>
<th>LEVEL OF HEALTH CARE</th>
<th>REQUIREMENTS</th>
<th>TIME FRAME FOR RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community (Level I)</td>
<td>Create and increase awareness on breast cancer in men and women. Inform them about BSE.</td>
<td>Immediate after teaching them</td>
</tr>
<tr>
<td>Dispensary (Level II)</td>
<td>Create and increase awareness. Counselling. Teach people and demonstrate BSE. Perform CBE.</td>
<td>Immediate</td>
</tr>
<tr>
<td>Health Centre (Level III)</td>
<td>Increase awareness. Counselling. Teach people and demonstrate BSE. Perform CBE.</td>
<td>Immediate after CBE</td>
</tr>
<tr>
<td>District and/or sub district Hospital (Level IV)</td>
<td>Increase awareness. Counselling. Teach people and demonstrate BSE. Perform CBE and FNA.</td>
<td>One week</td>
</tr>
<tr>
<td>LEVEL OF HEALTH CARE</td>
<td>REQUIREMENTS</td>
<td>TIME FRAME FOR RESULTS</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td></td>
<td>Screening/ Detection and Actions</td>
<td></td>
</tr>
<tr>
<td>Provincial Hospital (Level V)</td>
<td>As above, plus mammography and ultrasound</td>
<td>One week</td>
</tr>
<tr>
<td></td>
<td>Cytology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Histology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>As above, plus radical mastectomy, chemotherapy, palliative therapy, referral and feedback to the referring centre</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Management</td>
<td>As above, plus mammography and ultrasound equipment, cancer treatment unit (radiotherapy and chemotherapy unit), and data management centre</td>
</tr>
<tr>
<td></td>
<td>Equipment/Skill</td>
<td>As above, plus senior specialists (radiologist, pathologist/cytologist, oncologist), regional health information officers</td>
</tr>
<tr>
<td></td>
<td>Personnel</td>
<td>Waiting Period</td>
</tr>
<tr>
<td></td>
<td>One week</td>
<td></td>
</tr>
<tr>
<td>Tertiary/ Referral Centre (Level VI)</td>
<td>As above, plus bone scan</td>
<td>One week</td>
</tr>
<tr>
<td></td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>As above, plus chemotherapy, radiotherapy, palliative care, and referral (feedback to the referring centre)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>As above, plus cancer centre- (training and research facilities), radionuclide scanning machine, linear accelerator, cobalt machines, and data management centre</td>
<td>As above, plus radiation oncologists, national health information officers, hospice</td>
</tr>
<tr>
<td>National level</td>
<td>Development of national programs</td>
<td>Continuous and should be reviewed and updated from time to time</td>
</tr>
<tr>
<td></td>
<td>Community diagnosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Policy formulation, advocacy, resource allocation, training, monitoring and evaluation, national cancer registry</td>
<td></td>
</tr>
</tbody>
</table>
## Annex V11: Screening and treatment modalities of prostate cancer

<table>
<thead>
<tr>
<th>LEVEL OF HEALTH CARE</th>
<th>REQUIREMENTS</th>
<th>TIME FRAME FOR RESULTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level</strong></td>
<td><strong>Screening, Detection &amp; Actions</strong></td>
<td><strong>Diagnosis</strong></td>
</tr>
<tr>
<td>Community (Level I)</td>
<td>Create and increase awareness on magnitude of prostate cancer. Educate people on risk factors, presentation. Give them general counselling and information on screening.</td>
<td>-</td>
</tr>
<tr>
<td>Dispensary (Level II)</td>
<td>Increase awareness. Inform them about screening procedures (i.e., DRE). Perform counselling and DRE.</td>
<td>-</td>
</tr>
<tr>
<td>Health Centre (Level III)</td>
<td>Increase awareness. Inform them about screening procedures (i.e., DRE). Do counselling and DRE.</td>
<td>PSA</td>
</tr>
<tr>
<td>District and or sub-district Hospital (Level IV)</td>
<td>Inform them about screening procedures (i.e., DRE and PSA). Perform counselling, DRE, PSA and TRUS Biopsy Cystoscopy.</td>
<td>DRE and PSA TRUS biopsy X-Rays</td>
</tr>
<tr>
<td>LEVEL OF HEALTH CARE</td>
<td>REQUIREMENTS</td>
<td>TIME FRAME FOR RESULTS</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Level</td>
<td>Screening, Detection &amp; Actions</td>
<td>Diagnosis</td>
</tr>
</tbody>
</table>
| Provincial Hospital (Level V) | As above plus DRE, PSA, Cystoscopy, Ultrasound (TRUS). | DRE and PSA, TRUS biopsy X-Rays | All the above, plus endoscopic radical surgery, cryotherapy, histology reports on biopsy and tissues, chemo-therapy and hormonal therapy, palliative therapy, referral and feedback, histology | • Ultrasound equipment  
• Cancer treatment unit (radio-therapy unit, chemotherapy unit)  
• Functional, equipped operating theatre and laboratory  
• Data management centre  
• Cystoscopes | As above, plus senior specialists (urologists, radiologist, pathologist, counsellors oncologist), hospice, regional health information officers, laboratory technicians, radiographers | One week |
Annex VIII: ESSENTIAL SUPPLY NEEDS FOR VIA/CRYOTHERAPY AND LEEP SERVICE PROVISION

<table>
<thead>
<tr>
<th>Essential needs for VIA/ VILI/Cryotherapy and LEEP service provision</th>
<th>Amounts estimated per 100 women screened</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Counseling area</strong></td>
<td></td>
</tr>
<tr>
<td>Privacy</td>
<td></td>
</tr>
<tr>
<td>Table for writing</td>
<td></td>
</tr>
<tr>
<td>Chairs</td>
<td></td>
</tr>
<tr>
<td><strong>Equipment and Supplies</strong></td>
<td></td>
</tr>
<tr>
<td>Gynecology Examination Couch</td>
<td>3</td>
</tr>
<tr>
<td>Light Source (Torch or Halogen Lamp)</td>
<td>3</td>
</tr>
<tr>
<td>Instrument Tray</td>
<td>3</td>
</tr>
<tr>
<td>Instrument Trolley</td>
<td>3</td>
</tr>
<tr>
<td>Stool</td>
<td>3</td>
</tr>
<tr>
<td>Privacy screen</td>
<td>Adequate Coverage</td>
</tr>
<tr>
<td>Sheets and gowns</td>
<td>6</td>
</tr>
<tr>
<td>Mackintosh</td>
<td>3</td>
</tr>
<tr>
<td>Waste segregation bins</td>
<td>3</td>
</tr>
<tr>
<td>IP Buckets</td>
<td>3</td>
</tr>
<tr>
<td>0.5% Chlorine</td>
<td>3 litres</td>
</tr>
<tr>
<td>90% Isopropyl or ethyl Alcohol</td>
<td>1.5 litres</td>
</tr>
<tr>
<td>Utility Gloves</td>
<td>3 pairs</td>
</tr>
<tr>
<td>Plastic Apron</td>
<td>3</td>
</tr>
<tr>
<td>Autoclave or sterilizer</td>
<td>1</td>
</tr>
<tr>
<td>Soap or hand sanitizer</td>
<td>3</td>
</tr>
<tr>
<td><strong>Pelvic Examination / VIA procedure</strong></td>
<td>30 reusable or 100 disposable</td>
</tr>
<tr>
<td>Bivalve speculums (preferably graves)</td>
<td></td>
</tr>
<tr>
<td>Non sterile gloves</td>
<td>6 X 50 pairs</td>
</tr>
<tr>
<td>5% Acetic acid / Table vinegar</td>
<td>1.5 litre</td>
</tr>
<tr>
<td>Lugol's iodine</td>
<td>1.5 litre</td>
</tr>
<tr>
<td>Normal saline</td>
<td>1.5 litre</td>
</tr>
<tr>
<td>Formalin solution</td>
<td>500 mls</td>
</tr>
<tr>
<td>Large cotton roll (500 g)</td>
<td>3</td>
</tr>
<tr>
<td>Orange sticks or wooden sticks</td>
<td>500</td>
</tr>
<tr>
<td>Galley pots</td>
<td>9</td>
</tr>
<tr>
<td>Kidney dish</td>
<td>3</td>
</tr>
<tr>
<td>Specimen containers with lid</td>
<td>5</td>
</tr>
<tr>
<td>Masking tape/ labels</td>
<td>1 roll</td>
</tr>
<tr>
<td>Non sterile gauze</td>
<td>1 roll</td>
</tr>
<tr>
<td>K-Y jelly</td>
<td>3 tubes</td>
</tr>
<tr>
<td>Condoms</td>
<td>5 boxes</td>
</tr>
<tr>
<td>Timer or watch</td>
<td>3</td>
</tr>
<tr>
<td>Sponge holding forceps</td>
<td>6</td>
</tr>
<tr>
<td>Punch biopsy forceps</td>
<td>3</td>
</tr>
<tr>
<td><strong>Data forms and other writing materials</strong></td>
<td></td>
</tr>
<tr>
<td>Cervical cancer screening map forms</td>
<td>100</td>
</tr>
<tr>
<td>Register or log book</td>
<td>3</td>
</tr>
<tr>
<td>Pathology forms</td>
<td>As needed</td>
</tr>
</tbody>
</table>
### National Guidelines for Prevention and Management of Cervical, Breast and Prostate Cancers

#### Monthly summary forms
- 1

#### Client cards
- 100

### Cervical Cytology (if done)
- Cervical Brush / cervix brush or Ayres spatula
  - As needed
- Glass slides
  - As needed
- Fixative solution
  - 100 mls

### Cryotherapy procedure- supplies in addition to VIA supplies
- Gas cylinder (NO\(_2\) or CO\(_2\)) -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
- 2

#### Adjustable spanner
- As required

#### Gas cylinder adaptor
- As required

#### Monsel’s paste or silver nitrate sticks
- As required

#### Glutaraldehyde (cidex)
- 10 litres

### LEEP Supplies in addition to VIA supplies for sites providing LEEP

#### Estimates per 100 women treated

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEEP units</td>
<td>1</td>
</tr>
<tr>
<td>Loops</td>
<td></td>
</tr>
<tr>
<td>15mm x12mm x11cm shaft</td>
<td>35</td>
</tr>
<tr>
<td>10mm x 10mm x11cm shaft</td>
<td>5</td>
</tr>
<tr>
<td>5mm ball, 11cm shaft</td>
<td>30</td>
</tr>
<tr>
<td>Electro surgery pens</td>
<td>2</td>
</tr>
<tr>
<td>Dispersive pads</td>
<td>10</td>
</tr>
<tr>
<td>Dispersive pad adapter (ES -3160C)</td>
<td>1</td>
</tr>
<tr>
<td>Coated Speculum</td>
<td>3</td>
</tr>
<tr>
<td>Smoke evacuator and filters</td>
<td>7</td>
</tr>
<tr>
<td>Speculum tubing</td>
<td>10</td>
</tr>
<tr>
<td>Internal Filter (replace annually)</td>
<td>1 per unit</td>
</tr>
<tr>
<td>1 -2% lidocaine with 1:100 000 epinephrine</td>
<td>15 X 50cc bottles</td>
</tr>
<tr>
<td>Spinal needles 22 -25 gauge, 3.5 inches long</td>
<td>100</td>
</tr>
<tr>
<td>Syringes – 10cc</td>
<td>50</td>
</tr>
<tr>
<td>Needles 18 – 20 gauge</td>
<td>100</td>
</tr>
<tr>
<td>Wooden spatulas</td>
<td>100</td>
</tr>
<tr>
<td>Long needle holder</td>
<td>1 -2</td>
</tr>
<tr>
<td>Long mayo scissors -straight</td>
<td>1 -2</td>
</tr>
<tr>
<td>Suture- Vicryl no O on a taper cut needle</td>
<td>5</td>
</tr>
<tr>
<td>Long tissue forceps</td>
<td>3</td>
</tr>
<tr>
<td>Sterile surgical gloves (6.5 – 8.5 depending on provider)</td>
<td>400</td>
</tr>
<tr>
<td>Large Cotton swabs (Ob /Gyn or Proctology)</td>
<td></td>
</tr>
<tr>
<td>Sterile gauze- Raytec</td>
<td></td>
</tr>
<tr>
<td>Specimen containers with lid and labels</td>
<td>100</td>
</tr>
<tr>
<td>Monsel’s paste</td>
<td>1</td>
</tr>
<tr>
<td>Gluteraldehyde 2 -4 %)</td>
<td>100 cc</td>
</tr>
<tr>
<td>Formalin</td>
<td>6 litres</td>
</tr>
<tr>
<td>Pathology forms</td>
<td></td>
</tr>
</tbody>
</table>
## APPENDIX IX: TABLE FOR RECORDING PAIN RELIEF

<table>
<thead>
<tr>
<th>DRUG CATEGORY</th>
<th>NAME AND DOSE OF DRUG</th>
<th>DEGREE OF PAIN RELIEF (TICK AS APPROPRIATE)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No relief</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Note: This table is designed to be filled in as the patient experiences pain relief from different drugs.*
### ANNEX X: TABLE OF HOSPICES AND PALLIATIVE CARE UNITS IN KENYA

<table>
<thead>
<tr>
<th>HOSPICE/PCU</th>
<th>E-MAIL</th>
<th>TELEPHONE</th>
<th>CONTACT PERSON</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FREE STANDING HOSPICES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Meru Hospice</td>
<td><a href="mailto:pdirector@meruhospice.or.ke">pdirector@meruhospice.or.ke</a></td>
<td>+254 064 30109</td>
<td>Gladys Mucee</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:stellakathambi@yahoo.com">stellakathambi@yahoo.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Nairobi Hospice</td>
<td><a href="mailto:info@nairobihospice.or.ke">info@nairobihospice.or.ke</a></td>
<td>+254 020 2712361</td>
<td>Dr. Brigid Sirengo</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:ceo@nairobihospice.or.ke">ceo@nairobihospice.or.ke</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><a href="mailto:clinical@nairobihospice.or.ke">clinical@nairobihospice.or.ke</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Kisumu Hospice</td>
<td><a href="mailto:kisumuhospice@hotmail.com">kisumuhospice@hotmail.com</a></td>
<td>+254 057 530091</td>
<td>Dr. Julius Onyango</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+254 020 2393565</td>
<td></td>
</tr>
<tr>
<td>4 Coast Hospice</td>
<td><a href="mailto:amisi1977@yahoo.com">amisi1977@yahoo.com</a></td>
<td>+254 020 3577026</td>
<td>Eric Amisi</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:coasthospice@yahoo.co.uk">coasthospice@yahoo.co.uk</a></td>
<td>+254 041 221431</td>
<td></td>
</tr>
<tr>
<td>5 Nyeri Hospice</td>
<td>info@nyeri hospice.com</td>
<td>+254 061 2030382</td>
<td>Saraphina Gichohi</td>
</tr>
<tr>
<td></td>
<td>ceo@nyeri hospice.org</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Eldoret Hospice</td>
<td><a href="mailto:info@eldorethospice.org">info@eldorethospice.org</a></td>
<td>+254 053 2062049</td>
<td>Mr. Paul Asige</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:paul@eldorethospice.org">paul@eldorethospice.org</a></td>
<td>+254 020 2410800</td>
<td></td>
</tr>
<tr>
<td>7 Nyahururu Hospice</td>
<td><a href="mailto:nyahuhospice@yahoo.com">nyahuhospice@yahoo.com</a></td>
<td>+254 065 22114</td>
<td>Esther Biringi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>07112145741</td>
<td></td>
</tr>
<tr>
<td>8 Nakuru Hospice</td>
<td>nakuru <a href="mailto:hospice@yahoo.com">hospice@yahoo.com</a></td>
<td>+254 737-079707</td>
<td>Elizabeth Ndung’u</td>
</tr>
<tr>
<td></td>
<td>’elizabeth@nakuru hospice.org’</td>
<td>+254 722-771401</td>
<td></td>
</tr>
<tr>
<td>9 Thika Hospice</td>
<td><a href="mailto:unisnjeri@yahoo.com">unisnjeri@yahoo.com</a></td>
<td>0721354681</td>
<td>Eunice Wachira</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Embu-Mbeere Hospice</td>
<td>embumbeere <a href="mailto:hospice@yahoo.com">hospice@yahoo.com</a></td>
<td>+254 722-352 861</td>
<td>Niceta Njagi</td>
</tr>
<tr>
<td></td>
<td>’<a href="mailto:stellahwarui@yahoo.com">stellahwarui@yahoo.com</a>’</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Kakamega Hospice</td>
<td><a href="mailto:kakamegahospice@gmail.com">kakamegahospice@gmail.com</a></td>
<td>0725828829</td>
<td>Rose Otera</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:roseotera@yahoo.com">roseotera@yahoo.com</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 St. Catherine’s Home Kisumu</td>
<td><a href="mailto:srtnath@gmail.com">srtnath@gmail.com</a></td>
<td>+254 057 62251</td>
<td>Sr. Mary Thanh</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+254-720-049-787</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>+254-728-970-012</td>
<td></td>
</tr>
<tr>
<td>13 Catherine Mc Auley Hospice –</td>
<td><a href="mailto:gabbyvince@hotmail.com">gabbyvince@hotmail.com</a></td>
<td>+254 734 958 228</td>
<td>Sr. Vincent Finnerty</td>
</tr>
<tr>
<td>Muhoroni</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Murang’a Hospice</td>
<td><a href="mailto:jumamonica77@yahoo.com">jumamonica77@yahoo.com</a></td>
<td>0721961865</td>
<td>Monica Juma</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:joseph.gachie@yahoo.com">joseph.gachie@yahoo.com</a></td>
<td>+254 710-705049</td>
<td>Joseph Gachie</td>
</tr>
<tr>
<td>15 Pope John Paul II Huruma</td>
<td><a href="mailto:jphuruma@gmail.com">jphuruma@gmail.com</a></td>
<td>+254 720-708023</td>
<td>Sr. Mary Ewa</td>
</tr>
</tbody>
</table>
### HOSPICE/PCU E-MAIL  TELEPHONE  CONTACT PERSON

<table>
<thead>
<tr>
<th>Hospice - Nanyuki</th>
<th><a href="mailto:germandocs@wananchi.com">germandocs@wananchi.com</a></th>
<th>+254 721-389763</th>
<th>Sr. Lucy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baraka Medical Centre, Ruaraka</td>
<td></td>
<td>+254 20 2048468</td>
<td>Elizabeth Njoki</td>
</tr>
<tr>
<td>Siaya Roselyne Hospice</td>
<td><a href="mailto:celline1952@yahoo.com">celline1952@yahoo.com</a></td>
<td>+254 721 569662</td>
<td>Celline Ndolo</td>
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<tr>
<td>Laikipia Palliative Care Centre</td>
<td><a href="mailto:laikipiapcc@hotmail.com">laikipiapcc@hotmail.com</a>  <a href="mailto:joyce.marete@yahoo.com">joyce.marete@yahoo.com</a>  <a href="mailto:info@laikipiapalliativecarecentre.org">info@laikipiapalliativecarecentre.org</a> <a href="mailto:jmarete@laikipiapalliativecarecentre.org">jmarete@laikipiapalliativecarecentre.org</a></td>
<td>+254 20 2494148  +254 716 862762</td>
<td>Joyce Marete</td>
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<tr>
<th>HOISPICE/PC UNITS IN THE RURAL COMMUNITY (FBO &amp; CBO)</th>
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<tr>
<td>Kimbilio Hospice -Kipkaren</td>
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<td>Our Lady Hospice Thigio</td>
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<td>Ongata Ngong Palliative Care CBO</td>
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<th>MISSION HOSPITALS WITH PALLIATIVE CARE UNITS</th>
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<td>AIC Kijabe Hospital</td>
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<td>Chogoria Hospital</td>
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<td>Tenwek Mission Hospital</td>
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<td>Maua Methodist Hospital</td>
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- **Email**: 056-30051/2 chege200851@yahoo.com
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- **Contact**: Mr. Patrick M Chege
<table>
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<tr>
<th></th>
<th>TEACHING &amp; REFERRAL HOSPITALS</th>
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</table>
| 43 | Kenyatta National Hospital Palliative Care Unit | drcege@wananchi.com | +254 722 848114  
+254 020 2726300 Ext. 43790 | Dr. Esther Munyoro |
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| 45 | Cancer Care Kenya | info@cancercarekenya.com | 020-3740132/0227/0153 | Alison Welton |
REFERENCES


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