Malawi Ministry of Health and Population

National Service Delivery Guidelines for Cervical Cancer Prevention and Control

April 2019

With support from the U.S. President's Emergency Plan for AIDS Relief, through the Centers for Disease Control and Prevention, the University of Washington's International Training and Education Center for Health (I-TECH) provided the technical assistance for the development of the updated guidelines.

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Foreword

The *National Service Delivery Guidelines for Cervical Cancer Prevention and Control* are written for health professionals—including health surveillance assistants, nurses, medical doctors, and health managers—at all health facilities in Malawi. The guidelines form a practical guide for delivery of cervical cancer prevention and control services.

The guidelines have been developed through multi-sectoral participation of key stakeholders in cervical cancer prevention and control efforts, including the National Cervical Cancer Task Force, with technical support from I-TECH and financial support from the U.S. Centers for Disease and Control. The guidelines take into account the best available evidence, and have been adapted to the local context while adhering to internationally acceptable practices. They also adopt a public health approach, the goal being to maximise provision of the best possible evidence-based services for the greatest number of people in the target population.

Training on these guidelines is strongly recommended for all service providers, regardless of institutional affiliation, to ensure proper adherence. Based on emerging evidence in the field of cervical cancer prevention and control, health providers are encouraged to use their professional judgement while adhering to minimum standards for individual care. For any major deviation from these guidelines, collaboration with the Ministry of Health Cervical Cancer Control Program is highly recommended.

The Ministry of Health and Population will communicate the release of these guidelines through an official circular. The Ministry welcomes comments from service providers about any lack of clarity in the guidelines and any challenges providers face in implementing them. Comments should be submitted to the Ministry through the Reproductive Health Directorate for review and consideration; these will be used to improve future versions of the guidelines. The Ministry also hopes that service providers will make the most of these guidelines.

Dr Dan Namarika
Secretary for Health

Preamble

A clear need exists for this update to the Malawi cervical cancer prevention guidelines: the initial guidelines were developed in 2005. To enable Malawi's programmes for prevention, screening, and treatment of cervical cancer to gain momentum and move forward, it is essential for national guidance to be up-to-date, incorporating the latest innovations in cervical cancer prevention.

This edition of the guidelines contains revisions to several of the key cervical cancer prevention recommendations and other crucial topics for cervical cancer prevention:

- The guidelines address a new primary cervical cancer prevention effort—the HPV vaccine.
- Recommendations for target ages and frequency of screening have been updated, based on both national and international data and experience using VIA to detect cervical pre-cancer.
- Recommendations on the use of Pap smears and HPV DNA testing for screening purposes have been added.
- Guidance for thermocoagulation, a new cervical pre-cancer treatment that is now available and in use in Malawi, has been added.
- The guidelines now provide a more thorough review of cervical cancer treatment; a new section has been added to address palliative care.
- Information on community and health education has been added, including information that may be used for talking with clients and answering questions about HPV vaccination, cervical cancer screening, and messaging for men.
- Treatment algorithms for cervical and vaginal infections that may interfere with cervical cancer screening have been included.
- Information on monitoring and quality assurance that will help ensure the success of Malawi's cervical cancer screening programme has been included.

Although these guidelines are designed for use primarily by service providers, they also will be useful to policymakers as they develop and deploy cervical cancer prevention efforts. The development of high-quality guidelines to support cervical cancer prevention programmes and monitoring and evaluation systems will provide a foundation for Malawi's effort to plan, implement, monitor, evaluate, and expand screening and treatment programmes nationally.

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Abbreviations and Acronyms

ART	Antiretroviral therapy
BT	Brachytherapy
CECAP	Cervical cancer prevention
CHW	Community health worker
CIN	Cervical intraepithelial neoplasia
CKC	Cold knife conisation
CT	Computerised tomography (as in *CT scan*)
EBRT	External beam radiotherapy
ECC	Endocervical curettage
ECOG	Eastern Cooperative Oncology Group (developer of the ECOG Performance Status scale)
FAQ	Frequently asked question
FIGO	International Federation of Gynecology and Obstetrics (*Fédération Internationale de Gynécologie et d'Obstétrique*)
HPV	Human papillomavirus
HSA	Health surveillance assistant
ICRT	Intracavitary radiation therapy
IUCD	Intrauterine contraceptive device
LLETZ	Large loop excision of the transformation zone
M&E	Monitoring and evaluation
MOHP	Ministry of Health and Population
MRI	Magnetic resonance imaging
NSAID	Non-steroidal anti-inflammatory drug
PDSA	Plan—Do—Study—Act
PID	Pelvic inflammatory disease
PLND	Pelvic lymph node dissection
SCJ	Squamocolumnar junction
SOP	Standard operating procedure
STI	Sexually transmitted infection
VIA	Visual inspection with acetic acid
WHO	World Health Organization

Chapter 1. Cervical Cancer Prevention: Background

Key Points

- Cervical cancer is one of the leading causes of cancer-related deaths in women.
- Most cases are preventable and treatable—when identified early.
- Cervical cancer originates with human papillomavirus (HPV) infection.
- Most HPV infections will resolve on their own. It is when the virus persists that HPV can cause changes in the cervix that lead to pre-cancer and cancer.
- Being HIV positive makes it four to six times more likely that HPV will develop into cervical cancer.
- Women living with HIV tend to develop cervical cancer more quickly and die from it at younger ages.
- Women living with HIV are more likely to see their pre-cancer recur after treatment.

1.1 Why Focus on Cervical Cancer?

1.1.1 Cervical Cancer is Killing Women Unnecessarily

Cervical cancer is one of the leading causes of cancer-related deaths in women worldwide. Data for 2018 indicate an estimated 567 847 new cases were diagnosed during the year; 311 365 women died from the disease, with 85–90% of those deaths occurring in low-resource settings.

Most women who die from cervical cancer, particularly in developing countries, are 35–44 years old.[1] These are the years of a woman's life most commonly associated with such vital roles as child raising and employment (contributing to the financial well-being of her family). The loss of a woman's life is always a tragedy; the tragedy of deaths from cervical cancer is compounded by the fact that these deaths are unnecessary. There is compelling evidence that cervical cancer is one of the most preventable and treatable forms of cancer—when detected early and managed effectively.[2] According to World Health Organization (WHO) projections, **without urgent attention, cervical cancer deaths are expected to rise globally by almost 25% in the next 10 years.[3,4]**

The majority of cervical cancer cases are both preventable and treatable—when identified early.

The highest incidence of cervical cancer occurs in the countries of southern and east Africa. Southern Africa has age-standardised incidence and mortality rates of 43.1 and 20.1, respectively, per 100 000 population; in east Africa they are 40.1 and 30.1, respectively.[5]

Even among African countries, Malawi has an especially high burden of disease: It has the world's second highest age-standardised incidence and mortality rates, at 72.9 and 49.8, respectively, per 100 000 population.

Cervical cancer remains the leading cause of cancer deaths among women in Malawi. Each year, an estimated 3 684 women develop cervical cancer; 2 314 die from the disease.[6–8]

1.1.2 Cervical Cancer is an Equity Issue

Over the last 30 years, cervical cancer incidence and mortality rates have fallen in countries where social and economic status has improved, facilitating investment in the development and implementation of prevention efforts. Now only 35 000 total deaths, or 1 in 10 women with cervical cancer, occur annually in high-income countries.[9]

Although most cervical cancer is preventable and treatable, developing prevention and control strategies remains a challenge. Lack of policies and programmes, up-to-date data, and coordination of efforts are all barriers to comprehensive cervical cancer control. The wide disparities in incidence and mortality among cervical cancer deaths in different areas are the result of socioeconomic and geographic variation, gender bias, and culturally determined factors that can all severely restrict access to preventive services for some groups of women.

When women have access to cervical cancer screening, and treatment of pre-cancer is available, lives are saved.

The women in low- and middle-income countries who suffer from cervical cancer are typically those who are in some of the most productive years their lives—and actively contributing to their families and communities.[10] Because 9 of 10 deaths globally from cervical cancer occur in resource-constrained settings where screening programmes are not widely available, access to cervical cancer screening has been identified as an equity issue at the global level.[11,12]

1.2 What is Human Papillomavirus (HPV)?

Human papillomavirus (HPV) is an easily transmissible DNA virus. HPV has more than 150 sub-types, which are numbered according to the structure of a protein on its outer membrane. Different HPV types cause infections in different parts of the body. For example, some HPV types cause common skin warts; others cause infections in the genital tract. Most of the time, an HPV infection is transient; the body will clear it. In fact, 91% of infections clear up within three years.[13] Occasionally, an HPV infection persists; it is when this happens that it can become dangerous. Factors that contribute to persistent infections with HPV include smoking and immune-compromise, such as HIV.

HPV is easily transmitted from person to person. It is most frequently transmitted by intercourse, but can also be spread through any genital skin-to-skin contact. HPV infections are also very common. Studies show that by the time that person has had three or more sexual

partners they have a 50% chance of becoming infected with HPV. Condoms can reduce HPV transmission by about 60%,[14] but even with condom use HPV can still be transmitted through genital skin-to-skin contact with uncovered skin surfaces. The HPV vaccine, which will be discussed more fully in Chapter 3, is a way to prevent initial infection with the HPV virus types it targets. To prevent infection, the vaccine must be given prior to HPV exposure.

Some HPV types are referred to as **high-risk types** because these they have the ability to cause the cells in the body to change from normal cells into pre-cancer cells, and then to cancer. The longer the duration of infection, the greater the risk of developing pre-cancer. The good news is that, as with low-risk HPV infections, most high-risk HPV infections are transient, with a median duration of eight months.[15] Most cervical cancers (99%) are due to infection by high-risk HPV types. Of these high-risk types, HPV-16 and HPV-18 present the greatest risk, accounting for 70% of cervical cancers globally. HPV-16 is the most **oncogenic** (cancer-causing) type; it causes about 50% of cervical cancers globally, plus many other genital and oropharyngeal cancers.[16]

1.3 What Is Cancer?

Cancer refers to the biological process in which cells grow without regulation, overwhelming normal cells and function. When diagnosed late or left untreated, cancer is almost always fatal.

Cervical cancer originates in the cervix with an HPV infection. If not diagnosed and treated, cervical cancer spreads locally—i.e., to adjacent tissue. It can also spread into the local lymphatic system. In advanced stages, cervical cancer can spread beyond the pelvis.

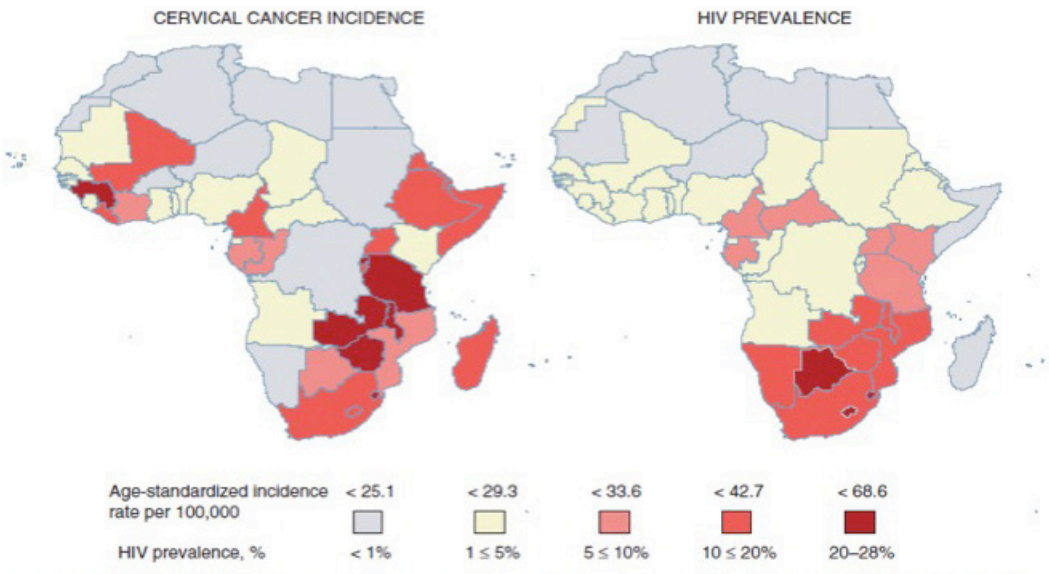
Cervical cancer has a 'pre-cancer' stage that can be identified through appropriate screening and treated before cancer occurs. As mentioned above, **the majority of cervical cancer cases are both preventable and treatable—when identified early**.

1.4 The Interaction of HIV and Cervical Cancer

As the map of Africa in **Figure 1-1** illustrates, the areas with the highest HIV prevalence tend to also have high cervical cancer rates.

- Being HIV positive makes it four to six times more likely that HPV will develop into cervical cancer—even if the client is on antiretroviral therapy (ART).[17]
- Women who develop cervical cancer progress and die from it more quickly when they are HIV positive.[18]

Figure 1-1. Map of cervical cancer incidence and HIV prevalence in Africa



Age-standardised (world) incidence rates of cervical cancer (Ferlay J et al. 2002) and HIV prevalence (UNAIDS, 2008) in Africa.

Compared to HIV-negative women, women living with HIV have:

- Higher rates of persistent HPV infection.
- Higher incidence of new HPV infection.
- Higher prevalence of HPV.
- Higher rates of infection with multiple HPV types.[19]

Whether infection with multiple HPV types increases the risk of cervical lesions is unknown.

Women living with HIV often carry more-persistent types of HPV (e.g., HPV-16, HPV-18). As a result, progression of HPV to pre-cancer and to cancer is accelerated by several years compared with HIV-negative women. Women living with HIV also tend to be significantly younger when they develop pre-cancer and cancer—with development of cancer sometimes accelerated by a decade or more.

For reasons that are not clear, this is true even if the immune system of a client living with HIV has been restored through treatment with highly active ART (HAART). Cervical cancer incidence is still higher among women living with HIV, their age at diagnosis is younger, and the disease progresses more rapidly than it does in HIV-negative women.[20,21]

In addition, when a woman living with HIV is treated for cervical pre-cancer or cancer, her risk of recurrence is much greater than it is for an HIV-negative woman who has received the same treatment.[22]

These factors all have implications when considering screening recommendations for women living with HIV. Screening should be performed more frequently; clients should be followed

closely once they have been treated. Integration of cervical cancer screening with HIV care is crucial.

For Malawi, which has a significant HIV burden among women of reproductive age, integration of cervical cancer screening with HIV care has the opportunity to save the lives of many women.

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Chapter 2. Community Mobilisation, Education, and Counselling

Key Points

- Community mobilisation, health education, and counselling are essential components of an effective cervical cancer prevention and control programme to ensure high screening coverage.
- Community strategies should reach and engage women who would most benefit from screening, as well as men and leaders in the community, and key stakeholders.
- Community mobilisation and health education are essential tools for overcoming common challenges that impede access to and use of preventive care; these barriers include social taboos, language barriers, lack of information, and lack of transport to service sites.
- Health education ensures that women, their families, and the community at large understand that cervical cancer is preventable.
- Health care facilities should have private rooms that can be used to provide individual clients with information and counselling, if appropriate, to help them make the best choices for their health.
- Health care providers should be trained to discuss sexuality in a non-judgemental way and address issues related to cervical cancer and HPV while protecting client privacy and confidentiality.
- It is critical that educational messages emphasise that clients with abnormal screening results must return for follow-up.

2.1 Increasing the Use of Cervical Cancer Prevention and Control Services

Cervical cancer screening is a preventive health care service that saves lives. The cost of losing a woman to cervical cancer is enormous, both for her family and the community. Effective community mobilisation, education, and counselling help people to understand and reduce their personal risk of illness, and that of their family members and friends, by accepting and using preventive care options such as screening.

In most cases, cervical cancer screening involves an examination of a client's genitalia when she does not have symptoms. In some cases, the client may be told after screening that she needs treatment in order to prevent cancer.

Women face many obstacles that make it difficult to come in for screening. These can range from fear of being diagnosed with an infection or disease, and feelings of shame around examination of the genital organs, to lack of time or affordable transportation to travel to the health care facility. Effective community mobilisation, education, and counselling are key to overcoming these obstacles. Without these components, a cervical cancer screening programme will not reach the women who need screening, diminishing the ability to save

lives. Community mobilisation involves working with communities to identify these challenges and develop strategies to overcome them.

2.2 Role of the Health Care Provider

Heath care providers play a central role in preventing and managing cervical cancer by increasing the use of screening services among those who are most likely to benefit. Health care providers in Malawi who fulfil this role include nurses, clinical officers, and medical doctors. Health surveillance assistants (HSAs) or community health workers (CHWs) who do not directly provide cervical cancer screening services can be excellent resources for community mobilisation and education, as can cervical cancer survivors, clients' peers, and community leaders. Using clear, sensitive language to convey key messages with consistent, accurate information can make a positive difference in the number of women who decide to have cervical cancer screening.

Box 2-1. Characteristics and communication skills of an effective health educator on the topic of cervical cancer

- **Knowledgeable:** Have correct understanding about cervical cancer and how to prevent it, including the reasons for prioritising particular age groups to receive services. Be able to anticipate and answer questions, and to seek further information as needed.
- **Comfortable with the topic:** Be comfortable talking about women's anatomy, and sex and sexuality.
- **Clear and consistent:** Share key messages that are easy to understand and appropriate for the audience; be consistent with these messages.
- **Sensitive and non-judgemental:** Issues related to sexual health can be very sensitive matters. Use appropriate language and tone. Ensure that wording does not contribute to stigma or promote harmful gender stereotypes.
- **Supportive:** Be a good listener. Show patience and understanding. Help women and families to find solutions to their problems and make good decisions about getting the care they need.
- **Welcoming and encouraging:** When people feel welcomed, they are more likely to return for care when they need it.

2.3 Health Education Outreach

Health education outreach refers to the efforts made beyond the health facility to reach target populations and increase knowledge about specific health issues—in this case, cervical cancer prevention. The role of the health care provider can include outreach activities; these activities and associated messaging must be carefully planned.

The goal of outreach is to maximise coverage and use of cervical cancer prevention and control services. To achieve this, target populations for messaging include:

- **Adult women:** women 25–49 years of age.

- **Vulnerable groups:** women who live far from health care facilities and are thus hard to reach, refugees and other marginalised groups, and women who may require a more intensive screening schedule, such as those who are immunosuppressed from HIV or illnesses such as cancer.
- **Community leaders and champions:** Community leaders are the custodians of culture and highly respected in their communities. Their involvement increases the chances of success of any community activity in Malawi; therefore, it is important to engage them in outreach efforts. Communities may also be more receptive to health services if they hear about it from their peers. Creating a cadre of local champions that includes women's organisations is another key element which enables outreach activities to be successful.
- **Men:** It is crucial to reach and involve men in outreach efforts, as men in Malawi continue to be the 'gatekeepers' through whom their family members access health care services. Gaining the support of men by increasing their knowledge and understanding of women's health issues will help them to make better health decisions and support use of health care services by their partners. Information about HPV and cervical cancer can be given to men in clinical and community settings, with an emphasis on messages about the importance of encouraging their partners to be screened and treated where necessary. (See Appendix 2.1, What Men Need to Know to Help Prevent Cervical Cancer.)

Once target populations have been defined, outreach plans can employ CHWs and peer-to-peer communication strategies to provide:

- Information and motivation to seek services.
- Mobile screening units and/or vaccine brigades (to bring services to communities).
- Posters, pamphlets, radio, television, and social media (to reach all segments of the target populations and people who can influence them).

At the end of this chapter, we have provided information that may be useful for answering questions providers are likely to be asked. (See Appendices 2.2, Key Messages for Cervical Cancer Outreach and Education, and 2.3, Frequently Asked Questions (FAQs) About Cervical Cancer.)

2.4 Community Mobilisation

Community mobilisation refers to the process of engaging the community and generating support for all those in need of cervical cancer screening. This process leads to community ownership and participation, which then becomes self-sustaining. Community partners include community leaders, religious leaders, teachers, traditional healers, and members of local women's groups. CHWs are a valuable resource for promoting available health services, as they can serve as a bridge between health services and the community. For example, if a

client's screening result is positive, a CHW can help answer questions, or even help relay messages.

Some HSAs are also CHWs assigned to rural communities within a health care facility's catchment area; they are involved in providing such outreach services as childhood vaccinations and contraception services. These CHWs can be used to provide histology results to women in hard-to-reach areas when further tests are conducted to confirm or rule out cancer, or to encourage women to present for screening.

Good relationships between health care providers and CHWs can help facilitate:

- Education in communities about cervical cancer prevention services and their importance.
- Support that women need to make informed decisions about screening.
- Screening of eligible women in the community, and early detection of cervical pre-cancer and cancer.
- Treatment and care for women with positive screening results.
- Ensuring that women who have been referred for further care get to their appointments.

Promoting preventive services such as cervical cancer screening is challenging, because people typically seek care only when they or their family members are sick.

To ensure that preventive health care services have an impact, it is important to not only set up the services, but also to create demand for them by engaging the community so that they understand and use those services.

2.5 Preventive Health Education

Preventive health education refers to the exchange of information to increase awareness and knowledge about how to stay healthy and prevent diseases (such as cervical cancer). This includes information about available services and the benefits of accessing those services. Health education is an on-going activity, not a one-time event; it requires providers to stay up-to-date so that they pass along accurate information.

Education should be accurate and presented in a non-judgemental manner, using simple language and avoiding unnecessary medical jargon so that the target audience easily understands key messages. Messages should be consistent with national cervical cancer prevention guidelines, and designed to address common fears, myths, and misconceptions.

Box 2-2. Essential questions to answer about cervical cancer

- WHAT is cervical pre-cancer?
- WHAT is cervical cancer?
- HOW can cervical cancer be prevented?
- WHO should be vaccinated?
- WHO should be screened?
- WHICH prevention services are available locally?
- WHERE and WHEN can these local services be accessed?

Remember: Effective communication can increase rates of HPV vaccination and screening—and save women's lives.

2.5.1 Addressing Misinformation, Misperception, and Stigma Through Messaging

Health care providers play an important role in preventing misinformation and reducing stigma around cervical cancer prevention. Given that misinformation and misperceptions are common with a programme such as cervical cancer screening, or when HPV is involved, it is important to carefully plan messaging on the topic, and to have a strategy in place to combat potential rumours or misinformation. (Appendix 2.4 lists some common misinformation and misperceptions associated with cervical cancer screening, and provides suggestions for addressing them.)

2.6 Counselling

Counselling refers to the process in which a knowledgeable person provides advice or guidance to facilitate decision making. Counselling is typically conducted confidentially and privately, and involves a two-way conversation about available options.

Here are some of the situations involving cervical cancer screening that indicate the need for counselling:

- Women living with HIV need to be given information about their increased risks of persistent HPV infection and development of cervical pre-cancer at a younger age.
- The result of a screening test that is positive for cervical pre-cancer.
- Treatment of cervical pre-cancer requires proper follow-up to ensure that the treatment was effective, and to prevent loss of the client to follow-up. Adherence to follow-up is one of the most important components of a successful screening effort.

Counselling should educate the client about the natural history of HPV infection and the importance of follow-up care and treatment. Additionally, all of the client's questions should be addressed.

2.6.1 Key Components of Counselling for Clients with Positive Results on a Test or Examination

It is recommended that the following components be included when counselling clients who have received positive results from a test or examination.

If the screening result is positive and the client is eligible for cryotherapy/thermo-coagulation or large loop excision of the transformation zone (LLETZ):

- Does the client understand the purpose of the screening test and the possibility of preventing cancer through early treatment?
- Does the client understand that a positive test result probably indicates early abnormal cervical changes—and that it only rarely indicates cancer?
- Does the client face any difficulties returning for care, such as an unsupportive or uncooperative partner, lack of transport, or financial difficulties? If so, discuss possible solutions and help the client make a plan to obtain the services she needs.

If the result of the examination is suspicious for cancer:

- Ask the client if she has someone with her today that she would like to have present for the discussion.
- Express concern about the seriousness of the findings—but do NOT tell the client she has cancer; it is too early at this point to be sure of that diagnosis. Do explain to the client that the screening result was positive, and that she needs to be referred for further testing/evaluation.
- Do reassure the client that she will receive the help she needs.
- Provide the client with clear information about where to go for diagnosis and treatment.
- Invite the client to return with any questions she may have.

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1. World Health Organization. Ch. 3: Community mobilization, education and counselling. In: Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. Pg. 83-104. Available from: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/

Appendix 2.1 What Men Need to Know to Help Prevent Cervical Cancer

This practice sheet provides basic information for reaching out to men and suggests ways to involve them in cervical cancer control.

Key messages for men

Men can play a very important role in the prevention and treatment of cervical cancer.

Men can:

- Encourage their partners, sisters, and mothers to be screened if they are 25–49 years of age.
- Encourage their partners, sisters, and mothers to be treated if pre-cancer or cancer is detected.
- Encourage their daughters, sisters, and female friends to get vaccinated with the HPV vaccine.
- Use condoms to prevent all sexually transmitted infections (STIs), including HIV/AIDS, as well as pregnancy (condoms offer some protection against HPV).
- Prevent infection with STIs by receiving treatment (where necessary) whenever their partners are diagnosed with STI.
- Reduce the number of sexual partners they have, and use condoms if they have more than one sexual partner.

Basic information for men about cervical cancer

- Although cervical cancer is exclusively a woman's disease, men can play an important role in preventing and treating it.
- Most cervical cancer is caused by infection with a virus called HPV. The infection usually causes no symptoms or problems, but a few infected women will get pre-cancer many years later. If not treated, some of these women will develop cervical cancer.
- Infection with HPV is easily passed during sexual contact penetration is not the only mode of transmission, as the virus can live on the skin around the genital area.
- The presence of other STIs, including HIV, increases the risk of HPV infection; therefore, condom use and male circumcision to prevent STIs in men can also help prevent HPV. However, although using a condom provides some protection, it does not offer complete protection against HPV, as the virus can live on the skin around the genital area.
- Male circumcision can help prevent transmission of HPV to female partners.
- Men cannot catch cancer or pre-cancer from their female partners.
- Some types of HPV that do not cause cervical cancer can cause genital warts in both men and women, although the warts do not lead to cancer. In rare cases, the types of HPV that cause cervical cancer in women can also cause cancers of the mouth, anus, or penis.

- Smoking tobacco can increase the risk of many cancers in men and women, including cervical cancer in women infected with HPV.
- A man whose partner is found to have pre-cancer or cancer can support and assist her in obtaining the recommended treatment by accompanying her to clinic appointments, and by learning about cervical cancer.
- A woman needs support (physical and emotional) when she is diagnosed and treated for pre-cancer or cancer.
- When women are treated for pre-cancer or cancer, they may need to abstain from intercourse while the cervix is healing.

Adapted from:
World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. p. 230–231. Available from: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/.

Appendix 2.2 Key Messages for Cervical Cancer Outreach and Education

This practice sheet provides evidence-based messages for health educators. Providing accurate, easy-to-understand information is the first step in helping women and families access services that can prevent cervical cancer. You can use these messages to develop your health promotion talks.

Health education efforts should result in women and men being able to answer the following questions:

- WHAT is pre-cancer?
- WHAT is cervical cancer?
- HOW can cervical cancer be prevented?
- WHO should be vaccinated?
- WHO should be screened?
- WHICH prevention services are available locally?
- WHERE and WHEN can these local services be accessed?

Five key messages

You can prevent cervical cancer with vaccination, early detection and treatment! The following specific messages are the most important ones to convey within your community. Learn these five simple messages and use them consistently.

1. Cervical cancer is a disease that can be prevented.
2. There are tests to detect early changes in the cervix (known as pre-cancer).
3. There are safe and effective treatments for pre-cancer. Without treatment, pre-cancer may lead to cancer.
4. All women aged 25–49 years should be screened for cervical cancer at least once.
5. There is a vaccine for girls that can help prevent cervical cancer.

More detailed cervical cancer messages to use in your health promotion talks

Who is at risk?

- Cervical cancer is a leading cause of cancer death in women.
- Women 25–49 years old are most at risk for cervical cancer.
- Any woman who has had sexual relations is at risk of developing cervical cancer.

HPV infection

- Cervical cancer is caused by infection with a virus called HPV. This virus is passed during sexual relations and is very common among men and women.
- Almost all men and women will be exposed to HPV in their lifetime. Most HPV infections go away in a short time without treatment.

- In some women, HPV infection persists and can slowly change the cells on the cervix. These changes are called pre-cancer. If not treated, they can develop into cancer of the cervix.

Vaccination

- All girls should be vaccinated with the HPV vaccine at some time between the ages of 9 and 14.
- Vaccination prevents infection with the types of HPV that cause most cervical cancers.
- The HPV vaccines are safe and effective. Adverse reactions, when they occur, are usually minor.
- The HPV vaccine has no impact on a girl's fertility; it does not affect her capacity to become pregnant and have healthy children later in life.
- The HPV vaccine, to be most effective, should be administered in accordance with the number and timing of doses as advised in the manufacturer's instructions.
- Even after vaccination, all women aged 25–49 years will require cervical cancer screening, as the vaccine prevents most, but not 100% of cervical cancer cases.

Screening and treatment

- There are screening tests for cervical cancer that can detect early changes of the cervix (pre-cancer).
- The screening tests for cervical pre-cancer are simple, quick, and do not hurt.
- If the screening test is positive, it means that there could be early changes (pre-cancer) that can be treated. A positive screening test outcome DOES NOT automatically mean cancer.
- To prevent cervical cancer, all women with positive screening tests should receive treatment.
- Women should have a screening test at least once between the ages of 25 and 49 years. It is important to follow the recommendation of the health care worker as to when to return for screening. Malawi also recommends screening every three years between the ages of 25 and 49.
- Women living with HIV are at higher risk for cervical cancer; they should be screened every two years.

Signs and symptoms of cervical cancer

- There are no signs or symptoms for pre-cancer. Screening is the only way to determine if you have pre-cancer.
- Occasionally, cervical cancer (instead of pre-cancer) is detected during screening.
- In early stages, cervical cancer may not cause any symptoms and signs. For those who do have symptoms, they include foul-smelling vaginal discharge, vaginal bleeding, bleeding after sexual intercourse, or any bleeding after menopause. Women with these symptoms should seek medical care promptly.

Making decisions about health

- Women have a right to make their own decisions about their health. To make informed decisions, women need correct information.
- Women may wish to involve their partners or families in their decision making.
- Although screening for cervical cancer and treatment of pre-cancer are highly recommended, women should understand that they are free to refuse any test or treatment.

Adapted from:
World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. p. 222–224. Available from: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/.

Appendix 2.3 Frequently Asked Questions (FAQs) About Cervical Cancer

Men and women, including health care providers, often lack information about cervical cancer. This practice sheet lists some FAQs and provides answers. You and your colleagues should add other questions and answers relevant to the local situation.

It should be noted that some of the answers are repetitive, so when a question is asked you do not need to go through all the answers in this practice sheet. If you familiarise yourself with all the information below, when asked a question you will be able to quickly find the best answer for it.

About Cervical Cancer

Q: What is cancer?

A: Cancer is the disease caused by uncontrolled growth of certain cells in the body, causing tumours or growths. Not all growths are cancer. When a cancer is allowed to grow and spread it can interfere with the normal functions of the body.

Q: What causes cancer?

A: Cervical cancer is caused by infection with a virus called **human papillomaviru**s or **HPV**. HPV is a very common virus that is passed during sexual relations, so most people will have it at some time in their lives. For most people, HPV will go away on its own, but in a small number of infected women the virus will persist. For these women, the virus can cause changes in the cells of the cervix that might develop into cervical cancer if they are not found during a screening test and removed.

Q: Does HPV cause any other diseases?

A: HPV can cause genital warts in both men and women. Genital warts are caused by different types of the HPV virus than the ones that cause cervical cancer. Genital warts will not turn into cancer, although they may require treatment if they do not go away on their own. In rare cases, HPV can cause other types of cancers, including cancer of the vagina, vulva, penis, or anus, or throat cancer.

Q: Who gets cervical cancer?

A: Almost all women who have had sexual relations, even without having had sexual intercourse, can be infected with HPV and are therefore at risk of cervical cancer. **The women at greatest risk are those who have never been screened.** Women living with HIV are also at greater risk because HIV makes them more likely to develop cancer when they are younger.

The good news is that most women's bodies will clear the HPV infection on their own and they will never get cancer—but screening is the only way to know who may develop the disease.

Because cervical cancer is not commonly found in women until they are in their 40s and 50s, the best time to screen for pre-cancer is between the ages of 25 and 49 years, before it becomes cancer.

Q: What can I do to prevent cervical cancer?

A: The most effective ways to prevent cervical cancer are for girls to get vaccinated with the HPV vaccine before they start sexual activity, and for women 25–49 years old to get screened.

If a woman's screening test is positive, she needs to be promptly treated. This can save her life. If the test is negative, it is a good idea to have repeat screenings. In Malawi, screening is recommended every three years for women who are HIV negative, and every two years for women living with HIV.

If you have a daughter, make sure she receives all recommended doses of the HPV vaccine. Also, teach her about the importance of screening and early treatment when she is older.

All sexually active people should also practise behaviours that prevent the spread of sexually transmitted infections (e.g., delaying initiation of sexual activity, using condoms, and having as few sexual partners as possible). Smoking tobacco can increase the risk of cervical cancer in women infected with HPV.

About Screening (Early Detection) and Treatment

Q: What is cervical screening?

A: Cervical screening is the testing of all women at risk for cervical cancer to detect if they have pre-cancer. If pre-cancer is found and not treated it may progress to cancer. This progression can take up to 10 years, but may occur sooner in some women.

In Malawi, visual inspection with acetic acid, or VIA, is the test used to screen for cervical cancer.

Q: Who should be screened for cervical cancer?

A: Women between the ages of 25 and 49 years should have a screening test to detect early changes on the cervix, called pre-cancer.

Q: I don't have any symptoms; why should I be tested?

A: The HPV virus lives in women's bodies for many years before it causes problems. After many years it starts to cause changes in the cells of the cervix, called pre-cancer.

Before they have developed cancer, most women with pre-cancer will not have any symptoms. You can have pre-cancer for many years without feeling anything abnormal before it becomes cancer.

When symptoms do occur—such as pain in the pelvic region or a foul odour from the vagina—they often are the result of advanced cervical cancer, which is difficult to treat. To avoid advanced cancer, women must be screened for pre-cancer at least once between the ages of 25 and 49 years, and must be treated if there are signs of disease. Treatment of pre-cancer is easy and very effective.

Q: What is done during screening?

A: There are different tests that can be used. Your health care provider will tell you about the test used at your local health care facility. For most tests, the provider will do a pelvic examination to gently swab the cervix. Although the test itself is not painful, it can be a little uncomfortable to have a speculum in the vagina in order to view the cervix. Your health care provider should try to make it as comfortable as possible for you. Some tests give the results right away; others require sending the sample to a lab and waiting for results.

Q: What if my test is negative?

A: If your screening test is negative, it means that you do not have any changes that might develop into cervical cancer. It is important to be screened every three years, if possible, to make sure any pre-cancer changes are caught early and treated right away.

Q: What if my test is positive?

A: In most cases, a positive screening test means you have pre-cancer, a condition that can be easily treated in a clinic setting.

In a few cases, your health care provider will want to do further testing to make sure that what you have is pre-cancer and not cancer. For those next steps, he or she may send you to another facility—a health centre or hospital. The provider may also refer you to a hospital for further care if he or she is not sure of the test results or cannot provide the required treatment.

Note for the provider: Unless you have a definitive diagnosis of cancer made using tissue from the cervix, you should not tell the client she might have cancer, because often the first impressions may be wrong, and you may frighten her unnecessarily.

Q: Does a positive screening test mean that I have cancer? Does it mean that I will die from cervical cancer?

A: A positive screening test does NOT mean you have cancer. Most often it means you have something called pre-cancer, or early changes that could become cancer in many years if not treated. Pre-cancer is easy to treat and is curable. Often pre-cancer goes away after only one treatment.

Very rarely, a woman is found to have signs of cervical cancer at the time of screening. If signs of possible cancer are found, your health care provider will either do further testing

or refer you to another health centre or hospital for testing and/or treatment. It is important to treat both pre-cancer and cancer.

A diagnosis of cancer does not mean you will die from it; if found early, it can be cured with available treatments.

Q: How do we treat pre-cancer?

A: If you have a pre-cancer, your health care provider might be able to treat it on the same day as the screening. The most common treatment for pre-cancer is thermal ablation or cryotherapy. Neither thermal ablation nor cryotherapy is painful, although, like a pelvic examination, it can be uncomfortable. Both treatments are very effective and safe. In most cases, your cervix will be healthy and normal after thermal ablation or cryotherapy. Another treatment is large loop excision of the transformation zone (LLETZ), although this is often not available on the same day.

Q: Are screening tests painful? Is part of a woman's cervix or womb removed during screening?

A: The screening tests are painless, though you may feel a little uncomfortable during a pelvic examination. No part of the cervix or womb is removed during screening.

Q: Is one screening enough?

A: Having at least one screening between the ages of 25 and 49 years is good. Just one screening has been shown to decrease a woman's chance of dying from cervical cancer. However, it is a best practice to be tested again every three years if you are HIV negative, or every two years if you are living with HIV.

Q: I am too shy to show my private parts to a male doctor; what can I do?

A: It may be possible to find a female doctor or nurse who can provide pre-cancer screening. But if that is not possible, ask for a female health care provider or a friend or family member to be present during the screening.

Even if you feel shy or embarrassed, please remember that male and female providers are all trained in the same way, and that their goal is to help you prevent cervical cancer. Do the right thing for yourself and for your family—get screened for pre-cancer, and treated if you have it. Screening and treatment are not painful. If you do not get screened only because you are shy and the provider is a man, try to overcome this fear. Remember that getting screened for cervical cancer can save your life.

Q: How similar is HPV to HIV, the virus that causes AIDS?

A: The two viruses—HPV (human papillomavirus) and HIV (human immunodeficiency virus)—are very different.

HPV is a much more common infection than HIV—almost everyone who is sexually active becomes infected with HPV at some point in his or her life. HPV lives on the skin and is transmitted when skin touches skin.

HIV lives in body fluids, like semen and blood, and is transmitted when those body fluids are exchanged between people; this is the reason that condoms are very effective at preventing HIV when sexual intercourse takes place.

However, condoms are not as good at preventing HPV infections, because this virus can live on the skin. The best way to prevent HPV infection is through vaccination.

There is currently no vaccine for HIV.

Common Worries About Cervical Cancer

Q: I have heard that cervical cancer is caused by poor female hygiene or by using sanitary pads more than once. Is that true?

A: No. Cervical cancer is caused by infection with HPV. The cancer has nothing to do with vaginal hygiene or sanitary pads.

Q: Is cervical cancer a sexually transmitted infection (STI)?

A: No. However, it is caused by HPV, which can be passed from one person to another during sexual relations. HPV is quite common in both men and women. Only a few women with HPV will get pre-cancer. If not treated, some of these women will develop cervical cancer many years after they were infected with HPV.

Q: Are women with many sexual partners at higher risk of HPV infection?

A: Yes. People with many sexual partners are at higher risk of all sexually transmitted infections.

The fewer sexual partners a person has, the less chance he or she has of becoming infected with any STI, including the many types of HPV, some of which cause cervical cancer.

Q: Do intrauterine contraceptive devices (IUCDs) or birth control pills cause cervical cancer?

A: No. IUCDs and birth control pills DO NOT cause cervical cancer. They protect against unplanned pregnancies.

Adapted from:
World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. p. 225–229. Available from: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/.

Appendix 2.4 Addressing Misinformation and Misperceptions About Cervical Cancer

Problem Message	Unintended Results	What to Say Instead
Cervical cancer is caused by HPV, which is a sexually transmitted infection (STI).	Some people will conclude that women who have cervical cancer or pre-cancer have an STI. This may create stigma around both the screening programme and the women who test positive and receive treatment. It may make women less willing to be tested, and may also cause problems in her relationship with her partner, including gender-based violence.	• Cervical cancer is caused by a virus called HPV that is passed through sexual contact, and which most people get at some time in their life. • Most HPV infections go away on their own without the person knowing they were infected. • In some women, the infection does not go away, and after several years may cause a pre-cancerous lesion. If not detected and treated, a lesion can develop into cervical cancer. • All women should be screened for cervical cancer at least once between the ages of 25 and 49 years, according to Malawi national guidelines. • Women living with HIV are at higher risk for cervical cancer; they should be screened more often.
Inaccurate information: A positive screening result means the client has cervical cancer.	Because screening is used to check for changes in the cervix that could lead to cancer, people frequently assume that a positive test means that a woman has cancer. This creates great stress and fear.	• Screening uses a simple test (Pap smear, VIA, or an HPV test) to detect very early changes in the cervix (also called pre-cancer) before cancer develops.
Misinformation: There is no point in going for cervical cancer screening: A positive test result means the client has a fatal condition and will die.	Few women will go for a screening test if they don't think there is a solution.	• Cervical cancer can be prevented when early changes in the cervix, called pre-cancer (lesions that may become cancer), are found using a simple test. • If these early changes are detected, there is safe and simple treatment that the client can receive. • If women are screened at the right ages, between 25 and 49 years, then cervical cancer can be prevented. • If detected early, cervical cancer can be cured.

Problem Message	Unintended Results	What to Say Instead
Misinformation: Intrauterine contraceptive devices (IUCDs) and birth control pills cause cervical cancer.	Even though this is incorrect, some women will be afraid to use contraception.	• IUCDs do not increase a woman's risk of cervical cancer. Prolonged use of birth control pills may cause a very slight increase in risk, but the benefits of preventing unwanted pregnancy are much greater than the very small increase in risk of developing cervical cancer.
Misinformation: The screening test is painful, and a part of a woman's body is removed.	Women will be afraid to go for a screening test, or family members might be afraid and stop them from going.	• The speculum examination may make some women uncomfortable, but the test itself is not painful. • During the test, a soft swab soaked in acetic acid (when cervical cytology is used, a brush may be used instead) gently touches the cervix. • The test is simple and takes just a few minutes. • Screening is not the same thing as a biopsy or surgery. There is no cutting involved in screening tests.

Chapter 3. Primary Prevention of Cervical Cancer

Key Points

- Human papillomavirus is the most common virus passed through sexual intercourse.
- Cervical cancer is caused by high-risk types of HPV; types 16 and 18 together are responsible for approximately 70% of all cervical cancer cases around the world.
- HPV vaccination is the most effective prevention technique for HPV infection.
- Two vaccines, the bivalent and quadrivalent HPV vaccines that prevent infection with high-risk HPV types 16 and 18, are presently available in most countries.
- Vaccinating girls before they become sexually active is an important primary prevention intervention.
- Vaccines do not treat pre-existing HPV infection or HPV-associated disease; this is why vaccination is recommended before women become sexually active.
- Other ways to help prevent HPV infection are having fewer partners, using a condom, and male circumcision.

Because frequent or persistent HPV infections can cause cervical cancer, the goal of **primary prevention** is to reduce acquisition of HPV infection. There are a number of methods available, but **HPV vaccination is the most effective and reliable primary prevention technique.**

3.1 HPV Vaccination

HPV vaccination prevents infection with the HPV subtypes included in the vaccine—as long as the vaccine is given ***prior*** to exposure to the virus, which means receiving the vaccine prior to any sexual contact. This is recommended because HPV vaccines are **prophylactic vaccines**—that is, they prevent acquisition of infection with the subtypes contained in the vaccine in persons who have not been exposed to them. If infection with that particular HPV subtype is already present, the vaccine does not cure that infection (i.e., it is not a *therapeutic* vaccine).

However, it is important to remember that the vaccine will still provide some benefit to a person who is already sexually active. Even if the person being vaccinated has already been exposed to one of the HPV subtypes contained in the vaccine, prior exposure to *all* the subtypes in the vaccine is quite unlikely. For example, even if HPV-18 infection were already present when the HPV4 vaccine were given, protection against HPV-6, HPV-11, and HPV-16 would still be acquired. However, maximum benefit is gained when the vaccine is given prior to any sexual exposure.

Three HPV vaccines are commercially available at present (with more in development):

- **Bivalent** (HPV2): protects against HPV types 16 and 18
- **Quadrivalent** (HPV4): protects against HPV types 6, 11, 16, 18
- **Nanovalent** (HPV9): protects against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58

HPV-16 causes 50% of cervical cancers, HPV-18 about 20%. When all the high-risk HPV types in the nanovalent vaccine are included in the vaccine given, it will prevent about 92% of cervical cancers. There are also data showing that the vaccines provide cross-protection. For example, when the HPV4 vaccine is given, protection against some of the other types (such as HPV-31 or 45) is likely provided as well, because it also protects against HPV subtypes that are closely related in structure to those types contained in the vaccine.

Because these vaccines are most effective when given prior to sexual exposure, the Malawi Ministry of Health and Population (MOHP) has designated girls 9 to 14 years of age as the primary target population for HPV vaccination. This aligns with WHO recommendations for the primary group to vaccinate. In Malawi, the HPV vaccine in use is HPV4 (Gardasil). WHO also suggest that, provided financially sustainable resources are available, vaccination can be expanded to include older girls, or even boys, once sufficient coverage has been reached among the primary target population.

Malawi's Ministry of Health and Population introduced the HPV vaccine nationally to 9-year-old girls in January 2019.

When administered to girls between 9 to 14 years of age, the HPV vaccine series consists of two doses given 6 to 12 months apart. If vaccination is initiated at age 15 or above, three doses are needed—the initial dose, the second dose two months later, and the third dose 6 to 12 months after the initial dose.

Table 3-1. HPV vaccination schedule

Target Group (age)	HPV Doses		
	Start	2 Months	6–12 Months
9–14 Years	x		x
15+ Years	x	x	x
All HIV+ (regardless of age)	x	x	x

Current data suggest that a booster dose is neither recommended nor necessary. Because prior exposure to multiple HPV types increases with the number of sexual partners, vaccination is not routinely recommended above the target age. Although the vaccine is safe in women above the target age, prior HPV exposure may render it less effective. In addition, the vaccine is not recommended during pregnancy—though it does not appear to pose any danger if inadvertently administered to a pregnant woman.

For those who are HIV positive, even in the 9-to-14 age group, three doses are needed. These doses are administered according to the same schedule followed for clients 15 years of age and older: the initial dose, a second dose two months later, and a third dose 6 to 12 months after the initial dose.

In addition, it is important to consider the confidentiality needs of girls living with HIV who are receiving the vaccine. For example, if the standard two doses (the initial dose and the dose given 6 to 12 months later) are administered at school, then it may be prudent to consider administering the second-month doses required for girls living with HIV at HIV care clinics to avoid drawing attention to their need for a third dose. The importance of maintaining confidentiality of HIV status in the school setting means that HPV vaccine doses must be carefully tracked.

When an HPV vaccination programme is initiated, the vaccine confers some protection against the virus upon those who have not received the vaccine, thanks to **herd immunity**. The concept behind herd immunity is that even those who have not received a vaccine derive some benefit from it, because the number of people who have been vaccinated effectively reduces the amount of virus circulating. In many countries that have begun vaccinating against HPV, herd immunity has been shown among both men and women who have not been vaccinated—demonstrating that the public health benefits of the vaccination programmes extend well beyond the target populations.[1]

(Frequently asked questions about the HPV vaccine are included in Appendix 3.1.)

3.2 Other Primary HPV Preventions

In addition to HPV vaccination, WHO offers these recommendations for primary prevention of cervical cancer:[2]

- Safe-sex education for boys and girls, tailored as appropriate to age and culture, with the aim of reducing the risk of HPV transmission (and that of other STIs, including HIV). Essential messages should include postponing sexual initiation and reducing high-risk sexual behaviours.
- Condom promotion or provision for those who are sexually active. When a male partner uses condoms, it reduces the risk that he will transmit HPV to a female partner by 60–70%.[3]
- Male circumcision, where relevant and appropriate. Studies show that women with circumcised male partners are less likely to develop cervical pre-cancer and cancer. One study found that, among women who had a 'high-risk' male sexual partner (i.e., one with six or more sexual partners and who had intercourse for the first time before the age of 17), cervical cancer was 82% less prevalent when the male partner was circumcised than if he were uncircumcised.[4]

The prevention behaviours that reduce the risk of acquiring HPV (fewer partners, condom use, and male circumcision) are the same behaviours that reduce the risk of acquiring HIV.

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Appendix 3.1 Frequently Asked Questions (FAQs) About HPV Vaccination

Men and women, including health care providers, often lack information about HPV vaccination. This practice sheet lists some FAQs and provides answers. You and your colleagues should add other questions and answers relevant to the local situation.

It should be noted that some of the answers are repetitive, so when a question is asked you do not need to go through all the answers in this practice sheet. If you familiarise yourself with all the information below, when asked a question you will be able to quickly find the best answer for it.

This practice sheet for providers assumes that most people may not know what causes cervical cancer; this is probably the case for parents of young girls in the target age range. Therefore, for convenience, we provide fuller information on cervical cancer causation and prevention here, rather than referring to other sections of this document where that information is covered.

About HPV

Q: What is HPV?

A: Human papillomavirus, or HPV, is a common virus that is easily spread by skin-to-skin sexual contact with another person involving genital skin, even without sexual intercourse. Most HPV-infected people have no signs or symptoms, so it is possible to spread the infection to another person unknowingly. Most HPV infections are eliminated by the body in the first few years. Those that are not eliminated are termed 'persistent'; they may cause cervical cancer.

Q: Why are HPV vaccines needed?

A: HPV vaccines are needed because they greatly reduce the occurrence of cervical cancer, a principal cause of death from cancer among women in Malawi.

Q: Do all women with HPV infection get cervical cancer?

A: No. In most women, HPV infections are eliminated by the body in the first few years. Among the many different types of HPV, only a few can cause cervical cancer if they are not eliminated by the body and persist for 10–20 years. Of the group of HPV viruses that cause cervical cancer, two types—HPV-16 and HPV-18—cause seven out of every 10 cervical cancers. Infection with these two HPV types can be prevented by HPV vaccination, so these vaccines can protect against 70% of cervical cancer if given as recommended.

In addition, cervical cancer can be prevented among women who have HPV infection, provided they participate in screening and treatment. If women aged 25–49 years are screened for changes in the cells of the cervix (pre-cancer) caused by persistent HPV infection, and treated as needed, then cervical cancer deaths will become rare even though HPV is common.

Q: How common is cervical cancer caused by HPV?

A: HPV is the main cause of cervical cancer. An estimated 567 847 cases of cervical cancer are diagnosed each year. Of the estimated 311 365 women who die every year from cervical cancer in the world, the great majority live in developing countries.

About HPV Vaccination

Q: Will the HPV vaccines keep my daughter from getting cervical cancer?

A: Yes. The HPV vaccines prevent infection with the two types of HPV that cause most cervical cancers. All sexually active people should also practise behaviours that prevent the spread of sexually transmitted infections (e.g., delaying initiation of sexual activity, using condoms, and having as few sexual partners as possible).

Women who have been vaccinated should also be screened for cervical cancer when they are older.

Q: Who should be vaccinated?

A: WHO recommends that girls should be vaccinated when they are aged 9–13 years. In Malawi, the guidelines specify that the HPV vaccine should be given to girls aged 9 to 14. The vaccines are not recommended for girls younger than 9 years of age.

Q: What is the recommended schedule for the two-dose HPV vaccine?

A: Two doses (shots/injections) are recommended for girls below 15 years of age, with the second dose given six months after the first. The provider who gives the vaccine will inform each girl who is vaccinated (and her parents) when she needs to return for the final dose. Although there is no maximum interval between the two doses, an interval of no longer than 12–15 months is suggested. If the interval between doses is shorter than five months, then a third dose should be given at least six months after the first dose.

Q: What is the recommended schedule for the three-dose HPV vaccine?

A: When three doses are recommended (for girls aged 15 years or older, and for those known to be immunocompromised and/or HIV-infected, regardless of whether they are receiving antiretroviral therapy), the second dose should be given one or two months after the first dose (depending on the type of vaccine), and the third dose given six months after the first. The provider who gives the vaccine will inform each girl who is vaccinated (and her parents) when she needs to return for the next or final dose. It is not necessary to screen for HPV or HIV infection prior to HPV vaccination.

Q: Can HPV vaccines cure or get rid of HPV infections or cervical cancer if a girl or woman is already infected with HPV when she gets the vaccine?

A: No. An HPV vaccine cannot cure HPV infections that may be present in a girl when she is vaccinated; neither can it cure cervical cancer or pre-cancer abnormalities, or prevent progression of disease in women who are already infected with HPV, when they receive the vaccination.

Q: Can girls who are living with HIV be vaccinated?

A: Yes! Studies show that HPV vaccine is safe to administer to girls who are living with HIV. Vaccination for these girls is recommended before they become sexually active, just as it is for all other girls. However, girls who are living with HIV should receive three doses of the HPV vaccine, whether or not they are already 15 years old.

Q: Why are boys not vaccinated?

A: The vaccine is safe for boys; however, we are not recommending vaccinating boys at present. Because the vaccines are rather costly and because boys can indirectly benefit from vaccinating girls, it is preferable to use available vaccines to protect those who are at risk of cervical cancer later in life (i.e., girls). Vaccinating girls has been shown to reduce the amount of HPV infection in the population; thus vaccination also benefits boys because the overall prevalence of HPV in the population is lower.

Common Worries About HPV Vaccination

Q: Are the HPV vaccines safe and effective?

A: Yes. Many studies conducted in developing and developed countries have found HPV vaccines to be very safe and effective. The HPV vaccines available in Malawi have been administered to millions of girls and women around the world without serious adverse events. As with all vaccines, the safety of these vaccines is monitored very carefully.

Common mild side effects include pain and redness where the shot was given, fever, headache, and nausea. Sometimes girls who get the HPV vaccine (or other vaccines) faint, so they should be observed for 15 minutes after vaccination; if they feel faint, they should lie down to avoid getting hurt.

Q: Will HPV vaccination affect my daughter's fertility? Will it be more difficult for her to become pregnant or to carry a pregnancy to term?

A: No! There is no evidence that HPV vaccination will affect a girl's future fertility or cause any problems with future pregnancies.

Q: Are all recommended doses needed for my daughter to be fully protected from HPV? Isn't one dose enough?

A: Like other vaccines, the HPV vaccine requires more than one injection. Without all the recommended doses, the vaccine might not be completely effective in preventing cervical cancer. It is important that your daughter receives all doses, and observes the minimum and maximum intervals between the doses, in order to be fully protected.

Q: Is the HPV vaccine safe in pregnancy?

A: HPV vaccines are not recommended for use in sexually active or pregnant girls or women. However, studies have shown that the vaccine causes no problems for the mothers or the babies born to women who inadvertently receive the HPV vaccine during pregnancy.

Receiving the HPV vaccine when pregnant is not a reason to consider ending a pregnancy. But, to be on the safe side, until more is known, girls and women should not be vaccinated while they are pregnant.

Adapted from:
World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. p. 239–243. Available from: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/.

Chapter 4. Secondary Cervical Cancer Prevention: Screening and Treatment of Pre-Cancer

Key Points

- Early detection and treatment of pre-cancerous lesions detected can prevent cervical cancer.
- To achieve the greatest possible benefit from cervical cancer screening, every woman in the targeted age group should be screened at least once.
- Routine cervical cancer pre-screening should start at 25 years of age; screening should end at 50 years of age. Screening women younger than 25 is not routinely recommended or encouraged, but may be offered to those sexually active women aged 21–25 who request it.
- VIA is currently the most widely available screening test in Malawi.
- After a negative screening result with VIA, HIV-negative women should be screened every three years; women living with HIV should be screened every two years.
- HPV testing is a highly sensitive cervical cancer screening test; when available, it offers great utility in Malawi, allowing for a longer follow-up period for screening.
- Pap smear screening may be the screening method of choice in select circumstances, where available and affordable, such as women aged 50 years and above (including post-menopausal women), women whose squamocolumnar junction cannot be visualised during a speculum exam, and follow-up screening of women who have been treated for cervical cancer.
- For cervical cancer prevention to be effective, clients with positive test results must receive effective treatment.
- A 'screen-and-treat' approach is recommended to minimise loss to follow-up.
- Thermocoagulation, cryotherapy, or LLETZ can provide effective and appropriate treatment for the majority of women who screen positive.
- After treatment, rescreen with VIA annually for three years. If screening results are negative, then return to routine screening.
- If cancer is suspected in women who come in for screening, they should not be treated immediately; instead they should be referred to a facility for diagnosis and treatment.

4.1 Cervical Cancer Screening

The most effective **secondary prevention** technique is cervical cancer screening and treatment of pre-cancers. For a secondary prevention programme to have significant impact, screening must be population-based, and not just 'opportunistic'. Additionally, for screening to have any impact, it must be linked with treatment of pre-cancer. As WHO have stated:

> *To have the maximum impact in terms of reducing cervical cancer suffering and death, priority should be given to maximizing coverage and treatment, rather than maximizing the number of screening tests in a woman's lifetime. This is true for all women regardless of HIV status.*[1]

This chapter provides details about the various types of screening tests available, as well as treatment options for pre-invasive disease. The goal is to expand access to screening to include VIA, and to have Pap smears available in certain settings; as HPV testing becomes more available, it also will be useful in screening. Hence, this chapter will also address how HPV testing may be used in the future in Malawi.

Crucial to cancer prevention and Malawi's programme is to provide timely on-site treatment with thermocoagulation or cryotherapy where appropriate, and referral for LLETZ if the pre-cancerous lesion is not appropriate for ablative therapy.

Routine secondary screening will start at age 25 for all women. Screening women younger than 25 is not recommended or encouraged, but may be offered to those sexually active women aged 21–25 who request it.

An option to consider for women under the age of 25 who request VIA screening is to perform only a speculum exam, and use the clinical encounter to provide cancer-related health education, teach the client about STI prevention, describe the lack of reliability of VIA in this younger age group, and schedule client for follow-up screening at age 25.

As discussed in Chapter 7, appropriate monitoring and quality assurance is crucial to any successful secondary cervical cancer prevention programme.

4.2 Screening for Pre-Cancer of the Cervix

Screening for cervical cancer saves lives. This chapter focuses on screening tests and treatments available in Malawi, and on population-based approaches that promote expansion of screening and treatment of pre-cancer. It also presents the Malawi government's recommendations for screening and treatment of pre-cancer changes on the cervix to prevent cervical cancer.

4.2.1 What Makes a Good Test?

Sensitivity and specificity measure the accuracy of a diagnostic test.

Sensitivity refers to the ability of a test to accurately detect the presence of a disease in people who have it—to return a 'true positive'. If a test is highly sensitive, a positive result means that you very likely have the disease.

Specificity is the ability of a test to accurately reflect that a disease is not present in someone who does not have it—to return a 'true negative'. If a test with 100% specificity is negative, you can be confident that you do not have the disease.

The ideal test for cervical cancer screening in Malawi is both highly sensitive and highly specific. It should be inexpensive, relatively easy to administer, acceptable to both client and the provider, and safe. Most importantly, it should be accessible to the entire target population in both urban and rural settings within Malawi.

(For additional information, see Appendix 4.1.)

4.3 Available Tests for Cervical Cancer Screening

4.3.1 Visual Inspection with Acetic Acid (VIA)

In the early 2000s, researchers began evaluating **VIA** as an alternative screening method to the Pap smear in resource-constrained settings. To perform VIA, the provider soaks the cervix in dilute acetic acid (table vinegar) for one minute. The application of acetic acid causes cervical lesions to appear white in the presence of a bright light, enabling the provider to see them.[2] If a pre-cancerous lesion is found during VIA, the lesion is treated and removed using, **thermocoagulation, cryotherapy, LLETZ**, or another method.

For detecting cervical intraepithelial neoplasia (CIN) stage 2 and above in developing countries, VIA has a higher sensitivity (mean, 74%; range, 67–79%) than the conventional Pap smear.[3,4] VIA's high sensitivity and low cost make it ideal for screening in Malawi, where frequent Pap re-screening is not possible.

VIA has a lower specificity (mean 73%; range 49–86%) than the conventional Pap smear.[5] Although the lower specificity of VIA may cause **overtreatment**, which is defined as mistaken or excessive treatment. Most experts feel that overtreatment is acceptable, given the high mortality rates associated with cervical cancer, the effectiveness of treatment, and the low rate of complications associated with treatment.

VIA also provides the benefit of requiring less equipment and money than other screening methods. VIA simply requires a speculum, a light source, and a trained health care provider to perform the procedure (Appendix 4.3). Because VIA is a point-of-care procedure, cervical lesions can be diagnosed and treated with ablative therapy (thermocoagulation or cryotherapy) in the same visit.

Both early changes and those representing more advanced cases of pre-cancer are detected by VIA. The immediate benefit is that the client can be offered immediate results. Training in the procedure can be accomplished in a few days, using a competency-based approach similar to that of the antiretroviral treatment programme in Malawi.

VIA is a subjective test; its effectiveness therefore depends on the skills and experience of the provider performing it. It is helpful to have the same providers perform the procedure on a consistent basis, so that they can maintain proficiency. Hence, quality control/quality assurance is particularly important for VIA. Chapter 7 describes plans for quality control and monitoring and evaluation.

When performed on women 21–25 years of age, VIA may detect abnormalities on the cervix that either are not CIN stage 2 or would resolve with time. Accordingly, if a woman younger than 25 requests VIA screening, it is reasonable to educate her about cervical cancer and the importance of screening, and offer counselling and testing for STIs, but defer VIA screening until 25. However, if a sexually active woman 21–25 continues to request VIA screening, the procedure may be offered.

4.3.2 HPV DNA Testing

HPV testing detects DNA from high-risk HPV types in vaginal and/or cervical samples (see Chapter 1 for information about HPV). Because most HPV infections will resolve, it is not recommended to test young women before they become sexually active. Typically, the recommended age for starting HPV DNA testing has been 30.

HPV DNA testing typically requires transport to and processing in a laboratory with sophisticated equipment before results can be returned. A new low-cost HPV test that can be processed on-site, at the same facility where the sample is taken, has been tested in several resource-constrained settings and is now available. Processing does require some equipment and training, but results can be available within just a few hours. This makes HPV DNA testing more feasible in Malawi, which has many geographic areas where follow-up can be challenging.

Additionally, the screening process for HPV DNA can be simplified through self-collection using vaginal swabs. This at-home procedure for collecting samples has been well validated; women often find this method more acceptable, as it allows them to be tested without the need for a speculum or pelvic examination by a trained provider, thereby increasing their access to testing.

HPV DNA testing is highly sensitive. Specificity, however, may be lower, especially among populations that are younger, or in which more people are HIV positive.[6] HPV DNA testing can be followed by a second test (such as VIA), and those who are positive for both HPV DNA and VIA are then treated. (see Appendix 4.4).

4.3.3 Papanicolaou (Pap) Smear

Cervical cytology is the study of the cells on the cervix using the **Papanicolaou (Pap) smear**. A Pap smear is performed by scraping the surface of the cervix to obtain cells, which are then studied under a microscope for signs of HPV infection and pre-cancerous or cancerous changes.

In Malawi, Pap smears are not routinely available. However, **VIA is not an appropriate screening method for post-menopausal women, nor is it a useful test once women have been treated for cancer and are being seen for follow-up after treatment.** Hence, there is a need for Pap smear testing in Malawi; capacity should be built to allow this.

4.3.3.1 Follow-Up on Abnormal Pap Smears

A woman with an abnormal Pap smear may require **colposcopy** to confirm the presence of a cervical lesion. During colposcopy, a **colposcope** (magnifying or photographic instrument) is used to observe the cervix in detail (see Appendix 4.5).

At the time of colposcopy, a **biopsy** and/or **endocervical curettage** may be done to characterise any lesions. In endocervical curettage, the provider removes potentially cancerous tissue from the endocervix using a narrow instrument called a **curette;** in a biopsy, the provider uses **biopsy forceps** to remove a small piece of tissue from the cervix (see Appendix 4.6). The tissue samples are analysed for the presence of pre-cancer or invasive cancer. If a pre-cancerous lesion is found, it is generally removed using LLETZ.

Cervical cancer prevention programmes do not use colposcopy for screening, because the equipment is expensive and requires specialised training. In many countries, including Malawi, colposcopy is available only at specific referral centres. This means that clients with abnormal Pap smears may need to travel quite far for further evaluation. As a result, both the wait to see a specialist and the distance that clients must travel for this procedure can be obstacles to adequate and early pre-cancer treatment.

The Pap smear is an effective test, especially if it can be repeated as recommended, and if follow-up with colposcopy and treatment is available. However, an effective population-based Pap smear screening programme requires extensive resources—and can be difficult to implement, regardless of available resources. In Malawi, the Pap smear will be reserved for use among post-menopausal women, women whose squamocolumnar junction (SCJ) cannot be visualised during a speculum exam, and women who have been treated for cervical cancer. This is because VIA is not an appropriate screening tool for post-menopausal women when the transformation zone is typically no longer visible, or for women who have been treated for cervical cancer.

The Pap smear, as with all screening methods, requires a well-functioning quality-control/quality-improvement programme. Without one in place, there can be delays and potential loss to follow-up.

A summary of the sensitivity and specificity of cervical cancer screening tests is presented in Table 4-2 below. In Malawi, VIA is currently the primary screening method in use.

Table 4-2. Summary of sensitivity and specificity of cervical cancer screening tests

Test	Sensitivity		Specificity	
	Average	Range	Average	Range
Pap Smear	60%	35–84%	>90%	
VIA	77%	56–94%	86%	74–94%
HPV Testing	90%	85–98%	85%	

Source: WHO 2006, ACCP.

4.4 Malawi Cervical Cancer Screening Recommendations

Malawi Target Population for Screening

Initiate cervical cancer screening:

- At age 25 for all women.
- Screening women younger than age 25 is not recommended or encouraged, but may be offered to those sexually active women aged 21–25 who request it.*

For women who have had a hysterectomy:

- First, evaluate with a speculum to see if the cervix has been removed.
- If the cervix is present:
  - Continue with routine screening.
- If the cervix is absent:
  - If the client did not have cervical pre-cancer prior to hysterectomy, no further screening is needed.
  - If the client had cervical cancer at time of hysterectomy: screen the vaginal cuff with pap smear for three years, then discontinue screening.

Discontinue cervical cancer screening at age 50 for women whose last screening was negative.

For women aged 50–65 who have never had a cervical screen, perform one screening:

- Insert a speculum to evaluate the cervix for visible lesions.
- If no lesion is present, perform a pap smear or HPV screen.
- If lesions are present, refer to the appropriate facility for biopsy.

* An option to consider for women under the age of 25 who are seeking VIA screening is to perform only a speculum exam, and then use the clinical encounter to provide cancer-related health education, teach the client about STI prevention, describe the lack of reliability of VIA in this younger age group, and schedule the client for follow-up screening at age 25.

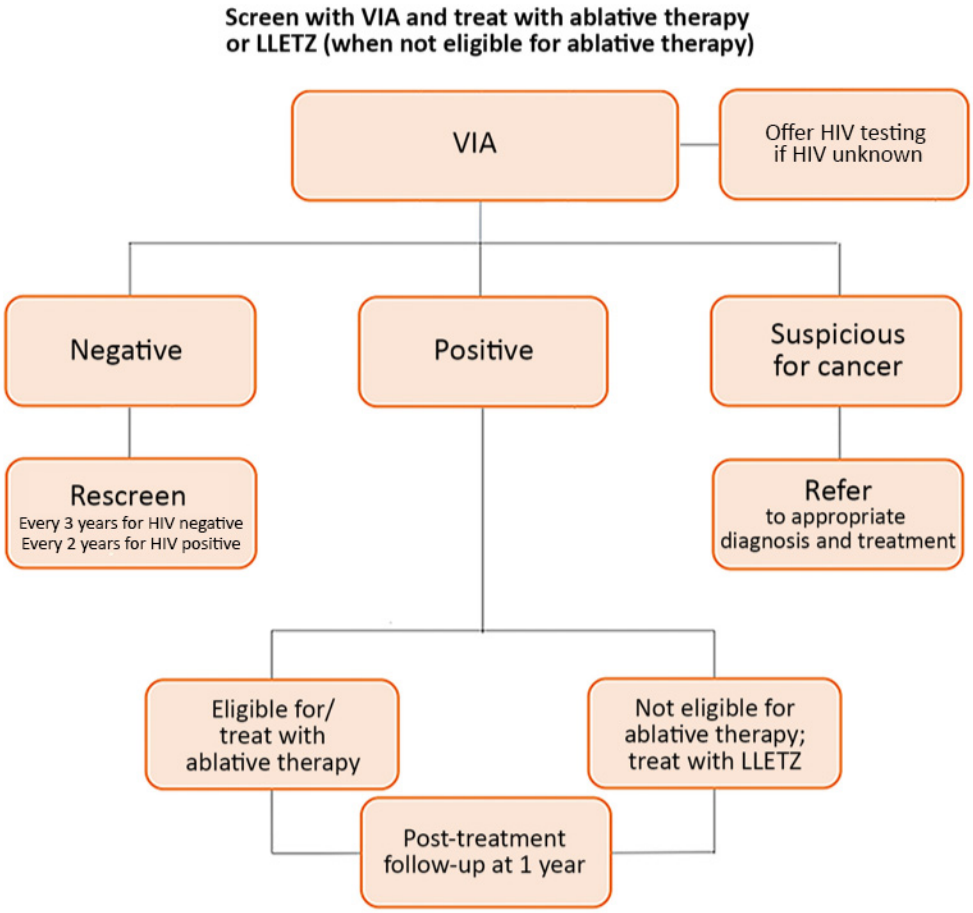
4.4.1 Screening Test and Frequency

Malawi will expand use of VIA and add capacity to have cytology (Pap) screening available in specific circumstances. The goal of a successful screening programme is to screen the broadest population possible, following the recommended testing frequencies and algorithms described below (see Figure 4-2).

- VIA: Screen every two years if HIV positive, every three years if HIV negative.
- Once treated, rescreen annually with VIA for three years, regardless of HIV status.

- Following treatment, return to routine screening after three consecutive negative annual screens.
- **Women of unknown HIV status should be offered HIV testing. If they do not consent to testing, follow the screening schedule for women living with HIV**.

Figure 4-2. VIA algorithm



4.4.1.1 Post-Menopausal Women

VIA is not indicated for post-menopausal women, as VIA screening requires visualisation of the SCJ. During menopause, the SCJ is typically not visible, because it moves up into the endocervical canal as oestrogen levels drop. Hence, Pap smear testing (or HPV testing if available) is recommended for women once menses have ceased.

For all post-menopausal women who present for cervical pre-cancer screening, a speculum examination is necessary. This is recommended even if no other screening tests (such as the Pap smear) are available. Observing the cervix with a speculum can allow the provider to ensure that no obvious lesions are present on the cervix.

Screening Post-Menopausal Women Who Have Not Previously Been Screened

- If HIV positive: Perform Pap smear annually for three years; if results are negative, then screen every two years until the age of 50.
- If HIV negative: Perform Pap smear annually for three years; if results are negative, then continue screening every three years until the age of 50.

The recommendation to discontinue screening for cervical cancer at age 50 is indicated for all women, whether they are post-menopausal or are still having menses, provided that they have had at least one negative screening result in the past three years (in the past two years, for women living with HIV).

However, if a post-menopausal woman has never had a cervical cancer screening and is under the age of 65, she should have a speculum examination. A single Pap smear or HPV screening test is also recommended.

4.5 Treatment Options for Cervical Pre-Cancer

4.5.1 Introduction

An effective cervical cancer screening programme ensures that women who screen positive for cervical pre-cancer receive proper treatment and appropriate follow-up. The objective of treatment is to prevent the progression from pre-cancer to invasive cancer by destroying or excising the entire transformation zone while protecting the surrounding normal tissues and minimising client discomfort, side effects, and complications.

Treatment for cervical pre-cancer varies, from simple procedures that can be offered in an outpatient clinic setup to those that can only be offered in operating theatres. Treatment is therefore available at all levels—primary, secondary, and tertiary—of the health care system. Under the 'screen-and-treat strategy' adopted nationally, women who screen positive can receive treatment the same day, without having to wait for diagnostic confirmation of cervical pre-cancer. Accordingly, every effort should be made to ensure that women who can be treated the same day receive effective treatment, so they do not need to return to the facility.

Two different treatment modalities (methods of treatment) for cervical pre-cancer are available, the choice of which depends on the following:

- The advantages and disadvantages of the method.
- The location, extent, and severity of the lesion.
- The cost and resources necessary to provide treatment.
- The training and competency of the health care provider.
- The availability of informed consent from the client.

Each of the two forms of treatment for cervical pre-cancer has its own eligibility criteria that should be met before proceeding with treatment.

4.5.2 Ablative Treatment

Ablative treatment aims at destroying the areas of the cervix identified as pre-cancerous and the entire transformation zone.[6–8] This can be done either by freezing or by burning the abnormal tissues. This type of treatment does not provide tissue specimens for histopathological confirmation of cervical pre-cancer. The advantage of ablative treatment is that it can be provided in outpatient clinics, enabling clients to return home the same day.

Available ablative treatments include:

- Cryotherapy
- Cervical thermocoagulation (aka cold coagulation)
- Cervical electrocoagulation
- Laser ablation

Cryotherapy and thermocoagulation are the most readily available ablative treatments in Malawi.[9]

4.5.2.1 Cryotherapy

Cryotherapy is an effective method for treating cervical pre-cancer. Cryotherapy uses compressed refrigerant gas—either carbon dioxide (CO_2) or nitrous oxide (N_2O)—to destroy cervical pre-cancer. The gas, which is supplied in cylinders (tanks), produces extremely cold temperatures upon release. Cryotherapy is delivered through a highly cooled metal disc (cryoprobe), which is used to freeze the areas of the cervix identified as pre-cancerous, including the transformation zone, to a temperature of –20°C or lower. When this temperature is applied to living tissue for at least one minute, the result is cryonecrosis.

The cryotherapy procedure involves a rapid freeze of three minutes, followed by a slow thaw of five minutes, and then another three-minute freeze. A sequence of two freeze–thaw cycles (freeze–thaw–freeze–thaw) should freeze more pre-cancerous tissue than a single cycle would. The procedure is generally well tolerated, with only mild discomfort reported; it is therefore performed without anaesthesia. The area of the cervix that is frozen later regenerates to normal cervical epithelium. (See Appendix 4.7.)

4.5.2.2 Cervical Thermocoagulation (aka Cold Coagulation)

Cervical thermocoagulation uses a reusable metal probe, heated to 100–120°C, to destroy cervical pre-cancer. (The term ‘cold coagulation’ is a misnomer; because a heated probe is used, ‘thermocoagulation’ is the appropriate term.) These high temperatures cause cervical tissue dehydration, desiccation, and destruction up to a depth of 4 mm after 20 seconds of application; the extent of desiccation depends on the temperature and duration of treatment. The procedure requires an energy source, such as electricity, batteries, or solar power. The heated area of the cervix later regenerates to normal cervical epithelium.

Although there is only a limited amount of data on its use and effectiveness in settings where HIV prevalence is high, thermocoagulation appears to be an effective treatment for cervical

pre-cancer. The procedure is easy to perform, and should be used as part of the screen-and-treat approach.

There are currently two brands of cervical thermocoagulator available: the WISAP C3 Cold Coagulator and the Liger TC Thermocoagulator. These devices are portable, which means that they are good for field clinics. Similar to cryotherapy, local anaesthesia is not typically used for thermocoagulation—although anaesthesia may be advisable when treating a lesion that is amenable to ablation, but large enough to require more than two or three overlapping applications to the transformation zone. (See Appendix 4.7.)

4.5.3 Excisional Treatment

Excisional treatment aims at surgically removing the areas of the cervix identified as pre-cancerous and the entire transformation zone. The main advantage of excisional treatment is that it provides a specimen for histopathological confirmation of cervical pre-cancer. Some types of excisional treatment can be offered in outpatient clinics; others, such as cold knife conisation and hysterectomy, require hospital surgical facilities.

Available excisional treatment procedures include:

- LLETZ
- CKC
- Electrosurgical cylindrical excision
- Hysterectomy

Hysterectomy is rarely the treatment of choice for cervical pre-cancer. However, the procedure can be offered when there are other reasons to remove the uterus, or when an older woman makes an informed choice to have the procedure, particularly when she is done having children.

When cervical cancer is suspected at screening, same-day treatment should be avoided until histopathological confirmation has been done. The appropriate course to take in such cases is to perform a cervical biopsy to confirm or rule out the diagnosis. When referral to treatment is made, it is essential to have procedures in place to minimise loss to follow-up.

In this section, we will focus our discussion on treatment modalities for cervical pre-cancer that are widely available and can be offered largely in outpatient clinics—particularly in such resource-limited settings as Malawi. These modalities are cryotherapy, thermocoagulation, LLETZ, and CKC (which requires hospital theatre facilities).

4.5.3.1 Large Loop Excision of the Transformation Zone (LLETZ)

LLETZ is the surgical removal of the areas of the cervix identified as pre-cancerous, including the transformation zone. An electrode (a curved or square tungsten loop, or a straight needle, depending on the size of the lesion) powered by an electrosurgical unit is used to excise the cervical pre-cancer and the entire transformation zone; a 3- or 5-mm ball electrode is then

used to coagulate the bleeding points, cut edges, and floor of the surgical wound. The excised area of the cervix later regenerates to normal cervical epithelium.[10,11]

Not only is LLETZ effective for treating cervical pre-cancer, as it removes the cervical lesions, but also it produces a specimen for histopathological examination, thereby permitting both diagnosis and treatment during the same visit.

Unlike ablative treatments, such as cryotherapy and thermocoagulation, LLETZ requires local anaesthesia. Although LLETZ is a relatively simple surgical procedure, it should only be performed by trained health care providers who have demonstrated competence in both performing the procedure and recognising and managing potential complications, such as bleeding. It is also essential to have backup surgical facilities for management of potential complications. In most cases, this procedure will be performed at secondary hospitals, such as district or mission hospitals. (See Appendix 4.8.)

LLETZ can be used as part of two clinical approaches:

- **Immediate 'see-and-treat' single-visit approach**: In most cases, LLETZ is performed after colposcopic identification of a cervical lesion when a high-grade abnormality is observed during cervical cytology, or when the client presents with a high-grade colposcopic lesion but is not expected to adhere to follow-up. Under this approach, a cervical lesion is excised without a preliminary histopathological diagnosis of CIN 2+ based on a biopsy; the LLETZ procedure provides the histopathological specimen.
- **Two-step approach**: LLETZ is performed during a subsequent visit, after the client has had colposcopic assessment, directed biopsies and endocervical curettage were collected (when necessary), and histopathological results are available.

However, with both approaches, if there is no suspicion of cancer, LLETZ can be offered without the use of colposcopy.

4.5.3.2 Cold Knife Conisation (CKC)

CKC is the surgical removal of a cone-shaped piece of tissue from the cervix, consisting of the area identified as pre-cancerous, and including portions of the ectocervix and endocervix. The size of the specimen removed varies with the size of the lesion and the likelihood of finding invasive cancer. The excised specimen is sent for histopathological examination to confirm complete removal of the abnormal lesion.

Unlike ablative treatments such as cryotherapy and thermocoagulation, CKC requires general or regional (spinal or epidural) anaesthesia.[12] Because of this, the procedure is largely done in hospitals where theatre (surgical) facilities are available. CKC requires good surgical skills; it should only be performed by trained health care providers who have demonstrated competence in both performing the procedure and recognising and managing potential complications, such as bleeding. Most of the time, the procedure will be performed by a senior clinical officer, a medical doctor with appropriate experience, or a gynaecologist. This means

that CKC will mostly be done in central hospitals, and only sometimes in select district and mission hospitals with trained health care providers. (See Appendix 4.9.)

4.5.4 Comparison of Methods of Treatment for Cervical Pre-Cancer

Table 4-3 on the following page summarises the methods of treatment for cervical pre-cancer, and their strengths and limitations.

Table 4-3. Comparison of methods of treatment for cervical pre-cancer

Method	Procedure	Strengths	Limitations
Cryotherapy	A highly cooled metal disc (cryotip) is applied to the cervix for the purpose of freezing and destroying pre-cancerous lesions, with subsequent regeneration to normal epithelium.	• Uses simple equipment and is less expensive than excisional procedures. • Can be performed by trained doctors and nurses. • Done as an outpatient procedure; can be performed in a primary care setting. • Fast; the double-freeze method takes about 15 minutes. • Does not require anaesthesia or electricity. • As part of a screen-and-treat approach, a positive screening result can be followed by treatment during the same visit, thereby maximising treatment coverage and reducing loss to follow-up. • Very low chances of complications; serious complications that require medical intervention or affect future reproductive outcomes are extremely rare.	• Does not provide a tissue sample for histopathological examination. • Cannot treat large lesions or lesions that extend into the endocervical canal. • Requires a reliable supply of CO_2 or N_2O; continuous supply of gas is a major challenge because of the recurring costs required. • Gas comes in large cylinders, which presents challenges for transport to outreach clinics. • Causes profuse watery discharge for up to one month.
Thermocoagulation	A reusable heated metal probe is applied to the cervix for the purpose of heating and destroying pre-cancerous lesions, with subsequent regeneration to normal epithelium.	• Easy to use; most thermocoagulators have an automated treatment cycle (unlike cryotherapy, where providers must time the treatment). • Takes less time than cryotherapy and excisional treatments; one treatment cycle lasts 40–60 seconds. • Does not require anaesthesia. • Portable (especially the battery-powered thermocoagulators). • As part of a screen-and-treat approach, a positive screening result can be followed by treatment during the same visit, thereby	• Requires an energy source, such as electricity, batteries, or solar energy. • Cannot treat large lesions or lesions that extend into the endocervical canal and vaginal walls. • Limited data on its effectiveness among women living with HIV. • Sterilisation

Method	Procedure	Strengths	Limitations
		maximising treatment coverage and reducing loss to follow-up. • Very low chance of complications; serious complications that require medical intervention or affect future reproductive outcomes are extremely rare.	
Large loop excision of the transformation zone (LLETZ)	Abnormal areas are removed from the cervix using a loop made of thin wire powered by an electrosurgical unit.	• Relatively simple; easily ~~learnt~~learned. • Unlike ablative therapies, LLETZ removes rather than destroys the pre-cancerous tissue, allowing the excised tissue to be examined. • Can be used to excise larger cervical lesions. • Using a two-layer excisional method, LLETZ can be used to excise cervical lesions extending into the endocervical canal. • As part of a screen-and-treat approach, a positive screening result can be followed by treatment during the same visit, thereby maximising treatment coverage and reducing loss to follow-up.	• Takes longer to achieve competency in performing the procedure. • Requires additional treatment facilities in case of complications. • Requires local anaesthetic and electricity. • Histology specimens can have charred borders, making lesion margins difficult to interpret. • The required equipment is quite sophisticated. • Can be associated with long-term reproductive outcomes. • Best done in tandem with colposcopic examination of the cervix, which requires competency-based training.
Cold knife conisation (CKC)	A cone-shaped area, including portions of the outer and inner cervix, is removed from the cervix.	• A single surgical specimen with clean edges is removed. This facilitates evaluation of the margins to confirm complete excision of the diseased area, enabling cancer to be diagnosed or ruled out. • Can excise larger lesions and treat microinvasive cancer.	• Requires regional or general anaesthesia. • Requires a highly skilled, surgically trained provider. • Requires an operating theatre. • Rates of complications requiring medical intervention are higher than for the other three methods.

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Appendix 4.1 Using Sensitivity and Specificity to Make Clinical Decisions

Table 4-1-1. Using sensitivity and specificity to make clinical decisions

Test Characteristic	Meaning
High Sensitivity	Almost all clients who have the disease will test positive. Similarly, we can assume that any client who tests negative likely does not have the disease.
Low Sensitivity	Some clients who have the disease may test negative. The provider should retest clients every few months or years to confirm that any clients who test negative do not have the disease.
High Specificity	Almost all clients who do not have the disease will test negative. Similarly, we can assume that any client who tests positive likely has the disease.
Low Specificity	Some clients who do not have the disease may falsely test positive. The provider should confirm that a client who tests positive actually has the disease before beginning treatment.

Appendix 4.2 Sample Consent Form

Consent for Treating Screen-Positive Women		
General (for health care workers)		
Done	Not done	Welcome the client into the room
Done	Not done	Introduce yourself by name
Done	Not done	Make the client feel comfortable
Done	Not done	Encourage the client to ask questions; answer questions appropriately
For the client		
Yes	No	I understand that the surface of my cervix will be visually inspected for signs of pre-cancer/cancer after the application of 3–5% acetic acid.
Yes	No	I understand that the procedure is generally harmless. I understand that I might experience discomfort, some irritation, and mild bleeding that can be easily controlled.
Yes	No	I understand that if the test result is positive, the diseased part may be treated with ablative therapy (cryotherapy) or thermocoagulation (circle the one that applies below).
		Cryotherapy
		Thermocoagulation
		LLETZ
Yes	No	I understand that if I receive treatment, I might experience abnormal vaginal discharge, bloody vaginal discharge, or abdominal cramping for some days, and that if I am worried about anything, I need to come back to the clinic as soon as possible.
Yes	**No**	**I understand the explanation and instructions that have been provided to me. I give my consent to undergo the above-mentioned tests, and to receiving treatment, if advised.**
Signature or Thumb Print		
Date		
Name		

Appendix 4.3 Performing Visual Inspection with Acetic Acid (VIA)

VIA should be used for cervical cancer screening of women aged 25–50 years, and women under the age of 25 who request screening. VIA is not recommended for women after menopause, because the entire transformation zone is typically not visible in a speculum exam.

The equipment and supplies needed for VIA are listed in Table 4-3-2 below.

Table 4-3-2. Equipment and supplies needed for VIA screening

- Examination couch with knee crutches, leg rests, or stirrups
- Good light source (can be a bright torch light)
- Sterile bivalved speculum (e.g., Graves speculum)
- Disposable or high-level disinfected examination gloves (need not be sterile)
- Cotton swabs, cotton-tipped buds, gauze
- Ring forceps or pick-up forceps
- Dilute acetic acid solution (3–5%) or white vinegar
- Soap and water (or alcohol-based handrub) for washing hands
- Steel or plastic container containing 0.5% chlorine solution for decontaminating instruments
- Steel or plastic container with a polythene bag for contaminated disposable supplies
- Sanitary pads or a roll of cotton wool
- A recording form and a pencil
- Plastic aprons

Preparation and Counselling

1. Prepare the exam room before the client arrives.
    - Prepare the instrument tray; ensure that all equipment and supplies needed for VIA are available and sterile.
    - Ensure that the examination couch and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
    - Ensure that aprons are available in the exam room, and that all persons who will be present (except the client) use them.
2. Welcome the client into the room.
3. Obtain the relevant gynaecological and obstetric history from the client.
4. Review what the client knows about VIA.
5. Explain the VIA procedure, possible results (with the aid of pictures), treatment options, and associated side effects to the client, along with the required follow-up actions for any result; avoid unnecessary use of medical terms.
6. Allow the client to ask questions and have her questions answered.
7. Obtain informed consent from the client.
8. Advise the client to empty her bladder (if full) before the procedure.
9. Allow other persons in the exam room ONLY if the client consents to their presence.

The Procedure

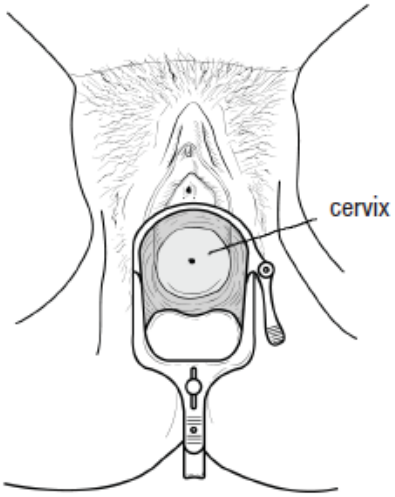
Step 1: Help the client onto the examination couch:

- Give the client privacy to undress from waist down.
- Help the client lie down in modified lithotomy position on a couch with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown, so that only the external genitalia are exposed.

Step 2: Perform a speculum examination:

- Hold the speculum blades together sideways and slip them into the vagina.
- Be careful not to press the speculum on the urethra or clitoris, because these areas are very sensitive.
- When the speculum is halfway in, turn it so the handle is down. Gently open the blades and look for the cervix.
- Move the speculum slowly and gently until you can see the entire cervix.
- Tighten the screw (or otherwise lock the speculum in the open position) so it will stay in place (Figure 4-3-1).
- Check the cervix, which should look pink, round and smooth. There may be small yellowish cysts, areas of redness around the opening (cervical os), or a clear mucoid discharge; these are normal findings.
- Look for any abnormalities, such as:
  - Vaginal discharge and redness of the vaginal walls; these are common signs of vaginitis (if the discharge is white and curd-like, there may be a yeast infection).
  - Ulcers, sores or blisters; these may be caused by syphilis, chancroid, herpes (the most common reason), or (in some cases) cancer.
  - Easy bleeding when the cervix is touched with a swab, or a mucopurulent discharge; both are signs of a cervical infection.
  - An abnormal growth or tumour; this might be cervical cancer.

Figure 4-3-1. Speculum examination



Step 3. VIA procedure:

- If no lesion on the cervix is noted on speculum exam, proceed with VIA.
- Use a cotton swab to remove any discharge, blood, or mucus from the cervix.
- Confirm that you are able to see the entire transformation zone, and identify the SCJ and the area around it.
- Using a cotton swab soaked in 3–5% acetic acid or white vinegar, gently but firmly apply acetic acid to the cervix.
- Wait for one minute, during which time any areas that become faintly white simply due to inflammation or physiological cell changes (metaplasia) will fade and become normal colour.
- Acetowhite changes (white colour that occurs after applying acetic acid) 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 (the area where the lining of the cervix meets the outside of the cervix), and have well-defined borders, they are considered positive results.
- If no persistent acetowhite changes are noted, a negative result is reported.
- For more details on VIA interpretation, see below.
- Gently pull the speculum towards you until the blades are clear of the cervix, then close the blades and remove the speculum.

Step 4. Interpretation of VIA results:

- Check the cervix for any white lesions, particularly in the transformation zone close to the SCJ, or dense non-removable acetowhite areas in the columnar epithelium. Note how rapidly the acetowhite lesion appears and disappears.
- Use a fresh swab to remove any remaining acetic acid from the cervix and vagina.
- Observe the following:
  - The intensity of the white colour of the acetowhite lesion: is it shiny, cloudy, pale, or dull?
  - Borders and demarcations of the white lesion. Are the margins distinct, clear, and sharp, or indistinct and diffuse? Are they raised or flat? Regular or irregular?
  - Is the lesion uniformly white in colour, or does the intensity of colour vary across the lesion? Are there areas of erosion within the lesion?
  - The location of the lesion: is it in, near, or far away from the transformation zone? Does the lesion touch the SCJ? Does it extend into the endocervical canal? Does it involve the entire cervix?
  - Size of the lesion: the extent (or dimensions) and number of the lesions.
- If in doubt about anything you are observing, repeat the test a few times or seek help from a trained provider (if available).

Step 5. Reporting VIA results:

Negative

The VIA test result is reported as negative when any of the following are observed:

- No acetowhite lesions on the cervix
- Polyps protrude from the cervix with bluish-white acetowhite areas
- Nabothian cysts appear as button-like areas, whitish acne, or pimples
- Dot-like areas in the endocervix; these are due to grapelike columnar epithelium staining with acetic acid
- Shiny, pinkish-white, cloudy white, bluish-white, faint patchy, or doubtful lesions with ill-defined, indefinite margins, blending with the rest of the cervix
- Angular, irregular, digitating acetowhite lesions, resembling geographical regions, distant (detached) from the SCJ junction (satellite lesions)
- Faint line-like or ill-defined acetowhitening at the SCJ
- Streak-like acetowhitening visible in the columnar epithelium
- Ill-defined, patchy, pale, discontinuous, scattered acetowhite areas

Positive

The VIA test result is reported as positive when any of the following are observed:

- Distinct, well-defined, dense (opaque, dull, or oyster-white) acetowhite areas with regular or irregular margins, either close to or abutting the SCJ in the transformation zone, or close to the external os (if the SCJ is not visible)
- Strikingly dense acetowhite areas visible in the columnar epithelium
- The entire cervix becomes densely white after the application of acetic acid
- Condyloma and leukoplakia occur close to the SCJ, turning intensely white after application of acetic acid

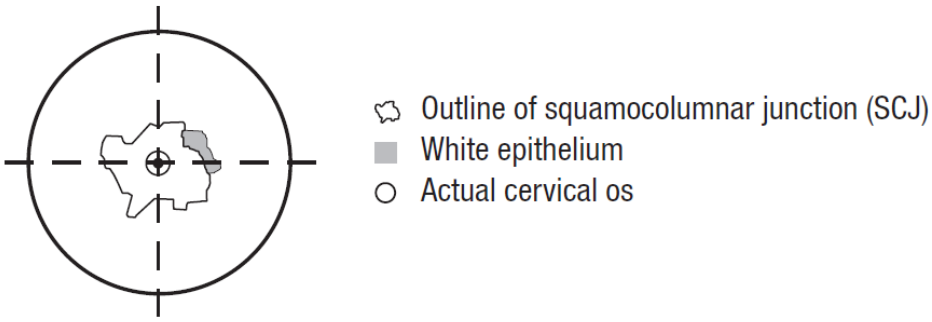
Cancer suspect

The test result is scored as cancer suspect when there is a clinically visible ulceroproliferative growth on the cervix that turns densely white after application of acetic acid and bleeds to the touch.

Step 6. Post-procedure care, counselling, and documentation:

- Thank the client and discuss the result of the test.
- IF NEGATIVE (normal):
  - Advise the client to return for her next screening as recommended in the national guidelines.
- If POSITIVE (abnormal):
  - Discuss the need for treatment with the client.
  - Emphasise that the test does not prevent or treat cervical cancer or pre-cancer, but that treatment for pre-cancer is the key to prevention after a positive result.
- If CANCER SUSPECT:
  - Advise the client that further evaluation is needed.
  - Discuss the recommended next steps.
  - Make arrangements for follow-up; provide the client with all necessary forms and instructions.
- Carefully document the result of the VIA screening in the both client's health passport and the cervical cancer screening register (Figure 4-3-2).
- Provide the client with instructions about the next steps to be taken.

Figure 4-3-2. VIA results recorded on a labelled drawing



Step 7. Infection prevention measures:

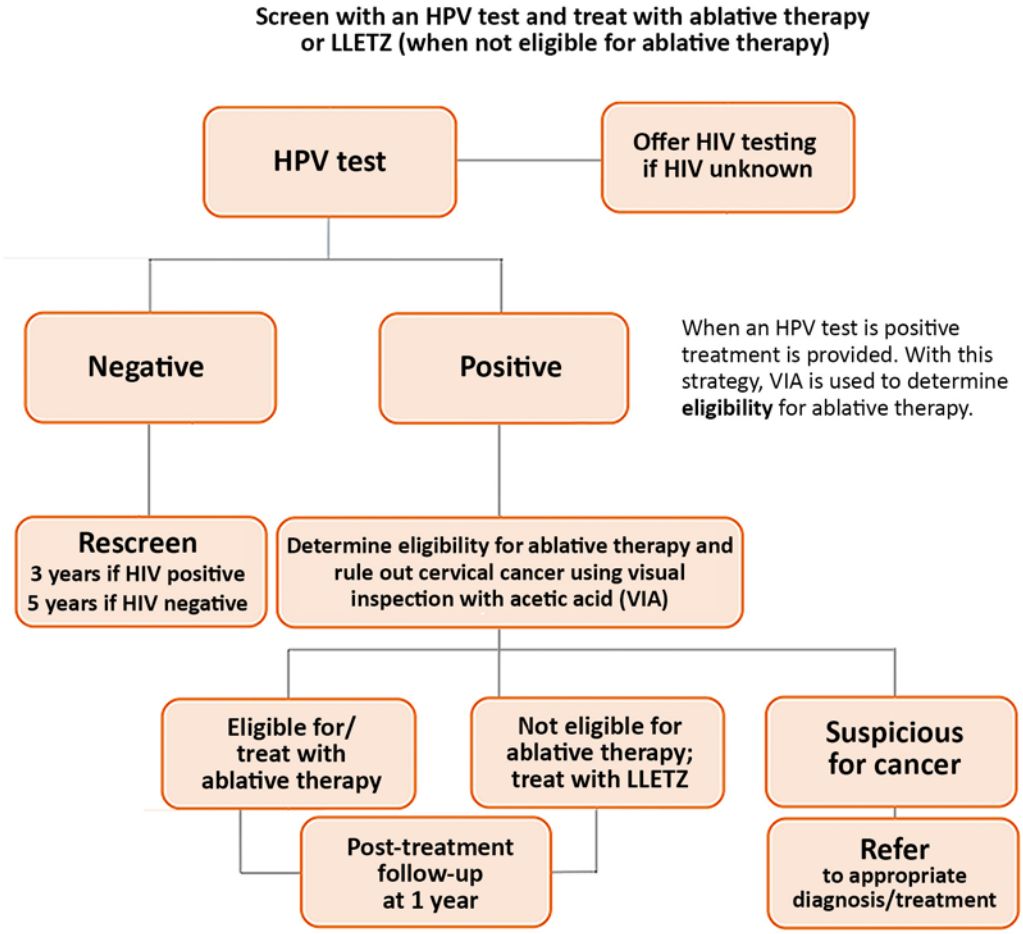
- Dispose of contaminated swabs, gauze, and other waste material in the designated container(s).
- Immerse the speculum and other instruments in a bucket full of soapy water. Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.

Appendix 4.4 HPV Testing

There are two options for using HPV testing. It can be used either as a single screening test, or in combination with a second screening test, such as VIA. When HPV testing is used as the only screening test in a screen-and-treat approach, clients who test positive for HPV are given treatment (Figure 4-4-1).

Women of unknown HIV status should be offered testing. If they do not consent to testing, follow the screening schedule for women living with HIV.

Figure 4-4-1. Screen for HPV and treat algorithm



In some regions of Africa, the HPV positivity rate is greater than 50% among women living with HIV. When HPV testing is used as part of a screen-and-tread approach, some clients who test positive for HPV will have pre-cancer and receive the appropriate treatment. However, some clients who test positive for HPV will not have pre-cancer, and thus will be treated unnecessarily—that is, they will have a false positive for pre-cancer. For this reason, a second screen-and-treat strategy, one that employs a second test after the initial positive result, is also an option (Figure 4-4-2).

Under a strategy that uses VIA as a second screening test, a client who tests positive for HPV would then undergo VIA screening; she would receive treatment only if the VIA screening result were also positive. If the VIA result were negative, the client would not be treated, but would be tested again for HPV in 12 months.

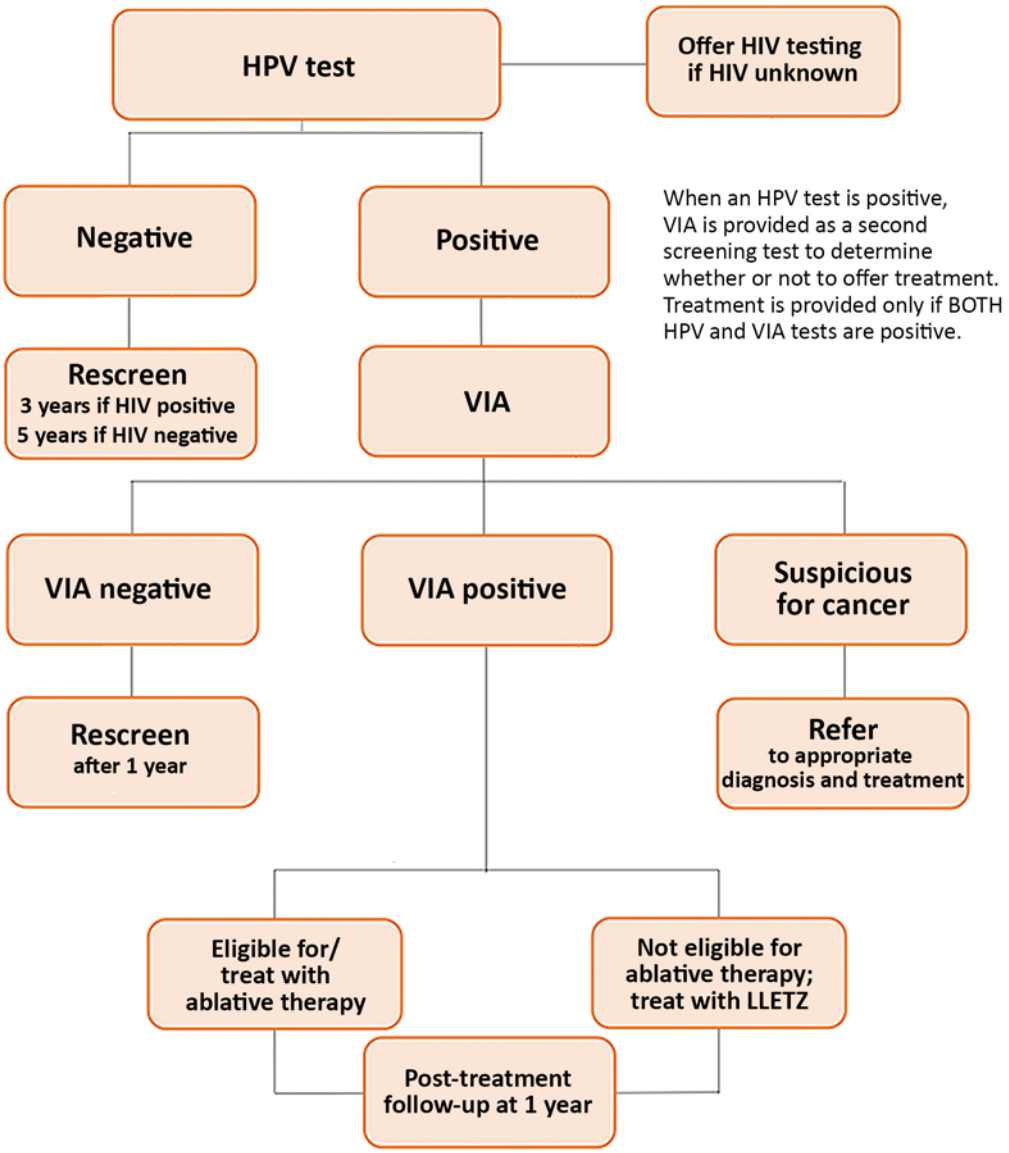
However, adding a second test does not always result in a better outcome, since false-negative results can occur on the second test. If the first test were, in fact, a true positive and the second test a false negative, then the client would not be treated even though she had pre-cancer. In the case of an initial test being positive and a second test being negative, it is important that the client be screened again in 12 months, as recommended.

HPV DNA Testing Followed by VIA Algorithm

Frequency:

- HPV negative: Screen with HPV every three years if the client is HIV positive, every five years if HIV negative.
- HPV positive, VIA negative: Rescreen with both HPV and VIA after one year regardless of HIV status.
- HPV positive, VIA positive: Treat with ablative therapy or LLETZ, as appropriate.
- Rescreen with HPV and VIA one year after treatment.
- After three consecutive negative screening results following treatment, return to routine screening schedule.
- **Women of unknown HIV status should be offered testing. If they do not consent to testing, follow the screening schedule for women living with HIV.**

Figure 4-4-2. HPV followed by VIA algorithm



Appendix 4.5 Performing Colposcopy

Colposcopy is the use of a colposcope—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 precancer neoplasia (Figure 4-5-1).[1,2] Some models have no binocular field microscopy (e.g., the MobileODT EVA System)(Figure 4-5-2).[3]

Figure 4-5-1. Binocular field colposcope

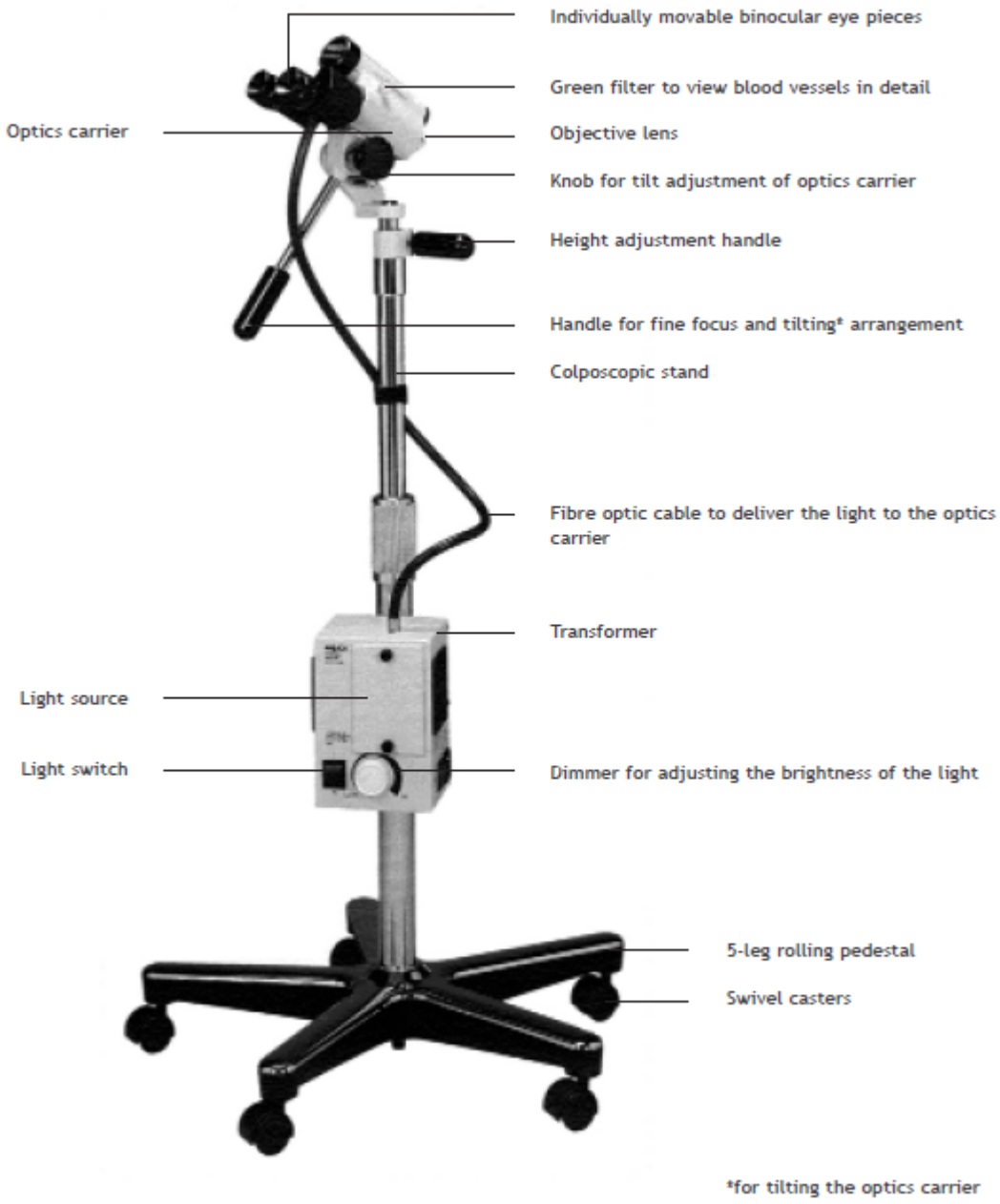


Figure 4-5-2. MobileODT EVA System

Colposcopy is used to:

- Assist with cryotherapy or LLETZ by mapping the site, size, and location of the pre-cancer.
- Guide biopsy of areas that appear abnormal or may be cancerous.

Table 4-5-1. Indications for colposcopy

- Suspicious-looking cervix
- Invasive cervical carcinoma on cytology
- Persistent (lasting more than 12–18 months) low-grade (CIN 1) abnormalities on cytology
- CIN 1 on cytology
- Persistently unsatisfactory cytology
- Infection with oncogenic HPV (positive HPV result)
- Positive VIA result, large lesion for ablation
- Positive result from visual inspection with Lugol's iodine, large lesion

Who Can Perform Colposcopy?

Colposcopy requires special training to understand how it operates and works. It can therefore only be performed by trained health care providers—such as medical and clinical officers, gynaecologists, and trained nurses—who have demonstrated competence in both performing the procedure and collecting cervical biopsies and endocervical curettings. To ensure quality of service, mentorship of providers who perform this diagnostic service is critical.

The basic equipment and supplies needed to perform colposcopy are the same as those needed for VIA (see Appendix 4.3). A list of additional equipment and supplies needed for colposcopy are listed in Table 4-5-2 below.

Table 4-5-2. Additional equipment and supplies for colposcopy

- Colposcope
- Punch biopsy forceps
- Endocervical curette
- Endocervical speculum
- Cervical cytology brushes or spatula
- Cotton-tipped fine swab sticks
- Specimen bottle with 10% formalin
- Monsel's solution
- Silver nitrate sticks (where possible)
- Saline solution

Preparation and Counselling

1. Prepare the exam room before the client arrives.
    - Prepare the instrument tray; ensure that all equipment and supplies needed for VIA are available and sterile.
    - Ensure that the examination couch and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
    - Ensure that aprons are available in the exam room, and that all persons who will be present (except the client) use them.
2. Welcome the client into the room.
3. Obtain the relevant gynaecological and obstetric history from the client.
4. Review what the client knows about colposcopy.
5. Explain the colposcopy procedure, possible results (with the aid of pictures), treatment options, and associated side effects to the client, along with the required follow-up actions for any result; avoid unnecessary use of medical terms.
6. Allow the client to ask questions and have her questions answered.
7. Obtain informed consent from the client.
8. Advise the client to empty her bladder (if full) before the procedure.
9. Allow other persons in the exam room ONLY if the client consents to their presence.

The Procedure

Step 1. Help the client onto the examination couch:

- Give the client privacy to undress from waist down.
- Help the client lie down in modified lithotomy position on a couch with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown, so that only the external genitalia are exposed.

Step 2. Perform a speculum examination (see Appendix 4.3)

Step 3. Colposcopy procedure:

- Inspect the cervix at low-power magnification (5x to 10x), looking for any obvious areas of abnormality, including ulcers, growths suspicious for cancer, cysts, and warts.
- Identify the transformation zone and the original and new SCJ. If advisable, or if the entire SCJ is not visible, you can inspect the cervical canal using an endocervical speculum. If the entire SCJ is still not visible, the colposcopy is termed inadequate or unsatisfactory, and an endocervical curettage (ECC) should be done.
- Apply saline to the cervix. Inspect the cervix with a green filter at 15x magnification, noting any abnormal vascular patterns. Lower magnification yields a wider view and greater depth of field for examination of the cervix.
- Using a cotton swab soaked in 3–5% acetic acid or white vinegar, gently but firmly apply acetic acid to the cervix.
- Wait for one minute to allow for colour changes to develop; using the colposcope, observe any changes to the cervix. Give special attention to abnormalities close to the SCJ.
- Integrate the findings of the saline and acetic acid tests to make a colposcopic assessment.
- Perform cervical biopsy and/or ECC on any abnormal looking areas; warn the client beforehand that there may be some cramping. (See Appendix 4.6.)
- If active bleeding is noted, apply pressure to the bleeding area with a swab or apply Monsel's paste.
- Gently pull the speculum towards you until the blades are clear of the cervix, then close the blades and remove the speculum.
- Wait a few minutes, and then ask the client to sit up slowly. Observe the client for possible vasovagal symptoms (light-headedness, sweating, fainting). If they occur, have the client lie down again; elevate her legs until she is feeling better.

Step 4. After the procedure:

- Thank the client and discuss the results of the procedure.
- If a biopsy and/or ECC was/were done:
  - Advise the client to abstain from sexual intercourse until she has no more discharge or bleeding (usually 2–4 days).
  - Provide the client with condoms, and counsel her on how to use them if abstinence is not possible.

- Explain to the client that she needs to return to the clinic if she experiences any signs or symptoms of complications, such as active or persistent bleeding, persistent cramping, and foul-smelling discharge.
- Counsel the client on what the recommended next steps are.
- Schedule an appointment with the client to review the histology results.

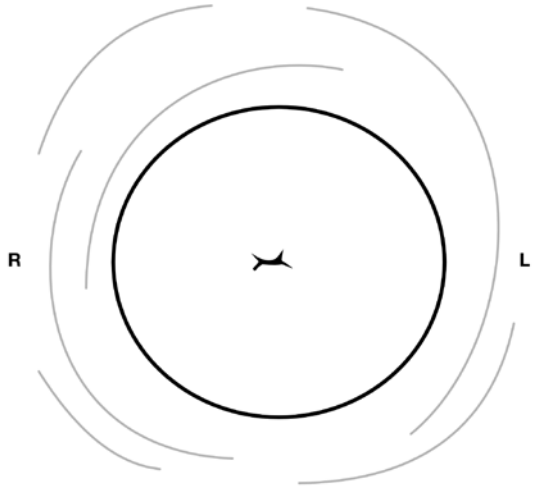
Step 5. Document the colposcopy procedure:

- Carefully document the result of the colposcopy in the client's health passport; use a drawing to document abnormal findings (see Figure 4-5-3 below).
- The documentation should answer the following questions:
  - Was the entire SCJ visible?
  - Was a lesion visible?
  - Did the lesion cover less than 75% of the cervix?
  - Was the endocervical border of the lesion visible?
  - Were there any vascular abnormalities suggestive of a high-grade cervical lesion or invasive cancer?
  - Was a biopsy and/or ECC done; if yes, make sure to label specimen container appropriately, and also complete the laboratory requisition form.
  - Document overall impression: Negative for precancer? Low-grade lesion? High-grade lesion? Or cancer?

Step 6. Infection prevention measures:

- Dispose of contaminated swabs, gauze, and other waste material in the designated container(s).
- Immerse the speculum and other instruments in a bucket full of soapy water. Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.

Figure 4-5-3. Cervical diagram for abnormal colposcopy findings



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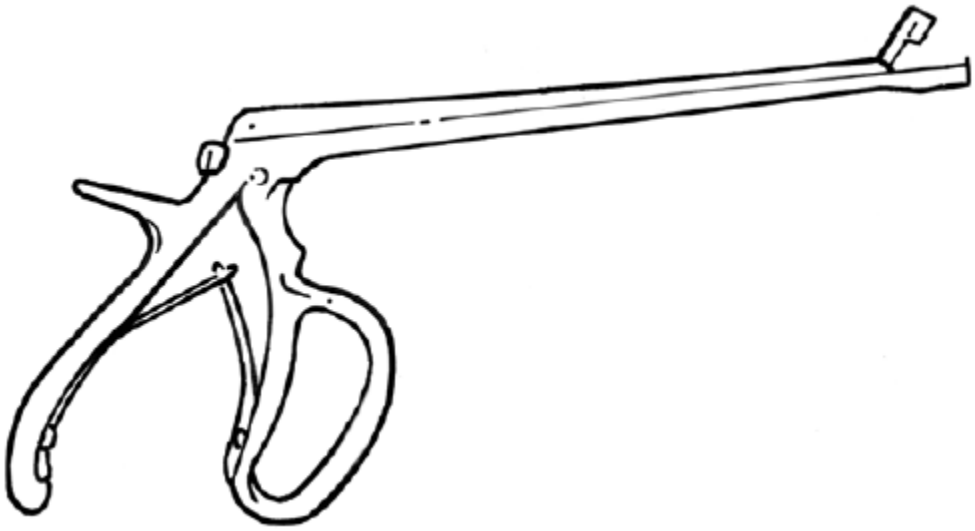
1. World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd edition. Geneva (Switzerland): World Health Organization; 2014.
2. Sellors JW, Sankaranarayanan R. Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual. Lyon: International Agency for Research on Cancer (IARC); 2003. Available from: http://screening.iarc.fr/doc/Colposcopymanual.pdf.
3. MobileODT [homepage on the Internet]. EVA System. Tel Aviv: MobileODT; c2018. Available from: https://www.mobileodt.com/eva-system/. Accessed 2019 Mar 4.

Appendix 4.6 Performing Cervical Biopsy and Endocervical Curettage

Cervical Biopsy

Cervical biopsy is the removal of small pieces of cervical tissue with a special punch biopsy forceps (Figure 4-6-1). The purpose of the biopsy is to diagnose abnormalities in the cervix,[1,2] whether detected without magnification (e.g., during pelvic examination as part of a cervical screening procedure, such as VIA) or with the aid of a colposcope (colposcopy-directed biopsy). The specimen collected is sent to the lab for histopathological examination. With a sample of sufficient size, and proper preservation in formalin, the histopathological results can identify cervical pre-cancer, invasive cancer, and non-cancerous lesions (e.g., warts).

Figure 4-6-1. Cervical biopsy forceps

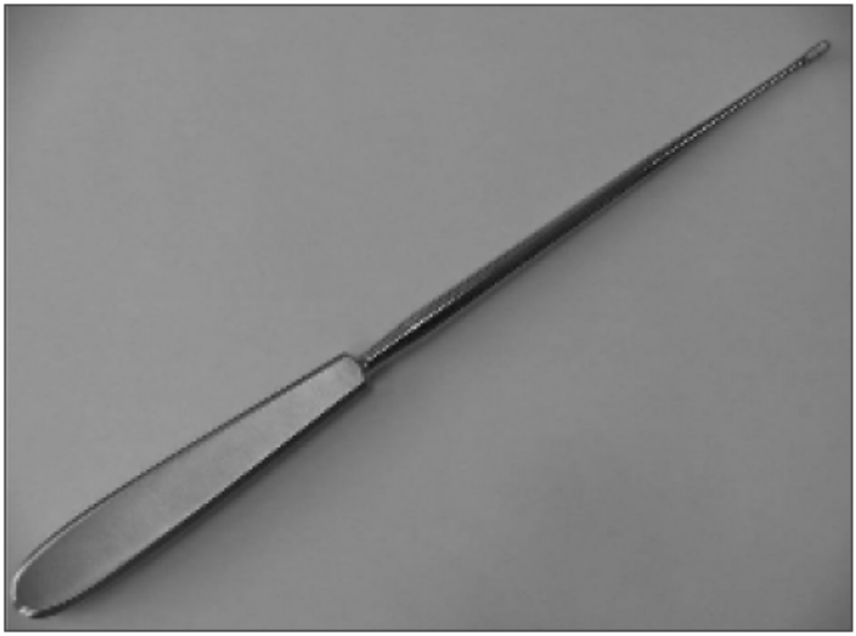


Cervical biopsy is usually performed without anaesthesia. It can cause slight pain or cramps. Bleeding can occur but is usually minimal; it can often be easily stopped by applying pressure with a cotton swab.

Endocervical Curettage

Endocervical curettage (ECC) involves use of a special thin instrument, an endocervical curette (Figure 4-6-2), to obtain a sample of abnormal tissue from the cervix during a cervical cancer examination.

Figure 4-6-2. Endocervical curette



ECC is often indicated when:

- A cytology-based screening test is positive, but no abnormalities are seen with a colposcope—there may be a pre-cancer or cancer hidden inside the canal.
- Abnormal glandular cells are seen during the cytology-based screening test.
- Colposcopy suggests abnormalities originating in the canal.
- The entire SCJ is not visible (colposcopy is reported as unsatisfactory).

Who can perform cervical biopsy and ECC?

Cervical biopsy is a very simple procedure that can be performed by a trained provider. This includes nurses, clinical officers, medical officers, and gynaecologists.

A list of equipment and supplies needed for cervical biopsy and ECC are listed in Table 4-6-1 below.

Table 4-6-1. Additional equipment and supplies needed for cervical biopsy and ECC

- Punch biopsy forceps
- Endocervical curette
- Endocervical speculum
- Specimen bottle with 10% formalin
- Monsel's solution
- Silver nitrate sticks (where possible)

Preparation and Counselling

Prepare the exam room before the client arrives:

- Prepare the instrument tray; ensure that all equipment and supplies needed for VIA are available and sterile.

- Ensure that the examination couch and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
- Ensure that aprons are available in the exam room, and that all persons who will be present (except the client) use them.

The Procedure

Step 1. Help the client onto the examination couch:

- Give the client privacy to undress from waist down.
- Help the client lie down in modified lithotomy position on a couch with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown, so that only the external genitalia are exposed.

Step 2. Perform a speculum examination (see Appendix 4.3)

Step 3. Perform a cervical biopsy at speculum exam, VIA, or colposcopy:

- Using cervical biopsy forceps, take biopsies of the most abnormal areas of the cervix, and place the tissue in a labelled specimen bottle.
- If active bleeding is noted, apply pressure to the bleeding area with a swab, or apply Monsel's paste.
- Gently pull the speculum towards you until the blades are clear of the cervix, then close the blades and remove the speculum.
- Wait a few minutes, and then ask the client to sit up slowly. Observe the client for possible vasovagal symptoms (light-headedness, sweating, fainting). If they occur, have the client lie down again; elevate her legs until she is feeling better.

and/or

Step 4. Perform ECC at speculum exam, VIA, or colposcopy:

- Holding the curette like a pen, insert into the endocervical canal and scrape in short, firm strokes until the sample is complete. Keep the curette inside the canal for the entire procedure.
- Place the curettings on gauze or brown paper, and immediately immerse in 10% formalin.
- If active bleeding is noted, apply pressure to the bleeding area with a swab, or apply Monsel's paste.
- Gently pull the speculum towards you until the blades are clear of the cervix, then close the blades and remove the speculum.
- Wait a few minutes, and then ask the client to sit up slowly. Observe the client for possible vasovagal symptoms (light-headedness, sweating, fainting). If they occur, have the client lie down again; elevate her legs until she is feeling better.

Step 5. After the procedure:

- Thank the client and discuss the results of the procedure.
- Advise the client to abstain from sexual intercourse until she has no more discharge or bleeding (usually 2–4 days).
- Provide the client with condoms; counsel her on how to use them if abstinence is not possible.
- Explain to the client that she needs to return to the clinic if she experiences any signs or symptoms of complications, such as active or persistent bleeding, persistent cramping, and foul-smelling discharge.
- Counsel the client on what the recommended next steps are.
- Schedule an appointment with the client to review the histology results.

Step 5. Document the biopsy and/or procedure:

- Carefully document the results in the client's health passport.
- Complete a lab requisition form.

Step 6. Infection prevention measures:

- Dispose of contaminated swabs, gauze, and other waste material in the designated container(s).
- Immerse the speculum and other instruments (e.g., biopsy forceps, endocervical curette) in a bucket full of soapy water. Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.

References

1. World Health Organization. Comprehensive cervical cancer control: A guide to essential practice. 2nd edition. Geneva (Switzerland): World Health Organization; 2014.
2. Sellors JW, Sankaranarayanan R. Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual. Lyon: International Agency for Research on Cancer (IARC); 2003. Available from: http://screening.iarc.fr/doc/Colposcopymanual.pdf.

Appendix 4.7. Treatment Options for Cervical Pre-Cancer: Cryotherapy and Thermocoagulation

Cryotherapy and thermocoagulation are the two available ablative treatments for cervical pre-cancer. The eligibility criteria for their use are presented in Table 4-7-1 below.

Table 4-7-1. Eligibility and exclusion criteria for cryotherapy and thermocoagulation

Eligibility Criteria (ALL must be met)	Exclusion Criteria (any can be met)
1. Positive screening test for cervical pre-cancer or histologically confirmed CIN 2+ 2. The cervical lesion occupies less than three quarters (75%) of the transformation zone. 3. The whole cervical lesion can be seen; the cryotip or thermocoagulator probe completely covers the lesion. 4. If the client was recently pregnant, she must be least 3 months post-partum. 5. The client consents to the procedure.	1. The cervical lesion extends more 2. than 3 mm into the endocervical canal and/or extends to the vaginal wall. 3. The cervical lesion has an irregular surface contour or is suspicious for cancer. 4. There is evidence of invasive cancer. 5. There is suggestion of adenocarcinoma in situ. 6. There are polyps or scarring that prevent full contact between the cervix and cryotip or thermocoagulator probe. 7. The client is pregnant. 8. The client is menstruating (re-schedule the procedure). 9. Clinical evidence of pelvic inflammatory disease or cervicitis (until treated) is present.

Who can provide treatment with cryotherapy or thermocoagulation?

These procedures can be performed by a variety of health care providers—including nurses, midwives, and medical officers—who can be easily trained in short sessions.

Table 4-7-2 below lists the equipment and supplies required for cryotherapy and thermo-coagulation.

Table 4-7-2. Equipment and supplies required for cryotherapy and thermocoagulation

General Pelvic Examination and VIA Supplies/Equipment	• Examination bed with knee crutches, leg rests, or stirrup • Clean paper or cloth to cover the examination bed • Good light source (can be a bright torch light) • Sterile bivalved speculum (e.g., Graves speculum) • Disposable or high-level disinfected examination gloves (need not be sterile) • Cotton swabs, cotton-tipped buds, gauze • Ring forceps or pick-up forceps • Dilute acetic acid solution (3–5%) or white vinegar • Soap and water (or alcohol-based handrub) for washing hands • Steel or plastic container containing 0.5% chlorine solution for decontaminating instruments • Steel or plastic container with a polythene bag for contaminated disposable supplies • Sanitary pads or a roll of cotton wool

	• Condoms (optional) • Analgesics: Ibuprofen or paracetamol (optional)
Cryotherapy Equipment	• Cryotherapy unit • At least 2 different cryotips: 29 mm and 25 mm in diameter • Gas cylinder with adequate gas supply (carbon dioxide or nitrous oxide)
Thermocoagulation Equipment	• A thermocoagulator unit • At least 2 different probes

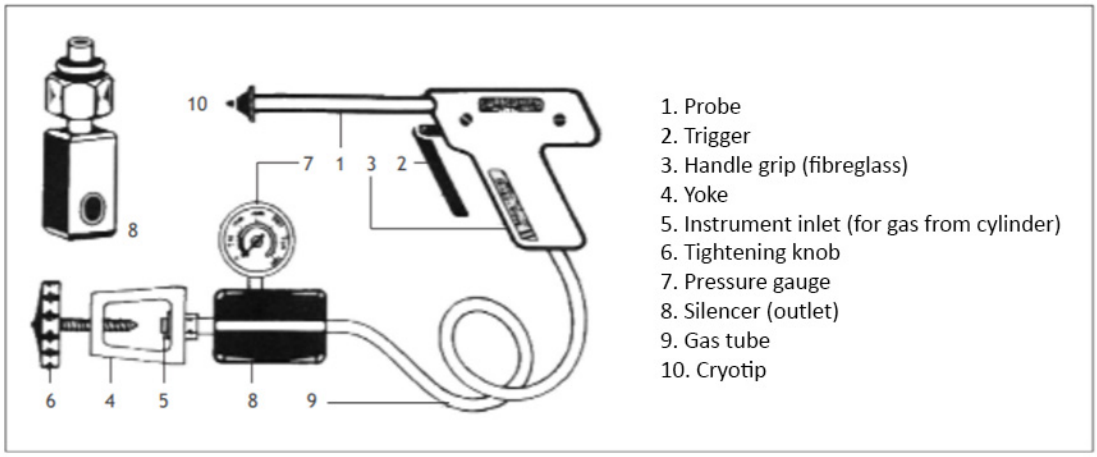
Preparation and Counselling

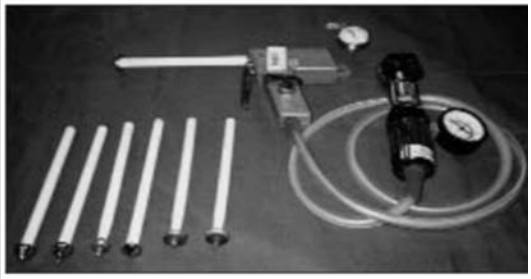
1. Prepare the exam room before the client arrives:
    - Prepare the instrument tray; ensure that all equipment and supplies needed for VIA, cryotherapy, or thermocoagulation are available and sterile.
    - Ensure that the examination couch and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
    - Ensure that aprons are available in the exam room, and that all persons who will be present (except the client) use them.
2. Check the cryotherapy equipment or thermocoagulator unit:
    - Confirm that the gas tank pressure is sufficient to provide an effective flow of gas through the cryotip or probe for the required duration of treatment.
    - Wipe the cryotip or probe surface with saline to ensure adequate thermal contact with the cervix and optimal tissue temperature.
    - Ensure that you are familiar with the operational use and safety of the equipment as provided by the manufacturer's instructions.
3. Welcome the client into the room.
4. Prepare the client for the screening and treatment procedures.
5. Explain the procedures you are about to perform; emphasise the importance of keeping follow-up appointments.
6. Explain the VIA procedure, treatment options, and associated side effects to the client.
7. Use pictures, where possible, to explain possible VIA results and the required follow-up actions for any result.
8. Show the equipment to the client, and explain how it works.
9. Obtain informed consent from the client.
10. Obtain a relevant gynaecologic and obstetric history from the client.
11. Advise the client to empty her bladder (if full) before the procedure.
12. Allow other persons in the exam room ONLY if the client consents to their presence (see the sample consent form in Appendix 4.2).
13. Use simple language; avoid unnecessary use of medical terms.

Cryotherapy

Cryotherapy uses compressed refrigerant gas delivered through a highly cooled metal disc (the cryotip) to freeze areas of the cervix identified as pre-cancerous, including the transformation zone.

Figure 4-7-1. Components of cryotherapy equipment





Cryoprobes (with tips), cryogun, pressure gauge, and stopwatch

Cryotherapy equipment

Source: Sankaranarayanan R, Wesley R. IARC technical publication no. 41: A practical manual on visual screening for cervical neoplasia. Lyon: International Agency for Research on Cancer (IARC); 2003.

The Procedure

Step 1. Help the client onto the examination couch:

- Give the client privacy to undress from the waist down.
- Help the client lie down in modified lithotomy position on a couch with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown so that only the external genitalia are exposed.

Step 2. Perform VIA (See Appendix 4.3)

Step 3. Perform cryotherapy (when indicated):

- Make sure that the client meets the eligibility criteria (see Table 4-7-1 above).
- Where possible, a directed biopsy may be done before performing cryotherapy; this enables a histopathological diagnosis to establish the nature of the lesion treated a posteriori.
- Firmly apply the cryotip, with the centre of the tip on the cervical os.
- Make sure that the cryotip adequately covers the lesion and does not inadvertently come into contact with (and freeze) any part of the vagina during the procedure.
- Set the timer, and then release or squeeze the gas trigger in the cryogun to cool the cryotip while it is in contact with the cervix. The gas escapes through the pressure gauge with a hissing noise.
- Observe ice being formed on the tip of the cryoprobe and on the cervix as freezing progresses.
- The treatment cycle consists of two sequential freeze–thaw cycles, with each cycle consisting of three minutes of freezing followed by five minutes of thawing (freeze–thaw–freeze–thaw).
- The elapsed time of treatment should be monitored using a stopwatch.
- Adequate freezing has been achieved when the margin of the ice ball extends 4–5 mm past the outer edge of the cryotip.
- Once the second freeze of three minutes is completed, allow time for adequate thawing before removing the probe from the cervix.
- Look for the ice formation on the cryotip to clear completely. Only then remove the probe by gently rotating on the cervix.
- Avoid any attempts to remove the probe tip from the cervix before complete thawing has occurred.
- After removing the probe, examine the cervix for any bleeding.
- Gently withdraw the speculum and inspect the vaginal walls for condyloma or acetowhite lesions.

Thermocoagulation

Cervical thermocoagulation uses a reusable heated metal probe to destroy areas of the cervix identified as pre-cancerous, including the transformation zone.

Figure 4-7-2. WISAP thermocoagulator

Source: WISAP® Medical Technology

Figure 4-7-3. C3 Cervical Cold Coagulator

Source: WISAP® Medical Technology

Step 3. Perform thermocoagulation (when indicated):

- Proceed as in steps 1 and 2 above.
- Make sure that the client meets the eligibility criteria (see Table 4-8-1 above).
- Where possible, a directed biopsy may be done before performing thermocoagulation; this enables a histopathological diagnosis to establish the nature of the lesion treated a posteriori.
- Activate the thermocoagulator, heating the probe to 100–120°C.
- Firmly apply the heated probe, with the centre of the tip on the cervical os, for 20–45 seconds. Multiple overlapping applications (of 20–45 seconds each) may be necessary to cover the entire transformation zone adequately. However, a small transformation zone may only need one or two applications.
- Treatment usually takes less than two minutes. A soft, crackling sound may be heard during treatment as the transformation zone is heated.
- Be careful not to allow the hot probe to accidentally come in contact with the vulva or vagina while introducing and removing it.
- Newer thermocoagulator models automate the duration of the treatment cycle. Otherwise, the elapsed duration of treatment time should be monitored using a stopwatch.
- Once a treatment cycle is completed, remove the probe and examine the cervix for any bleeding.
- Gently withdraw the speculum and inspect the vaginal walls for condyloma or acetowhite lesions.

Step 4. Post-procedure care and counselling:

- Avoid packing the vagina with gauze or cotton; allow any secretions to escape.
- Provide the client with sanitary pads; advise her to use them to prevent secretions from staining her clothes.
- Advise the client that she may experience mild cramps and a clear or lightly blood-stained watery discharge for up to 4–6 weeks after treatment.
- Advise the client against vaginal douching or using tampons.
- Advise the client to avoid sexual intercourse for one month after treatment; when abstaining from intercourse is not possible, encourage the client to use condoms.
- Offer the client a supply of condoms for use when needed.
- Instruct the client to report to the clinic if she has any of the following symptoms during the first six weeks after treatment:
  - Fever (with or without chills)
  - Severe lower abdominal pain
  - Foul-smelling vaginal discharge
  - Unusual bleeding (heavier than a menstrual cycle or with clots)
- Document the result of the VIA screening in the client's health passport.
- Provide the client with instructions for a follow-up visit.
- Ask the client to return for a follow-up screening in 12 months.
- Thank the client.

Step 5. Document the VIA and treatment procedures:

- Carefully document the result of the VIA screening in the cervical cancer screening register.
- If a specimen (cervical biopsy) has been taken, label it appropriately, and fill out the laboratory requisition form.
- Document the treatment provided (where applicable).

Step 6. Infection prevention measures:

- Dispose of contaminated swabs, gauze, and other waste material in the designated container(s).
- Immerse the speculum and other instruments in a bucket full of soapy water.
- Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.
- If cryotherapy was performed:
  - Clean and disinfect the cryoprobe, and decontaminate the cryogun, tubing, pressure gauge, and gas tanks as follows:
  - Decontaminate the cryotherapy unit, hose, and regulator by wiping them with alcohol.
  - Wash the cryoprobe and the plastic sleeve with soap and water until visibly clean.
  - Rinse the cryoprobe and plastic sleeve thoroughly with clean water.
  - High-level disinfect the cryoprobe and plastic sleeve using 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) for 20 minutes, and then rinse with boiled water.
  - It is critical that the hollow part of the cryoprobe is completely dry when next used, otherwise the water will freeze and the probe may crack or the treatment may 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 used again.
  - If none of the options for high-level disinfection options are available, the cryoprobe and sleeve may be disinfected by soaking in 70–90% ethanol or isopropanol for 20 minutes. Allow them to air-dry and then reassemble.
- If thermocoagulation was performed:
  - Clean and disinfect the probe without dipping the connector end into the disinfectant.
  - It is critical that the probe is completely dry when next used.
  - If none of the options for high-level disinfection are available, the probe and sleeve may be disinfected by soaking in 70–90% ethanol or isopropanol for 20 minutes. Allow them to air-dry and then reassemble.
  - Make sure to read the manufacturer's instructions for using and cleaning thermocoagulators.

Appendix 4.8 Treatment Options for Cervical Pre-Cancer: Large Loop Excision of the Transformation Zone (LLETZ)

LLETZ is the surgical removal of the areas of the cervix identified as pre-cancerous, including the transformation zone. An electrode (a curved or square tungsten loop, or a straight needle, depending on the size of the lesion) powered by an electrosurgical unit is used; a 3 mm or 5 mm ball electrode is then used to coagulate the bleeding points, cut edges, and floor of the surgical wound.

Table 4-8-1. Eligibility and exclusion criteria for LLETZ

Eligibility Criteria (ALL must be met)	Exclusion Criteria (any can be met)
1. Positive screening test for cervical pre-cancer or histologically confirmed CIN 2+, but the client is not a good candidate for ablative treatments because: a. The lesion is too large (occupies 3 quadrants of the cervix). b. The lesion extends into the endocervical canal or the SCJ is not fully visualised. 2. Specimen for histopathological examination required. 3. The cervical lesion is not suspicious for cancer. 4. If the client was recently pregnant, she must be least 3 months postpartum. 5. The client consents to the procedure.	1. Allergy to local anaesthetic 2. History of haemorrhagic disorder or anticoagulant therapy 3. Pregnancy 4. Evidence of invasive cervical cancer 5. There is no suggestion of adenocarcinoma in situ. 6. The client is menstruating (re-schedule). 7. Clinical evidence of pelvic inflammatory disease or cervicitis (until treated) is present.

Who can perform LLETZ?

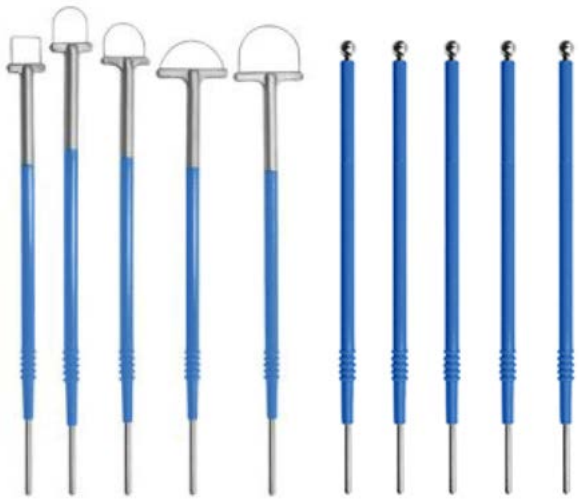
Although LLETZ is a relatively simple surgical procedure, it should only be performed by trained health care providers—medical and clinical officers, gynaecologists, and (in some settings) trained nurses—who have demonstrated competence in both performing the procedure and managing potential complications, such as bleeding. To ensure quality of service, mentorship of providers who perform this surgical procedure is critical.

The equipment and supplies needed to perform LLETZ are listed in Table 4-8-2 below.

Table 4-8-2. Equipment and supplies for LLETZ

General Pelvic Examination and VIA Supplies/Equipment	LLETZ Equipment
• Examination bed with knee crutches, leg rests or stirrups • Clean paper or cloth to cover the examination bed • Good light source (can be a bright torch light) • Disposable or high-level disinfected examination gloves (need not be sterile • Examination bed with knee crutches, leg rests or stirrups • Clean paper or cloth to cover the examination bed	• Non-conducting sterile bivalved speculum (e.g., Graves speculum, preferably with side retractors) • Reliable power supply • Electrosurgical generator and electrode handle • Non-conducting sterile bivalved speculum (e.g., Graves speculum, preferably with side retractors)
• Good light source (can be a bright torch light) • Disposable or high-level disinfected examination gloves (need not be sterile) • Cotton swabs, cotton-tipped buds, gauze • Ring forceps or pick-up forceps • Dilute acetic acid solution (3-5%) or white vinegar • Lugol's iodine (optional) • Soap and water (or alcohol-based handrub) for washing hands • Steel or plastic container containing 0.5% chlorine solution for decontaminating instruments • Steel or plastic container with a polythene bag for contaminated disposable supplies • Sanitary pads or a roll of cotton wool • Condoms (optional) • Analgesics: Ibuprofen or paracetamol (optional)	• Reliable power supply • Electrosurgical generator and electrode handle • Return electrode • Loop electrodes in several sizes (see Figure 4-8-1) • Ball electrode • Smoke evacuator • Colposcope • Local anaesthetic: 1% or 2% lignocaine or lidocaine with or without 1:100,000 adrenaline • Monsel's paste • Needles and suture material • Specimen containing 10% formalin

Figure 4-8-1. Loop and ball electrodes



Preparation and Counselling

1. Prepare the exam room before the client arrives.
    - Prepare the instrument tray; ensure that all equipment needed for VIA and LLETZ is available and sterile.

- Ensure that the examination couch and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
- Ensure that aprons are available in the exam room, and that all persons who will be present (except the client) use them.

2. Check the LLETZ equipment.
3. Welcome the client into the room.
4. Prepare the client for the screening and treatment procedures.
5. Explain the procedures you are about to perform; emphasise the importance of keeping follow-up appointments.
6. Explain the VIA procedure, treatment options, and associated side effects to the client.
7. Use pictures, where possible, to explain possible VIA results and the required follow-up actions for any result.
8. Show the LLETZ equipment to the client and explain how it works.
9. Obtain informed consent from the client.
10. Obtain a relevant gynaecologic and obstetric history from the client.
11. Advise the client to empty her bladder (if full) before the procedure.
12. Allow other persons in the exam room ONLY if the client consents to their presence the sample consent form in Appendix 4.2).
13. Use simple language; avoid unnecessary use of medical terms.

The Procedure

Step 1. Help the client onto the examination couch:

- Give the client privacy to undress from the waist down.
- Help the client lie down in modified lithotomy position on a couch with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown so that only the external genitalia are exposed.

Step 2. Perform VIA (see Appendix 4.3):

In addition to VIA, visual inspection with Lugol's iodine is sometimes preferred, but not mandatory:

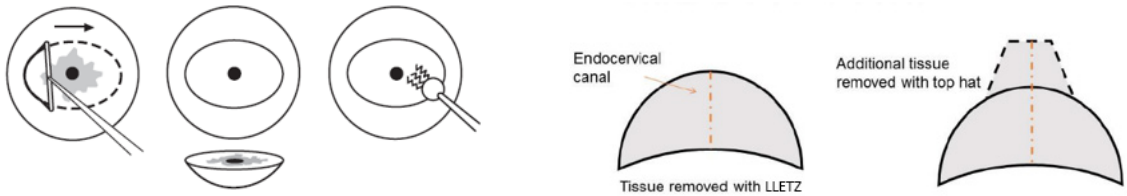
- Using a cotton swab soaked in Lugol's iodine, gently but firmly apply the iodine solution to the cervix to highlight the abnormal areas.
- If in doubt about anything you are observing, repeat the test a few times or seek help from a trained provider (if available).

Step 3. Perform colposcopy (where available) (see Appendix 4.5)

Step 4. Perform LLETZ (when indicated)

- Make sure the client meets the eligibility criteria (see Table 4-8-1 above).
- While stabilising the cervix with a tenaculum, inject 3–5 ml of local anaesthetic (1% or 2% lignocaine or lidocaine with 1:100 000 epinephrine to control bleeding), using a long 27-gauge needle, just beneath the cervical epithelium at the 12, 3, 6, and 9 o'clock positions. (If the client has cardiac problems, use lidocaine without epinephrine.) Use of epinephrine reduces the risk of heavy bleeding.
- Wait for several minutes; transient tachycardia is normal.
- Select the appropriate electrode to enable removal of 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 an electrode 2.0 cm wide by 0.8 cm deep. Every effort should be made to excise as much of the required specimen as possible in a single continuous pass.
- Turn the vacuum suction on and activate the generator.
- 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 (side to side is preferable). This will produce a dome-shaped circle of tissue with the endocervical canal in the centre (see Figure 4.8.2 below).
- DO NOT insert the electrode deeper than 5 mm at the 3 and 9 o'clock positions; this could damage the cervical branches of the uterine artery.
- Additional passes with the loop can be made to excise residual tissue.
- Perform a cervical top hat extension, if indicated.
- Retrieve all excised tissue with the forceps, and place in a labelled bottle with formalin to send to the laboratory.
- Perform an ECC and place the tissue in a specimen bottle with formalin.
- Coagulate any bleeding tissue in the crater base and edges using a ball electrode and coagulation current.
- Apply Monsel's paste to the crater base to prevent further bleeding, and then remove the speculum.

Figure 4-8-2. LLETZ procedure demonstration



Source:
WHO. Comprehensive cervical cancer control:
A guide to essential practice. 2nd ed. Geneva (Switzerland):
World Health Organization; 2014. p. 138.

Step 5. Post-LLETZ care and counselling:

- Avoid packing the vagina with gauze or cotton, to allow the secretions to escape.
- Provide the client with sanitary pads; advise her to use sanitary pads to prevent the secretions from staining her clothes.
- Advise the patient that she may experience mild cramps and a clear or lightly blood-stained watery discharge for up to 4–6 weeks after treatment.
- Advise the client against vaginal douching or using tampons.
- Advise the client to avoid sexual intercourse for one month after treatment; where abstaining from intercourse is not possible, encourage the client to use condoms.
- Offer the client a supply of condoms for use when needed.
- Instruct the client to report to the clinic if she has any of the following symptoms during the first six weeks after treatment:
  - Fever (with or without chills)
  - Severe lower abdominal pain
  - Foul-smelling vaginal discharge
  - Unusual bleeding (heavier than a menstrual cycle or with clots)
- Document the results of the VIA screening, colposcopy (if performed), and LLETZ procedure in the client's heath passport.
- Provide the client with instructions for a follow-up visit; schedule a post-procedure check-up at six weeks.
- Provide the client with ibuprofen or paracetamol on discharge.
- Recommend the client take two days off work (if she is working); advise her to avoid heavy or strenuous exercise.
- Ask the client to return for a follow-up screening in 12 months.
- Thank the client.

Step 6. Document the VIA and treatment procedures:

- Carefully document the result of the VIA screening, colposcopy (if performed), and LLETZ procedure in the cervical cancer screening or colposcopy clinic register.
- Label the LLETZ specimen appropriately and fill out the laboratory requisition form.

Step 7. Infection prevention measures:

- Dispose of contaminated swabs, gauze, and other waste material in the designated containers.
- Immerse the speculum and other instruments in a bucket full of soapy water.
- Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remember to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.
- Clean and disinfect the loop and ball electrodes.

Managing Complications of LLETZ

Table 4-8-3 below provides guidance for managing commonly encountered complications of LLETZ.

Table 4-8-3. Managing possible complications of LLETZ

Complication	Treatment
Bleeding during the procedure: can be diffuse or arterial	• For diffuse bleeding: use a combination of pressure and coagulation with ball electrode. • For arterial bleeding: place ball electrode in firm contact with the source and apply coagulation current.
Post-procedure bleeding (this happens in less than 2% of cases)	• Remove blood clot, clean with 5% acetic acid, identify bleeding area, and anaesthetise with lidocaine and epinephrine. • If bleeding is not heavy, and no arterial bleeding is present, apply Monsel's paste. • If bleeding is heavy, coagulate using either a 5 mm ball electrode or a macroneedle electrode and coagulation current.
Post-procedure infection: pus-like discharge, persistent cramping pain, fever	Treat with antibiotics as follows: • Gentamicin 240 mg IM stat, plus • Doxycycline 100 mg orally, twice daily for 7 days, plus • Metronidazole 400 mg orally, three times a day for 7 days.

Post-LLETZ Follow-up Visit

- Usually scheduled for six weeks after the procedure.
- Get a post-procedure history from the client, focusing on any complications:
  Did the client experience foul-smelling vaginal discharge, persistent fever, persistent bleeding, and/or cramping pains?
- Review the histopathology results; advise the client on the recommended follow-up steps.
- Perform a speculum examination to check the healing progress of the biopsied part of the cervix.
- Remind the client to return for repeat cervical screening in 12 months.

Appendix 4.9 Treatment Options for Cervical Pre-Cancer: Cold Knife Conisation (CKC)

CKC is the surgical removal of a cone-shaped piece of tissue from the cervix, consisting of the area identified as pre-cancerous, and including portions of the ectocervix and endocervix.

Table 4-9-1. Eligibility and exclusion criteria for CKC

Eligibility Criteria (ALL must be met)	Exclusion Criteria (any can be met)
1. Positive screening test for cervical pre-cancer or histologically confirmed CIN 2+, but the client is not a good candidate for ablative treatments or LLETZ because: a. A specimen for histopathological examination is required. b. The cervical lesion is not suspicious for cancer. 2. The client consents to the procedure. **And/or** 3. Suspected microinvasive cervical cancer or adenocarcinoma in situ 4. Cervical or vaginal distortion 5. The cervix is fixed in a downward-pointing position. 6. The external os is obliterated or flush with the vaginal apex. 7. High-grade cervical lesions extend deep into the endocervical canal.	1. Allergy to local anaesthetic 2. History of haemorrhagic disorder or anticoagulant therapy 3. Pregnancy 4. Evidence of invasive cervical cancer 5. There is no suggestion of adenocarcinoma in situ. 6. The client is menstruating (re-schedule). 7. Clinical evidence of pelvic inflammatory disease or cervicitis (until treated) is present.

Who can perform CKC?

CKC requires good surgical skills; it should only be performed by trained providers who have demonstrated competence in both performing the procedure and recognising and managing potential complications, such as bleeding. Most of the time, the procedure will be performed by a trained clinical officer, a medical officer with appropriate experience, or a gynaecologist. CKC is performed in theatre, with the client admitted to hospital for at least one day after the procedure.

The equipment and supplies needed to perform CKC are listed in Table 4-9-2 below.

Table 4-9-2. Equipment and supplies for CKC

General Pelvic Examination and VIA Supplies/Equipment	CKC Supplies/Equipment
• Clean paper or cloth to cover the examination bed • Good light source (can be a bright torch light) • Disposable or high-level disinfected examination gloves (need not be sterile) • Cotton swabs, cotton-tipped buds, gauze	• Operating theatre containing an operating table with knee crutches, leg rests, or stirrups • Reliable power supply • Electrosurgical generator and electrode handle • Return electrode

General Pelvic Examination and VIA Supplies/Equipment	CKC Supplies/Equipment
• Ring forceps or pick-up forceps • Dilute acetic acid solution (3–5%) or white vinegar • Lugol's iodine (optional) • Soap and water (or alcohol-based handrub) for washing hands • Steel or plastic container containing 0.5% chlorine solution for decontaminating instruments • Steel or plastic container with a polythene bag for contaminated disposable supplies • Sanitary pads or a roll of cotton wool • Condoms (optional)	• Size #11 surgical blade • Surgical blade holder for size #11 surgical blade • Ball electrode • Local anaesthetic: 1% or 2% lignocaine or lidocaine with or without 1:100 000 adrenaline • 5 ml or 10 ml syringes with long 27-gauge needles; spinal needles can also be used • Monsel's paste • Analgesics: pethidine can be used in first 24 hours, followed by ibuprofen or paracetamol • Specimen bottle containing 10% formalin • Needles and suture material

Preparation and Counselling

1. Prepare the client for the procedure on admission.
2. Obtain a relevant gynaecologic and obstetric history from the client.
3. Explain the procedure, anaesthesia, and possible side effects and complications to the client; answer any questions she may have.
4. Obtain informed consent from the client.
5. Prepare the operating theatre:
   - Prepare the instrument tray; ensure that all necessary equipment for VIA and CKC is available and sterile.
   - Ensure that the operating table and light source are clean. If they have not already been cleaned, wipe down with a towel soaked in 0.5% chlorine solution.
6. Have the client empty her bladder before the procedure.

The Procedure

Step 1. Position the client on the operating table to receive general or regional anaesthesia:

- Help the client lie down in modified lithotomy position on an operating table with leg rests, knee crutches, or stirrups.
- Cover the client's waist and thighs with a cloth or gown so that only the external genitalia are exposed.
- Administer general or spinal anaesthesia to the client so that she does not feel any pain during the operation.

Step 2. Perform VIA (see Appendix 4.3):

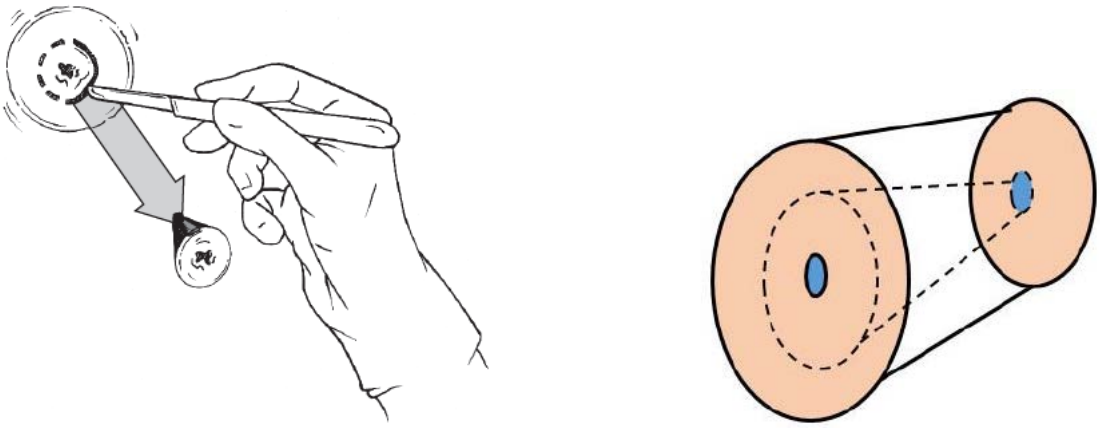
In addition to VIA, visual inspection with Lugol's iodine is sometimes preferred, but not mandatory:

- Using a cotton swab soaked in Lugol's iodine, gently but firmly apply the iodine solution to the cervix to highlight the abnormal areas.
- If in doubt about anything you are observing, repeat the test a few times or seek help from a trained provider (if available).

Step 3. Perform CKC (when indicated):

- Make sure the client meets the eligibility criteria (see Table 4-9-1 above).
- While stabilising the cervix with a tenaculum, inject 3–5 ml of local anaesthetic (1% or 2% lignocaine or lidocaine with 1:100 000 epinephrine to control bleeding), using a long 27-gauge needle, just beneath the cervical epithelium at the 12, 3, 6, and 9 o'clock positions. (If the client has cardiac problems, use lidocaine without epinephrine.) Use of epinephrine reduces the risk of heavy bleeding.
- Place stay sutures, using a 2-0 delayed absorbable suture, at the level of the internal os at the 3 and 9 o'clock positions.
- These sutures may be used for traction, and also for haemostasis, by loosely tying them together to hold a Surgicel at the end of the procedure.
- Using a curved or straight #11 surgical blade, remove a cone-shaped area of the cervix, including the endocervical canal (see Figure 4-9-1).
- Remove 360° of the transformation zone beginning 2–3mm beyond the lesion, and, using curved scissors, remove tissue from the endocervical canal to the depth of the cone.
- Pick up the excised cone-shaped specimen with the forceps, and place in a labelled specimen bottle with formalin to send to the histopathology laboratory.
- Place a stitch into the cone specimen to mark the orientation of the specimen for pathology; the location of this stitch should be recorded on the appropriate histology form (e.g., stitch at 12 o'clock).
- Coagulate any bleeding tissue in the crater base and edges using a ball electrode and coagulation current.
- Apply Monsel's paste to the crater base to prevent further bleeding.
- A gauze pack may be placed in the vagina to apply pressure and control the bleeding, but this should not be done if Monsel's paste has been used.

Figure 4-9-1. Removal of cone-shaped area of the cervix



Source: WHO. Comprehensive cervical cancer control: A guide to essential practice. 2nd ed. Geneva (Switzerland): World Health Organization; 2014. p. 138.

Step 4. Post-CKC care and counselling:

- Provide the client with a sanitary pad.
- Monitor the client in the recovery room. If no concerns are noted during immediate post-operative monitoring, she can be moved to the regular ward.
- The client can be discharged the following day if no significant bleeding is noted.
  - Provide the client with ibuprofen or paracetamol on discharge.
  - Recommend the client take two days off work (if she is working); advise her to avoid heavy or strenuous exercise.
  - Make sure to remove any gauze packing from the vagina within 6–12 hours to avoid infection.
- Advise the patient that she may experience mild cramps and a clear or lightly blood-stained watery discharge for up to 4–6 weeks after treatment.
- Advise the client against vaginal douching or using tampons.
- Advise the client to avoid sexual intercourse for one month after treatment; where abstaining from intercourse is not possible, encourage the client to use condoms.
- Offer the client a supply of condoms for use when needed.
- Instruct the client to report to the clinic if she has any of the following symptoms during the first six weeks after treatment:
  - Fever (with or without chills)
  - Severe lower abdominal pain
  - Foul-smelling vaginal discharge
  - Unusual bleeding (heavier than a menstrual cycle or with clots)
- Document the results of the VIA screening in the client's health passport.
- Provide the client with instructions for a follow-up visit; schedule a post-procedure check-up at six weeks.
- Ask the client to return for a follow-up screening in 12 months.
- Thank the client.

Step 5. Document the VIA and treatment procedures:

- Carefully document the result of the VIA screening in the cervical cancer screening register, and the procedure in the theatre register.
- Label the CKC specimen appropriately and fill out the laboratory requisition form.

Step 6. Infection prevention measures:

- Dispose of contaminated swabs, gauze, and other waste material in the designated containers.
- Immerse the speculum and other instruments in a bucket full of soapy water.
- Avoid immersing the instruments in a 0.5% chlorine solution unless you can be sure to remember to remove them after 10 min of decontamination. Specula can quickly become damaged if left in chlorine for too long.
- Otherwise, at the end of clinic hours, immerse all specula and instruments in 0.5% chlorine solution for 10 minutes, and then clean with detergent and water.
- The cleaned instruments may be re-used after high-level disinfection by immersing them in boiling water for 20 minutes, or by sterilising them using an autoclave.
- Clean and disinfect the ball electrodes.

Managing Complications of CKC

Table 4-9-3 below provides guidance to managing commonly encountered complications of CKC.

Table 4-9-3. Managing possible complications of CKC

Complication	Treatment
Bleeding during the procedure: can be diffuse or arterial	• For diffuse bleeding: use a combination of pressure and coagulation with ball electrode. • For arterial bleeding: place ball electrode in firm contact with the source and apply coagulation current.
Post-procedure bleeding (this happens in less than 2% of cases)	• Remove blood clot, clean with 5% acetic acid, identify bleeding area, and anaesthetise with lidocaine and epinephrine. • If bleeding is not heavy, and no arterial bleeding is present, apply Monsel's paste. • If bleeding is heavy, coagulate using either a 5 mm ball electrode or a macroneedle electrode and coagulation current.
Post-procedure infection: pus-like discharge, persistent cramping pain, fever	Treat with antibiotics as follows: • Gentamicin 240 mg IM stat, plus • Doxycycline 100 mg orally, twice daily for 7 days, plus • Metronidazole 400 mg orally, three times a day for 7 days.

Post-CKC Follow-up Visit (at six weeks post-procedure)

- Get a post-procedure history from the client, focusing on any complications:
  Did the client experience foul-smelling vaginal discharge, persistent fever, persistent bleeding, and/or cramping pains?
- Review the histopathology results; advise the client on the recommended follow-up steps.
- Perform a speculum examination to check the healing progress of the biopsied part of the cervix.
- Remind the client to return for repeat cervical screening in 12 months.

Chapter 5. Tertiary Cervical Cancer Prevention: Diagnosis and Treatment of Invasive Cervical Cancer

Key Points

- Early-stage cervical cancer is curable with effective treatment.
- Health care providers should be able to recognise symptoms and signs of cervical cancer.
- Definitive diagnosis of cervical cancer requires a tissue biopsy and histopathological confirmation.
- Cervical cancer requires a multidisciplinary approach; cases should be discussed thoroughly by a multidisciplinary team.
- Treatment options for cervical cancer include surgery, radiotherapy, and chemotherapy.
- Clients should be counselled about the potential side effects of treatment, which include infertility, lymphoedema, pain during intercourse, bowel and urinary bladder changes, and premature menopause.
- Clients who have undergone treatment should be counselled about the need for long-term follow-up.
- Providers at tertiary hospitals should discharge clients who have been diagnosed with cervical cancer, and provide them with a proper management plan that can be easily referred to by other providers who might provide care to the client.
- An effective referral system should be available for clients who have been diagnosed with cervical cancer.
- Cervical cancer is fatal if left untreated.
- Palliative care is an essential component of cervical cancer control; it is best provided through a multidisciplinary team involving health professionals, HSAs, palliative care workers, and family members.
- Palliative care uses a combination of medical and non-medical methods.
- The quality of palliative care requires adequate training, communication, and supervision of all players involved.

5.1 Presentation and Diagnosis of Cervical Cancer

Cervical cancer is sometimes diagnosed in asymptomatic clients during cervical cancer screening. However, it is more often diagnosed in clients presenting with symptoms; these symptoms vary depending on the location and extent of disease (Table 5-1). Symptoms are more common with advanced disease.

Table 5-1. Symptoms of cervical cancer[1]

Early	• Abnormal vaginal discharge (usually foul-smelling) • Irregular vaginal bleeding (in women of reproductive age) • Post-coital bleeding or spotting (in women of any age) • Post-menopausal bleeding or spotting
Advanced	• Frequent and urgent urination • Backache • Pelvic pain • Weight loss • Leakage of urine or faeces through vagina • Decreased urine output • Swelling of lower limbs • Breathlessness (due to anaemia, or, more rarely, lung metastasis or effusion)

A biopsy is required to establish a diagnosis of cervical cancer. It is important that any client who presents with symptoms suggestive of cervical cancer be thoroughly examined, with the assessment including a speculum examination. When a cervical lesion is visible with the naked eye during a speculum examination, a biopsy should be collected and sent for histo-pathological diagnosis. Cervical punch biopsies taken from the edges of the lesion are recommended. This can be performed by trained providers, including nurses, clinical officers, and medical officers. Cervical cancer can also be diagnosed following a colposcopically directed cervical biopsy.

There are several different types of cervical cancer. Squamous cell carcinoma is the most common, accounting for more than 90% of cervical cancer cases. Adenocarcinomas make up approximately 10% of cases. Less common is clear cell (mesonephric) carcinoma, which occurs in just under 1% of cases. Unusual histological variants include neuroendocrine carcinoma and adenosquamous carcinoma.[2]

5.2 Cervical Cancer Staging

Once cervical cancer has been confirmed by histology, it is essential to understand the extent of the disease at the time of the diagnosis. This helps the health care provider in both selecting and planning the best treatment option available for the client

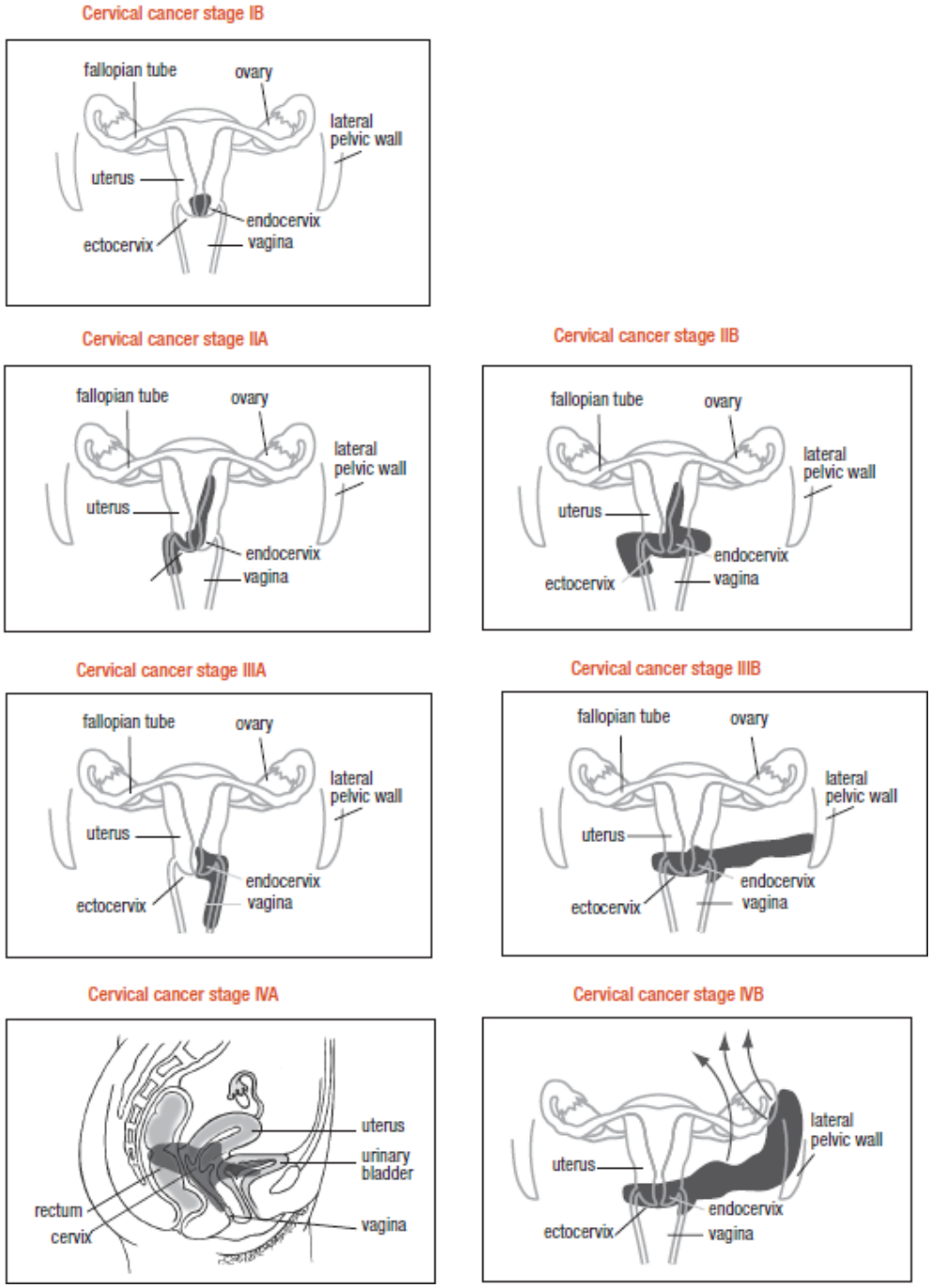
Cervical cancer is a clinically staged disease. Clinical staging is based on clinical evaluation, including bimanual vaginal and rectal examination, imaging studies, and specific procedures. The most commonly used staging system is the one established by the International Federation of Gynecology and Obstetrics (FIGO) (updated 2018) (Table 5-2 and Figure 5-1).[3]

Table 5-2. FIGO staging of cancer of the cervix uteri (2018)[4]

Stage	Description
I	The carcinoma is strictly confined to the cervix (extension to the uterine corpus should be disregarded)
IA	Invasive carcinoma that can be diagnosed only by microscopy, with maximum depth of invasion <5 mm[a]
IA1	Measured stromal invasion <3 mm in depth
IA2	Measured stromal invasion ≥3 mm and <5 mm in depth
IB	Invasive carcinoma with measured deepest invasion ≥5 mm (greater than Stage IA), lesion limited to the cervix uteri[b]
IB1	Invasive carcinoma ≥5 mm depth of stromal invasion, and <2 cm in greatest dimension
IB2	Invasive carcinoma ≥2 cm and <4 cm in greatest dimension
IB3	Invasive carcinoma ≥4 cm in greatest dimension
II	The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
IIA	Involvement limited to the upper two-thirds of the vagina without parametrial involvement
IIA1	Invasive carcinoma <4 cm in greatest dimension
IIA2	Invasive carcinoma ≥4 cm in greatest dimension
IIB	With parametrial involvement but not up to the pelvic wall
III	The carcinoma involves the lower third of the vagina and/or extends to the pelvic wall and/or causes hydronephrosis or nonfunctioning kidney and/or involves pelvic and/or para-aortic lymph nodes[c]
IIIA	The carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
IIIB	Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney (unless known to be due to another cause)
IIIC	Involvement of pelvic and/or para-aortic lymph nodes, irrespective of tumor size and extent (with r and p notations)[c]
IIIC1	Pelvic lymph node metastasis only
IIIC2	Para-aortic lymph node metastasis
IV	The carcinoma has extended beyond the true pelvis or has involved (biopsy proven) the mucosa of the bladder or rectum. (A bullous edema, as such, does not permit a case to be allotted to Stage IV)
IVA	Spread to adjacent pelvic organs
IVB	Spread to distant organs

When in doubt, the lower staging should be assigned.
[a]Imaging and pathology can be used, where available, to supplement clinical findings with respect to tumor size and extent, in all stages.
[b]The involvement of vascular/lymphatic spaces does not change the staging. The lateral extent of the lesion is no longer considered.
[c]Adding notation of r (imaging) and p (pathology) to indicate the findings that are used to allocate the case to Stage IIIC. Example: If imaging indicates pelvic lymph node metastasis, the stage allocation would be Stage IIIC1r, and if confirmed by pathologic findings, it would be Stage IIIC1p. The type of imaging modality or pathology technique used should always be documented.

Figure 5-1. FIGO staging of cancer of the cervix uteri



Note that cervical cancer stage IIIC is guided by imaging or pathology, where available, to supplement clinical findings with respect to tumour size and extent in all stages.[5]

In resource-limited countries such as Malawi, vaginal and rectal examinations, ultrasound scans, and, in some cases, cystoscopy (which examines the urinary tract) and proctoscopy (which examines the digestive tract) may be the only tools available for staging (Table 5-3). These tests are mostly available at tertiary facilities. Using these limited tests, gynaecologists (with the support of other specialised trained providers, such as urologists and surgeons) can determine:

- The location of the cancer.
- Whether the tumour growth is outward (exophytic) or inward (endophytic) relative to the cervical tissue.
- The size of the cancer.
- Whether or not the cancer has spread to the parametrium, uterus, ligaments holding the uterus in place, or the pelvic side walls.
- Whether there is any urinary bladder or rectal involvement.

Clinical staging sometimes requires examination under anaesthesia, particularly when the examination would be uncomfortable and/or painful for the client. In these cases, proctoscopy and cystoscopy are also recommended, especially in clients with advanced disease (FIGO stage IIB or greater), or when rectal and/or urinary symptoms are present. Suspected bladder or rectal involvement should be confirmed by biopsy and histological evidence of tumour involvement. Further recommended laboratory tests are shown in Table 5-3.[6]

Table 5-3. Investigations for staging and treatment for cervical cancer

Mandatory for Staging	Supplementary for Staging	Additional Tests
• Speculum, vaginal and rectal examination • Abdominal ultrasound for hydronephrosis or intravenous pyelogram • Vaginal ultrasound	• Cystoscopy • Proctoscopy • Cone biopsy • ECC or smear • Chest X-ray • Skeletal X-ray or bone scan (if the client reports bone pain)	• Complete blood count • Blood chemistries, including creatinine • Liver function tests • Pregnancy test (when the client is of childbearing age) • HIV testing • Syphilis • Computerised tomography (CT) scan or magnetic resonance imaging (MRI) of the abdomen and pelvis (to help plan radiotherapy) where available

5.3. The Principles of Treatment

An efficient system of referral, follow-up, and treatment of clients diagnosed with cervical cancer is a crucial component of an effective cervical cancer prevention programme. Treatment options should be based upon the national guidelines, while taking into consideration the availability of resources and provider expertise.

The best treatment outcomes are realised in facilities with multidisciplinary teams composed of gynaecologists, clinical oncologists, and palliative care providers. It is essential that the treatment plan chosen together with the client takes into consideration the extent of the disease and the overall health and preferences of the client. The ultimate goal of treatment is curing the disease, or at least reducing the extent of the disease while addressing the client's symptoms and suffering, and minimising side effects as much as possible. Special

considerations should also be taken in managing the treatment of clients who wish to have children, or who are living with HIV.

Cervical cancer care requires long-term follow-up. In order to realise the best outcomes for a chosen treatment, it is essential that the client understand the treatment plan and have the necessary support structures in place. When discussing treatment plans, providers should make sure to use appropriate language and avoid unnecessary medical terms that may be confusing or difficult for the patient to understand. In addition to these considerations, the following factors need to be considered before starting treatment:

- The client's personal and family situation, including ability to travel to the health care facility where treatment will be provided.
- Out-of-pocket costs for the client and her family.
- The effectiveness of treatment, and expected side effects.
- The consequences of not receiving treatment.
- Linkages to social support services.

5.4 Treatment Options

The treatment options for cervical cancer are surgery, radiotherapy, and chemotherapy; in some cases, a combination of these treatments may be used. The option chosen is guided by the stage of the disease, the overall health of the client, the availability of expertise and facilities (including radiotherapy and chemotherapy), and the client's own preferences. Client co-morbidities and social factors may also impact treatment decisions and ultimate outcomes. In Malawi, treatment in most cases would take place at a tertiary facility.

Primary therapy, also called primary treatment or first line therapy, is the first treatment offered for invasive cancer; it usually has the goal of curing the disease. The primary therapy may be surgery or radiotherapy, either with or without chemotherapy. **Adjunctive (or adjunct) therapy** is treatment used together with the primary therapy to assist the primary therapy. **Secondary therapy** refers to treatment given after another (usually primary) treatment has been used, as in the case with recurrent invasive cancer. To facilitate decision making, clients diagnosed with invasive cancer may be classified into two groups, based on staging (Tables 5-4 and 5-5).[7–11]

Table 5-4. FIGO staging of early and advanced-stage cervical cancers

Group	FIGO Stages
Early stage	IA1, IA2, IB1, IIA1
Advanced stage	IB2, 1B3, IIA2, IIB, IIIA, IIIB, IIIC, IVA, IVB

Table 5-5. Guide to cervical cancer treatment options

Disease Stage(s)	Fit for Surgery		Treatment Option	Who Can Perform the Procedure?	Comment
	Yes	No			
1A1	x		Cone knife conisation	Clinical or medical officer trained in the procedure, gynaecologist	Diagnosis and stage usually based on specimen from CKC, LLETZ, or hysterectomy
	x		Simple hysterectomy	Trained clinical or medical officer, gynaecologist	
		x	Intracavitary brachytherapy	Clinical oncologist	
1A2	x		Simple or radical trachelectomy and pelvic lymph node dissection (PLND) (if client wishes to remain fertile)	Gynaecological oncologist, gynaecologist trained in the procedure	Diagnosis and stage usually based on specimen from CKC, LLETZ, or hysterectomy
	x		Modified (class II) radical hysterectomy and PLND with adjuvant radiotherapy	Gynaecological oncologist, gynaecologist trained in the procedure	
1B1 IIA1	x		Modified (class II) radical hysterectomy and PLND with or without 'tailored' adjuvant radiotherapy	Gynaecological oncologist, gynaecologist trained in the procedure	
		x	Standard external beam radiotherapy (EBRT) and brachytherapy (BT) with or without concomitant chemotherapy	Clinical oncologist	
1B2 IIA2			Standard EBRT and BT with or without concomitant chemotherapy	Clinical oncologist	
IIB–IVA			Standard EBRT and BT with or without concomitant chemotherapy	Clinical oncologist	
IVB			Palliative care	Palliative nurse, other providers trained in palliative care	

5.4.1 Surgery

Surgery to remove tissue from the cancer-affected area and its surroundings is a treatment option used mainly for early-stage cervical cancers. Depending on the extent of the cancer, this could be cervical conisation, simple hysterectomy, or radical hysterectomy.[12–16] Although surgery is usually a primary treatment, it can be offered as secondary therapy after another treatment has been used.

5.4.1.1 Surgery as a Primary Therapy

Cold Knife Conisation (CKC)

CKC is the surgical removal of a cone-shaped piece of tissue from the cervix, consisting of the area identified as pre-cancerous and portions of the ectocervix and endocervix. Microinvasive cervical cancers are cancerous areas contained within the cervical epithelium; these can be treated with CKC, particularly if the client wishes to remain fertile. The diagnosis of microinvasive disease is usually made through microscopic examination of CKC specimens (including LLETZ specimens done for their specific indications) (see Appendices 4.8 and 4.9). CKC can be performed by gynaecologists, or by other providers with competency to perform the procedure, such as clinical and medical officers.

Simple Hysterectomy

Simple hysterectomy is the surgical removal of the entire uterus, including the cervix (Figure 5-2). This is done either through an incision in the lower abdomen or through the vagina. When the expertise and equipment are available, the surgery can be performed laparoscopically.

As with CKC, a simple hysterectomy is considered the therapy of choice when histopathological examination of a specimen reveals microinvasive cancer. In cases of microinvasive cancer of the cervix, the ovaries are not routinely removed unless they are abnormal, or the client is post-menopausal.

Simple hysterectomy is an ideal treatment for early-stage microinvasive cancers in post-menopausal women, and in younger women who do not intend to have children. The procedure can be performed by gynaecologists, or by clinical and medical doctors with competency in the procedure.

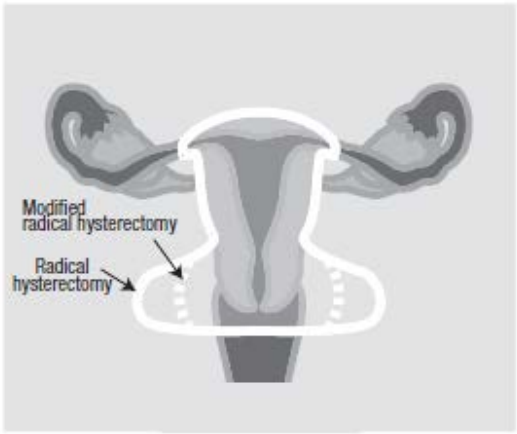
Figure 5-2. Simple hysterectomy

Radical Hysterectomy

Radical hysterectomy is the surgical removal of the entire uterus, the cervix, tissues from the sides of the uterus, a portion of the upper vagina, and lymph nodes in the pelvis (Figure 5-3); it is indicated for early-stage cervical cancer. The ovaries are not routinely removed during the procedure unless they appear abnormal or the client is post-menopausal.

Because radical hysterectomy frequently requires highly specialised skills, it is often done by gynaecological oncologists, and general gynaecologists with interest in gynaecological oncology who have received competency-based training in performing the procedure.[17–20]

Figure 5-3. Radical versus modified radical hysterectomy



5.4.1.2 Surgery as a Secondary Therapy

Salvage Surgery

Surgical treatment after primary treatment, referred to as **salvage surgery**, can still bring about a cure in a client diagnosed with cervical cancer. This secondary surgery consists of radical hysterectomy to reduce the chances of recurrence of the cancer; it is often offered in the following scenarios:

- The client underwent surgery, but microscopic examination of the surgical specimen shows the margin of normal tissue around the cancer is too thin.
- The client underwent radiotherapy and/or chemotherapy, but early recurrence or incomplete destruction of the cancer are observed on follow-up.

Salvage surgery is so complex, even in the hands of experienced gynaecological oncologists, that it is seldom offered in tertiary hospitals.

Palliative Surgery

Palliative surgery is sometimes performed in advanced cases to relieve bowel obstructions, or to treat fistulae that result from radiation or extension of the primary disease. As with salvage surgery, palliative surgery is often not offered because the chances of complication are high and treatment failure is common.

5.4.1.3 Possible Side Effects and Complications of Cervical Cancer Surgery

Cervical cancer surgery is not without side effects or complications. The risk of complications increases with the extent of the surgery offered: for example, radical hysterectomy is associated with greater risk of complications than CKC and simple hysterectomy.

It is important to discuss the possible side effects and complications of surgery with the client prior to the procedure. These include:

- Infection at the surgical site.
- Bleeding, often during surgery.
- Injury to structures around the surgical site, such as the bowel, bladder, ureters, and nerves.
- Deep vein thrombosis (blood clots in deep veins of the legs), often seen in clients kept in bed for days after surgery without being given anticoagulants to prevent clotting.
- Increased risk of pre-term labour and/or mis-carriage, particularly in clients who undergo CKC.
- Bladder and bowel dysfunction, often seen after radical hysterectomy.

As part of the consent process for hysterectomy, it is appropriate to discuss with the client that she will become infertile as a result of the surgery.

5.4.2 Radiotherapy

Radiation therapy, or **radiotherapy**, uses sophisticated equipment to produce invisible rays—similar to rays of light but with higher energy; these rays are aimed at the cancer and surrounding areas. Radiation destroys cancer cells, resulting in full or partial elimination of the cancer. Although radiation is not painful, it may cause significant side effects. Recent developments involving the use of computer technology and imaging (e.g., CT scanning, MRI) in planning and delivery of radiotherapy have dramatically transformed radiotherapy practice, resulting in improved clinical outcomes and reduced side effects.

Radiotherapy can be offered with or without chemotherapy to destroy cancer cells. It is often indicated for early-stage cervical cancers in which the client is determined to be unfit for surgery, or for advanced-stage cervical cancers. Radiation can be used as a primary therapy, or as adjuvant therapy to prevent locoregional recurrence in clients who have undergone surgery. However, dual treatment (i.e., radiotherapy with surgery) is discouraged, as it is associated with greater risk of side effects and complications without improving survival.

Radiation can also be used as secondary therapy for recurrent locoregional pelvic disease after primary surgical therapy, and as palliative therapy to alleviate distressing symptoms (such as persistent vaginal bleeding that causes anaemia, or persistent abnormal vaginal discharge) in clients with advanced disease.

Radiation can be administered as intracavitary radiation therapy (ICRT), or brachytherapy, as external beam radiation therapy (EBRT), or as a combination of the two. Radiotherapy is usually administered by radiation oncologists (with support from physicists) and performed at national cancer centres in tertiary hospitals.

This treatment is not expected to be available in Malawi until mid-to-late 2019, when the national cancer centre at Kamuzu Central Hospital in Lilongwe opens.

5.4.2.1 Side Effects of Radiotherapy for Cervical Cancer

When using radiotherapy to treat cervical cancer, radiation is targeted at the lower abdomen, including the bladder, rectum, and regional bone marrow. Because these areas are directly exposed to radiation, they may be affected, resulting in such side effects as premature menopause, infertility, discomfort or pain during intercourse, and bladder and bowel changes (including the development of fistulae, though this is rare).

5.4.3. Chemotherapy

Chemotherapy uses toxic drugs to treat cancer. A combination of chemotherapeutic drugs is given intravenously to kill rapidly diving cells (a hallmark of cancer cells). As a primary therapy, chemotherapy alone is not effective in treating cervical cancer; rather it is used in combination with radiation therapy and, less often, with surgery. Chemotherapy can be used to reduce tumour size for a tailored radical hysterectomy and pelvic lymph node dissection (e.g., for stage 1B2). In some cases, after careful consideration of benefits versus side effects, chemotherapy can also be used as palliative care to relieve symptoms in clients who have metastatic disease of the liver, lung, or bone.

5.4.3.1 Side Effects of Chemotherapy

Chemotherapeutic drugs are administered intravenously, and circulate in the blood; as a result, the side effects of chemotherapy are widespread. Since chemotherapy kills rapidly dividing cells, it kills not only cancer cells, but also rapidly dividing cells everywhere else in the body: the bone marrow, the digestive system, the urinary system, the skin, and any other organs lined with epithelial cells. Thus anaemia, low blood cell counts and concomitant

infections, bleeding due to low platelet counts, nausea, diarrhoea, and allergic reactions to the drugs are all side effects associated with chemotherapy. However, these side effects are usually transient.

5.4.4. Supportive Care

Clients with cervical cancer need to be adequately treated for both their symptoms and any complications that may arise during treatment. Clients experiencing pain should be treated with painkillers while minimising side effects. The WHO three-step ladder of cancer pain relief provides guidance on how to manage cancer pain.[21,22] Depending on the severity of pain, simple analgesics, such as non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen), may be used. In most cases of advanced cancer, opioid analgesics (such as oral morphine) may be indicated (see Appendix 5.3).

Clients with cervical cancer may develop anaemia as a result persistent vaginal bleeding; this may diminish the effectiveness of radiotherapy, and generally impair the client's overall health (as measured by ECOG Performance Status score). Anaemia can be minimised through healthy diet and the use of iron and folate supplements. A healthy diet may also reduce the risk of chronic malnutrition, which is common in cancer patients. Linkage to social support systems is also beneficial to cancer patients. Although formal support systems are not well established in Malawi, effort should be made to link cancer patients to social services, where available.

Clients with cervical cancer also suffer from debilitating vaginal discharge; often this discharge has a foul odour, compromising the client's dignity. Gentle vaginal douching and use of antibiotics such as metronidazole can help reduce or eliminate the discharge.

Finally, clients undergoing chemotherapy and/or radiotherapy require regular monitoring of blood counts, and liver and renal function tests, to identify and/or prevent infection or other treatment-related co-morbidities. Most of the facilities capable of such monitoring are located at tertiary hospitals. It is thus essential to ensure that definitive cancer care is available at tertiary hospitals, where appropriate facilities for both treatment and monitoring are available.

5.5 Managing Cervical Cancer in Special Situations

5.5.1 Managing Cervical Cancer During Pregnancy

Cervical cancer can sometimes be suspected and/or diagnosed in clients who are pregnant. Timely evaluation for cervical cancer should be made to facilitate the appropriate counselling and treatment during pregnancy.

Evaluation of cervical cancer does not change because the client is pregnant. Although some procedures, such as cervical biopsy, may carry an increased risk of bleeding, they do not need to be postponed because of pregnancy. All clients suspected for cervical cancer should have a cervical biopsy taken for histological confirmation; cervical biopsy is not contraindicated in pregnancy.

Once confirmed, the treatment plan needs to take into consideration the following:

- Stage of the disease.
- Treatment options available and accessible to the client.
- Whether or not the client (and/or partner) wishes to maintain the pregnancy.
- Laws governing abortion, as set forth by the Malawi Penal Code (Chapter 7:01, Sections 149, 151, and 231).[23]
- The general health of the client.

If the client wishes to maintain the pregnancy, most treatment will be postponed until after delivery. The safest mode of delivery for clients who wish to maintain their pregnancy is caesarean section. Clients who wish to continue their pregnancy must be advised in advance to ensure that their delivery is planned, and that if they do go into labour, they need to seek medical attention as soon as possible. Labour in pregnant women with cervical cancer can cause catastrophic haemorrhage resulting in death; therefore, it should be avoided.

As provided for by Malawi's laws on abortion, and after consideration of gestational age, if the client does not wish to maintain the pregnancy, termination may be considered. Counselling a pregnant client with cervical cancer requires special skill and sensitivity. It is best administered through a multidisciplinary team of providers, and should be as inclusive as possible, with the client consenting as to who else should be involved (e.g., partners, family members). Pregnant women who have been diagnosed with cervical cancer should be advised that cervical cancer does not cross the placental barrier.

5.5.2. Managing Cervical Cancer in Clients Living with HIV

Managing cervical cancer in clients living with HIV is complex. To ensure a holistic approach to care, it is important to involve a multidisciplinary team at a tertiary hospital. The evaluation and treatment of clients living with HIV who have been diagnosed with cervical cancer is no different than that for clients who are HIV negative. However, both radiotherapy and chemotherapy are immunosuppressive therapies, meaning they can worsen the client's overall health in the presence of other co-morbidities, such as tuberculosis. Surgery for cervical cancer may also be associated with serious post-operative complications in clients with immunosuppression, such as infection.

It is therefore recommended that clients living with HIV who have been diagnosed with cervical cancer be evaluated for overall health; stage of the disease; existence of other chronic illnesses, whether or not they are on ART; and the level of viral suppression (if they are on ART). For those clients not on ART, it may be prudent to start them on ART and allow time for the immune system to recover before implementing definitive cervical cancer treatment.

5.6 Client Follow-Up

Clients who have undergone cervical cancer treatment need a follow-up plan for continued care and assessment for persistence or recurrence of the disease. It is recommended that

clients be seen every 3–4 months for the first two years after completing treatment, or after the immediate post-operative follow-up appointment (if surgery was performed), and in the absence of symptoms. It is during this period that most cases of with persistent or recurrent cancer will present. It is also during this period that side effects from treatment are the most acute; with timely identification, their effects can be mitigated.

Follow-up reviews include the following evaluations:

- Medical history of any symptoms experienced by the client since the last review.
- Assessment of the client's social, psychological/emotional, and economic situation, and how these affect the course of her disease (or vice versa).
- Clinical examination (including a speculum exam) to assess the vaginal vault, and digital vaginal and rectal examination to assess for recurrence of disease in the pelvis.
- Blood tests guided by the elicited symptoms and signs.
- Pap smears (or alternatively, a thorough examination and/or colposcopy, if available) can be done annually for the next 2–3 years (in clients who have had surgery).

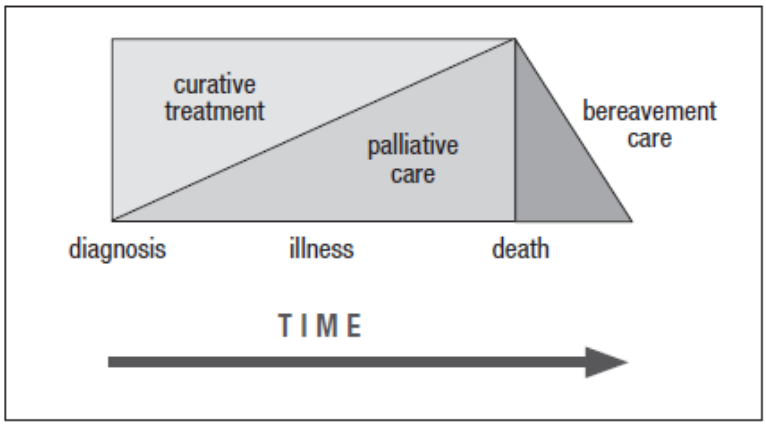
In most cases, treatment of persistent or recurrent cancer depends on the primary therapy. For example, clients who have undergone surgery may be treated with radiotherapy, chemotherapy, or both. However, if radiotherapy was used as the primary therapy, care should be taken when considering repeating the treatment.

When it becomes clear during follow-up that a treatment is not helping the client, the decision to stop the cancer-focussed treatment needs to be made. Once this decision has been made, treatment should then focus on controlling pain and alleviating any symptoms the client may be experiencing. With the proper treatment plan, and communication with the client's primary health care facility, the client can continue required care at a facility closer to home.

5.7 Palliative Care

Palliative care is an essential component of cervical cancer care. It aims at improving the quality of life of both clients and their families in the event of a life-threatening cervical cancer diagnosis. Palliative care is critical for clients with advanced cervical cancer; however, it should not be restricted to only those clients. It also includes interventions that may be applied throughout the course of the disease (Figure 5-4).[24,25]

Figure 5-4. The role of palliative care throughout the course of the disease



Palliative care uses a combination of medical and non-medical methods to relieve distressing symptoms, such as pain or foul-smelling vaginal discharge, and provides for the emotional, social, and spiritual needs of the client. It involves the full spectrum of health professionals, from doctors and nurses to HSAs and community volunteers. Palliative care can be provided in the client's home, at community-based institutions, and in health care facilities. In most cases, it is best when care is provided closer to home.

Palliative care comprises the following essential elements:

- Prevention and management of symptoms (including pain relief)
- Psychosocial and spiritual support
- Nutritional support
- Affirmation of life, with death regarded as a normal process

The quality of palliative care depends on adequate training, communication, and supervision of all players involved. It is critical to involve and train family members and community workers in offering support to the client. Such support uses a team approach, and includes, but is not limited to, daily activities (such as bathing) and helping the client live as actively as possible until death. In cases where home-based care is not feasible, admission to a health care facility may be necessary.

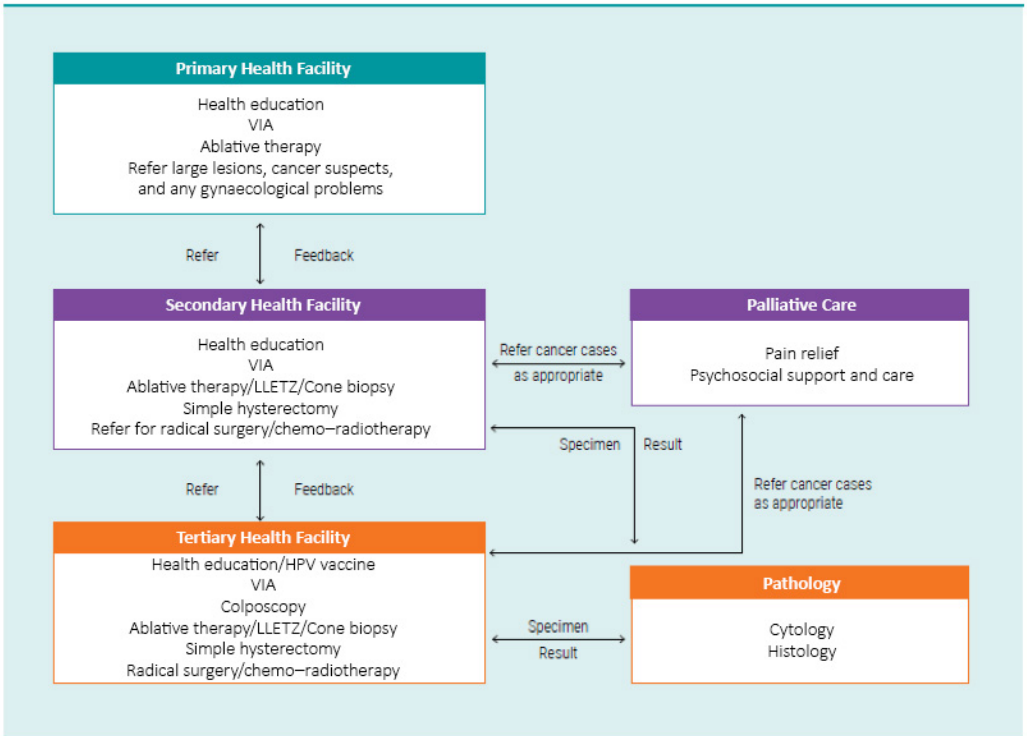
It is also essential to prepare the family for the client's death, while at the same time being sensitive to the family's culture, beliefs, and practices. Encouraging communication within the family can make death less stressful and ease bereavement.

(For more about symptom relief, see Section 5.4.4 above and Appendix 5.3.)

5.8 Referral System

A cervical cancer control programme must have an effective referral system. Malawi's Cervical Cancer Control Program has such a referral system in place (Figure 5-5).[26]

Figure 5-5. Overview of the CECAP referral system



Essential to an effective referral system are close relationships and good communication between all levels of the health care system; this ensures that clients receive the best possible care closest to home. A good referral system can help ensure the following:

- Clients receive the best possible affordable care at the appropriate level of the system (e.g., ablative therapy conducted at the same primary health care screening site).
- Health facilities are used optimally and cost-effectively.
- Clients who need specialist services can access them in a timely manner.
- Primary health services are effectively used, and their reputation enhanced.

5.8.1. Components of an Effective Referral System

5.8.1.1. Health Systems

Access to Facilities and Services

For a referral system to be effective, all levels of the health system must be functioning properly, and able to offer the services assigned to them. Each level has clear roles and responsibilities; their limitations need to be recognised and addressed where feasible. A properly functioning referral system provides solutions for some of the limitations that might exist at lower levels of the health system. For example, it would enable access to the facilities and expertise needed to provide tertiary health care services to clients diagnosed with cervical cancer.

Performance Expectations

An effective referral system ensures that all health care providers work within it, thereby making the appropriate referrals. Good communication among health care providers will ensure that all clients receive necessary care. Making protocols available to all health care providers will also minimise unnecessary referrals.

Support for facilities and outreach services at lower levels of the health system by experienced tertiary and district hospital staff also helps to build capacity and improve access to better-quality care. Monitoring and evaluation of how well facilities within the referral system are meeting performance expectations will help to improve and strengthen the system. Use of referral statistics can facilitate this process.

5.8.1.2 Initiating Facilities

The health facility that starts the referral process is called the **initiating facility**. The health care provider at the initiating facility must be familiar with the designated referral protocols; every effort should be made to ensure that clients receive optimal care as close to home as possible. It is important to note that deciding to refer a client to another facility does not mean the provider is inadequate or bad at their job.

5.8.1.3. Referral Practicalities

When the decision to refer has been made, it is important that providers give the client (and family members) the relevant information, with empathy, using language that the client can easily understand. Referral can cause anxiety for the client (and family members); it is therefore important to address any concerns or fears the client may have. At a minimum, the discussion should include:

- Reasons for referral, and why it is important.
- Risks associated with non-adherence to referral.
- How to get to the receiving facility (location and transport).
- The type of care the client should expect, and the follow-up that may be required.

Once discussion with the client (and family members) has taken place, the provider should appropriately document the findings at evaluation and the reasons for referral. In some cases, advance communication with the receiving facility may be helpful. Standardised referral forms are available at government facilities; these should be used at all times. The CECAP VIA stamp is also used for documenting referrals from VIA clinics.

The provider should also ensure that the referral is properly documented in the referral register (Appendix 5.1). A referral register should be available at all health facilities; this can help with regular M&E of referral cases.

Every effort should be made to collect as much information from the client to facilitate follow-up of referral outcomes. It is not uncommon for clients to be referred to a tertiary hospital but then fail to show up because of personal difficulties, such as lack of transport. The initiating

facility should put in place mechanisms to ensure that they can trace clients who fail to show up at the facility to which they have been referred.

To minimise loss to follow-up, the initiating facility can:

- Ensure that transport is provided to the client.
- Collect personal information from the client—such as where the client lives, the name of the village headman, the name of the HSA who serves her area, or the name of a family member who is well-known in the village. This information can then be passed on to HSAs or other CHWs to help them track down the client and follow up on referral outcomes, particularly when the client does not return to the initiating facility with information about the results of her referral.

5.8.1.4 Receiving Facilities

The **receiving facility** accepts cases referred from the initiating facility. Using the referral letter, providers at the receiving facility begin a thorough assessment of the client and institute the appropriate treatment plan.

Providers at the receiving facility should avoid using inappropriate language, even in cases of inappropriate referral, or saying anything that might discredit the initiating facility or cause the client to lose trust in the facility that is usually closest to home.

The receiving facility should make sure to provide feedback to the initiating facility for each case referred to them. This feedback can either be provided through the client, or sent under separate cover to the initiating facility. This feedback helps not only with follow-up, but also with continuing education of staff at the initiating facility. The referral meetings held between tertiary and district hospital staff can be used to provide feedback on both the appropriateness of referrals and the care given to the clients. The receiving facility should also ensure that all referrals (in and out) are documented in a referral register (Appendix 5.2).

5.8.1.5 Supervision and Capacity Building

It is important to monitor all referrals made to and from facilities on a regular basis. Using summaries from the referral registers, health facility leadership should discuss these cases at their referral meetings.

On a monthly basis, facility leaders should review referred cases and perform the following tasks:

- Identify cases that should have been treated at the facility instead of being referred elsewhere.
- Identify cases that should have been referred to other facilities but were handled by the facility itself.
- Review feedback received to determine whether the information was adequate, and whether or not it was acted upon.

- Follow up on cases that were referred to other facilities, but for which feedback has not yet been received. This may require contacting clients at home. HSAs can be used for this activity, as they will be more familiar with their catchment areas.
- Identify any issues regarding the timing, promptness, and completeness of information sent and received.

The information generated from this analysis can help staff to identify any issues in the referral system, and take steps to resolve them. It can also help to identify training needs and areas that may need strengthening, whether in the referral system, its procedures, or both.

5.8.1.6 Continuous Quality Improvement

The referral system must be adaptable. Changes in the level of care provided at a health facility can come from the presence of more expertise, support from higher levels of the system (through supervisory visits), and expansion or upgrading of the facility. It is therefore important to be open to making changes to the referral system and its protocols in response. Periodic analysis of the referral system beyond statistical patterns and trends is therefore vital.

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Chapter 6. Treatment of Sexually Transmitted Disease in the Context of Cervical Cancer Screening

Key Points

- Abnormal discharge from the cervix or vagina can obscure the acetowhite changes that would otherwise be detected through VIA screening.
- The provider should treat the client for abnormal discharge before performing the screening.
- Adhering to the procedures set forth in the national guidelines for treating STIs (see the following text and flow charts) will assist the VIA provider in treating clients who have abnormal discharge.
- Recommend the client return for VIA screening one month after treatment for abnormal discharge.
- Abnormal vaginal and cervical discharge can also be a symptom of cervical cancer.
- If the client's abnormal discharge symptoms do not resolve after treatment, or recur within three months, she should be examined with a speculum to view the cervix.

When a client presents for cervical cancer screening with VIA, abnormal discharge in the vagina or on the cervix may prevent the examination from being performed during that visit. If the cervix is inflamed, application of acetic acid or vinegar may cause the entire surface of the cervix to turn white, thereby obscuring any acetowhite changes that occur because pre-cancerous cells are present. In such cases, it is recommended that the client return for VIA screening after she has been treated for the abnormal vaginal discharge or cervicitis and her symptoms have resolved. **She should return for VIA screening one month after treatment**.

In 2017, MOHP published the *Malawi Guidelines for Syndromic Management of Sexually Transmitted Infections*.[1] The following is a brief review of some of the principles from that guide. By providing those performing cervical cancer screening with these summary items, we aim to help providers to manage vaginal and cervical inflammation and infections that interfere with VIA screening. This review does not replace training in management of STIs; rather, the goal is to consolidate STI management strategies.

6.1 Abnormal Vaginal Discharge

On the following page is a flow chart illustrating syndromic management of abnormal vaginal discharge.

Figure 6-1. Abnormal vaginal discharge management flow chart

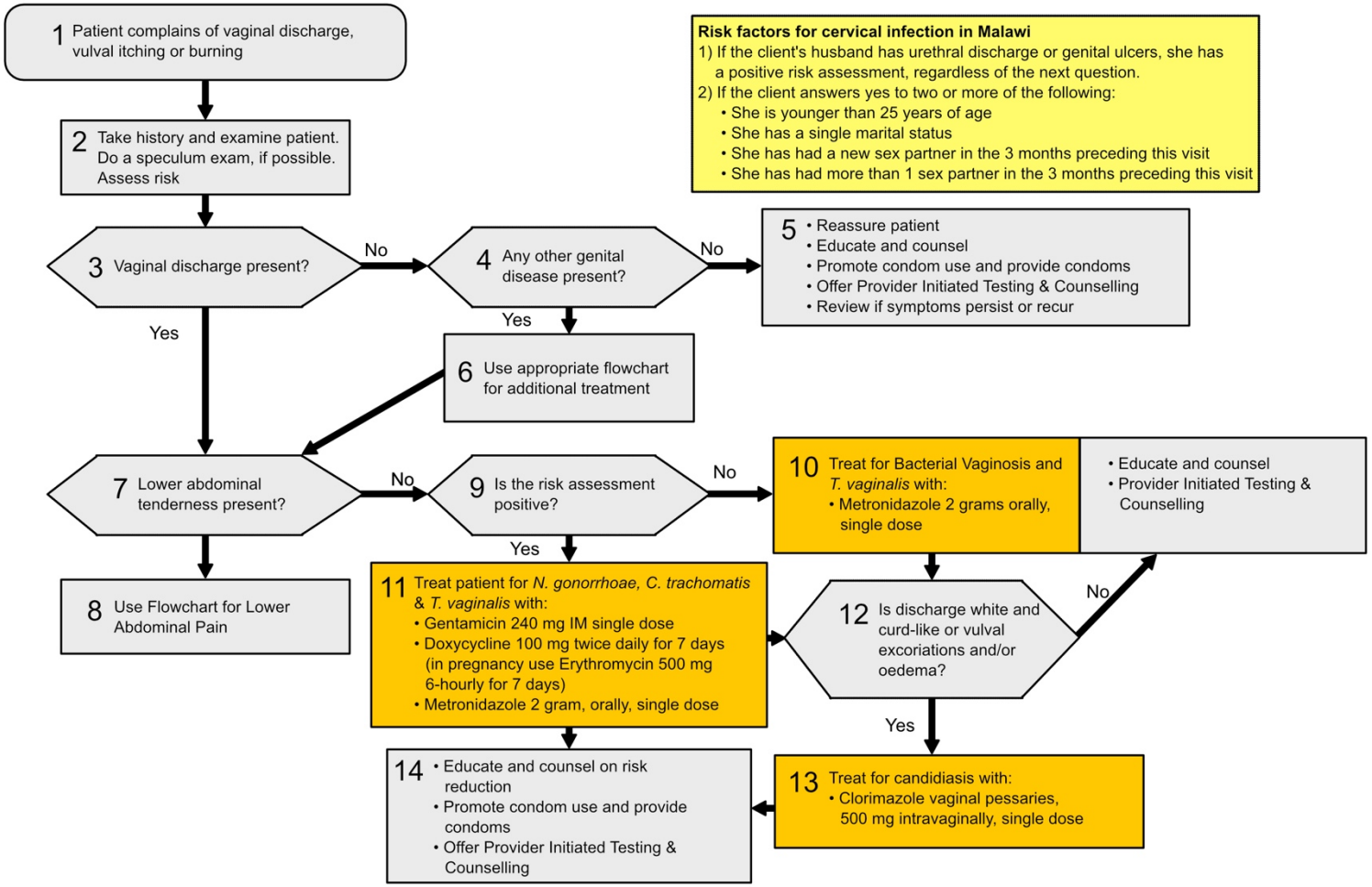

Table 6-1 below summarises the medications recommended for syndromic management of vaginal infection.

Table 6-1. Recommended treatments for vaginal infection

Infection Covered	Recommended Medication	Effective Substitutes (choose one)	Options During Pregnancy* (choose one)
Bacterial vaginosis	Metronidazole 2 g orally, as a single dose	• Metronidazole 400 mg or 500 mg orally, twice daily for 7 days • Clindamycin 300 mg orally, twice daily for 7 days	• Metronidazole 200 mg or 250 mg orally, 3 times a day for 7 days • Metronidazole gel 0.75%, one full applicator (5 g) intravaginally, twice daily for 7 days • Clindamycin 300 mg orally, twice daily for 7 days
Trichomonas vaginalis	Metronidazole 2 g orally, as a single dose (Note: Only one 2 g dose is required to cover both TV and BV)	• Metronidazole 400 mg or 500 mg orally, twice daily for 7 days • Tinidazole 2 g orally, as a single dose • Tinidazole 500 mg orally, once daily for 5 days	• Metronidazole 200 mg or 250 mg orally, 3 times a day for 7 days • Metronidazole gel 0.75%, one full applicator (5 g) intravaginally
Candida albicans (yeast infection)	Clotrimazole vaginal pessary, 500 mg, as a single intravaginal application	• Fluconazole 150 mg (or 200 mg) orally, as a single dose • Miconazole vaginal pessaries, 200 mg at night for 3 nights	• Miconazole 200 mg vaginal pessaries, once daily for 3 days • Clotrimazole vaginal pessary, as a single dose • Nystatin pessaries, 200 000 units at night for 7 nights

** Note: Metronidazole can be given during the first trimester, if necessary.*

6.2. Cervicitis

Clinical cervicitis is manifested by yellow cervical mucus coming from the cervical os. Other signs can be a friable cervix (a cervix that bleeds easily when touched with a cotton swab), in addition to the acetowhite appearance of the entire ectocervix when acetic acid is applied during the VIA procedure. Table 6-2 on the following page summarises Malawi treatment guidelines for cervicitis.

Table 6-2. Recommended treatments for cervical infection

Infection Covered	Recommended Medication	Effective Substitutes (choose one)	Options for Women Who Are Pregnant or Breast-Feeding (choose one)
Neisseria gonorrhoeae	Gentamicin 240 mg IM single dose	• Cefuroxime 1 g orally, as a single dose • Cefixime 400 mg orally, as a single dose • Ceftriaxone 250 mg IM single dose	• Ceftriaxone 250 mg IM single dose • Cefixime 400 mg orally, as a single dose

Infection Covered	Recommended Medication	Effective Substitutes (choose one)	Options for Women Who Are Pregnant or Breast-Feeding (choose one)
Chlamydia trachomatis	Doxycycline 100 mg orally, twice a day for 7 days	• Azithromycin 1 g orally, as a single dose • Erythromycin 500 mg orally, 4 times a day for 7 days	• Erythromycin 500 mg orally, 4 times a day for 7 days • Azithromycin 1 g orally, as a single dose

References

1. Malawi Ministry of Health and Population. Malawi guidelines for syndromic management of sexually transmitted infections. Lilongwe, Malawi: Ministry of Health and Population; 2017.

Chapter 7. Implementation Considerations

Key Points

- **Monitoring and evaluation** (M&E) is a process that helps improve performance and achieve results.
- Establishing a data M&E process is fundamental to successful implementation of a cervical cancer screening programme.
- M&E data must be collected and analysed at all levels of the health care system: on-site and at the district, regional, and national levels.
- Accurate on-site data is crucial, as is use and analysis of this data for understanding and improving the quality of the screening programme.
- Timely M&E maximises those processes/decisions/systems that are working, and identifies those that are not working so that adjustments can be made.
- Core indicators used for M&E of services provided under the comprehensive cervical cancer prevention and control programme include performance and impact indicators.
- A site readiness assessment ensures that all screening sites—whether existing or newly opened—meet and pass minimum requirements in order to provide the appropriate services.
- Integration of cervical cancer screening with HIV services and other sexual repro–ductive health services offers excellent opportunities to increase coverage in all programmes.

Improving access to cervical screening and treatment of pre-cancer of the cervix for all clients in the target population will reduce cervical cancer deaths in Malawi. As the MOHP expands cervical cancer screening, implementation considerations are relevant for several areas of focus. This chapter aims to offer guidance on several important implementation considerations that are essential to a successful national cervical cancer screening pro-gramme. These include the essential package of services, M&E, training, and the importance of integrating cervical cancer screening with other health services.

7.1 Essential Package of Services

Comprehensive cervical cancer control encompasses the following essential services, which have been extensively covered in earlier chapters:

- Primary prevention
- Secondary prevention
- Tertiary prevention

Although strides have been made to expand the cervical cancer screening programme, gaps still exist in some essential cervical cancer control services. The major development has been the introduction and rollout of the national HPV vaccination programme for adolescent girls. While the impact of HPV vaccination cannot be over-emphasised, strengthening the cervical

cancer screening programme remains critical, as the impact of HPV vaccine on incidence and mortality of cervical cancer will take years to be realised.

The cervical cancer control programme requires the following essential elements to be consistently available and/or met:

- Logistics and supply management of equipment and supplies for cervical cancer screening and treatment (Appendices 4.3–4.9)
- Diagnostic services for clients who are cancer suspects (including access to histopathology laboratories)
- Treatment services for clients diagnosed with cervical cancer
- Training of health care providers in screening and treatment modalities (including biopsy for diagnosis and LLETZ)
- Quality assurance
- M&E
- Infection prevention and control
- Referrals and linkages
- Management of other cervical conditions (including STIs)

Furthermore, clients presenting for cervical cancer screening may be found to have abnormal vaginal discharge; this could cause challenges in interpreting VIA screening results. It is recommended that clients with abnormal vaginal discharge suggestive of cervicitis or abnormal discharge combined with tenderness suggestive of pelvic inflammatory disease (PID) be treated, and then **return for VIA screening one month after treatment**. For this reason, screening providers should receive training on STI management through MOHP's national training programme.

As screening services expand, more clients will soon be diagnosed with cervical cancer, and will need effective treatment. Though radiotherapy is currently not available, early-stage cervical cancers can be treated surgically, provided that investment is made in the appropriate infrastructure and training of health care providers (particularly gynaecologists). The cancer centre being built at Kamuzu Central Hospital (and anticipated to open later in 2019) will have radiation therapy services, thereby filling in a missing element of comprehensive cervical cancer control. Otherwise, the lack of treatment options for clients diagnosed with cervical cancer can be a hindrance to screening services, as some clients may feel hopeless after a diagnosis of cervical cancer.

7.1.1. Site Readiness

All screening sites—whether existing or newly opened—must meet minimum requirements in order to provide the appropriate services. It is important to make sure that the proper infrastructure—buildings, human resources (trained health care providers), and equipment and supplies—is in place before screening services are offered. Where feasible, integrating VIA services at ART clinics, and into family planning and other reproductive health services,

can facilitate leveraging existing infrastructure needs for cervical cancer screening services. It is also essential to consider referral networks in addition to the supervisory support that facilities will need.

7.1.2. Minimum Requirements

A standardised checklist is an essential component in assessing site readiness to provide cervical cancer screening services. The standardised facility readiness assessment tool and other necessary checklists will be further developed to complement these guidelines. However, the following are components for consideration:

- Type of services to be provided (e.g., VIA screening and treatment with ablative therapy or thermocoagulation for those clients who screen positive).
- Demand-creation activities: community awareness and mobilisation.
- Staffing: number of trained, qualified health care providers.
- Infrastructure: space, equipment, and supplies (including medicines).
- Availability of cervical cancer screening guidelines and registers.
- Referral mechanisms.

7.2 Monitoring and Evaluation (M&E)

7.2.1 Introduction

M&E is an integral part of the management process. These guidelines emphasise M&E as the key to ensuring programme effectiveness and efficiency, and quality improvement to safeguard customer satisfaction, safety, and health.

This section is specifically dedicated to M&E for the Cervical Cancer Secondary Prevention Programme ('screen-and-treat'), and will define important M&E concepts. Core indicators will be developed as a follow-up to these guidelines. These core indicators will set forth the main data management requirements and mechanisms, and also outline important actions required as part of managing programme quality.

7.2.2 What is Monitoring and Evaluation?

In general, **monitoring and evaluation** (M&E) is a process that helps improve performance and achieve results.

Monitoring refers to routine continuous assessment that attempts to provide stakeholders with real-time detailed information on progress of on-going activities. As part of oversight of an activity's implementation stage, monitoring determines whether the outputs and schedules planned have been achieved, so that action can be taken to correct any deficiencies or obstacles as quickly as possible.

Evaluation refers to a systematic, objective, episodic examination of the effectiveness, efficiency, and impact of certain activities. The idea here is that evaluating projects helps isolate errors so that they are not repeated, and that successful techniques or tools for current

and future projects are discovered and promoted. Although evaluations are often retrospective, their purpose is forward-looking. Evaluation applies lessons and recommendations to decisions about current and future programmes.[1]

7.2.3 Why is M&E Important?

Timely M&E maximises those processes, decisions, and systems that are working, and identifies those that are not working, so that adjustments can be made. It allows for better use of resources, thereby resulting in better client care. M&E is intertwined with quality assessment and quality improvement.

When a 'screen-and-treat' programme is expanded to reach the envisaged population health impact as quickly as possible, some aspects may need to be altered in order to ensure that the local context receives proper attention, and that the programme reaches the greatest number of clients and saves the most lives in its catchment area.

For that reason, as an integral part of the programme rollout, M&E data must be collected and analysed all levels (site, district, regional, and national). Site-level M&E work in particular must actively engage with service providers to improve and strengthen site operations. At the same time, MOHP will ensure that regional and national M&E processes are in place to deliver the required knowledge that will drive on-going higher-level programme planning and decision making.

7.2.4 Core Indicators

Core indicators used for M&E of services provided under a comprehensive cervical cancer prevention and control programme include **performance and impact indicators**. The impact of the Cervical Cancer Secondary Prevention Program on reductions in cervical cancer incidence or mortality must be evaluated. These indicators will be developed more fully in the forthcoming M&E framework.

For each core indicator, denominators and numerators must be defined. Additionally, it is important to decide how frequently to monitor these indicators. Due to considerable variation in HIV prevalence across Malawi, the MOHP may also want to use this review to consider applying more nuanced approaches in some regions to enhance responsiveness to particular regional HIV disease patterns.

7.2.5 Data Collection Methods

7.2.5.1 Current Methods Used in Malawi

At present, clinics record VIA results in paper registers. These registers will require updating to fit the new screening guidelines, and will require standardisation across clinics, with agreement on what is recorded and what is reportable. These data should be evaluated locally at the facility on a regular, scheduled basis to ensure completeness of data, and to adjust procedures or data entry as appropriate. It is also important to initiate consistent submission of reports to MOHP so data can be tracked centrally and compared by region. For example,

ART clinics also may perform VIA; results from these clinics need to be tracked in the same way they are tracked at other clinics performing the procedure. As electronic medical records with care prompts become more readily available in ART clinics, these electronic records may be utilised to supply prompts to facilitate cervical cancer screening.

7.2.6 Quality Improvement and Assurance

A regular, on-going quality improvement system with the necessary processes and mechanisms must be implemented at all levels. The system must cover primary screen-and-treat sites, treatment facilities, laboratories, and training programmes, as well as the M&E and data collection and management systems.

As part of a comprehensive quality improvement system, a set of relevant standards and standard operating procedures (SOPs) must be compiled over time. Quality standards are needed and should be developed in these key areas:

- **Screening:** VIA, and how certification and monitoring will be conducted.
- **Treatment:** how often treatment is to be available; maximum waiting times before referral.
- **Laboratories:** SOPs on cytology and histology; quality assurance assays (where applicable).
- **Data collection and management:** completeness of registers, timeliness of report submission.

Similarly, sites and higher-level units must implement mechanisms that will ensure appropriate evaluation of these quality standards and provide for timely feedback and subsequent adjustment of current practices as part of the standard PDSA (plan-do-study-act) cycle. A comprehensive, consistent quality improvement system for the programme, implemented at all levels of the MOHP, will result in better service, better training, better-quality data—and, therefore, better cared for, more satisfied clients and communities.

7.3 Training

An effective cervical cancer control programme requires that health care providers are well equipped with the skills and knowledge to provide the full spectrum of preventive services. Training is therefore essential to maintaining quality and competence.

MOHP has approved national training courses in cervical cancer control. Prior to the launch of the HPV vaccination programme for adolescent girls, training courses were conducted for all key stakeholders, including:

- Health care providers (nurses, HSAs)
- Ministry of Education staff (including teachers)
- Local government staff

Certification of health care providers is a necessary prerequisite to providing screen-and-treat services. Health care providers are expected to complete a competency-based national training course, which includes both classroom sessions and practical training. This course covers:

- Screening with VIA
- Treatment with cryotherapy (thermocoagulation is now covered as well)
- Infection prevention and control
- M&E, including reporting of data to the national cervical cancer control programme
- Roles and responsibilities of health care cadres

The course is largely geared towards nurses and clinical officers; however, it is important to broaden its coverage, both to include medical doctors and to add the following key elements of cervical cancer control to the curriculum:

- STI treatment
- Performing cervical biopsies (in district hospitals or equivalent facilities where expertise and facilities are available)
- Performing colposcopy, LLETZ, and cone biopsies (in district hospitals or equivalent facilities where expertise and facilities are available)

In order to cover the above competencies, a cervical cancer screening and treatment course will most likely require two weeks; it should cover both theory and practice, and include adequate STI training to allow for treatment of cervical and vaginal infections. Periodic mentorship and supportive supervision are critical in order to strengthen competencies. Use of digital images as a way to offer supportive supervision and/or quality assurance may be an appropriate adjunct to maintaining competency for cervical screening with VIA where appropriate confidentiality and ethics approvals are obtained.

There may also be a role for task shifting to expand cervical cancer control services. With the participation of the Kamuzu Colleges of Nursing and Medicine, the Medical Council of Malawi, and the Nurses Council of Malawi, some procedures (such as LLETZ and cervical biopsies) may be performed by nurses who have adequate training and supervision. Task shifting has shown to enhance coverage and system efficiency in ART; if similar approaches can be adopted to the prevention and control of cervical cancer, the programme's coverage is likely to increase.

There is a shortage of gynaecologists who can also perform radical hysterectomies to treat early-stage cervical cancer. In developed countries, gynaecological oncologists have typically been the main providers of this service. However, in Malawi and other similarly resourced countries, general gynaecologists have received training, and are thus able to master the skills and competence necessary to perform radical hysterectomies. Hence, investment in the training of additional general gynaecologists by both local and expatriate gynaecologists who are already competent in performing this life-saving procedure is a prudent way to expand capacity for early cancer treatment within Malawi.

Finally, with these revised guidelines comes the need for the training curriculum and programme to be revised so that they align with the new set of recommendations. The national cervical cancer control programme should implement a system for continuous professional development and M&E to ensure that quality and evidence-based practices are maintained at all times. This can be done by engaging with the relevant stakeholders.

7.4 Importance of Integration

Each time a client needs to leave her job, her duties at home, and her family to obtain transport to come to an appointment and receive care, it creates hardship. Given the increased prevalence of cervical pre-cancer and cancer in women living with HIV, it is crucial that cervical screening be integrated into HIV care sites. Linkage with HIV education and care and integration of cervical cancer screening for clients 25 years of age and older who are living with HIV will offer excellent opportunities for both cervical cancer and HIV programmes to increase their coverage.

Where feasible, integrating VIA services at ART clinics, and into family planning and other reproductive health services, can facilitate leveraging existing infrastructure needs for cervical cancer screening services

Linkage and integration are especially appropriate within the sexual and reproductive health services group, as well as across well-baby and nutrition/breast-feeding services. The integration of health delivery services will lead to improved health care for clients and more efficient use of human and financial resources.

Thinking through, and planning for, the necessary linkage between existing primary health care services at the specific facilities where VIA screening is to be provided will be a key component of success. Integration will be facilitated by cross-training of VIA providers in other reproductive health areas, such as family planning and treatment of STIs. Patient flow among various services could also be integrated. For example, during the several hours a client waits for HIV care, she could undergo VIA screening. Having both programmes share clinic space will also greatly facilitate integration.

Integration of cervical cancer screening should encompass these delivery points:

- ART
- STI
- Family planning
- Gynaecology clinics/departments
- Under-5 clinics

The establishment of cervical cancer screening and prevention services therefore creates important opportunities to move overall integration efforts forward and thereby enhance quality of care and sustainability.

References

1. Open database: Monitoring and evaluation. Wikipedia. Accessed 29 Oct 2017; last updated 1 Dec 2017. Available from https://en.wikipedia.org/wiki/Monitoring_and_evaluation.


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