NATIONAL GUIDELINES FOR CERVICAL CANCER PREVENTION AND CONTROL

ERITREA

MINISTRY OF HEALTH

July 2018

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ACRONYMS AND ABBREVIATIONS

ANC	Ante Natal Care
CC	Cervical Cancer
CCS	Cervical Cancer Screening
CCCPCP	Comprehensive Cervical Cancer Prevention and Control Program
CDC	Communicable Disease Control
CIN	Cervical Intraepithelial Neoplasia
DQA	Data Quality Assurance
DG	Director General
FIGO	International Federation of Gynaecology and Obstetrics
GDP	Gross Domestic Product
GLOBOCAN	Global Cancer Incidence, Mortality and Prevalence
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HSIL	High Grade Intra Epithelial Lesion
IARC	International Agency for Research on Cancer
I$	International Dollar
ICER	Incremental Cost-Effectiveness Ratio
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large Loop Excision of the Transformation Zone
LSIL	Low Grade Squamous Intraepithelial Lesion
LMIC	Low- and Middle-Income Countries
MOH	Ministry of Health
M&E	Monitoring and Evaluation
NCD	Non-Communicable Diseases
NHL	National Health Laboratory
ONRH	Orotta National Referral Hospital
PID	Pelvic Inflammatory Disease
RMNCAH	Reproductive Maternal Neonatal Child & Adolescents Health
SITAN	Situation Analysis
SVA	Single Visit Approach
TWG	Technical Working Group
TOR	Terms of Reference
TZ	Transformation Zone
UNFPA	United Nations Population Fund
VIA	Visual Inspection with Acetic Acid
WHO	World Health Organization
WRA	Women of Reproductive Age
YLS	Year of Lives Saved

FOREWORD

Cervical cancer is major public health concern in Eritrea. It is the second most frequent cancer in women aged 15-44 years (the first being breast cancer) and also the second most frequent cause of cancer related deaths in women of reproductive age (WRA). There are an estimated 265 new cases of overt cervical cancer annually, out of which 189 result in deaths. Cervical Cancer however, is easily preventable through strategies such as behavioural changes, vaccination, screening and treatment of precancerous lesions.

The high burden of advanced cancers of the reproductive organs and subsequent mortality is due to poor access to prevention (including vaccination, screening services and treatment services) and delay in seeking health care. These are further compounded by inadequate capacity of health workers to screen and manage pre-cancer lesions at primary health care facilities, and scarcity of infrastructure to manage advanced disease.

The Government of Eritrea, through the National Operational Cancer Policy, seeks to reduce the incidence, morbidity and mortality associated with cancers. In response to this, the Ministry of Health (MOH), as part of the integrated RMNCAH & N Strategic Plan, seeks to reduce the incidence of cervical cancer by 10%, and increase cervical pre-cancer screening coverage to 25 % of eligible population (25-49 years) by 2021.

To achieve this there is, therefore, the need to strengthen the capacity of all cadres of health care workers, at all levels our healthcare system, to provide preventive, promotive, screening, early detection, diagnosis and appropriate management of pre-cancer and cancers. It is also critical to streamline, standardize and monitor screening, diagnosis and treatment practices at all levels of health care.

The aim of this manual is to provide guidelines for service delivery for comprehensive cervical cancer prevention and control program for Eritrea, in line with the latest WHO recommendations. The guideline outlines key strategies for primary, secondary and tertiary prevention of cervical cancer, including HPV vaccination, screening and treatment of precancerous lesions, diagnosis and staging of overt cancer, management options, including palliative care for those with advanced disease. The guide provides basic concepts on anatomy of the uterine cervix, to lay the foundation for appreciating the role of Visual methods of screening. It also provides some programmatic guide on data and indicators for monitoring and evaluation of program Impact, as well as monitoring quality of services. In addition, it is intended to galvanize community awareness and participation, demand creation and resource mobilization.

This guideline is intended for a wide range of health care providers, program managers, supervisors, training institutions and other stakeholders working in public health programs for cervical cancer prevention and control. It provides all health care workers with a practical reference source for service delivery. The guidelines will be made available in all health facilities. The guide is not intended to be used a training package, but rather as a reference guide to be used with other learning resource packages.

I therefore urge all health care providers at all levels of care, training institutions, partners, stakeholders, other relevant government sectors such as ministry of education to embrace and consistently use these guidelines so as to achieve universal access to comprehensive cervical cancer prevention and control; reduce the incidence, morbidity and mortality associated with cervical cancer.

Mrs Amina Nurhusien

THE MINISTER FOR HEALTH

ACKNOWLEDGEMENT

Many thanks to Mrs Amina Nurhusien, Minister for Health, for providing guidance and inputs into the content of the guideline. We are most grateful Dr Berhana Haile, FCH Director and Mr. Solomon Kelifa, RH Unit, and Ministry of Health for providing enthusiastic leadership and coordination of all the activities leading to the development of this guideline. We also acknowledge the great contributions made by Mr Berhane Ghebretensae, DG of Clinical Services, Dr Andeberhan Tesfazion, DG of Public Health, Dr Berhane Debru, DG of Human Resource and Research for their unwavering support and technical guidance into the document. We are also thankful to the members of the technical working group who laboured tirelessly to make great contributions to the various chapters of the guidelines.

This work could not have been possible without the support from WHO, for which we are grateful. Many thanks to Dr. Josephine Namboze, the WHO Representative Eritrea, for facilitating the funding, and to all the stakeholders who participated in the dissemination meetings for the country situation analysis results, and the subsequent National Technical Working Group workshops for guideline development. We are most grateful to Dr. Nancy Kidula – WHO AFRO IST ESA, Dr. Assefash Zehaie, MD, MSc Epidemiology, NPO ATM/FHP/CAH focal person, Program Support Cluster Coordinator, and Solyana Ngusbrhan, WHO for providing technical support throughout the process.

CHAPTER 1: INTRODUCTION AND OVERVIEW OF CERVICAL CANCER

1.1 Overview of Cancer

Globally Cancer is the second leading cause of death, responsible for nearly 1 in 6 deaths and resulting in 8.8 million deaths in 2015. Approximately 70% of deaths from cancer occur in low- and middle-income countries. (WHO Fact sheet – Cancer- 1 February 2018) Late-stage presentation and inaccessible diagnosis and treatment services are common. In 2017, only 26% of low-income countries reported having pathology services generally available in the public sector. More than 90% of high-income countries reported treatment services are available compared to less than 30% of low-income countries. The economic impact of cancer is significant and is increasing. The total annual economic cost of cancer in 2010 was estimated at z.

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. Table 1.1 below shows the leading 10 causes of cancer in men and women globally as compared to the African Continent.

Both Sexes	Global	Africa	Men	Global	Africa	Women	Global	Africa
Lung	1	8	Lung	1	4	Breast	1	1
Breast	2	1	Prostate	2	1	colorectal	2	4
Colorectal	3	5	Colorectal	3	5	Lung	3	11
Prostate	4	3	Stomach	4	11	Cervix	4	2
Stomach	5	11	Liver	5	2	Stomach	5	11
Liver	6	4	Bladder	6	7	Uterine Corpus	6	11
Cervix	7	2	Esophagus	7	8	ovary	7	5
Esophagus	8	9	NHL	8	6	Thyroid	8	11
Bladder	9	10	Kidney	9	11	Liver	9	3
NHL	10	7	Leukemia	10	11	NHL	10	6
others	11	11	others		11	Others	11	7

Table 1: *Top Ten Causes of Cancer in Men and Women*

Source: GLOBOCAN 2012, IARC 2014)

1.2 Cervical Cancer

Cervical Cancer is ranked 4th most common type of cancer in women globally, but second in Africa. According to GLOBOCAN estimates [1], there were 572,624 new cases of cervical cancer worldwide, accounting for 7.9% of all cancers in women. The highest incidences of cervical cancer were recorded in Africa, Latin America and the Caribbean; while the lowest incidence were recorded in Northern America and the Oceania (IARC, 2012).

It is therefore not surprising that in Africa, where screening rates are low or non -existent, the majority of women present with advanced disease. This is compounded by lack of treatment facilities and inadequate personnel to manage invasive disease. The cost of treatment of invasive cancer is enormous. Many developing countries do not have the systems necessary for promotive preventive, screening and treatment of pre-cancer as well as management of invasive cancer 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 by the government and other stakeholders therefore translates to cost savings by individuals, families, communities and the country at large.

1.3 The Eritrean Context

According to the ICO/IARC Information Centre on HPV and Cancer 2017-, categorization of countries or areas has been done for statistical convenience, with Eritrea falling in the Eastern African states. These countries include Burundi, Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Mayotte, Mozambique, Reunion, Rwanda, Seychelles, Somalia, South Sudan, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. This region is characterised by low screening coverage, for example Kenya has coverage of 3.5%. WHO recommends that countries should have screening coverage of over 70% in order to have meaningful impact on the disease. The region (apart from Rwanda and Uganda) also lacks National HPV vaccination programs.

Eritrea has a population of 1.51 million women aged 15 years and older who are at risk of developing cervical cancer. Current estimates indicate that every year, 265 women are diagnosed with cervical cancer and 189 die from the disease. Cervical cancer ranks as the 2nd most frequent cancer among women in Eritrea and the 2nd most frequent cancer among women between 15 and 44 years of age.

Currently, Eritrea does not have a cancer registry; however, data from the HIS indicates that cervical cancer ranks second to breast cancer in the country. In a rapid situation analysis report by WHO, 2018, data from Orotta Maternity Hospital, involving 2,069 women screened using Pap smear indicated that 2.9% had Low grade intraepithelial lesions (LSIL); 1.8% had high Grade Intraepithelial lesions (HSIL), while 1.7% had invasive cancer on cytology. The screening pilot project at Orotta involved women aged 20-65 years out of which those eligible for screening by policy (25-49) comprised 72.3%. Pick up rate for lesions in the screen-eligible population was 78.3% for LSIL, 84.2% for HSIL and 54.3% for invasive cancer; 45.7% of invasive cancer was in women older than 49 years of age. Data from the National Health Laboratory indicated that 30% of colposcopic directed biopsies had overt cancer.

1.4 Prevention and Control of Cervical Cancer

The elements of comprehensive cervical cancer prevention and control program include community engagement, primary prevention strategies, HPV vaccination, screening and treatment of cervical precancerous lesions, early diagnosis and treatment of palliative cancer and palliative care. Community engagement includes community involvement for health education, behaviour change communication, and demand creation for services. The services should reach all appropriate age groups, all men and women regardless of socioeconomic status. A clearly laid down community mobilization and implementation plan is important, in which as many people as possible should be reached. Moreover, community involvement and education is known to increase confidence for utilization of preventive services.

A robust HPV vaccination program targeting adolescent girls 9-13, with appropriate coordination between different ministries and agencies to ensure effectiveness, is necessary. The messages need to be targeted to create awareness amongst young people, and integrated with other NCD prevention messages. Screening should be available as close to the community as possible and must be linked with treatment and follow up. The community should also be educated on treatment requirements and processes, including palliative care.

All cadres of the healthcare workforce (health assistants, nurses and nurse midwives, medical officers, laboratory staff and specialists); faculty of training institutions; and all healthcare levels of the Ministry of Health need to be involved. Investment need to be made on capacity building tailored to the various cadres, improvement of facility functionality and capability to provide easy access to screening and treatment. Strengthening of the referral systems is important to ensure screen-positive lesions are linked to care.

Monitoring of the program through selected indicators for the Health Information System will ensure appropriate response is made toward reaching the country's target. There is also the need to ensure appropriate indicators are selected in order to track performance of the program at the facility, ZOBA, and at the national level. Structured supportive supervision is essential to ensure quality of the services being provided. Technical support such as the National technical working group can be valuable to regularly interrogate data and provide insight to adjustments needed to improve the program coverage, access, quality, and align these to the country goals.

The Government of Eritrea, through the National operational cancer policy, seeks to reduce the incidence, morbidity and mortality associated with cancers. The Ministry of Health (MOH), as detailed in the integrated RMNCAH & N Strategic Plan, seeks to reduce the incidence of cervical cancer by 10%, increase cervical pre-cancer screening coverage to 25 % of eligible population (25-49 years) by 2021.

There is therefore the need to strengthen the health system to have the necessary equipment, human resource, capacity of all cadres of health care workers, at all levels of health care, to provide screening, early detection, diagnosis and appropriate management of pre-cancer and cancers. It is also critical to streamline, standardize and monitor screening, diagnosis and treatment practices at all levels of health care.

1.5. The Purpose of the Guidelines

This guideline includes the following: anatomy of the uterine cervix, primary prevention, HPV Vaccination, screening and treatment of precancerous cervical lesions. It also highlights diagnosis and management of overt cancer including palliative care. The guideline provides programmatic considerations including: data management, reporting, monitoring and evaluation, quality improvement, health education, community mobilization and advocacy for resource mobilization. It also provides annexes comprising of tools that can be adopted easily for initiation of the program. For the cervical cancer prevention and control program to have an impact, all the key components (community engagement, primary prevention including HPV vaccination; screening and treatment of precancerous lesions; diagnosis and treatment of overt cancer including palliative care, monitoring and evaluation) have to be implemented in a coordinated manner.

CHAPTER 2: CAUSES OF CERVICAL CANCER

2.1 Global Burden of HPV and HPV-Related Diseases

Human papillomavirus (HPV) is a common sexually transmitted infection, which affects three-quarters of sexually active people at some period of their life. HPV- infected persons often have no symptoms and can transmit the virus to others.

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. In this regard, HPV is the primary cause of 99.7% of all cervical cancers. Infection with one or more of the 15 high-risk oncogenic types usually results in invasive cervical cancer after 10-20 years. The other five HPV-related cancer include vulva, vagina, anus, penis and oropharynx, which accounted for 80,000 cancer cases in 2012 (GLOBOCAN)

The global prevalence of HPV infection in women with normal cytology is around 11-12%, with the highest prevalence in sub-Saharan Africa (24%), Eastern Europe (21%) and Latin America (16%). Maximum rates of HPV prevalence are observed in women less than 25 years, declining in older ages in many populations, some of which have a secondary peak in peri-menopausal or early menopausal women.

According to GLOBOCAN (2012), in the Eastern Africa region 4.8% of women in the general population are estimated to harbour cervical HPV-16/18 infection at a given time, and 67.9% of invasive cervical cancers are attributed to HPVs. Data is not yet available on the HPV burden in the general population of Eritrea.

2.2 Mode of Infection Pathway

HPV infection is very common. It has been noted that every sexually active person - even one who has had only one sexual partner - is at risk of contracting HPV at least once in his or her lifetime. Transmission requires access to basal cells through micro cuts, abrasions or small tears in the squamous or mucosal epithelium. Infection with other STIs (genital warts, herpes simplex, C. Trachomatis) may cause inflammation and breaks in the epithelial barrier, thus allowing HPV direct access to the basal epithelial cells.

Anogenital HPV infections are contracted through sexual intercourse, anal sex and skin-to-skin contact in the genital region. Some HPV infections that result in oral or upper respiratory lesions are contracted through oral sex. HPV can spread through both heterosexual and homosexual relationships. Of note, gay and bisexual men are about 17 times more likely to develop anal cancer than men who only have sex with women. In addition, HPV may be transmitted perinatally from mother to child during vaginal delivery.

2.3 HPV Types

There are over 150 types of HPV. More than 40 of these infect the anogenital area of women and men. Among all existing types of HPV only a few cause cancers. In estimating the risk to cause cervical cancer, HPV are classified into low-risk such as type 6, 11, 34, 40, 42, 43, 44; high-risk including types 16, 18, 31, 33, 35, 39, 45, 52, and 58.

HPVs type 16 and 18 are the most common high-risk types and are responsible for 70% of cervical cancers worldwide. HPVs 31, 33, 35, 45, 52, and 58 are responsible of another 20% of cases. These proportions are constant across all world regions. Among the non-cancerous HPV-associated preventable conditions, genital warts and recurrent respiratory papillomatosis are unequivocally linked to HPV 6 and 11.

2.4 The Natural History of HPV and Cervical Cancer

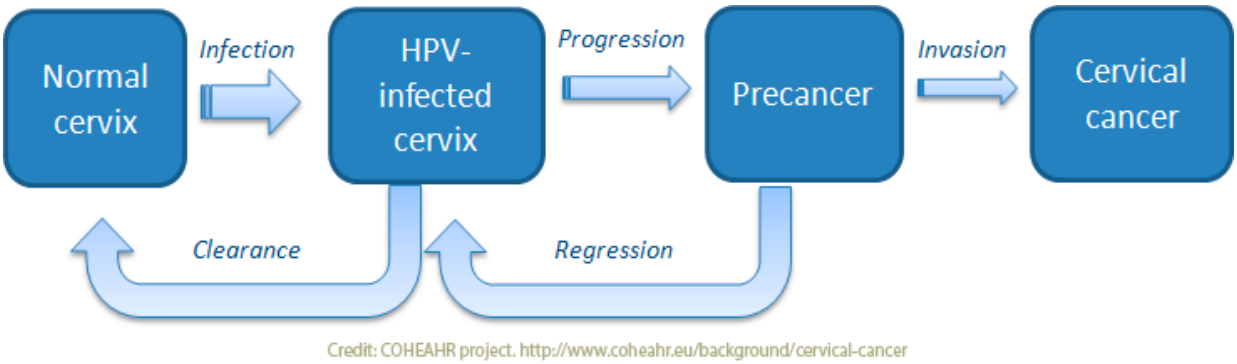


Figure 1: *Natural Progression of Cervical Cancer*

In many industrialised countries the prevalence of HPV infections in young adult females' ranges between 30% and 80%, and the lifetime probability of ever encountering HPV is as high as 80-90%.

Approximately 90 % HPV infections spontaneously regress on their own without any clinical signs and symptoms or intervention. Cervical cancer is the rare, end-stage of an unresolved HPV infection, currently defined as persistent presence of HPV DNA in repeated testing of cervical specimens.

The fraction of persistent carriers of HPV in the middle ages is estimated to be in the range of 4-10% and these women are the true high-risk group for cervical cancer and probably for any other HPV-related cancer. The time lag between the peak of HPV infection and the peak of cancer incidence is two to four decades, making the initiating infections and precursor lesions of cervical cancer an appropriate target for screening and early detection.

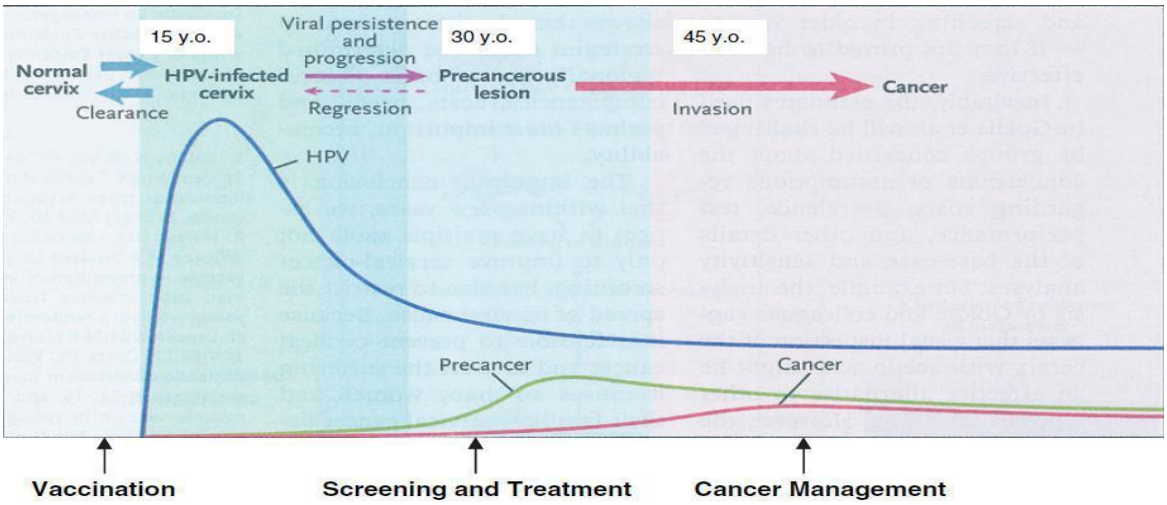


Figure 2: *Natural Progression of Cervical Cancer*

2.5 Cervical Carcinogenesis

It is important that the high-risk HPV (especially, 16 and 18) enters the basal cells of the squamous epithelium in the skin or cervical mucous membrane. Once in the cell, the virus begins to generate oncogenic proteins – E6 and E7 (oncoproteins) which promote cervical carcinogenesis including interfering with cell functions that normally prevent excessive growth (tumour suppressors p53), helping the cell to grow in an uncontrolled manner and circumventing cell death.

2.6 Risk Factors that Increase the Likelihood of HPV Progression to Invasive Cervical Cancer

The most important risk factor for development of cervical cancer is infection with oncogenic types of HPV such as type 16 and 18. There are several factors that may influence the risk of acquisition or expression of the HPV infection. These include: unsafe sexual behaviour, mode of infection pathway, smoking, alcohol, long-term use of oral contraceptives, co infection with other sexually transmitted infections and immunosuppression (e.g. with HIV infection).

a) Unsafe Sexual Behaviour

More than 40 % of young women are infected with HPV during the first 2 years after the onset of sexual activity. Adolescents and sexually active women < 25 years are particularly vulnerable to HPV infection because of anovulatory cycles that result in inadequate production of cervical mucus – a protective barrier against infectious agents. Moreover, during puberty the cervix undergoes cellular changes at the transformation zone (ectropion / ectopy) in which the columnar epithelium of the cervix -which is only one cell thick- is directly exposed to the vagina. This in itself increases the susceptibility to HPV infection, and more persistence of the infection especially among women who had their first sexual intercourse prior to 16 years of age.

Having multiple sexual partners also increases the chances of coming into contact with a person who is carrying HPV. The most consistently reported risk factor for HPV infection in men is a greater lifetime number of female or male sex partners. Men, who had more than 10 partners during their lifetime, have twice bigger chance to get infected by HPV. A positive association has also been noted between HPV detection, sexual frequency and condom use, with lower prevalence of HPV infection reported in clients who consistently used condoms.

b) Circumcision

A lot of studies have been done to detect the influence of circumcision. Circumcised men are less likely to get penile and prostate cancer. The foreskin is simply more sensitive to HIV infection than the skin on the shaft, according to the Centres for Disease Control and Prevention (CDC). Another possible explanation is that the foreskin is susceptible to tearing during the intercourse, which would give viruses an easy pathway into the body. The folds of the foreskin provide an environment for viruses and bacteria to thrive, initiating inflammatory changes that make it susceptible to HPV.

c) Smoking

Several studies have revealed that cigarette smoking (passive or direct) is associated with HPV prevalence, incidence, and persistence. Women who smoke are twice as likely as non- smokers to get cervical cancer. The cervical mucus of smokers contains measurable amounts of cigarette constituents and their metabolites. Cigarette metabolites damage the DNA of cervix cells, increase cell proliferation and may contribute to the development of cervical cancer. Smoking was recently identified as a risk factor for HPV detection in men, and it has been reported to be associated not only with virus persistence but also with anal and penile cancer. It is known that smoking also makes the immune system less effective in fighting HPV infections associated with the oropharyngeal and genital areas (especially warts).

d) Alcohol

Alcohol usage is a potent modulator of immune function and can therefore lead to immune deficiency and increased sensitivity to different chronic and infectious diseases. These adverse effects to the immune system are not only caused by chronic alcohol abuse but acute and moderate alcohol consumption as well. Pathogen response is separated into two phases: the first phase is an inflammatory reaction, which provides protection against the immediate effects of the infection, and the second phase involves the development of immunity to the pathogen. Alcohol interferes with both phases of the immune response. Men and

women who take a high amount of alcohol are associated with an increased risk of having multiple HPV types, which leads to higher cervical/anal lesion and more common genital warts.

e) Immunosuppression

Human immunodeficiency virus (HIV) damages the immune system and puts women and men at higher risk for HPV infections. HPV is believed to be more dangerous among HIV- positive individuals due to the impact of HIV on cell-mediated immunity, a critical component required for clearance of HPV infection and slowing the growth and spread of cancer cells. Therefore, in women with HIV, cervical pre-cancer might develop into an invasive cancer faster than it normally would.

Another group of people at risk of HPV infection are these taking immunosuppressive treatments (chemotherapy, monoclonal/polyclonal antibodies, glucocorticoids etc) to reduce their immune response, because of being treated for an autoimmune or oncological disease, or who have had an organ transplant. In this case, because of lowered blood cells, especially, white cells, human organism can be placed at greater risk of infection.

f) Sexually Transmitted Infections (STI)

Infection with Chlamydia trachomatis has been found to be associated with high-grade cervical intraepithelial lesion or cancer in HPV positive women. It is also associated with high-risk HPV types of long-term persistence. HPV infection of the cervix is not believed to be inflammatory. However, during C. trachomatis infection higher amounts of cytokines are secreted resulting in a severe inflammatory state. This inflammatory effect to the C. trachomatis infection may lead to chronic cervical tissue damage, triggering an inflammatory cascade, decreasing cellular immunity, and promoting angiogenesis.

Infection with Herpes simplex virus-2 is also one of several factors that work in conjunction with HPV in enhancing cervical cancer risk. In fact, increasingly higher levels of HSV-2 and serological positivity have been noted from cases of cervicitis to cervical intraepithelial neoplasia to squamous cell carcinoma. Infection with HSV-2 has also been shown to have a positive correlation with an increased risk of precancerous and cervical cancer.

g) Having Multiple Full-Term Pregnancies

Women who have had 3 or more full-term pregnancies have an increased risk of developing cervical cancer. Studies have pointed to hormonal changes during pregnancy as possibly making women more susceptible to HPV infection or cancer growth. Another thought is that pregnant women might have weaker immune systems, allowing for HPV infection and cancer growth.

h) Having a Family History of Cervical Cancer

Cervical cancer may run in some families, with higher chances of developing the disease if your mother or sister had cervical cancer than if no one in the family had it. Some researchers suspect that this may be due to an inherited condition that makes some women less able to fight off HPV infection than others. In other instances, women in the same family as a patient already diagnosed could be more likely to have one or more of the other non-genetic risk factors previously described in this section.

Finally, when considering risk factors for cervical cancer, it is recommended to focus on those factors that can easily be modified (such as smoking or human papillomavirus infection), rather than those that cannot be changed (such as your age and family history).

CHAPTER 3: FEMALE PELVIC ANATOMY AND PHYSIOLOGY

An appreciation of the female pelvic anatomy will assist the healthcare providers to communicate, educate, counsel, interpret laboratory results and more importantly, understand screening and treatment of pre-cancer. Moreover, it will assist healthcare workers understand the need for referral of appropriate cases.

3.1 Gross Anatomy

The Female Reproductive Organs

The female reproductive system is divided in two. Namely external and internal organs.

a) The External Organs

Figure 3 below shows the external organs of a woman's reproductive system. These include all areas visible to the naked eye when a woman of reproductive age spreads her legs. These are: the vulva, the perineum and the anus. The vulva comprises the vaginal opening (introitus), which, with nearby structures, is protected by the labia majora and minora. The clitoris is a small and very sensitive organ that enhances sexual pleasure. The urinary opening (urethra) is a very small opening above the introitus. The perineum is the area between the vaginal opening and the anus. Bartholin glands produce clear mucus, which lubricate the introitus when a woman is sexually stimulated.

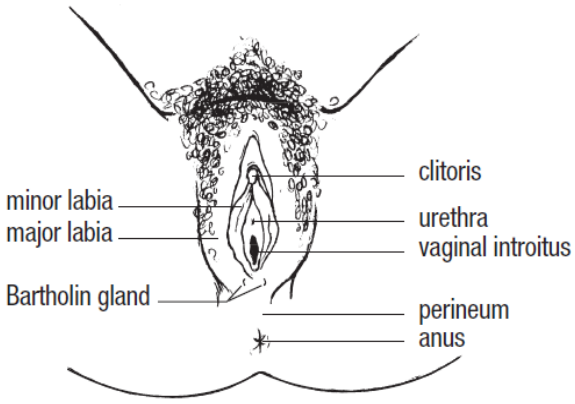


Figure 3: *The External Organs of a Woman's Reproductive Organs*

b) The Internal Organs

These are the organs inside the pelvis. They include the vagina, the uterus, the fallopian tubes and ovary. *Figure 4* shows the internal female reproductive organs

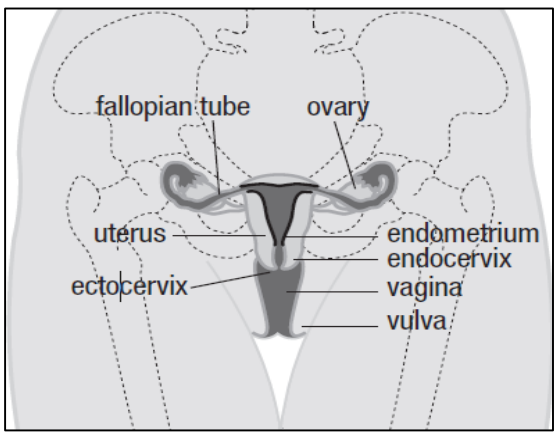


Figure 4: *The Internal Female Reproductive Organs*

i. Vagina

The vagina is an elastic muscular tube with multiple folds, leading from the introitus to the cervix. The lower portion of the cervix (ectocervix) protrudes into the upper end of the vagina and the vaginal area surrounding it is called the vaginal fornix.

ii. Cervix

The cervix is the lower third of the uterus. In a non-pregnant woman of fertile age, it measures approximately 3 cm in length and 2.5 cm in diameter. The lower part of the cervix (ectocervix) lies within the vagina and is visible when a speculum is inserted. The upper two thirds of the cervix (endocervix) lies above the vagina and is not visible. Most cervical cancers originate in the area where the endocervix and ectocervix meet. Figure 3.3 below shows the uterus and the relative size of the cervix as part of the uterus in a woman of reproductive age.

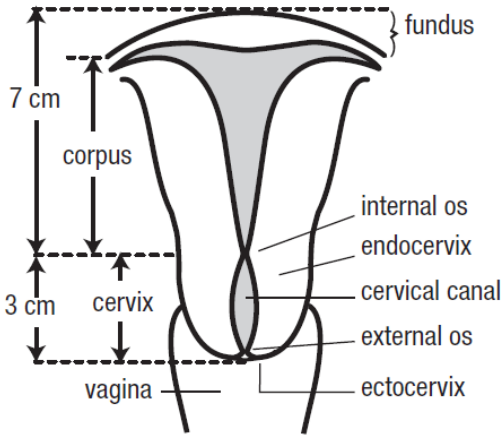


Figure 5: *Uterus and the relative size of the Cervix*

The cervix is composed of dense fibro-muscular tissue. The cervical canal runs through the centre of the cervix from the internal OS (the opening at the entrance to the cavity of the uterus) to the external OS (where the cervix opens into the vagina)

Figure 6 below is a slightly enlarged photograph of the cervix as seen with a speculum in place. It shows the slightly irregular opening to the cervical canal, or external OS, in a woman of reproductive age who has not had any vaginal deliveries. In a woman who has had one or more deliveries, the OS would look like a wide, mouth-like, irregular slit. In this figure, the darker area surrounding the OS is an extension of the columnar epithelium lining the canal; the lighter area around it is composed of stratified squamous epithelium extending from the vagina. The line where the two epithelia join is the squamo-columnar junction (SCJ).

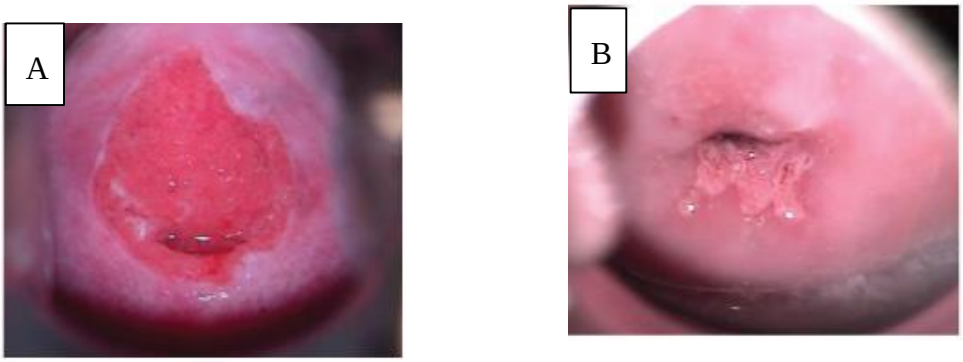


Figure 6: *A slightly Enlarged Photograph of the Cervix*

The location of the squamo-columnar junction (SCJ) is variable.

A. The SCJ is located on the ectocervix and is fully visualized.
B. The SCJ is located near the external OS and is not entirely visible.

iii. Uterus

The uterus or womb is a thick-walled, pear-shaped, hollow, muscular organ. When not enlarged by pregnancy or a tumour, the uterus measures approximately 10 cm from its top (fundus) to the bottom of the ectocervix (see Figure 1.5). It is supported by several ligaments formed by thickenings of the peritoneum (the very thin membrane lining of the abdominal wall), which are attached to the pelvic wall. The area between the uterus and the pelvic wall is known as the parametrium. The cavity of the uterus is lined by the endometrium, a layer of epithelium that contains many glands. It is the endometrium which undergoes dramatic changes during the menstrual cycle and during pregnancy.

iv. Fallopian Tubes

The fallopian tubes are thin hollow tubes and are the route used by the egg to travel from the ovary to the uterus. It is in the fallopian tube that fertilization of the egg takes place if the woman has intercourse in the days immediately before and/or after ovulation without contraception.

3.2. The Cervical Epithelia and Normal Changes during the Reproductive Years

Description of the Cervical Epithelia

The lining found on the skin and inside hollow organs is known as the epithelium. Two types of epithelium line the surface of the cervix. The ectocervix is covered by the strong, protective, stratified (multi-layered) squamous epithelium, which is a continuation of the vaginal covering. A single layer of tall columnar cells –the columnar epithelium covers the endocervical canal. The two epithelia meet at the squamo-columnar junction (SCJ).

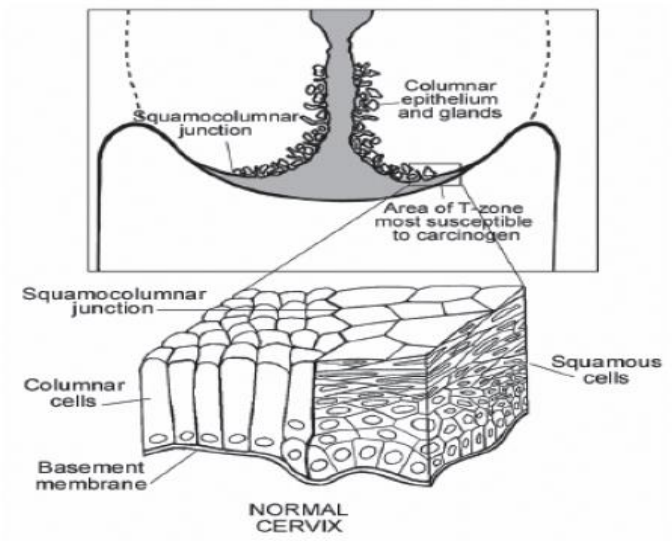


Figure 7: *The Squamocolumnar Junction*

The two types of cervical epithelium and the squamocolumnar junction (SCJ)

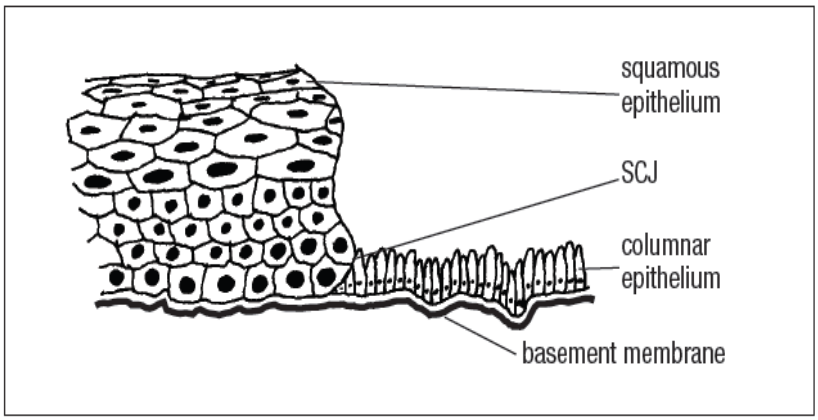


Figure 8: *A Magnified Squamocolumnar Junction*

The columnar epithelium is a single layer of tall cells, that lines the cervical canal and extends outwards to cover variable portion of the ectocervix. It is much thinner and more fragile than the squamous epithelium of the ectocervix and contains multiple glands that produce cervical mucus, which lubricates the canal.

The SCJ is the place where the two types of epithelia meet. The SCJ is seen as a sharp line with a step caused by the different thicknesses of the two epithelia as illustrated in figure 3.4. The location of the SCJ varies with a woman's age, hormonal status, birth trauma, pregnancy status and use of oral contraceptives.

During a woman's reproductive years, the more fragile columnar epithelium that extends out from the cervical canal onto the face of the cervix is replaced by tougher squamous epithelium when exposed to the acidic environment of the vagina. This normal replacement process is termed squamous metaplasia. When this occurs, the position of the SCJ changes. The area of variable size between the original and the

new SCJs is known as the transformation zone. The cells of the transformation zone are particularly vulnerable to HPV infection and it is here that most squamous cell carcinoma develops (see figure 3.6).

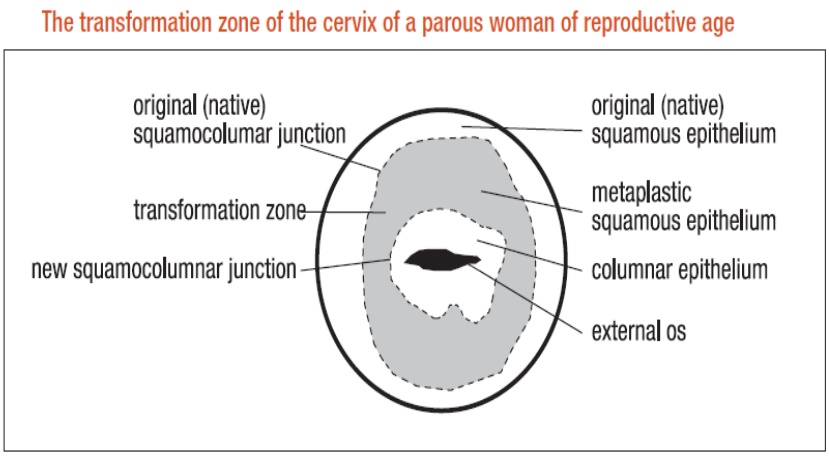


Figure 9: The face of the cervix of a woman who has had one or more vaginal births. It shows the normal changes that now include the squamous metaplastic epithelium, the transformation zone and both SCJs.

Figure 9: *The Transformation Zone of the Cervix*

3.3 Normal changes in the Appearance of the cervix throughout Reproductive Cycle

In addition to the epithelial changes on the cervix, the appearance of the cervix also undergoes striking changes from birth to post menopause. Figure 3.7 below is composed of schematic drawings showing these age-induced changes on the cervix. It should however be noted that in real life the appearance and demarcation of the epithelium on cervix at different life-stages

a) From birth to pre-puberty: - The original SCJ is present in girls at birth, and is found at or near the external os.

b) From menarche to early reproductive age: - At puberty when the ovaries begin to secrete oestrogen, the cervix grows in size; columnar cells from the endocervix and the original SCJ become visible on the ectocervix.

c) In women in their 30s: - Under the influence of oestrogen, the normal maturing process or squamous metaplasia has occurred and the original and new SCJs are both in place. The transformation zone is the area between the two SCJs.

d) In perimenopausal women: - As women age and the influence of oestrogen decreases around the time of menopause, the cervix shrinks, and the columnar epithelium and transformation zone retreat back from the ectocervix into the cervical canal.

e) In postmenopausal women: - Without oestrogen stimulation, the original SCJ is still visible on speculum examination, but the new SCJ and a variable portion of the metaplastic epithelium of the transformation zone have retreated into the cervical canal.

Progressive changes may be uneven, however, in some postmenopausal women, the cervix may look like in perimenopausal women, with the new SCJ still partly or completely visible.

Appearance of the cervix across a woman's lifespan

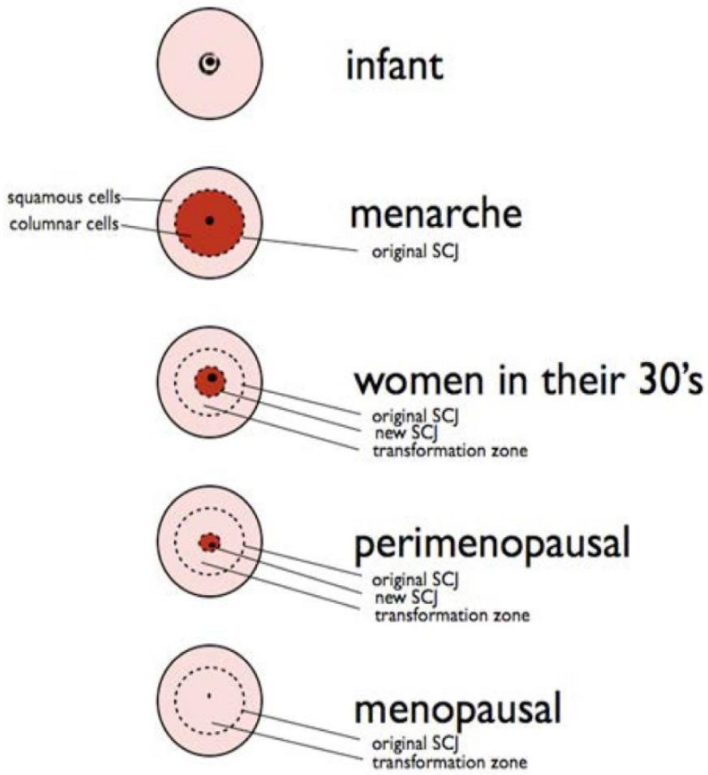


Figure 10: *Appearance of the Cervix across a Woman's Lifespan*

CHAPTER 4: HPV VACCINATION AND OTHER PRIMARY PREVENTION STRATEGIES

Human papillomavirus (HPV) is the most common viral infection of the reproductive tract and it causes a range of conditions in both men and women, including precancerous lesion that may progress to cancer. Most HPV infection resolve spontaneously however under some conditions it remains persistent and results in pre-cancer which if untreated will result in cancer. Cervical cancer comprises 84% of all HPV related cancers. Other HPV related cancers include vulvar, penile, anorectal or oro-pharingeal cancers.

WHO recommends that countries should prioritize HPV immunization of girls prior to sexual debut in order achieve prevention of cervical cancer. There are three vaccines in the market: Bivalent, Quadrivalent and Nanovalent. All these three vaccines have been licenced and have been shown to have excellent, safety, efficacy and effectiveness. HPV types 16 and 18 have been associated with more than 70% of all cases of cervical cancer. Other high oncogenic types include type 31, 33, 45, 52 and 58.

4.1 Strategies for Implementation of HPV Vaccines

HPV vaccination should be introduced as part of coordinated comprehensive cervical cancer prevention strategy. HPV vaccination ids a primary preventive intervention, however it does not entirely eliminate the need for screening in later life because existing vaccines do not protect against all exiting high risk HPV types. HPV vaccination also has limited impact on cervical cancer in women who are older than the vaccine eligible group. There is need to integrate HPV vaccination introduction to other vaccinations done at the same age e.g. tetanus vaccination.

HPV vaccination can be integrated with school health and other adolescent health services. Health facility based and outreaches to the community are other strategies that can be used

Useful criteria for Determining the Approach Method

Countries should use the methods that are

- Compatible with their delivery structure and cold chain capacity
- Affordable cost effective and sustainable
- Capable of achieving the highest possible coverage

Efforts should be made to prioritize populations that are less likely to access vaccination.

4.2 Target Groups for Vaccination

a) Primary Target Groups for Vaccination

WHO recommends primary target population for HPV Vaccination to be 9 to 14 prior to becoming sexually active. Achieving high vaccination coverage in >80% in girls reduces the risk of HPV infection for boy's as well.

b) Secondary Target Groups for vaccination

Vaccination of secondary target population e.g. females over 15 years or males is recommended only if this is feasible affordable and cost effective.

4.3 Cohorts for Vaccination

Vaccination of multiple cohorts of girls is cost effective in the age range 9-14 years in particular when the two-dose schedule id used. The initial vaccination of multiple cohorts of the age group is recommended when the vaccine is first introduced. Girls who are older than 15 would require a three dose schedule

rather than a two dose schedule because they are more likely to be already sexually active hence vaccinating them would not be cost effective.

4.4 Choice of HPV Vaccine

The present evidence indicates that from a public health perspective, the three vaccine types provide comparable immunogenicity efficacy and effectiveness of cervical cancer which is mainly caused by HPV type 16 and 18. Determinants of which vaccine type to use should include country data on prevalence of HPV related problems such as ano-genital warts of oro-pharyngeal cancers. Other characteristics include the cost of the vaccine.

4.5 HPV Vaccination Schedule

A two-dose schedule with adequate spacing between the first and the second dose for those aged 9 to 14 years is cost effective and may facilitate high coverage. The two-dose schedule with s sic moth interval between the first and the second vaccination is recommended for individualised receiving the first dose before the age of 15 years. Those aged greater than 15 years at the time of the second dose are adequately covered by the two doses.

There is no maximum recommended interval between the first and the second dose however the interval should not exceed 12-15 months because the schedule needs to be completed before the girls become sexually active. If the interval between the 2 doses is less than five months a third dose has to be given at least six months after the first dose.

4.6 Girls Older than 15 Years of Age

A 3-dose schedule (0, 1-2, 6) months should be used for all vaccinations it initiated for girls older than 15 years of age.

4.7 Vaccination in HIV Infected

A 3-dose schedule, (0, 1-2, 6) months should be used for all vaccinations for girls infected with HIV infection in spite of whether they are receiving antiretroviral therapy.

4.8 Co-Administration with Other Vaccines

HPV vaccines can be administered together with other live and non -live vaccines as long as separate syringes and different injection sites are used e.g co-administration of HPV vaccine with booster dose of tetanus could be considered.

4.9 Interchangeable use of HPV Vaccine

There is limited data on the safety, efficacy of immunogenicity of the three vaccines when used interchangeably. Hence every effort should be made to administer the same vaccine. However, if the vaccine used for the prior doses is unknown or unavailable any HPV vaccine can be administered to complete recommended schedule.

4.10 Vaccine Safety

Adverse events resulting from HPV vaccinations are often non-serious and last for a short duration. The vaccine can be safely used for immune compromised or HIV infected. Administration of the vaccine on pregnancy should be avoided and if the lady becomes pregnant after initiating, the subsequent dose should be delayed until after delivery. Termination of pregnancy is not indicated where vaccination was done in

avertedly during pregnancy. HPV vaccination is contraindicated in cases of severe allergic indication following a previous vaccination. Surveillance should be in place to monitor the HPV vaccine safety.

4.11 Monitoring and Evaluation of HPV Vaccination

The monitoring and evaluation will be conducted routinely through the existing EPI program 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

4.12 Other Primary Prevention Strategies

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 behaviour, and discouragement of tobacco use/ cigarette smoking – a known risk factor for cervical cancer.

4.13 Education and awareness to Reduce High-Risk Sexual Behaviour

The following strategies are recommended for primary prevention:

a) 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). Male circumcision is universal in Eritrea (MoH advocates for Early Medical Infant circumcision).

b) Reduction of high-risk sexual behaviour: Abstinence, delay in age of sexual debut, limiting the number of sexual partners, and correct and consistent use of condoms are all effective measures for reducing the risk of STI that act as co factors to cervical cancer

c) Reduction of cigarette smoking and other substances

The harm caused by cigarette smoking is well articulated in the guide on NCD in Eritrea

a) Screen and treat sexually transmitted infections

b) Promote condom use. This results in the following:

- 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.

CHAPTER 5: SCREENING FOR CERVICAL 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. Secondary prevention aims to prevent invasive cervical cancer by detecting

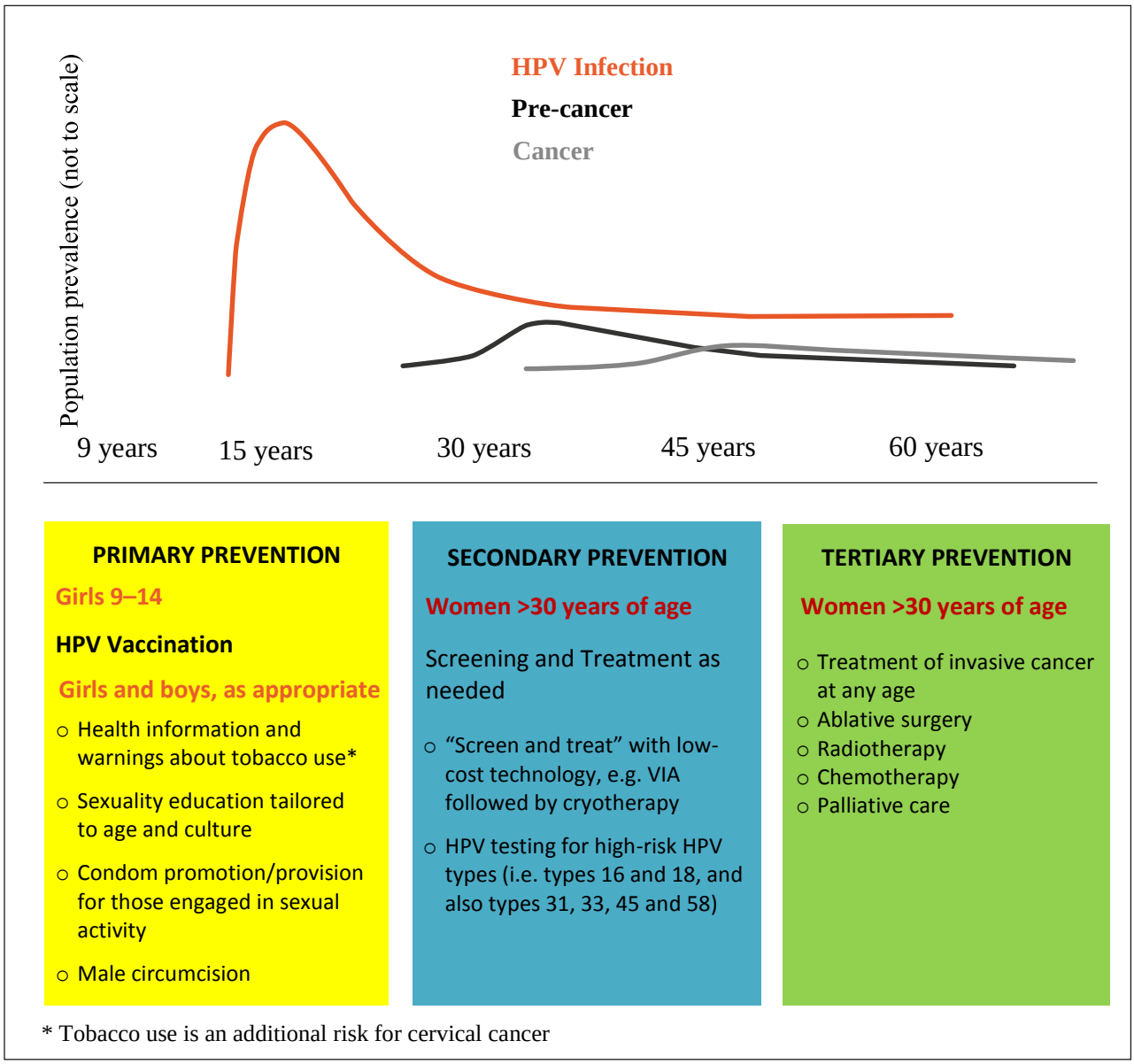


Figure 11: *A healthier future for girls and women. Geneva: World Health Organization; 2013*

Source: Adapted from WHO Guidance Note: Comprehensive Cervical Cancer Prevention and Control

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), 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.

5.1 Definition of Screening?

Screening is a public health intervention provided to an asymptomatic target population. Screening is not undertaken to diagnose a disease, but to identify individuals with increased probability of having either the disease itself or a precursor of the disease.

The following criteria is used to determine if a disease is appropriate for a screening:

- The disease must have serious consequences.
- The disease must have a detectable preclinical, asymptomatic stage.
- Treatment of the preclinical stage must favourably influence the long-term course and prognosis of the disease being screened for.
- Treatment must be available and accessible for those who have a positive screening test.

5.2 Benefits of Cervical Cancer Screening

The desired outcome of screening is the reduction of cervical cancer through detecting and treating pre cancer cases before they progress to overt cancer. in addition, screening can detect cervical cancer at an early stage when the cancer can be treated successfully. Screening by itself has no preventive value unless it is linked to treatment. If the screening programme is not linked to treatment it will have no impact on the incidence of cervical cancer.

5.3 The Risk of Cervical Cancer Screening

One the risks of screening, is over-detection of pre-cancer lesions (i.e. false-positive results), which in turn leads to overtreatment of women who are not at increased risk of invasive cancer. However, the benefits of early detection and treatment (i.e. true-positive results) far outweigh the relative minor consequence of overtreatment. Another significant screening risk involve obtaining a false negative result and hence missed opportunity to treat the pre-cancer lesion early. Care must be taken to ensure that adequate resources, training and supportive supervision are done to ensure quality services in order to minimise false negative result. WHO recommends countries to cover 100% of the screening target population and also conduct the necessary management, referral and follow up.

5.4 Characteristics of a Good Screening Test

A good screening test should be:

- Available: accessible to the entire target population.
- Accurate: the result of the test is correct
- Affordable: inexpensive to the health system in terms of both financial and human resources, and from patient's perspective.
- Acceptable: well tolerated by both the patient and the provider.
- Simple: Not complicated to perform and to provide follow-up care for women with abnormal results.
- Reproducible: repeating the same test will give the same result.
- Safe: the test procedure and management of screen-positive subjects have no or minimal adverse effects.

Top-level decision-makers must select a screening test that regard the aforementioned factors. the selection is made considering a trade-off between the tests performance affordability and sustainability, potential to reach target population and its capacity to be performed at different levels of healthcare facility (in outreach, health station, health centre, national facility, church and Zober). the tests should also have the lowest rate of false negative and false positive.

5.5 Determining Targets Groups for Frequent Screening

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 pre-cancer 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

a) The Screening Age

High-risk HPV infections are very common in young women, but most of these infections are transient: the woman's body eliminates them spontaneously. Only a small percentage of all HPV infections that persist and may lead to invasive cancer taking 10–20 years from early preconcert to invasive cancer. Cervical cancer is rare before the age of 30. Screening younger women will often detect lesions that will not develop into cancer and this leads to substantial number of cases of overtreatment, and subsequent increased cost

WHO recommends that cervical cancer screening should be done between the ages of 30 and 49 years, at least once in a lifetime. Screening may be extended to younger ages if there is evidence of a high risk of CIN2+ (see chapter 1: Eritrean context).

b) Screening Frequency

WHO recommends that for women be tested at least once in the lifetime, between the age of 30-49 years. Those who test negative with visual inspection with acetic acid (VIA) or cytology, the interval for re-screening should be 3 to 4 years. Among those who test negative with HPV testing, re-screening should be done after 5 years. Following a subsequent screen negative test result, and also for older women, the screening interval should be longer than five years. Women who have been treated for cervical pre-cancer should have a follow up treatment test after 12 months.

c) Screening for Women Living with HIV

For women living with HIV Screening for cervical cancer should be done in women and girls who have initiated sexual activity regardless of age. If the screen result is negative rescreening should be repeated within three years. If treatment for pre-cancer has been done rescreening has to be done after 12 months.

d) 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. Women presenting for cervical cancer screening should also receive HIV counselling 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. If negative they should be rescreened after 3 years. Note that in HIV positive women lesions on VIA 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.

e) 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 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 following: 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 negatively affecting utilization of ANC services. For those ineligibles 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.

5.6 Target Groups for Cervical Cancer Screening

The focus of the 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.

5.7 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 Methods

The following screening methods are recommended for the program:

- HPV Testing
- Visual Inspection with Acetic Acid (VIA)
- Cytology using Conventional Pap smear

5.8 HPV Testing

a) Description

Molecular HPV testing methods are based on the detection of DNA from high-risk HPV types in vaginal and/or cervical samples. 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 and most specific screening tool available at this time for the detection of CIN 3 and cervical cancer. 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.

Testing women younger than 30 years old for these viruses is not advised because many young women are infected with them, but most HPV infections will be spontaneously eliminated from their bodies before they reach the age of 30.

Thus, HPV testing in women younger than this will detect many women with transient HPV infections and may subject them to unnecessary procedures and treatment. In women older than 30 if high-risk HPV is detected, it's more likely that her HPV infection is persistent. Since persistent HPV infection is the cause of nearly all cases of cervical cancer, a positive test result indicates that she may have an existing lesion or may be at risk for future pre-cancer and cancer. Treating these screen-positive women can therefore greatly reduce the risk of future cervical cancer.

HPV testing is being incorporated into cervical cancer prevention programmes in high-resource settings as a primary screening test. Currently the tests require transportation to and processing at a laboratory before results can be returned. But a new low-cost HPV test that can be processed on-site at the same facility where the sample is taken is being tested in several low-resource settings and will soon be available on the market. When planning to use a molecular screening test for HPV in a cervical cancer screening programme, it is important to use a standardized, clinically validated HPV test. Locally developed HPV tests are not appropriate unless they have been rigorously standardized and clinically validated.

b) Who should one be Tested?

For the reasons described above, HPV testing should be reserved for women over the age of 30, or the age specified in updated national guidelines.

c) How to screen using HPV Testing

HPV testing does not necessarily require a pelvic examination or visualization of the cervix, unlike other screening tests. A health-care provider can collect a sample of cells by inserting a small brush or other appropriate device deep into the vagina, and then placing it in a small container with an appropriate preservative solution. It may also be collected at the time of a speculum examination.

The sample can also be self-collected by the woman; she can be given the brush and the special container and instructed how to use them. This strategy can be implemented at substantially lower cost to the health service and offers greater convenience to women. With the use of HPV testing as currently available, the specimen containers need to be transported to the laboratory for processing by a trained technician who then documents and returns the results. But new tests will soon allow for on-site processing.

d) Strengths of HPV Testing

HPV testing is highly sensitive for detecting HPV infection in women. However, while an HPV infection is a necessary precursor for cervical cancer, a positive HPV test does not confirm that the woman has pre-cancer lesion; it only confirms that there is an HPV infection.

HPV testing of self- collected vaginal samples provide high sensitivity and this may be useful in certain cultures. As well as relieving pressure on clinician's time, self- sampling also provides an option for women

to access cervical cancer screening, even if they are resistant to a pelvic examination. HPV testing- though more recent- is an effective and objective method for cervical cancer screening. Women who do not have persistent high-risk HPV types are very unlikely to develop cervical cancer.

e) Limitations of HPV Testing

At present, the need to process molecular HPV tests in a laboratory with a special clean room to avoid contamination and with equipment and reagents as specified by the manufacturers of the test as well as trained technicians can limit the utility of HPV screening in some settings. If there is no reliable method for processing and returning results to the patient within a reasonable time, this may present barriers to the use of HPV testing, in terms of cost and quality.

The new low-cost HPV rapid tests that will soon be available on the market will address this limitation because they can be processed at the clinic where samples are collected, using simpler equipment, and requiring less training to perform.

f) 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 VIA to determine eligibility for cryotherapy, is recommended.

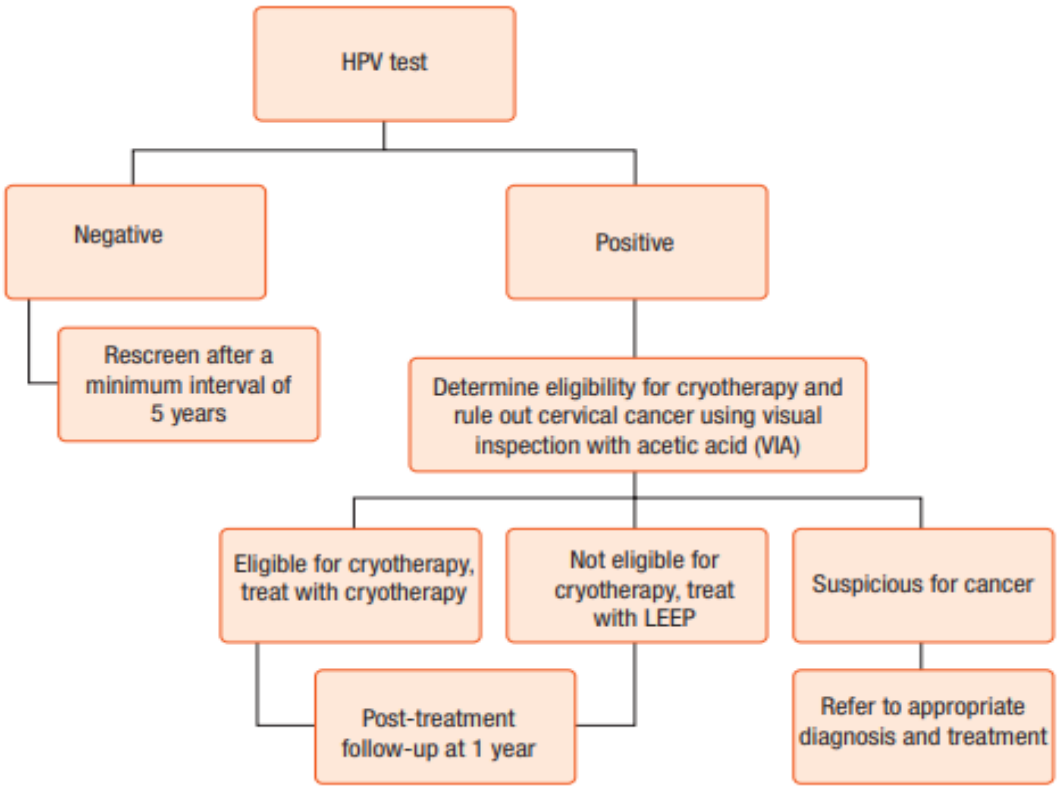


Figure 12: *Recommendations for HPV Testing*

5.9 Visual Screening Methods

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 pre-cancer. These studies show the relatively high sensitivity of VIA but a specificity that is slightly lower than cytology. In addition, VIA uses instrument sets and equipment usually available at primary health facilities e.g. health centres. 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.

a) Description of VIA

Visual inspection with acetic acid (VIA) is a method for detecting early cell changes that are visible when using a speculum to inspect the cervix with the naked eye after applying dilute (3–5%) acetic acid to it. [1] It requires training and supervision of primary care providers, as well as on going quality control and quality assurance.

b) Who should be tested with VIA?

VIA is appropriate to use in women whose squamo-columnar junction (SCJ) is visible, typically in those younger than 50. This is because the SCJ gradually recedes into the endocervical canal at menopause, making it possible to miss lesions when relying on VIA. Screening using VIA can be done at any point in the menstrual cycle. The transformation zone may be difficult to visualize if menstrual blood flow is heavy—in such cases, you may need to re-examine when menstruation is over. It can also be done during pregnancy, and at the postpartum 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·

c) How to Screen using VIA

VIA requires use of a speculum and light source, and a trained health-care provider. The provider performs a speculum examination, noting the anatomical landmarks of the cervix. The provider identifies the SCJ and carefully inspects the cervix for visual signs suspicious for cancer or pre-cancer. A 3–5% acetic acid solution is liberally applied to the cervix with a large cotton swab.

After removing the cotton swab, the provider waits for at least one minute, during which time any areas that became faintly white simply due to inflammation or physiological cell changes (metaplasia) will recede. Acetowhite changes on the cervix that do not recede after one minute are more likely to be associated with cervical pre-cancer or cancer. If these changes are seen in the transformation zone and have well-defined borders, they are considered a positive result. If no persistent acetowhite changes are noted, a negative result is reported.

Who can Perform VIA

VIA can be performed by healthcare providers including nurse, health assistants, nurse mid-wife, medical officer and specialist who have been trained to perform the procedure.

- **Settings for performing VIA**

it may be performed at any level of healthcare including within the community (such as in a church building or any other appropriate public building).

- **How VIA Works**

the procedure involves applying 4- 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. this is known as acetowhite changes. notably acetowhite staining is not specific for CIN and may also occur to some extent in areas of squamous metaplasia and inflammation.

- **Reporting VIA Results**

The VIA results are generally categorized into three subsets: VIA negative, VIA positive and suspicious for cancer. A VIA test 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).

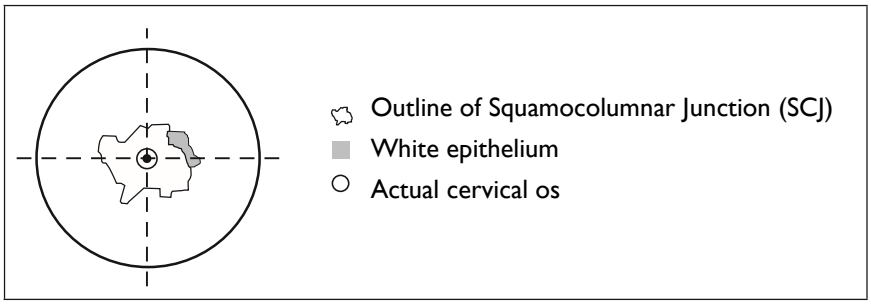


Figure 13: *VIA Results Recorded on Labelled Drawing*

- **Strengths of VIA**

VIA testing can detect both early changes and those representing more advanced pre-cancer. The immediate result allows the patient to be offered treatment at the same visit (i.e. the single visit approach). Alternatively, if the patient prefers not to do it immediately or if treatment is not available, then treatment can be done at a subsequent visit soon after.

A diagnostic step, such as a colposcopy and/or biopsy, is usually not performed at this time (at the same screening facility), but if the cervix shows any unusual signs or the provider suspects cancer, the patient can be referred for further diagnosis.

VIA is quite inexpensive, utilizes locally sourced supplies (vinegar and cotton), and does not rely on laboratory services. It can be performed by trained providers, with adequate visual acuity, at any level of the health system. Training can be accomplished in a few days using a competency-based approach.

- **Limitations of VIA**

VIA is a subjective test and therefore depends on the skills and experience of the provider executing the test. Skills must be used regularly, and refresher courses are recommended. Due to the subjective nature of the test, quality control and quality assurance of VIA is particularly important. This can be achieved through supervision and routine monitoring.

Since VIA is known to have a lower specificity than other methods, there is a potential for overtreatment 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.

5.10. 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.

a) Description

Cytology-based screening involves taking a sample of cells from the entire transformation. The cells are either fixed on a slide at the facility (Pap smear) or placed in a transport medium (liquid-based cytology) and then sent to the laboratory where expert cytotechnologists examine the cells under a microscope. If abnormal cells are seen on microscopic examination, the extent of their abnormality is classified using the Bethesda System.

A cytology-based screening programme can use one of the two available methods: the conventional Pap smear (or Pap test) or liquid-based cytology (LBC). With conventional cytology, a sample of cells is smeared on a glass slide, and preserved by a fixative agent. LBC was introduced in the mid-1990s; it is a refinement of conventional cytology and is increasingly being used in high- and mid-resource settings. For LBC, instead of smearing the sample onto a slide, it is placed in a container of preservative solution and sent to the laboratory for microscopic examination.

b) Who should be Tested?

Cytology-based screening can be used with women in the target population for screening (25-49 years).

c) The procedure for Pap smear is outlined below:

- A Cusco's or Grave's Speculum is inserted into the vagina and the 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

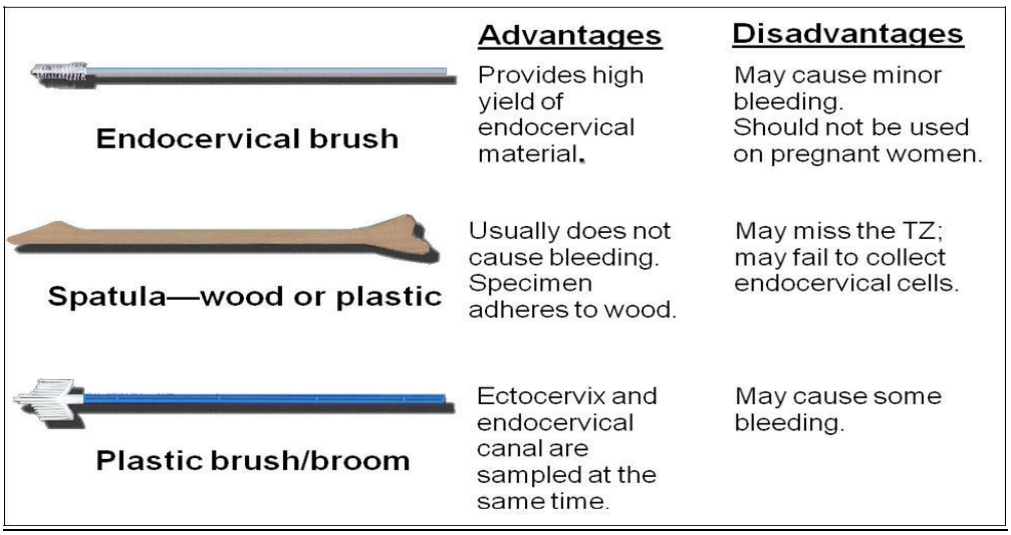


Figure 14: *Cytology Collection Tools*

- The cells are then placed on the glass slide and "fixed" in absolute alcohol.
- The slide is then treated with Pap stains to colour the cells or The provider takes specimens from the face of the cervix and transfers them to a preservative solution (LBC)
- Note that the slide serves as a permanent record
- Thereafter, a specially trained cytotechnologist and/or pathologist examines for signs of cellular changes by reading the slide.

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

5.11 Correlation between Dysplasia, CIN and Bethesda System

Source: Colposcopy & treatment of cervical intraepithelial neoplasia – a beginner's manual. IARC; edited by J.W. Sellors and R. Sankaranarayanan)

Dysplasia Terminology	Original CIN	Modified CIN	Bethesda System (SIL)
Normal	Normal	Normal	Within normal limits, Benighn cellular Changes (Infection or repair)
Atypia	Koilocytic atypia, flat condylomata without epithelial changes	Low grade CIN	A typical squamous changes of undefined significance (ASCUS) / AGUS / LSIL
Mild dysplasia or mild dyskaryosis	CIN1	Low grade CIN	Low grade squamous intraepithelial lesion(LSIL)
Moderate dysplasia or moderate dyskaryosis	CIN2	High grade CIN	High grade squamous intraepithelial lesion (HSIL)
Severe dysplasia or severe dyskaryosis	CIN 3	High grade CIN	HSIL
Carcinoma in situ	CIN 3	High grade CIN	HSIL
Invasive carcinoma	Invasive carcinoma	Invasive carcinoma	Invasive carcinoma

Table 2: Cytology Collection Tools

5.12 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 premenopausal or postmenopausal clients, the yield of cells may be improved using the endocervical brush or use of hormone therapy prior to taking the smear:

a) 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.

b) Limitations of Pap Smear

Although cytology-based screening has relatively low sensitivity, 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 required infrastructure (laboratories), human resources (cytotechnicians), equipment and supplies, absence of quality control for laboratories, poor cytology reporting and inadequate or limited 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.
- It requires microscopes, laboratory, trained technicians, pathologists, transport of specimens, reporting, and supplies.

- Immediate results are not possible therefore screening and treatment cannot be provided in a single visit (SVA is not possible).
- The required multiple visits in many countries 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 SCJ 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 does not detect the precancerous cells when reviewing the slides.
- 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.

5.13 Management of Abnormal Cytology Results

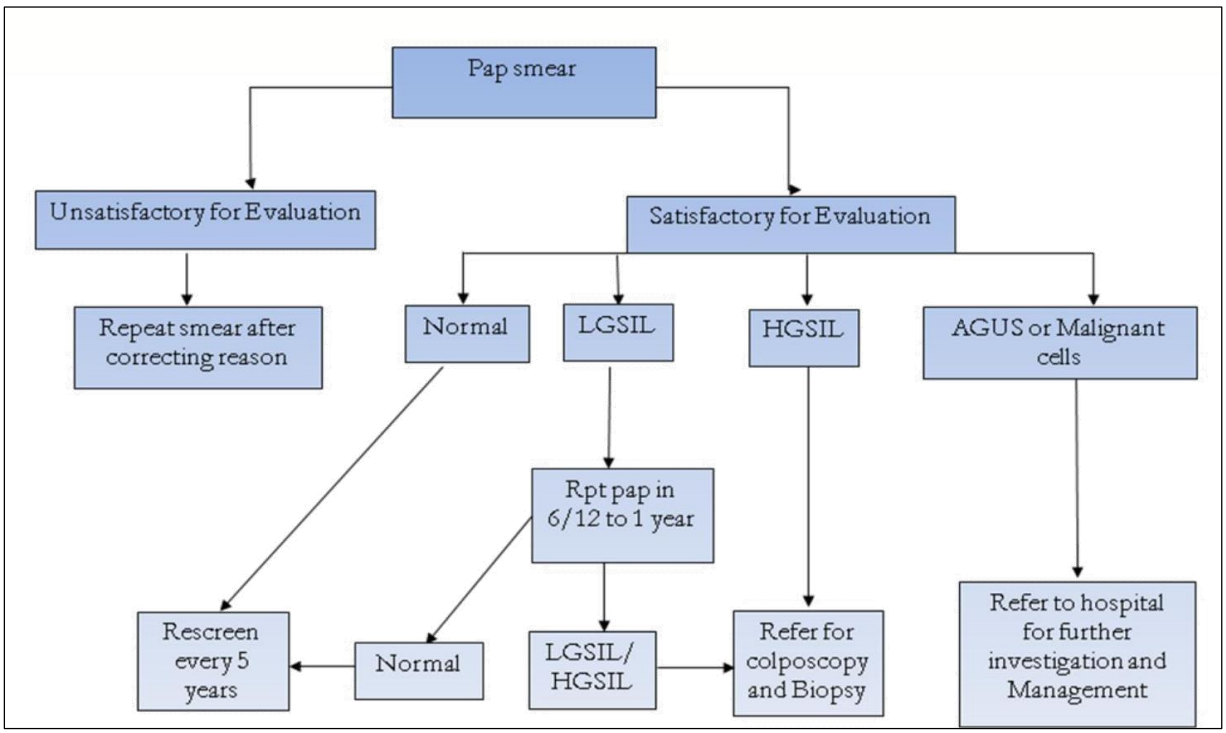


Figure 15: *Management of Abnormal Cytology Results*

Characteristics	Conventional Cytology	HPV DNA tests	Visual inspection with acetic acid (VIA)
Sensitivity	47 – 62%	66 – 100%	67 -79%
Specificity	60 -95%	62 – 96%	49 – 86%
No. Of visits required for	2 or more	2 or more	1 or 2

screening and treatment			
Health Systems requirements	Requires highly trained cytotechnicians and cytopathologists; microscope, stains, slides, transport systems, system for informing and tracking positive cases	Required trained lab workers, electricity, kits, reader, transport system	Requires training and regular supervision, no equipment, few supplies
Comments	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	Assessed over the last decade in many developed countries and some developing countries due to high sensitivity,	Assessed over the last decade in many developing countries with good results

Table 3: *The comparison between the different screening Methods*

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

5.14 Diagnosis of cervical precancerous lesions

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 involve providing treatment on the basis of a positive screen test without further diagnostic interventions.

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 from 6 times to 40 times. 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 pre-cancer. However, 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 positivity
- To map abnormalities before cryotherapy or LEEP

The key ingredient of colposcopic practice is the examinations 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 visualize the vessels more clearly.

Special Considerations

a) The entire transformation zone is not visible. This indicates an unsatisfactory colposcopy and endocervical curettage should be done

b) 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 postpartum and take a biopsy at that time if indicated

c) The woman is postmenopausal. The transformation zone may not be visible. One may therefore have to use an endocervical speculum or perform as endocervical curettage

d) 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 immediately after biopsy.

Indications for Endocervical curettage:

a) Patient with positive cytology but no abnormality is seen on colposcopy

b) Pap smear reveals a glandular lesion

c) 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)

In low and middle-income countries without well-established cytology-based programs, WHO recommends visual inspection with acetic acid (VIA) followed by cryotherapy of screen positive eligible cases at the same sitting (a single visit strategy).

CHAPTER 6: TREATMENT OF PRE-CANCEROUS LESIONS

The elements of a comprehensive cervical cancer prevention programme include a treatment arm, which should be available at primary care facilities. 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). A robust referral system is necessary where treatment cannot be provided because, for various reasons such as invasive cancer, which require higher-level facilities. 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 and resource availability

Cryotherapy and LEEP and relevant equipment are the recommended treatment options for most cases of pre-cancer. Women should be offered the same treatment options irrespective of HIV status.

6.1 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_2O) or carbon dioxide (CO_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_2O-based cryotherapy will achieve –89°C and CO_2-based system will achieve –68°C at the core of the ice ball and temperatures around –20°C at the edges. Cells reduced to –20°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 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 anaesthesia since it results in very minimal discomfort.

6.1.1 Eligibility Criteria for Cryotherapy

- The screening test for cervical pre-cancer 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

6.1.2 Who can perform Cryotherapy?

Healthcare providers who have been trained and may include nurses, nurse mid-wife, medical officer and specialist can perform cryotherapy

6.1.3 Settings for performing Cryotherapy

It may be performed at any level of healthcare including within the community (such as in a church building or any other appropriate public building).

6.1.4 The Procedure

a) 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.

b) 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.

c) The secretions are removed with a cotton swab soaked in saline. Then VIA/ VILI is performed to delineate the limits of the lesion.

d) The cryoprobe surface is wiped with saline to ensure adequate thermal contact with the cervix and optimal lowering of the tissue temperature.

e) 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.

f) 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.

g) 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.

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

i) 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.

j) 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.

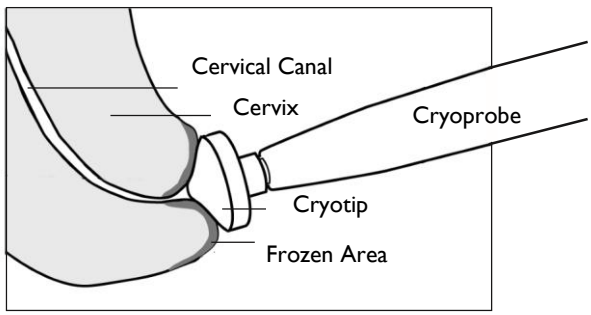


Figure 16: *Position of Cryoprobe on the Cervix and Ice Forming*

6.1.5 Complications of Cryotherapy

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.

6.1.6 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 coloured 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.

6.1.7 Follow up

Appointments should be made for a follow-up visit 9- 12 months after treatment. During the follow-up, the client should be rescreened 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 the screening programme

6.1.8 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 oestrogen 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 oestrogen treatment and colposcopic reassessment preferably at a higher level of care.

6.1.9 Care and Maintenance of Equipment

The cryoprobes /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.

6.1.10 Programmatic considerations

Correct handing of the cryo-refrigerant is very important in ensuring both the safety of the health care worker and also the correct functioning other cryo-equipment. The room where the procedure takes place should be well ventilated. The use of rotating stools will provide comfort to the healthcare provider thus minimising injuries associated with uncomfortable posture during procedure. It's important to have an assortment of different sizes of different cryoprobes.

6.2 Loop Electro Surgical Excision Procedure (LEEP)

LEEP - also referred to as Large Loop Excision of the Transformation Zone (LLETZ), is an excisional method for 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 and 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 colposcopy guidance.

6.2.1 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

6.2.2 Who can Perform LEEP Settings

LEEP is a complex procedure often performed by specialist in a hospital setting. It may not be performed in low level facilities due to lack of supportive care. In Eritrea it may be performed at the Zober level and national level facilities where specialists are found. Private facilities with trained specialist may also perform the procedure.

6.2.3 LEEP Procedure

1. Explain the procedure, obtain informed consent and prepare the patient for a gynaecological 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 anaesthetic (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 labelled 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.

6.2.4 Complications of LEEP Surgery

- 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.

6.2.5 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:

   i. fever with temperature higher than 38 °C or shaking chills;
   ii. severe lower abdominal pain;
   iii. foul-smelling or pus-like discharge;
   iv. Heavy bleeding or bleeding with clots.

6.2.6 Follow up

At 2-6 weeks post op, the patient should return to the health facility 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.

6.2.7 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 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 counselling and testing as part of the RH /HIV integration strategy.

6.2.8 Programmatic Considerations

In order to be functional, the LEEP unit should have an assortment of different loop sizes, special speculums (insulated speculums) regular power supply as well as solutions for managing bleeding (Monsell solution/paste) instructions for making the paste may be obtained elsewhere.

6.3 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.

6.3.1 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 postpartum or less than
j. There should be no evidence of cervicitis or PID
k. There should be no obvious invasive cancer

6.3.2 Procedure of Cold Knife Conisation

This is outlined in standard gynaecologic surgery manuals

6.3.3 Complications

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 might occur. In some women due to destruction of the internal OS, cervical incompetence may result.

6.3.4 Post Treatment Instructions

These are similar to those for LEEP

a. Before she leaves hospital, the woman should be given counselling 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.

6.3.5 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 6months 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.

CHAPTER 7: CERVICAL CANCER DIAGNOSIS AND TREATMENT

When diagnosed early, invasive cancer can be cured with effective treatment. It is therefore imperative that women are aware about signs and symptoms of invasive cancer and that health care providers at all levels of care can promptly recognise and initiate the appropriate interventional measures. All invasive cancer cases should be referred immediately! Details of management of overt cancers are beyond the scope of these guidelines. However, the ability to recognize invasive cancer and be familiar with the management is crucial for any service provider involved in a cervical cancer prevention programme.

Health care providers at all levels (in particular lower and middle level facilities) should know the common symptoms and signs of cervical cancer and how these are managed. This understanding will assist the providers to explain to the patient, her family and community concerning issues around 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 contact bleeding, abnormal uterine bleeding or 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).

Women in low and middle-income countries (LMIC) often present with late stage disease. 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. Specialists should treat invasive cervical cancer at central-level facilities. Treatment modalities include surgery, radiotherapy and chemotherapy. Treatment often poses a number of side effects, which include infertility, menopause and bowel and bladder changes. Access to treatment greatly improves prognosis and survival rates.

7.1 Diagnosis

Symptoms and Signs of Invasive Cervical Cancer

Micro invasive cancers are usually asymptomatic, and may be detected only on 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 4* below shows the common symptoms and signs of Invasive Cervical cancer

Early	• Vaginal discharge – foul smelling • Irregular bleeding • Post coital bleeding • Post-menopausal bleeding – unresponsive to treatment • Lower abdominal pain
Late	• Urinary frequency • Backache • Brown colour vaginal discharge-fouls smelling • Lower abdominal pain
Very Late	• Severe backache • Weight loss, pallor • Decreased urinary output • Urinary and or faecal incontinence • Swelling of the lower limbs • Breathlessness-due to anaemia, metastasis or pleural effusion • Brown colour foul smelling vaginal discharge

Table 4: *Symptoms and Signs of Invasive Cancer*

Any woman presenting with any of the above symptoms should be referred to tertiary level hospital and should have a speculum examination. A biopsy (punch or cone biopsy) should be taken on any visible lesion. If the woman is pregnant, she should be referred to a tertiary level to be checked by 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.

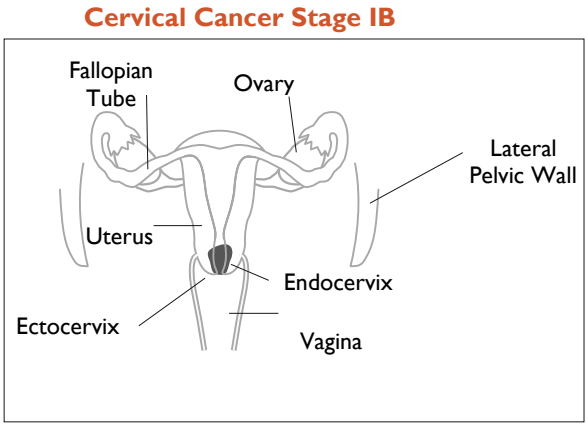
7.2 Cervical Cancer Staging

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 Gynaecology and Obstetrics (FIGO), which is based on tumour 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 tumour and possible involvement of the vaginal fornixes, the parametric (transverse cervical and uterosacral ligaments), the pelvic walls, the bladder and the rectum. This assessment can be done without anaesthesia. However general anaesthesia 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



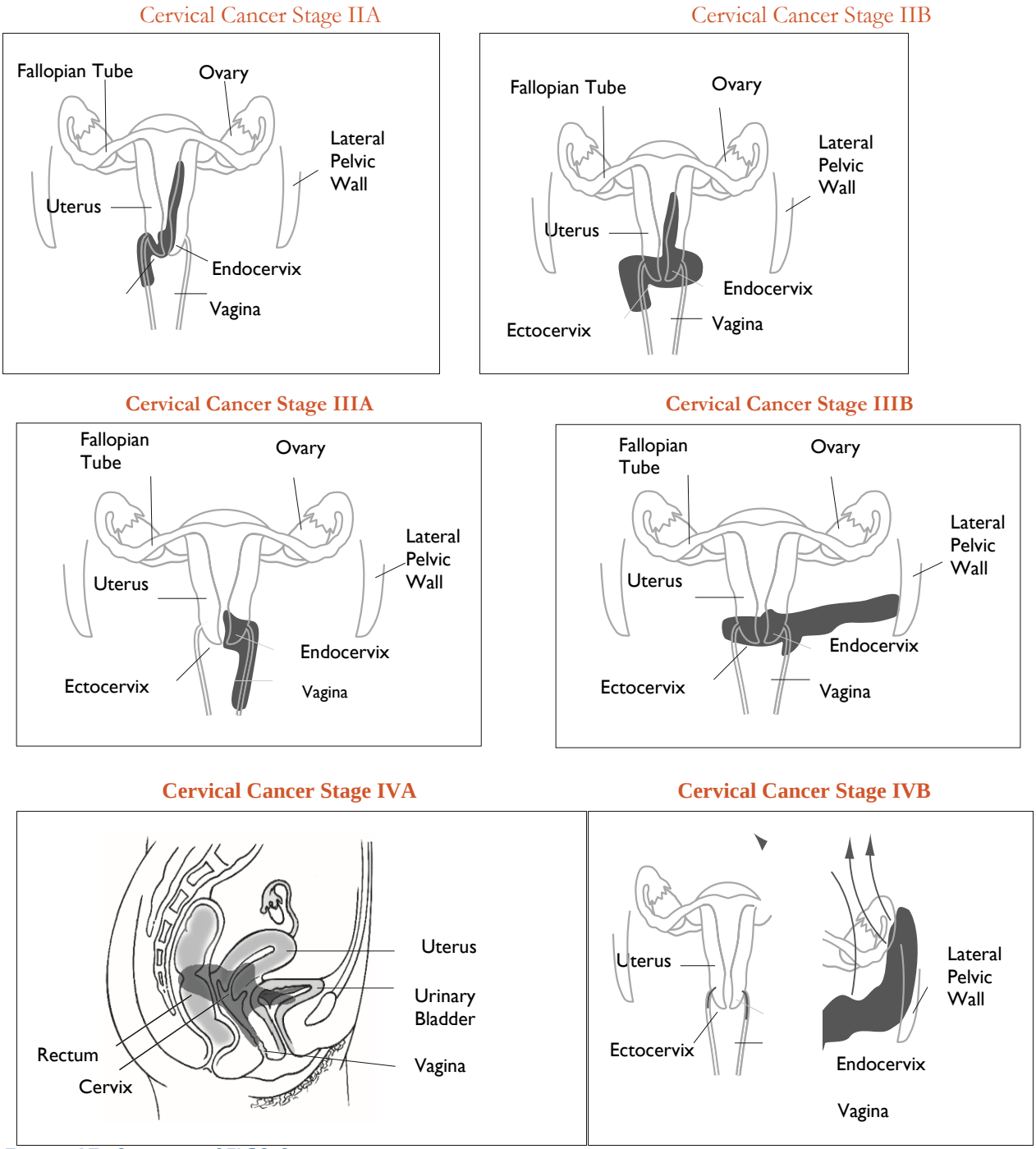


Figure 17: *Overview of FIGO Staging*

Sources: Edge et al. (2010), Gold et al. (2008), Pecorelli (2009);

Summary of the FIGO Stages and sub stages (as shown in *Figure 17*)

Stage I: The disease is confined to the cervix (includes sub stages IA1, IA2, IB1 and IB2).

Stage II: Cancer has spread outside the cervix into the upper vagina or to the tissue beside the cervix (parametrium), but not to the sidewall(s) of the pelvis (includes sub stages IIA1, IIA2 and IIB).

Stage III: Cancer has spread to the lower part of the vagina or all the way through the parametrium to the sidewall(s) of the pelvis (includes sub stages IIIA and IIIB).

Stage IV: Cancer has spread to surrounding organs or distant tissue, such as the lungs and distant lymph nodes (includes sub stages IVA and IVB).

7.3 Management of Invasive Cancer

Principles of Treatment

Treatment of cervical cancer often involves a multidisciplinary team composed of gynaecologist, oncologist, surgeons and medical physicists. The team, upon evaluation of the patient, will select the best options that will improve the health of the patient. 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 surgery, radiotherapy and/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 i.e. stage, 1A – 95 -98%; 1B- 75 -85%; 11 -65 -75%; 111 – 30%; IV – 5 -10%.

Not all treatment options are available in tertiary facilities and sometimes a patient may need to be referred outside the country for specific therapeutic options.

7.3.1 Surgery

Surgery consists of removal of varying amounts of tissue from the area involved with cancer and its surroundings. Surgery can be used as primary therapy as well as secondary therapy, after another treatment has been instituted.

a) Surgery as Primary Therapy

Surgery as primary therapy for cervical cancer consists of the removal of a varying amount of tissue based on the extent of the cancer spread within the pelvis and other individual case characteristics. Cone biopsy is the removal of a wide circle of tissue that surrounds the opening of the uterus and includes the lower portion of the cervical canal. Micro invasive cancers (those that are entirely contained within the cervical epithelium) can be treated with cone biopsy. This is beneficial where fertility needs to be retained.

Simple hysterectomy is the surgical removal of the entire uterus, including the cervix. The tubes and ovaries are not routinely removed. However, in postmenopausal women, if they appear abnormal they may be removed. Simple hysterectomy is indicated for the treatment of early micro invasive cervical cancers in postmenopausal women and younger women who are not interested in preserving fertility.

Radical hysterectomy is the most common surgery for early invasive censers. This surgery removes tissues to the side of the uterus and often lymph nodes in the pelvis and around the aorta. The tubes and ovaries are not routinely removed unless they appear abnormal.

b) Surgery as Secondary Therapy

Salvage surgery can still have the objective of curing the patient. It consists of radical hysterectomy including removal of a portion of the upper vagina to decrease chances of recurrence of the cancer. It is performed when:

- The patient has had primary surgery, but microscopic examination of the removed tissue shows that the margin of normal tissue around the cancer is too thin; or
- The patient has undergone radiotherapy and/or chemotherapy, but early recurrences or incomplete destruction of the cancer are noted on follow-up.

Palliative surgery is sometimes done in advanced cancer to relieve obstruction of the bowel, or to treat fistulae.

c) Complications of Cervical Cancer Surgery

Common complications associated with cervical cancer surgery are those common to other surgical intervention including: haemorrhage; a risk of deep Venus thrombosis; infection; injury to surrounding organs such as bladder and bowels. Additionally, procedures such as cone biopsy are associated with pre-term labour and mis-courage. Hysterectomy results in infertility.

7.3.2 Radiotherapy

Radiation therapy uses special equipment to produce rays that are beamed onto the cancer and the surrounding affected areas. The rays penetrate the body and destroy cancer cells so that the cancer is fully or partially eliminated. Destroyed cancer cells are eliminated from the body. Radiation itself is not painful but it may cause significant complications.

a) Radiation as Primary Therapy

Primary radiotherapy, with or without chemotherapy, is used with the intention to cure. It is used for women with cancer at stage IIA2 or greater. Primary radiotherapy, intended to cure early stage cancers, is provided on a daily basis for 5–6 weeks.

Two modes of delivery are available:

- External-beam radiotherapy or tele therapy, uses radiation originating from a machine located outside the body.
- Internal radiotherapy, also called brachytherapy, uses radiation originating from radioactive material placed within the body (i.e. inside the vagina, close to the cancer).

b) Radiation as Adjunctive Therapy

Brachytherapy Radiotherapy, with or without chemotherapy, may be given as adjunctive therapy in combination with primary surgery for the following indications:

- When the cancer has spread beyond the cervix to the parametric (tissues between the uterus and the pelvic wall) or to distant organs;
- After hysterectomy, if the pathology report indicates that the disease-free margin is less than 5;
- If the cancer involves the lymph nodes.

c) Radiation as Secondary Therapy

Radiotherapy, with or without chemotherapy, may be given as secondary therapy for the following indication: the disease is localised within the pelvis only in women who underwent primary surgery.

d) Radiation as Palliative Therapy

Palliative radiotherapy may be used in a variety of settings in combination with other treatment options or alone:

- To control severe symptoms, such as bleeding, offensive discharge and/or pain;
- To assist a patient who is too ill to tolerate full-dose chemotherapy or radiotherapy;
- To treat isolated cases of metastases (e.g. to vertebrae).

e) Side-effects of Radiation for Cervical Cancer

Radiotherapy affects multiple organs with those directly exposed to radiation more; in the case of cervical cancer, the lower abdomen, urinary bladder, rectum and regional bone marrow are affected. Other possible side effects include menopause, infertility, discomfort or pain with intercourse and possible bowel or bladder changes. Fistula is a rare side effect.

7.3.3 Chemotherapy

Chemotherapy is the administration of repeated treatments with drugs that are highly toxic. A series of several treatments with one or more chemicals is given intravenously to kill rapidly dividing cells (a hallmark of all cancers).

a) Chemotherapy as Primary Therapy

Chemotherapy is rarely used alone as primary treatment for cervical cancer. It is often used in combination with radiotherapy and less often with surgery.

b) Chemotherapy as Primary Therapy Combined with Radiotherapy

Chemotherapy is used first in women with very bulky tumours in order to reduce their size. This is then followed by radiotherapy. Treatment is done in this sequence because cancer is shown to respond better to radiation when the tumour is smaller in size.

c) Chemotherapy as Palliative Care

Palliative chemotherapy is sometimes used, after careful consideration of the expected benefits versus the adverse side effects, to relieve symptoms in women with widespread metastases to liver, lung and bone.

d) Complications of Combined Therapy

The side effects of combination therapy may be additive: those caused by the chemotherapy and the radiation. Because the toxic chemotherapy drugs circulate with the blood around the entire body, side-effects of chemotherapy will be widespread in the body. On the other hand, those caused by radiation will be limited to the pelvic area.

Chemotherapy treatments affect not only cancer cells but also rapidly dividing cells in systems of the entire body. There includes bone marrow, digestive system, urinary system, skin and other organs lined by epithelia. Consequently, patients risk suffering from anaemia, low white blood cell counts and infections, or bleeding from low platelet counts. Chemotherapy can also cause nausea and diarrhoea or allergic reactions.

7.4 Managing Cervical Cancer in Women living with HIV

Because there are no well-designed or longitudinal studies on the treatment of cervical cancer in women living with HIV, there are no evidence-based guidelines on this subject to include in this guide. In their absence, this section presents some practices that are commonly used in the international and national arenas.

It is best for women living with HIV who have cervical cancer to be fully diagnosed, staged and treated at a tertiary-level institution with the appropriate expertise. Most institutions treating women living with HIV use multidisciplinary teams; each woman will be evaluated individually and an assessment made of her overall health and the existence of other chronic illnesses that may further compromise her immune system and her ability to tolerate immunosuppressive anti-cancer therapy (e.g. tuberculosis).

Both radiotherapy and chemotherapy are immunosuppressive therapies and surgery requires women to be relatively healthy in order to avoid complications such as postoperative sepsis, bleeding or wound problems. Therefore, a baseline CD4 count is a key element of care for women living with HIV and should be one of the initial evaluative tests obtained, regardless of the extent of the cancer. CD4 counts will also be needed to monitor the patient's immune status throughout treatment. If the CD4 count is or becomes low during therapy, she may be started on antiretroviral therapy, which may delay treatment to allow for recovery of her immune system.

7.5. Management of Invasive Cancer in Pregnancy

Diagnosis of invasive cervical cancer during pregnancy is rare but poses serious dilemma to the pregnant women, her family and attending physician. Management should be individualized, taking into consideration her concerns and health and the impact on the outcome of the pregnancy. The patient should be counselled on all available options and allowed to make an informed consent. However, it is also related to the gestational age of the pregnancy. Skilled counselling is necessary to assist the woman and her family to come to terms with the diagnosis and arrive at a decision about management. As for non-pregnant women, management by surgery or by radiotherapy depends on the stage of the cancer.

In early pregnancy, radiotherapy is appropriate for management and should begin with pelvic irradiation. This will result in foetal death and abortion. uterine evacuation is accomplished by hysterectomy. An ultrasound scan must be done to verify that the foetus is no longer viable.

In the third trimester, definitive treatment is usually delayed until the foetus is mature /able to survive outside the uterus. Delivery is done by classical Caesarean section. Subsequent surgery and radiotherapy are done after uterine involution, which occurs in six weeks.

7.6. 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 across 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.

7.6.1 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 the disease or similar lesions in vulva or rectum;
- Other investigations depending on the clinical findings and resources available.
- Recurrent disease in these women can be treated with radiation.

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

CHAPTER 8: PALLIATIVE CARE FOR CANCER PATIENTS

Palliative care is a crucial part of a comprehensive cervical cancer control program, as it aims to improve the quality of life of patients and family as they encounter challenges associated with life threatening disease. It consists of prevention and relief of suffering by use of various treatment modalities such as pain control, spiritual and psychosocial support. Thus, it provides care to help people face the end of life with dignity and peace. Palliative care is best provided by a multidisciplinary team approach, which include the patient, the family, friends, community, health care workers, spiritual leaders and palliative care workers as well as health care providers at all levels of the health care system. Access to all necessary medication equipment and supply is critical for successful management of the patient's symptoms both at the facility and in the home. Quality of care highly depends on appropriate training and supervision of heath care workers at the community and facility level.

8.1 Importance of Palliative Care

Palliative care aims to improve quality of life of patients facing complex problems associated with life threatening conditions. It is not only end of life care but also includes interventions applied during the disease process to manage distressing symptoms such as pain. The patient's family members also need to be trained in their roles, including how to obtain and use needed supplies to care for the patient. It also helps to address current and future emotional needs of their families. Palliative care services can be provided in the home within communities and across the whole spectrum of the health system such as health stations and health centers. Palliative care is a basic human right recognized under the human rights law.

The following features characterize palliative care:

- It provides relief from pain and other distressing symptoms.
- It affirms life and regards dying as a normal process.
- It is intended neither to hasten nor to postpone death.
- It integrates the physical, psychological and spiritual aspects of care.
- It gives the patient and her family the desired control and decision-making power
- It offers a support system to help patients live as actively as possible until death.
- It offers a support system to family to cope during the patient's illness and in their bereavement.
- It uses a team approach.
- It will enhance quality of life, and may also positively influence the course of the illness.
- It applies therapies that are intended to improve quality of life, such as surgery and radiotherapy see (figure 8.1 bellow)

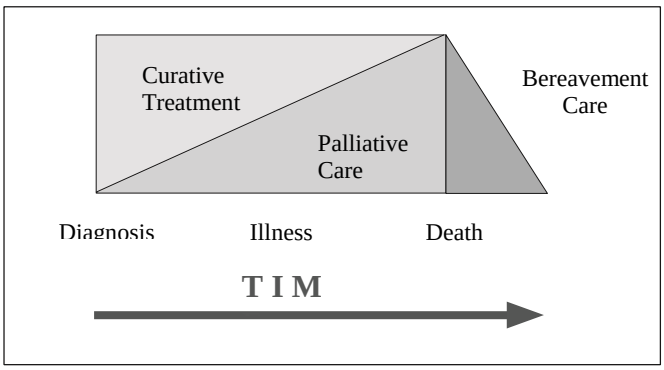


Figure 18: *The Role of Palliative Care throughout the Disease Course: The Continuum of Care*

8.2 Essential Components of Palliative Care

Palliative care services need to include all elements that will keep the patient well nourished, clean, while managing distressing symptoms such as vaginal discharge, fistulae, vaginal bleeding, nutritional problems, bedsores, fever and contractures.

All efforts should be made to train family member and community workers on aspects of palliative care while the patient is still in the hospital. This training and advice should address prevention and management of problems and how to be supportive to the patient in her daily activities, such as eating, bathing, going to the toilet and moving around. They should also be taught how to recognize when there is need for further support by the appropriate level of facility (e.g. severe anemic patients will need blood transfusion at a regional facility).

8.3 A Team Approach to Palliative Care

Members of teams providing palliative care, from home-based care providers to specialists in tertiary settings, need to work together in a coordinated manner to ensure best quality of life and outcomes for their patients. Where resources allow teams in tertiary settings should comprise of a gynecologist, a radiotherapist, a radiotherapy technician, a psychologist or counselor, a nutritionist, a physiotherapist, an oncology nurse, a pharmacist, a social worker and a palliative care nurse. In resource settings teams should be comprised of the available human resource such community health workers, health assistants, nurses, medical officers and specialists.

It's important that patient information is shared and transferred appropriately through proper documentation and record keeping. Effective channels of communication and protocols need to be put in place to enable the patient and the family to access resources necessary to manage prevailing problems especially attention to pain control.

8.4 General Issues that need to be Addressed

Many families may find it difficult to prepare for the likelihood of their relative dying. As such health care providers should be sensitive to the patient and family's capacity to deal with such a situation. While acknowledging the need for hope it's also important to plan for the worst and thus its helpful to address important issues with the patient and her family in a culturally appropriate and sensitive manner. This should include:

- The goals of care (e.g. prolonging conscious life until distant family can come to say goodbye, reducing distress and pain);
- How to go about putting personal affairs in order, such as wills, funeral arrangements, family finances and completion of obligations, which may help patients and their families gain a sense of greater control in this difficult situation;
- What to do when death occurs, including avoidance of unnecessary resuscitation and prolonging of life if it is against the patient's wishes.
- How to support the family during bereavement

8.5 Management of Common Symptoms of Cancer Patients

Patients with advanced cancer often suffer a myriad of multiple symptoms that include pain, dehydration, nausea and vomiting, diarrhea or constipation, fever, poor appetite and wasting, weakness and fatigue, swelling or lymphedema, bed sores, systemic and wound infections, coughing and difficulty breathing, and incontinence. Pain is almost always one of those symptoms and its relief goes a long way to provide comfort to the patient.

a) Pain Management

Moderate and severe pain should always be addressed, and opioid analgesics are often essential for pain management. In many settings including high resource settings, patients suffer needlessly as appropriate pain management strategies is largely underutilized. Most pain can be relieved satisfactorily. Often the patient is the best person to provide information concerning the source and intensity of pain. It important to have a good collaboration between all members of the care giving team and the patient. Some of the pain-relieving medications have adverse effect; care needs to be exercised to mitigate these. WHO recommends that all countries adopt policies that allow patients to have accedes to essential medications when they need them.

Key Points for the Control of Chronic Pain

Caregivers 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, radio, or using some other regular local event(s) to prevent "breakthrough" 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 advice on one of three actions to be taken: 1) increase the dose, 2) add another drug, or 3) switch to a new drug.
- 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.

b) Non- opioid Analgesics used 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.

- Ibuprofen can similarly be used to reduce fever and relieve moderate pain in doses of 400 mg to 00mg 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.

c) Opioid Analgesics used 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 need to be increased gradually. 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.

Opioids often cause constipation, and therefore there will be need to manage this appropriately by encouraging the patients to take measures to minimize this such as more fluids. Laxatives may be indicated. Nausea and vomiting while on opioids often reflect constipation and may lessen after a few days.

d) Helper Analgesics

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

- Ibuprofen for Bone Pain: ibuprofen helps by reducing swelling and inflammation.
- Amitriptyline for Neuropathic Pain: Amitriptyline is commonly available for treating depression. It helps relieve reduce unpleasant neuropathic pain.

8.6 Other Symptoms of Cancer Patients

a) Dehydration

Dehydration in cancer patients results from diarrhea, 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 and 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.

b) 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 drinks mentioned above are ideal in nausea and vomiting. In addition, ginger tea 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, dry bread and un-spiced food may be eaten.

c) Antiemetic

Two of the most commonly used antiemetic is 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 is recommended.
- If the cause is chemotherapy, prochlorperazine started at least 24 hours before administration of chemotherapy works best.

Where severe vomiting and diarrhea 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.

d) Diarrhea

In managing diarrhea it's important to allow the patient eat whatever she prefers, though fatty and spiced food is likely to worsen diarrhea and should therefore be avoided. Suggestions on feeding include:

- Maintain regular food intake and frequent oral rehydration, particularly if there is concurrent nausea and vomiting.
- A Loperamide 2 mg tablet is useful.
- If the patient has a fever for more than 24 hours and bowel infection is suspected, the patient may should be treated with appropriate antibiotic e.g. Cotrimoxazole.

Managing 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 diarrhea.

e) Constipation

Constipation in cancer patients may result from stasis, intestinal obstruction or the use of opioids. A considered practical, feed the patient on fruits, green vegetables and other foods with natural fiber, such as carrots, ground nuts, flax seeds and pumpkin will prevent constipation. As far as is possible cancer patients should be ambulated. 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).

For faecal impaction, rectal examination and digital dis-impaction can be done to relieve the patient. Where this fails, use an enema (either soap & water, or any of the several preparations available locally) considers colostomy if there is suspicion of rectal or bladder metastasis.

f) 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.

g) 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.

h) 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 anemic, 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.

i) Body Swelling

Lymphedema, 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. There is no fully successful treatment for lymphedema, 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.

j) 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 cleanup after toileting or vomiting. Once bedsores develop, they take a long time to heal. For Established bedsores the following can be done:

- 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 iodine solution
- 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).

8.7 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.

a) 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 anemia, 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 dyspnea results in undue anxiety in the patient
- For end stage cancer that has spread to the lungs, make the patient as comfortable as possible.

Specialized attention should be sought: -

- If the patient has constant dyspnea 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 orthopnea develops, congestive heart failure should be ruled out

b) 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 tumor invasion of the vagina and bladder or following radiotherapy. F0ecal incontinence can follow invasion of the tumor 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), anemia and alopecia. Some control measures are described below.

a) 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 regimens 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.

b) Myelo-suppression / Anemia

Myelo-suppression manifests as anemia 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 anemia is anticipated with every round of chemotherapy. Look out for anemia with neutropenia which increases chances of infection.

Severe thrombocytopenia (below 50 x 100^9/L) increases the risk of hemorrhage. 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.

c) Stomatitis

Stomatitis, or inflammation of oral mucosa, is an important complication of chemotherapy. Starting as erythema and edema, 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 anesthetics such as viscousxylocaine can relieve pain and help maintain food intake.

d) 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 cyclophosphomide, 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 color.

8.8 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.

8.8.1 Social Symptoms

The reality of an incurable illness changes the way a sick person, family members and close friends treat one other. 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.

a) Family Stress

The person suffering from cervical 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.

b) Stigma and Avoidance

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

c) 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.

d) 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 counseling ensured.

8.8.2 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.

a) Depression

Depression is often anticipated and frequently a socially acceptable reaction. The patient and care unit should be assessed for this and appropriate professional counseling 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.

b) 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 counselor, rather than confrontation.

c) 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.

d) 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 businesses with family members, close friends or associates. Understanding, reassurance and support are needed to prevent patients from being overwhelmed by feelings of guilt.

e) 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.

f) 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 counselors, 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.

8.9. Organizational Aspects of Palliative Care

8.9.1 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 caregivers 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. Specific institutions for palliative care should be in place if local circumstance permits.

8.9.2 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, patiently and be empathic 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 when appropriate.
    - 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 caregivers make time for themselves so they can relax for specified periods of time. This will help renew their energy and avoid quick burnout of health care providers and family members.
- Encouraging them to talk about their feelings and assure them that such feelings are normal. Help them find a trusted friend or counselor to continuously support them.
- Ensuring they can seek and reach for further medical help and information from the specific institution of palliative care when needed.
- Establishment and linking affected patients with cancer support groups.

8.9.3 Follow-up on Professional Care

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

CHAPTER 9: UNIVERSAL PRECAUTIONS FOR INFECTION PREVENTION IN CERVICAL CANCER PREVENTION

Universal precautions are simple measures that help prevent the spread of infection. All health care providers must use universal precautions to protect patients, themselves and other health care workers from the spread of infectious diseases. The current epidemic spread of blood borne viruses, including hepatitis B, C and D, and HIV, underscores the importance of paying scrupulous attention to preventing infection in clinical practice. Many transmissible infections are asymptomatic, and it is not always possible to know who is infected. Therefore, precautions against spreading infection should be used with all patients, whether they appear sick or well, and whether their HIV or other infection status is known or not. Quality control and supervision are essential to ensure that infections are prevented. A pelvic infection after a clinical procedure is an indicator of poor infection-prevention measures.

a) Infection Prevention: Universal Precautions: Wear latex gloves whenever:

- You handle items or body surfaces that might be contaminated;
- You perform clinical examinations or procedures (cryotherapy, biopsy, endocervical curettage and LEEP), or give injections;
- You clean the area where the patient has been lying
- You handle used instruments

b) Remember:

- If gloves get damaged, remove them, wash your hands thoroughly, and then put on new gloves.
- Gloves are not a substitute for hand washing. Wash your hands with soap and water for at least 30 seconds:
  - before and after contact with each client or patient;
  - if you touch blood or body fluids;
  - immediately after you take off latex gloves.

c) Handle contaminated disposable items and clinic surfaces as follows:

- Discard disposable items that are soiled with blood or body fluids in a tightly sealed plastic bag.
- Disposable needles need special handling; use your health facility's protocols.
- Wash linen and reusable cloth items. Use detergent, dry them in the sun, and iron them if possible.
- Clean and disinfect surfaces such as examination tables and floors.

d) Process reusable instruments and gloves after each use, as follows:

- All instruments that have been in contact with the vagina or cervix (e.g. specula, biopsy forceps, gloves, etc.) should be decontaminated, cleaned, and sterilized or high-level disinfected.
- Cryoprobes should be cleaned, decontaminated, and high-level disinfected.
- The examination or procedure table must be decontaminated after each patient.

Other instruments (e.g. colposcope, cryogun, torch lights) must be decontaminated at least once a day, and more often if visibly soiled. Processing instruments there are three basic steps for processing instruments used in clinical and surgical procedures, before they can be reused: (1) decontamination, (2) cleaning, and (3) sterilization or high-level disinfection (HLD).

9.1 Decontamination

Decontamination is the process by which used instruments and gloves are made safe for handling; this step inactivates hepatitis B and HIV. To decontaminate instruments and gloves immediately after use, immerse them in a large plastic bucket containing 0.5% chlorine solution for 10 minutes (not longer, as the instruments may become corroded); remove and rinse with clean water. The chlorine solution can be prepared by diluting one-part household bleach in 9 parts clean water. It must be prepared fresh daily and discarded as soon as it appears dirty. For surfaces in the clinic, 60–90% ethanol or isopropanol can be used as an alternative to chlorine solution.

9.2 Cleaning

Soon after decontamination, a person wearing heavy gloves and glasses or goggles should clean instruments. Use a brush to scrub instruments with water and detergent, and rinse thoroughly with boiled water. Special attention must be given to instruments with teeth, joints and screws.

9.3 Sterilization

Sterilization destroys all microorganisms and must be used for all instruments that come into contact with sterile parts of the body, e.g. that penetrate the skin or enter the womb. Sterilization can be achieved by one of the following:

- Expose instruments to superheated steam in an autoclave: 20 minutes for unwrapped instruments and 30 minutes for wrapped instruments. Autoclaving is the preferred method of sterilization.
- Soak instruments in either 2–4% glutaral for 8 to 10 hours, or 8% formaldehyde for 24 hours. Then rinse thoroughly with sterile water.

9.4 High-Level Disinfection

HLD destroys all organisms except bacterial spores, and is used when sterilization equipment is not available or the instrument is too delicate to be sterilized. One of the following processes can be used for HLD:

- Boil instruments for at least 20 minutes in plain tap water, which is changed at least daily. Make sure that instruments are fully covered by the water, and start timing after the water with the instruments is fully boiling. Do not add anything to the pot once you have started to time.
- Soak instruments in 0.1% chlorine or 2% glutaral solution for 20 minutes, or 6% hydrogen peroxide for 30 minutes. Rinse thoroughly in boiled water, air-dry and store in a sterile cloth. These chemicals may be corrosive and can reduce the useful life of instruments that are repeatedly disinfected with them.

Supplies and equipment the following supplies and equipment are needed for infection prevention (depending on the processing methods used):

- Clean and boiled water; Detergent;
- Household bleach or commercial chlorine powder;
- One or more sterilizing chemicals (2–4% glutaral, 8% formaldehyde);
- One or more HLD chemicals (0.1% chlorine, 2% glutaral, 6% hydrogen peroxide);
- 60–90% ethanol or isopropanol;
- Sterile cloths; plastic bucket scrubbing brush; large jars for storage of solutions; heavy gloves for cleaning; sterilization or high-level disinfected gloves and long-handled forceps for handling processed instruments; autoclave or vessels for boiling and soaking instruments; close with tight closure to prevent entrance of dust, for storage of processed instruments and supplies.

CHAPTER 10: DATA MANAGEMENT, MONITORING AND EVALUATION, QUALITY IMPROVEMENT AND SUPERVISION FOR THE CERVICAL CANCER PROGRAM

10.1 Introduction

Good-quality health care services require a continuous collection of data on various components of the program, including commodities and supplies. Providers of Cervical cancer prevention and control services are the most important link in ensuring sin the contraceptive supply chain that moves commodities from the manufacturer to the client. Accurate and timely reports and orders from providers help supply chain managers determine what products are needed, how much to buy, and where to distribute them. Health facility staff members do their part when they properly manage contraceptive inventory, accurately record and report what is provided to clients, and promptly order new supplies. The aim of this chapter is to provide guidance on documentation and reporting of FP data with regards to:

- Understanding the principles of data quality
- Outlining roles and reporting requirements for services data at various service delivery points and levels
- Describing the data collection and reporting tools available
- Highlighting the role of data in decision making at all levels

10.2 Importance of data

Data is required for monitoring and evaluation of the cervical cancer programs and for responding to information requests from stakeholders. Stakeholders use information for specific purposes that target;

- Decision making and programming.
- Guide decision making
- Allocation of resources
- Mobilization of resources
- Where to concentrate efforts
- Planning

Decision-making can be at different levels (International, Regional, National, Sub-national and facility levels) for Monitoring of progress and trends, Development of (new) evidence-based interventions

10.3 Key Definitions

a) Data: Factual information used as a basis for reasoning, discussion or calculation

b) Report: Narrative description of happenings/events. Reports involve filling out, compiling specific information on data for use at a certain level.

c) Record (noun): A documentation of a specific event

d) Record keeping: Involves Documentation and custody of information to facilitate future planning and reference.

e) Standard: A performance standard defines, in the clearest and most objective terms, the agreed-upon level of performance desired for a specific service, based on scientific evidence and best practices. It is usually measurable in terms of timing and quantity. It states what the health-care service is expected to deliver.

f) Indicator: An indicator is a variable that measures one aspect of a programme that is directly linked to the programme's objectives. In the context of a health-care service, indicators tell us specifically what to measure to determine whether the objectives or the standards have been achieved.

g) Quality improvement: Quality improvement is a structured approach to analysing performance and applying systematic efforts to improve it.

10.4 Roles and Reporting Requirements by Service Delivery Levels

Providers at all levels are required to report on services provided, using the appropriate tools and submit at the recommended timelines. All service providers should maintain proper records on each client served. The appropriate client cards, screening forms, daily activity registers and monthly summery forms should be completed.

Service providers from private sector should also follow the Ministry of Health's service provision and reporting guidelines. Health care providers will collect the various data according to the main data points:

- Facility details (includes Zoba, facility name, type and reporting period)
- Clients vaccinated, screened, treated and referred
- Commodity status

10.5 Data Quality Management

It is of utmost importance that data errors be minimized starting with individual patient data. Dimensions of data quality need to be met in order to generate trust in the usability of the data generated from the Health system.

Increasing access and use of quality data is nested on the development and operationalization of an efficient Data Quality Assessment (DQA) system, which will harness evidence-based decision-making. The service provider should incorporate strategies for data quality assessments. Deliberate efforts should be put in place to ensure the reported data are verified on a regular basis also called "Data Audit". These strategies include supportive supervisions, data review meetings and Routine Data Quality Assessment and audits. Examples of these can include assessing Screen positive rates between various providers, facilities, and regions.

Dimensions of Data Quality	How to Ensure Quality is Achieved
Timeliness	Reports are submitted by an accepted deadline at each level
Accuracy	Data that has been reported matches the primary source documents at the point of collection. The data is also realistic and a true reflection of what is happening.
Reliability	Data collection was aligned with protocols and procedures that do not change depending on the data collector or when or how often they are used; data is reliable because it is collected consistently
Precision	Data contains sufficient detail. For example, if an indicator requires "the number of girls receiving HPV vaccination – first dose
Integrity	The data collection system is protected from bias or manipulation for reasons other than medical care
Confidentiality	Personal client data are not inappropriately disclosed or left unsecured; clients are assured of the confidentiality of their personal data.

Table 5: *Dimensions of Data Quality and how to ensure it is Achieved*

10.6. Monitoring and Evaluation for Cervical Cancer Programs

a) Monitoring – is the routine tracking of a program's activities by measuring on a regular basis whether planned activities are being carried out. Results reveal whether program activities are being implemented according to plan and assess the extent to which program services are being used

b) Evaluation – involves the assessment of how well program activities are being performed in relation to the set objectives, inputs and expected outcomes

Difference between 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 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 Sub Zoba, Zoba and national levels.

10.7 Basic Tools for Data Collection for Cervical Cancer Program at All Levels

- **Client's Card:** The client card is completed with the client's name and identification number with full address. 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 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 Daily Activity 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 sub zoba level.
- **Monthly Reporting Summary Tool:** This will capture summary information from the service delivery point's registers that will be forwarded to the HMIS on monthly basis to inform policy and decision making.
- **National Cancer Register:** This office will be located at the MOH headquarters.

10.8 Indicators for Cervical Cancer Program

The following indicators will be tracked by the country to monitor the performable of the cervical cancer program. Some of the indicators are also tracked globally

10.8.1 Proposed Indicators for Screening and Retreatment:

Number of women:

a) Screened for the first time within target age group (25-49)
b) 30-49 Who have had screening at least once in life time
c) Receiving Initial screening (screening for the first time
d) Receiving repeat screening, using VIA, Pap smear, or HPV test
e) Screened older than 49
f) Screened using VIA, Pap smear, and HPV test
g) Women with Pre-cancerous Lesion (e.g. VIA +ve; LSIL, HSIL)
h) Number of women suspicious cancer
i) Women with screened with HIV status
j) Women Receiving Cryotherapy Same Day
k) Women referred for LEEP or Surgery or
l) Receiving other forms of care e.g. Colposcopy
m) Referred who completed referral

10.8.2 Proposed Indicators for HPV Vaccination

a) Number of girls Eligible for vaccination (9-14)
   - Enrolled in school per Zoba
   - Out of school per Zoba

b) Number of girls 9-14 vaccinated for HPV
   - One dose (partial vaccinated)
   - Second dose (Fully vaccinated)
   - One dose

10.8.3 Performance Indicators

a) Screening rate of the target population (women aged 25–49 years): Percentage of women aged 25–49 years who have been screened for the first time with VIA in the previous 12-month period.
b) Positivity rate: Percentage of screened women aged 25–49 years with a positive VIA test result in the previous 12-month period.
c) Treatment rate: Percentage of VIA-positive women receiving treatment in the previous 12-month period.

10.8.4 Results Indicator

- Coverage Rate Indicator: Percentage of women aged 25–49 years who have been screened with VIA or another screening test at least once between the ages of 30 and 49 years.

10.8.5 Impact Indicator

- Cervical cancer age-specific incidence.

10.9.6 Quality Improvement

Every health facility that conducts screening for cancers 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.

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. Trainers developed at national and zoba levels who then cascade the training to the sub zoba and health facilities conduct skills-based training. Note that for example - the specificity of VIA 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.

10.9.7 Quality Improvement Teams

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 cervical cancer guidelines (and other 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

10.9.8 Supportive Supervision

Supportive supervision is essential in ensuring that quality is maintained across the service delivery chain. In order for systematic supportive supervision to take place, the quality control and Quality assurance plan needs to describe the following:

- Describe the purpose of the supervision and monitoring activities, including expected deliverables;
- Describe the data sources and forms to be used at each level of supervision and monitoring;
- Describe the flow of information from the health-facility level to the national level, and identify who is responsible at each level of the health system for collecting this information;
- Describe the strategies that will be used to conduct supervision, based on the country context and resources available (this may include routine visits to each health facility by a supervisor or the transfer of facility-level data by the heads of health facilities to a supervisor using computers or mobile technologies);
- Identify who is responsible for coordinating the process at each level of the health system;
- Describe the human resources and budget required at each level, and identify financial resources to cover the costs.

When setting up a supervision and monitoring system, it is critical to clearly define the roles and responsibilities of each person involved in the process. *Table 6* provides a sample of common roles within supervision and monitoring systems.

Position	Role
Facility – Level Supervisor	▪ Monitor quality of VIA and cryotherapy services ▪ Review site-level data to ensure that health-care providers are maintaining good quality records ▪ Mentor and coach health-care providers ▪ Ensure that required supplies and equipment are available, including data collection tools ▪ Facilitate communication with the ZOBA -level supervisor ▪ Work with health-care providers to use feedback from external supervision to improve programme performance
ZOBA – Level Supervisor	▪ Provide external supervision of quality of VIA and cryotherapy services (i.e. review of coverage, positivity rates, etc.), with regards to nationally agreed-upon indicators ▪ Review site-level or aggregated data to ensure that health-care providers are collecting good quality data ▪ Provide evidence-based feedback and recommendations for strengthening programmes ▪ Mentor and coach health-care providers ▪ Support additional training as needed to bring skills up to standard ▪ Facilitate communications with the national-level supervisor
National – Level Supervisor	▪ Review aggregated data to ensure that health facilities are collecting good quality data ▪ Provide evidence-based feedback and recommendations for strengthening programmes ▪ Support additional training as needed to bring skills up to standard ▪ Advocate at the national level for resources and activities required to strengthen programme performance

Table 6: *Roles and Responsibilities in the Supervision and Monitoring Systems*

Adopted from: WHO VIA Quality Assurance Guideline, 2013

The supervisory visit will require at least half a day, sometimes as much as a full day, to conduct. It is not necessary to assess every indicator or every provider at every visit. The supervisor should review the indicators for which an action plan was developed at a previous visit or those indicators that have not been reviewed for some time. During or after the meeting with the staff of the facility, the supervisor should develop an action plan to address areas where improvement is needed. After the visit, the supervisor should write up the performance support evaluation report.

A number of tools and checklists can be used to support supervisory visits for screening programmes. Performance standards tools should be used to assess individual performance and to make recommendations for improvement where gaps are identified. The supervisors and health-care providers should be oriented to these tools during training. Performance standards tools should be used to assess individual performance and to make recommendations for improvement where gaps are identified.

CHAPTER 11: COMMUNITY MOBILIZATION

A clearly laid out community mobilization plan is key to creating and sustaining demand for screening and early management of cervical cancer, and other reproductive tract 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 mobilization.

11.1 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 Eritrea, the health system recognizes community leaders and community health workers as an essential part of care providers, 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 should 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.

11.2 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:

a) Well-trained staff to provide education and counselling to clients

- 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.
- Health care workers should help patients understand the enormous advantages offered by the various cancer prevention services, as well as their limitations.

b) Appropriate key informational and educational messages for clients

- The cervical, breast and prostate cancer prevention information guide should be tailored to specific key audiences.
- Educational materials that are culturally appropriate, and contain consistent and accurate information should be disseminated.

c) Identified settings for delivery of information

The MOH recommends integration of cervical and breast cancer prevention services in the following settings: MCH/FP clinics, gynaecology 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.

11.2 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:

- Community leaders' meetings, Community health days, religious and cultural meetings, at market places, social gathering points, sports activities such as football matches,
- Electronic media, print media, Pamphlets, Brochures, murals, fliers, Posters, banners, billboards, caravan, Road shows, T-shirts, 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

11.3 Counselling

Counselling 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 counselling. Clients being screened for cancers of the reproductive organs need accurate information about the disease, the tests and the treatment procedures.

Clients also need counselling 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.

11.3.1 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, screening procedures, process of arriving at a diagnosis and the treatment procedures for each disease
- 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

11.3.1 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 non-judgmental 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

11.4 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.

CHAPTER 12: ADVOCACY AND RESOURCE MOBILIZATION

Effective policy advocacy for cervical cancer involves careful planning for clarity in defining the issues to be addressed, identifying the correct stakeholders and proper implementation of the ensuing cervical cancer control programmes. It encompasses a wide range of activities that influence decision makers. 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.

12.1 Methods of Advocacy

There are six distinct methods one can use in policy advocacy as outlined below:

i. Political Advocacy: the advocate seeks to impact public policy through lobbying. This can be at the local government or national government forum. Either serving on advisory committees for the government in policy formulation, or in sensitizing the leadership to take action towards cancer management can do this.

ii. Community Outreach Advocacy: This form of advocacy aims to reach out to the community in a manner that encourages a two-way dialogue. It involves identifying the needs of the community and advocating to have various stakeholders come together to formulate solutions that best meet these needs.

iii. Education Advocacy: involves efforts to inform and educate the general public about cervical cancer in order for them to make informed decisions. Such information could be on topics of interest such as cervical cancer risk factors, signs & symptoms, prevention, treatment and palliation / patient care and survivorship issues.

iv. Fundraising Advocacy: includes taking an active role in activities that raise money to support the various advocacy activities such as cancer research, support services, and patient education.

v. Support Advocacy: is all about providing support to cancer patients and their families. It involves provision of appropriate palliative care for patients, their families and care givers. It can be in the form of emotional, financial, nutritional and/or physical assistance.

vi. Research Advocacy: The goal for research advocacy is to ensure high quality research that is sensitive to the priorities of communities and the patients.

Either of these forms of advocacy can be carried out on their own or a combination of the methods can be used to supplement and complement in advocating for comprehensive cervical cancer control and management in Africa

Some of the key elements for cervical cancer prevention and control strategy is understanding the rational and current attitude or situation, by using the problem tree approach, to identify key bottlenecks.

12.2 Evaluating Issues for Advocacy

Key problems for cervical cancer prevention and control that can be addressed through advocacy include:

a. Comprehensive national policy or plan on cervical cancer prevention and control

b. Access to vaccination and/or screening services and treatment (including palliative care)

c. Cost of vaccination and/or screening and treatment (including palliative care)

d. Integration into family planning, maternal health HIV, vaccines and adolescent health programmes.

e. A functioning referral system that links screening services with the treatment of precancerous lesions and invasive cancer

f. A functioning monitoring system to track coverage HPV vaccination, screening and follow –up treatment

g. Development of a cancer research agenda

h. Awareness raising for women to be screened and treated, men to support partners, mothers, sisters to be screened and treated. Families to support girls aged 9-14 being vaccinated

12.3 Establishing Goals and Objectives of Advocacy

It is crucial to develop advocacy goal framework, with SMART (specific, measurable, achievable, realistic and time bound) objectives.

12.4. Target Audience

It is worth noting that the targets could be classified to decision makers; which have the authority to make the change that is being advocated for (Government, Development Partners, community partners etc.) and Influencers; who can be person or groups that can influence the decision making (Consumer groups, health care professionals etc.)

Target Groups

The WHO recommended target groups for cervical cancer and control include:

a) Young Adolescents (and their families): Research indicates that the HPV vaccines are most effective if provided to girls and/or women prior to the onset of sexual activity and exposure to HPV infection; therefore, the target population for the HPV vaccine, as recommended by WHO, is young adolescent girls aged 9–14 years. However, it is important to include boys in awareness and informational campaigns.

b) Adult Women: The greatest benefit from cervical screening can be gained by limiting the use of screening resources to women in the 30–49 age group, as recommended by WHO. This is because most women are infected with HPV in their teens and twenties and the virus normally takes 10–15 years to produce precancerous changes. Inclusion of family members and particularly male partners when conveying related health education messages is critical to ensuring acceptance of screening services.

c) Vulnerable Groups: Evidence shows that services tend to be used least by those most at risk. It is not enough to set up services and assume that girls and women who are at risk will arrive to make use of those services. Special efforts need to be made to reach the most vulnerable populations. These groups include:

- Girls who are hard to reach, especially those not attending formal education;
- Women who live far from services and have fewer resources;
- Migrant workers, refugees and other marginalized groups;
- Women and girls living with HIV and other immunosuppressed individuals

A key message is the most important element in deciding how an audience perceives the issue. Should be:

- Clear, compelling, concise, consistent and convincing
- Simple and direct
- Frequently repeated and reinforced by a combination of sources.

Some Key Messages

1) Cervical cancer is a disease that can be prevented.
2) There are tests to detect early changes in the cervix (known as pre-cancers) that may lead to cancer if not treated.
3) There are safe and effective treatments for these early changes.
4) All women aged 30-49 years should be screened for cervical cancer at least once.
5) There is a vaccine for girls that can help prevent cervical cancer.

Key messages for men. Men can:

1) Encourage their partners, sisters and mothers to be screening if they are 30-49 years of age
2) Encourage their partners, sisters and mothers to be treated if pre-cancer or cancer is detected
3) Encourage their daughters, sisters and female friends to get vaccinated with the HPV vaccine
4) Use condoms to prevent all sexually transmitted infections, including H IV/AIDS, as well as pregnancy (condoms offer some protection against HPV)
5) Reduce the number of sexual partners they have, and use condoms if they have more than one sexual partner.

12.5 Resource Mobilization

In planning advocacy activities, one needs to have a realistic approach. This means that the TWGs need to consider available resources and existing services in your country. Based on what already exists, it is then possible to reinforce means needed to achieve selected advocacy goals and objectives. The following list will help appraise what is analysed and what is needed in order to plan your advocacy approach appropriately. The table below highlights types of resources and possible sources

Type of Resources	Sources
Information & Communication	Media, Local Administrators; Community Health Workers; Civil Society; Religious Leaders; Women leaders, School Head
Community Awareness & Education	School; Family; Volunteers; Religious Institutions
Financial	Government; Development partners; NGOs; Religious organizations; Foundations;
Human Resources	General practitioners; Oncology Doctors; surgeons; Specialists; Nurses; Laboratory Technicians; Pathologists, Planners
Health Care Infrastructure	Infrastructure; Services; Materials; Personnel

Table 7: *Type of Resources*

BIBLIOGRAPHY

Bosch, F. X., Muñoz, N., Sanjosé, S. de, Izarzugaza, I., Gili, M., Viladiu, P., … Shah, K. (n.d.). Risk factors for cervical cancer in Colombia and Spain. *International Journal of Cancer*, *52*(5), 750–758. https://doi.org/10.1002/ijc.2910520514

Eritrea: Human Papillomavirus and Related Cancers, Fact Sheet 2017. (2017). *Fact Sheet*, 2.

Fiander, A. (2011). The Prevention of Cervical Cancer in Africa. *Women's Health*, *7*(1), 121–132. https://doi.org/10.2217/WHE.10.74

GLOBOCAN Cancer Fact Sheets: Cervical cancer. (n.d.). Retrieved July 15, 2018, from http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp

pp_hpv_may2017_summary.pdf. (n.d.). Retrieved from http://www.who.int/immunization/policy/position_papers/pp_hpv_may2017_summary.pdf?ua=1

Sankaranarayanan, R. (2015). HPV vaccination: The most pragmatic cervical cancer primary prevention strategy. *International Journal of Gynecology & Obstetrics*, *131*, S33–S35. https://doi.org/10.1016/j.ijgo.2015.02.014

WHO | Reaching teenagers with three-times jab is a first for most countries. (n.d.). Retrieved July 15, 2018, from http://www.who.int/bulletin/volumes/90/12/12-021212/en/

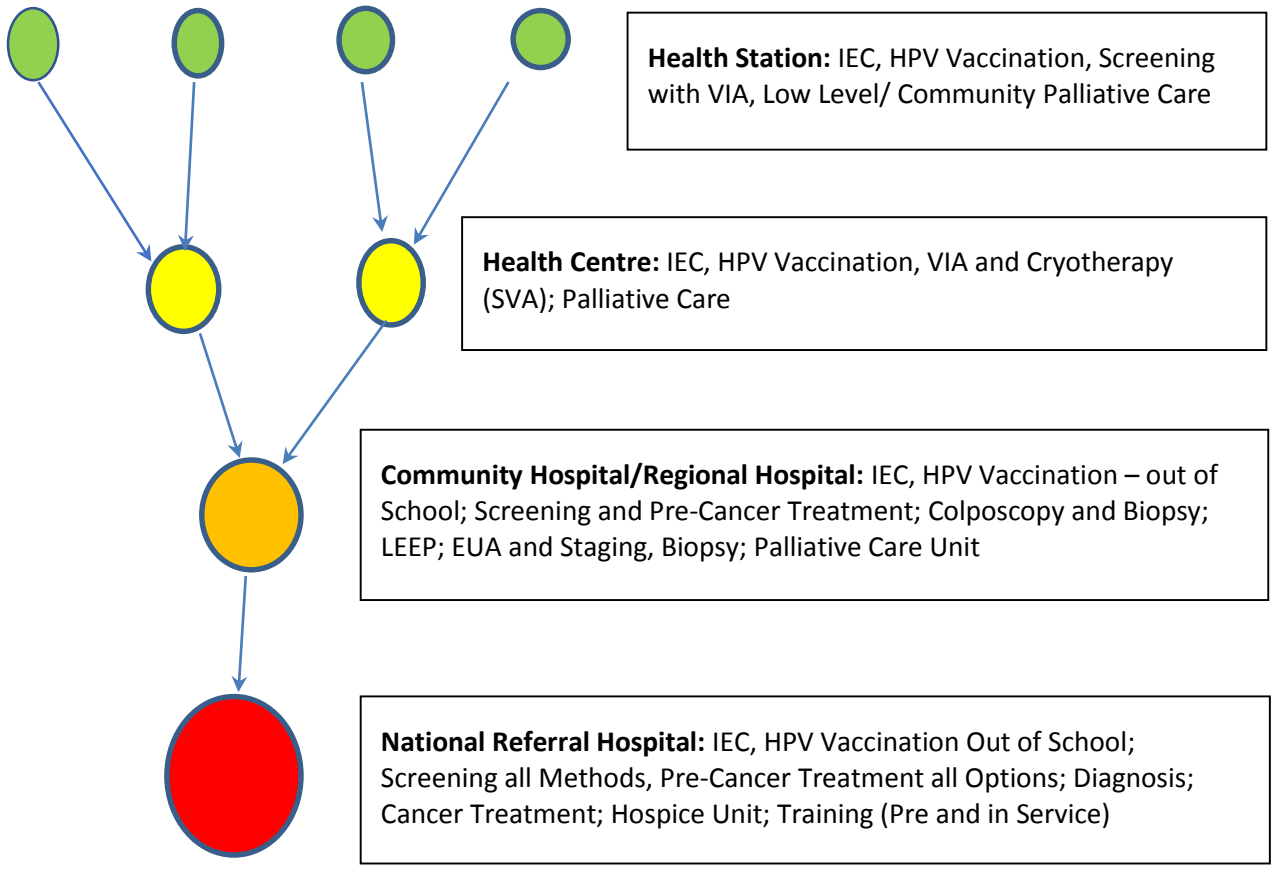
World Health Organization. (2014). Assessing Country Capacity and Preparedness for Introducing or Scaling up a Comprehensive Cervical Cancer Prevention and Control Programme. Regional Office for Africa Geneva.

World Health Organization, World Health Organization, & Reproductive Health and Research. (2014). *Comprehensive cervical cancer control: a guide to essential practice.* Retrieved from http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf?ua=1

Zitkute, V., & Bumbuliene, Z. (2016). Risk Factors Affecting HPV Infection, Persistence and Lesion Progression in Women and Men, 4.

ANNEXES

Appendix 1: Model of Service Delivery Eritrea



Appendix 2. Visual Inspection with Acetic Acid (VIA) Test Procedure

In a VIA test, the provider applies acetic acid to the cervix, and then looks to see if there is any staining. A VIA test is positive if there are raised and thickened white plaques or acetowhite epithelium. The test is suspicious for cancer if a cauliflower-like fungating mass or ulcer is noted on the cervix. Visual screening results are negative if the cervical lining is smooth, uniform, pink with acetic acid and featureless.

Note: Visual methods are not recommended for use in postmenopausal women, because their transition zone is usually inside the endocervical canal and not visible on speculum inspection.

a) Materials and Equipment Needed

- Soap and water for washing hands
- A bright light source to examine the cervix
- A speculum, high-level disinfected (it need not be sterile)
- Disposable or high-level disinfected examination gloves (need not be sterile)
- Examination table covered by clean paper or cloth
- Cotton-tipped swabs
- Dilute acetic acid solution (3–5%) or white vinegar
- 0.5% chlorine solution for decontaminating instruments and gloves
- Recording form.

b) Preparation

i. Explain the procedure, how it is done and what a positive test means. Ensure that the woman has understood and obtain informed consent.

ii. Do a speculum examination.

c) Procedure

i. Adjust the light source to get the best view of the cervix.

ii. Use a cotton swab to remove any discharge, blood or mucus from the cervix.

iii. Identify the SCJ, and the area around it.

iv. Apply acetic acid to the cervix; wait a minute or two to allow colour changes to develop. Observe any changes in the appearance of the cervix. Give special attention to abnormalities close to the transformation zone.

v. Inspect the SCJ carefully and be sure you can see all of it. Report if the cervix bleeds easily. Look for any raised and thickened white plaques or acetowhite epithelium. Remove any blood or debris appearing during the inspection.

vi. Use a fresh swab to remove any remaining acetic acid solution from the cervix and vagina.

vii. Gently remove the speculum.

d) After Screening

i. Record your observations and the test result. Draw a map of any abnormal findings on the record form.

ii. Discuss the results of the screening test with the patient. If the test is negative, tell her that she should have another test in three years. If the test is positive or cancer is suspected, tell her what the recommended next steps are. If she needs to be referred for further testing or treatment, make arrangements and provide her with all necessary forms and instructions before she leaves.

iii. If you can make the appointment immediately, do so.

Source: WHO, 2006 (1).

Appendix 3: Eligibility Criteria for Cryotherapy

Eligibility Criteria	Exclusion Criteria
▪ Positive screening test for cervical pre-cancer ▪ Lesion small enough to be covered by the cryoprobe ▪ Lesion and all edges fully visible with no extension into the endocervix or onto the vaginal wall	▪ Evidence or suspicion of invasive disease or glandular dysplasia ▪ Lesion extends beyond the cryoprobe edge ▪ Pregnancy ▪ Pelvic inflammatory disease (until treated) ▪ Active menstruation

Appendix 4: Cryotherapy Procedure

Cryotherapy is the freezing of the abnormal areas of the cervix by the application of a very cold disc to them. It takes only a few minutes and usually only causes some cramping.

Materials and Equipment Needed

- A speculum, high-level disinfected (it need not be sterile)
- Disposable or high-level disinfected examination gloves (need not be sterile)
- Cotton swabs for wiping the cervix
- Normal saline solution
- Colposcope, if used in the particular venue
- Cryosurgery unit with adequate gas supply.

Before the Procedure

i. Explain the procedure, and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.

ii. Show her the cryotherapy equipment and explain how you will use it to freeze the abnormal areas on the cervix.

iii. Prepare the patient for a gynaecological examination and perform a speculum examination.

iv. If there is no evidence of infection, proceed with cryotherapy.

v. If there is a cervical infection, provide treatment. You may proceed with the cryotherapy, or you may give the patient an appointment to return once the infection is cured.

The Procedure

i. Wipe the cervix with a saline-soaked cotton swab and wait a few minutes.

ii. Apply acetic acid to outline the abnormality and wait a further few minutes.

iii. Tell the woman she might feel some discomfort or cramping while you are freezing the cervix.[1]

iv. Wipe the cryoprobe surface with saline to ensure optimum effectiveness.

v. Apply the cryoprobe tip in the centre of the os and make sure the probe adequately covers the lesion (Figure 5). If the lesion extends more than 2 mm beyond the probe, discontinue the procedure. Explain to the woman why you are doing this and what needs to be done for her as an alternative.

vi. Ensure that the vaginal wall is not in contact with the cryoprobe or you may cause a freezing injury to the vagina.

vii. Set the timer and release the gas trigger to cool the probe.

viii. You will observe the ice forming on the tip of the cryoprobe and on the cervix (Fig. 5). When the frozen area extends 4–5 mm beyond the edge of the cryoprobe, freezing is adequate.

ix. Allow two cycles of freezing and thawing: 3 minutes freezing, followed by 5 minutes thawing, followed by a further 3 minutes freezing.

x. Once the second freezing is complete, allow time for thawing before attempting to remove the probe from the cervix. Removing it before it is fully thawed will pull tissue off the cervix.

xi. Gently rotate the probe on the cervix to remove it. The area you have frozen will appear white.

xii. Examine the cervix for bleeding. If bleeding is noted, apply Monsel's paste.

xiii. Do not pack the vagina.

xiv. Remove the speculum.

After the Procedure

i. Provide a sanitary pad.

ii. Instruct the woman to abstain from intercourse and not to use vaginal tampons for 4 weeks, until the discharge stops completely. This is to avoid infection.

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

iv. Invite the patient to return in 2–6 weeks to be checked for healing, and again in 6 months for a repeat VIA test and possible colposcopy.

v. Inform her of possible complications and ask her to return immediately if she notes:
- Fever with temperature higher than 38°C or shaking chills
- Severe lower abdominal pain
- Foul-smelling or pus-like discharge
- Bleeding for more than two days or bleeding with clots.

vi. Clean and disinfect the cryoprobe and decontaminate the cryogun, tubing, pressure gauge and gas tank[2]:

a) Decontaminate the cryotherapy unit, hose and regulator by wiping them with alcohol.

b) Wash the cryotip and the plastic sleeve with soap and water until visibly clean.

c) Rinse the cryotip and plastic sleeve thoroughly with clean water.

d) High-level disinfect the cryotip and plastic sleeve by one of the following methods:
- Boil in water for 20 minutes; or
- Steam for 20 minutes; or
- Soak in chemical disinfectant (0.1% chlorine solution or 2–4% glutaral) for 20 minutes and then rinse with boiled water.

Note:

❖ It is critical that the hollow part of the cryotip is completely dry when used next, otherwise the water will freeze and the probe could crack or the treatment not work.

❖ Either use a rubber cap to seal off the hollow part of the cryoprobe during processing, or thoroughly dry the cryoprobe before it is reused.

Follow-Up

a) Perform a pelvic examination to check for healing 2–6 weeks after the cryotherapy.

b) At 6 and 12 months, do a VIA test and a colposcopy and take a biopsy if necessary.

Source: WHO, 2006 *(1)*.

Appendix 5: Summary of Proposed Core Indicators

Indicator 1: Screening Rate

Indicator 1	Screening Rate
What it Measures	Percentage of women aged 30–49 years who have been screened for the first time with VIA in a 12-month period. This is a monitoring indicator that measures how many VIA screenings were performed in a 12-month period targeting women aged 30–49 years.
Rationale	Programme managers should aim to achieve high screening rates in the age range in which women present the highest risk for precancerous lesions, that is, 30–49 years of age. Measuring screening rates annually will permit measurement of a cumulative incidence of women screened. Ideally a programme should aim for a cumulative incidence of 100% screening rate over a target time frame defined at the initiation of the programme.
Numerator	Number of women aged 30–49 years who have been screened for the first time with VIA in a 12-month period
Denominator	Number of women aged 30–49 years in the population
Data source	The numerator should be collected through the HIS (facility level or centralized); the denominator should come from the population census.
Frequency	Annually
Proposed Target	Programme managers have to set realistic targets for the 12-month period based on the number of providers and the available hours of work at the screening centres, and should prioritize the age range recommended by the national programme and women who have never been screened.

Indicator 2: VIA Positivity Rate

Indicator 2	VIA Test Positivity
What it Measures	Percentage of VIA-screened women aged 30–49 years with a positive result
Rationale	VIA test positivity provides useful information for identifying health-care providers in need of retraining. If test positivity is too low there is the possibility of missing disease cases, and if it is too high, there is the possibility of a high number of false positives.
Numerator	Number of women aged 30–49 years reported positive in a 12-month period
Denominator	Total number of women aged 30–49 years screened in a 12-month period
Data Source	The numerator and denominator should be collected through the HIS (facility level or centralized).
Frequency	Annually

Comments	The positivity rate of VIA depends on the age distribution of the screened women, the prevalence of cervical neoplasia in the target population, and the skill and experience of the VIA providers. VIA test positivity will be high in younger women, particularly those below 30 years, due to the metaplastic changes in the cervix and high prevalence of low-grade intraepithelial lesions. In various studies it has been observed that newly trained providers tend to report higher positivity rates initially. As they acquire skills and gain confidence, the test positivity tends to come down and stabilize at a rate appropriate for the population. The range of VIA test positivity is 5–10% in women aged 30–60 years. Some research studies have observed very high VIA positivity rates, but it is likely that was because no attempt was made to differentiate between the acetowhitening of neoplasias and that of non-neoplastic conditions like metaplasia, or because the screened populations had a high prevalence of HIV.
Proposed Target	It is important to consider the trends of VIA positivity when seeking to identify deviations that may require corrective action.

Indicator 3: Treatment Rate

Indicator 3	**Treatment Rate**
What it Measures	Percentage of VIA-positive women who have received treatment in a given year
Rationale	Screening alone will not be able to reduce the disease burden of cervical cancer unless screening is linked to treatment of the screen-detected neoplasias. Treatment options include cryotherapy, loop electrosurgical excision procedure (LEEP) and cold knife conization (CKC) for precancerous lesions, and surgery, chemotherapy and radiotherapy for invasive cancer. Collecting data on the proportion women with a positive result who have been treated will aid the programme manager to ensure that women have adequately completed their care for precancerous lesions or invasive cancers.
Numerator	Number of VIA-positive women aged 30–49 years completing appropriate treatment in a 12-month period
Denominator	Number of VIA-positive women in a 12-month period
Data source	The numerator and denominator should be collected through the HIS (facility level or centralized).
Frequency	Annually
Comments	Compliance with treatment can be improved if a ‘screen and treat’ approach is adopted where VIA is followed by cryotherapy for precancerous treatment (when eligible) during the same visit.
Proposed Target	Programme managers will have to ensure that at least 90% of the VIA-positive lesions and invasive cancers receive treatment.

Appendix 6: Age specific Cervical Cancer Incidence

Indicator	Coverage of the Target Population
What it measures	Percentage of women aged 30–49 years who have been screened with VIA or another method at least once between the ages of 30 and 49 years. This indicator measures the effectiveness of the screening programme in reaching the target population at least once.
Rationale	From a natural history perspective of cervical changes, the best time to catch cervical dysplasias that result from chronic persistent HPV infection is between the ages of 30 and 49 years. Ensuring the participation of the majority of the target population of women who are in the high-risk age group will lead to overall reduction in cervical cancer mortality. Evidence from some countries where screening programmes are in place shows that more than 50% of women diagnosed with cervical cancer have never been screened. Increasing coverage is generally more important than marginal increases in the frequency of screening or increases in the sensitivity of the screening test, particularly for countries with low screening coverage.
Numerator	All women aged 30–49 that answered "YES" to the question in the survey
Denominator	All women aged 30–49 that answered the question in the survey
Data source	Specific health survey conducted on a representative sample of households.
Frequency	WHO recommends that countries do surveys approximately every 5 years, in the context of the WHO STEP wise approach to Surveillance (STEPS).[3]
Comments	The ages at which screening will be initiated and discontinued need to be predetermined depending on the capacity and resources available. Similarly, the interval between each round of screening may vary from programme to programme. The programme manager will have to ensure that all women within the specified age group have access to screening. In an opportunistic programme with low participation rates, low-risk women typically undergo unnecessarily frequent rounds of screening while those with significantly higher risk are left out. There can be a significant reduction in cervical cancer mortality if more than 70% of the target population of women has regular cervical screening. Screening of women outside of the target age range should be discouraged and should be as low as possible.
Proposed Target	This indicator refers to the comprehensive global monitoring framework, including indicators and a set of voluntary global targets for the prevention and control of non-communicable diseases. It will be collected through specific surveys.

Appendix 7: Age Specific Cervical Cancer Incidence

Indicator 5	Age-Specific Cervical Cancer Incidence
What it measures	Number of new cases of cervical cancer that occur in a defined population of disease-free individuals in a specified period of time[4]
Rationale	Age-specific cervical cancer incidence supports the measurement of programme impact.
Numerator	Number of cases in the age group
Denominator	Number of women in the age group (1 person-year per person, if it is an annual measure)
Data source	Population-based cancer registry, sentinel hospital-based cancer registry
Frequency	Annually
Comments	The desired impact of a screening programme is the reduction of cervical cancer incidence and mortality rates. Initially, the programme is likely to detect many of the undiagnosed prevalent cancers, such that initial results may appear to show an increase in the incidence. Subsequently, there will be a stage-shift of the detected invasive cancers with more and more cases being diagnosed at earlier stages. As the cervical pre-cancers are detected and treated, there will be a gradual reduction in new cases of invasive disease detected. However, reduction in incidence and mortality as an impact of the screening programme may take a decade to become evident.
Proposed Targets	The target for this indicator will vary by country depending on baseline incidence and trends.

Appendix 8: Additional Indicators

i. ***Percentage of VIA – Positive Women with Lesions Eligible for Cryotherapy treated during the same visit.***

Method of Calculation:

- Numerator: Number of VIA-positive women with lesions eligible for cryotherapy treated during the same visit x 100
- Denominator: Number of VIA-positive women with lesions eligible for cryotherapy.

i. ***Percentage of VIA – Positive Women with Lesions Not Eligible for Cryotherapy referred to Colposcopy and who Complete Adequate Treatment.***

Method of Calculation:

- Numerator: Number of VIA-positive women with lesions not eligible for cryotherapy referred to colposcopy and who complete adequate treatment x 100
- Denominator: Number of VIA-positive women with lesions not eligible for cryotherapy.

ii. Percentage of Women with Suspected Invasive Cancer on VIA who Complete Appropriate Treatment or Appropriate Follow-Up.

Method of Calculation:

- Numerator: Number of women with suspected invasive cancer on VIA who complete appropriate treatment or follow-up x 100
- Denominator: Number of women with suspected invasive cancer on VIA.

Explanation:

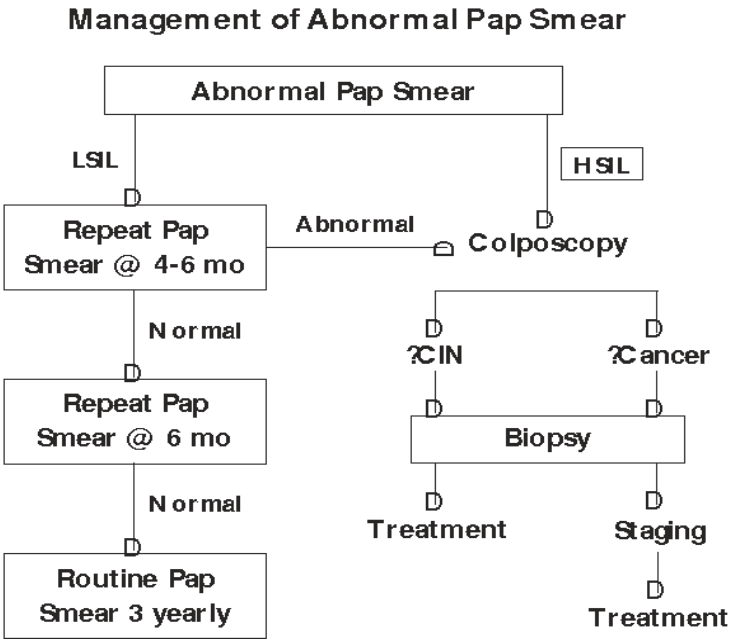
Health-care providers conducting screening with VIA can visually identify cases of suspected invasive cancer. Visibly invasive cancer can have a variety of appearances. Most commonly, if the cancer is detected early, the cervix will appear densely white, with a thick, knobby mass extruding from some portion of the cervix. Such masses may have a cauliflower-like appearance and will bleed easily upon contact. Sometimes contact will cause fragments of the mass to break off, which can also cause bleeding. A bimanual exam will confirm the presence of an enlarged, hardened cervix, which may or may not be mobile (depending on the stage of progression)[5]. Other characteristics that may be observed visually include an extensive fungating growth, or a haemorrhagic tumour mass in the vagina. Health-care providers should be trained to refer all cases of suspected cancer for follow-up, including confirmation of diagnosis and further management as necessary.

Appendix 9: Classification of Pap Smear

Comparison of cervical cytology classification systems

Bethesda	CIN	Dysplasia	Papanicol.
NL	NL	NL	I
Infection, reactive,repair	Inflammatory atypia	Inflammatory atypia	II
ASC-US	Squamus+HPV atypia	Squamus+HPV atypia	IIR
LSIL	CIN I	Mild dysplasia	III
HSIL	CIN II CIN III CIN III	Moderate dyspl. Severe dyspl. Carcinoma insitu	III IV IV
SCC	SCC	SCC	V

Appendix 10: Algorithm Management of Abnormal Pap Smear



Appendix 11: Algorithm for Management of Abnormal Histology results

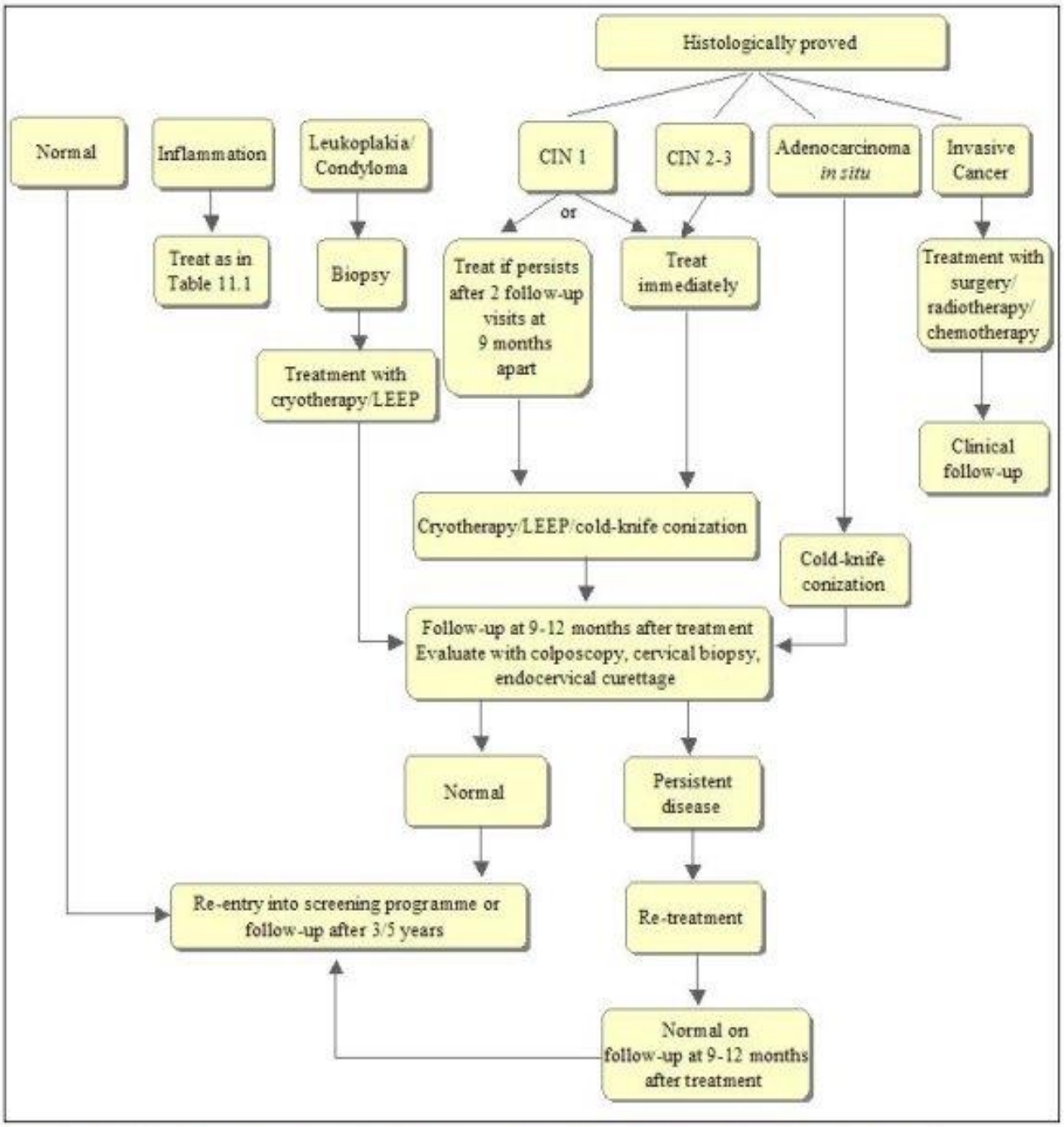


FIGURE 11.1: Flow chart of management decisions in cervical neoplasia and other conditions in low-resource settings. (CIN-cervical intraepithelial neoplasia; LEEP-Loop electrosurgical excision procedure)

Appendix 12: Sample Supervisory Visit Report Template

Staff name: **Senior Nurse Supervisor**

Date of visit: **1 June 2012**

Facility visited: **Urban Health Centre**

Date report submitted: **7 June 2012**

Objective(s) of the Visit:

To follow up on the previous action plan for the Urban Health Centre, with specific attention to recruitment rates, infection prevention practices and client–provider interaction (in particular, counselling after VIA-positive test result). Nurse Agatha needed improvement at the time of the last supervisory visit.

Activities carried out at the Facility:

Met with six providers to review monthly logbook to determine recruitment and screening rates. Observed two providers performing VIA and cryotherapy: Nurse Agatha and Nurse Elizabeth. Assessed performance of the two providers using performance standards checklist and co-assessment of VIA test and client management. Reviewed individual self-assessment of counselling for both providers.

Findings:

Nurse Agatha's VIA and client management recommendations were satisfactory and her counselling skills have improved. Nurse Elizabeth's co-assessment for VIA test was unsatisfactory. Review of monthly logbooks indicated 20% increase in recruitment over the previous period.

Recommendations:

Ship/send additional community outreach and educational materials to the Urban Health Centre for use during recruitment. Strongly encourage supervisor and service providers to regularly use peer and/or supervisor assessment for VIA test findings and client management. Send Nurse Elizabeth for follow-up training on VIA test and client management.

Appendix 13: Example of an Action Plan to Introduce Corrective Measures

The purpose of this particular action plan is to improve performance of cervical cancer prevention services at Site C.

SAMPLE ACTION PLAN FOR SITE C

Facility Name: Site C – VIA and cryotherapy provided at a Family Planning/Reproductive Health clinic

Problems:

a) Long waiting time for screening
b) Rate of same-visit treatment among eligible VIA-positive women is <50% (target is >_ 90%)

Area/Issue	Person(S) Responsible	Resources Needed	Time Frame	How to Monitor the Activity	Expected results and How to Measure
Overall service Problem: ○ Long waiting time for screening **Reason:** – High demand for screening – VIA only available every 2 weeks – Only 1 trained provider (who is also the FP/RH provider)	Clinic administrator / manager	Training for 1 more provider	3 months	– Additional provider identified and selected for training – Budget available for training – Training scheduled – Training completed – Revision of service – Schedule planned	– Name of additional provider – Budget allocated for training – Request for training submitted – Training completed – Practice started – Service available every week
Counselling: No issues or problems identified					
VIA testing: No issues or problems identified					
			1 month	– Check for procurement of larger gas cylinder (> 10 kg) – Plans for supervisory visit – Draft instrument processing steps	– New 10 kg gas cylinder at the facility – Supervisory visits completed Job aid for cryotip processing
Others				–	–
Cryotherapy Problem: Patients asked to return because of – Inadequate gas supply – long wait for screening – not enough cryotips **Reason:**	– Clinic manager – Clinic manager	– Order larger gas cylinder – See training plan above		–	–

– Small gas tank needs refill after each patient – Only 1 provider doing both screening and treatment – Processing of cryotips takes 1 hour	– Clinic manager and provider	– Work with supervisor to review instrument processing steps			

Appendix 14: List of Participants for Stakeholders Consensus Building Meeting on Comprehensive Cervical Cancer Prevention and Control Service in Eritrea

Sr. No.	Name of Participant	Title	Organization
1	Tesfamariam Mehari	MLT	NHL
2	Kibrom Haile	MLT	NHL
3	Lidia Biniam	MLT	NHL
4	Neghisty Tesfamicael	Program Manager	CDCD
5	Mulugeta Alemu	Director	Pharmacy
6	Tesfalidet Weldeab	Program Manager	MOH
7	Berhane Yohannes	Instructor	ACHS
8	Ghebremicael Andemicael	Instructor	ACHS
9	Dr. Habteselassie Zerezghi	Director	Orotta Maternity
10	Zufan Berhe	Staff	Orotta
11	Zekarias Meles	Oncologist	Orotta
12	Dr. Gebrehiwet Semere	Oncologist	Orotta
13	Dr. Kebreab Mahari	Gynecologist	Orotta
14	Yodit Huruy	Health Specialist	UNICEF
15	Abeba Habtom	Manager	MOE
16	Thomas Asfaha	Finance	CDC
17	Amanuel Kifle	Program Manager	HMIS
18	Dr. Theodros Tekste	NPO	WHO
19	Dr. Yohannes Ghebrat	NPO	WHO
20	Tedros Yehdego	Manager	MOH
21	Dr. Teblets AT/Michael	Gynecologist	Orotta Maternity
22	Dr. Dawit Estifanos	Gynecologist	Orotta Maternity
23	Dr. Mulugeta Haile	Oncologist	Orotta
24	Yordanos Mehari	Deputy Manager	UNFPA
25	Berhane Gebretinsae	DG	MOH
26	Andeberhan Tesfazion	DG	MOH
27	Berhane Debru	DG	MOH
28	Goitom Mebrahtu	Director	MOH
29	Mariana Groba Gomes	Resident coordinator	UNRCO
30	Susan Ngonga	Resident Coordinator	UNRC
31	Fesseha Zerai	Staff	MOH - CAH
32	Freweni Weldehawariat	Staff	MOH - NCD
33	Dr. Araya Berhane	Director	MOH
34	Dr. Berhana Haile	Director	MOH/FCH
35	Solomon Kelifa	Staff	MOH/FCH
36	Solyana Kidane	NPO	WHO
37	Selam Berhane	Information Assistant	WHO
38	Dr. Nancy Kidula	AFRO IST ESA,	WHO
39	Dr. Ruth Jahonga	Consultant	WHO

Appendix 15: TWG List of Participants on the Development of the Guideline for CCCPCP

Workshop held at Median Hotel, Asmara, Eritrea on 17th – 18th May 2018

Sr. No.	Name of Participant	Title	Department	Organization
1	Neghisty Tesfamicael	Program Manager	CDCD	MOH
2	Eyerualem Beyene	Nursing Midwife	Nursing	MOH
3	Thomas Asfaha	Finance	CDC	MOH
4	Ephrem Zebai	Nursing -	Public Health	MOH
5	Freweini Wedlehawariate	Nurse Midwife	MNCD	MOH
6	Solomon Kelifa	Nursing Midwife	FCH	MOH
7	Tesfamariam Mehari	MLT	Pathology	MOH
8	Dr Kebreab Mehari	OBGYN Specialist		ORH
9	Dr Tiblets Tesfamichael	OBGYN Specialist		ORH
10	Dr. Dawit Estifanos	Gynecologist		ORH
11	Dr. Mulugeta Haile	Oncologist		ORH
12	Sirak Abraham	Pharmacist	Pharmacy	MOH
13	Berhane Yohannes	Instructor		ACHS
14	Seyoum Teame	NPPP	Program	UNFPA
15	Haddish Tesfamariam	Pharmacist	Public Health	MOH
16	Habteslassie Zerezghi	Gynecologist	OMH	ORH
17	Dr. Berhana Haile	Director	FRH	MOH
18	Amanuel Kifle	PHO	FCH	MOH
19	Solyana Kidane	NPO	Program	WHO
20	Dr. Assefash Zehaie	NPO ATM/FHP/CAH Focal Person	Program	WHO
21	Dr. Ruth Jahonga	Consultant		WHO