



CLINICAL PRACTICE STANDARDS: CERVICAL CANCER PREVENTION

Cervical Cancer Prevention Practice Guideline Participants' Handbook

Version 2.0 28th October 2015



Clinical standard of practice for Cervical Cancer Prevention with VIA and Cryotherapy

This clinical practice guideline is adapted from the WHO standards for Comprehensive Cervical Cancer Control - a Guide to Essential Practice and Pathfinder International's Clinical Standards of Practice (SOP) and Counselling Guide (2012).

The purpose of this guide is to enable the service provider and programme managers at implementation sites to provide quality cervical cancer prevention services.

Version 2.0

ACKNOWLEDGEMENTS

In order to increase access to quality cervical cancer prevention services, the Ministry of Health has worked jointly with World Health Organisation [WHO] to adapt these clinical practice guidelines for cervical cancer prevention.

Our appreciation goes to WHO for the financial and other logistical assistance used in the development and printing of these documents. We appreciate WHO for kindly allowing us use their literature and MoH Uganda.

We thank Dr. Daniel Murokora for the technical guidance, input and leading the whole process of development of these materials including field testing; the following people devoted time beyond the call of duty and should be appreciated. Specifically; they are; Mrs Twambilire Phiri, Dr Kelias Msyamboza, Wesley Sichali, Willy Kwenda, Mrs Mary Wiseman, Mrs Harriet Ndhlovu, Mrs Lydia Chiwale, Mrs Ruth Ngwalo, Mrs Jean Chibwe, Savel Kafwafwa, Dr Sue Makin, Mrs Sellina Nlashi, Mrs Judith Chimenya and Mrs Varuli Kapito.

It is the Ministry of Health's hope that these materials will be effectively utilised to ensure a high uptake of cervical cancer prevention services.



Table of Contents

ACKNOWLEDGEMENTS	2
1.0 Purpose of CCPST Guidelines	5
2.0 Background	7
3.0 Visual Inspection with Acetic Acid test	12
4.0 Cryotherapy	21
5.0 Follow up of women who have had VIA or cryotherapy	28
6.0 Guidelines For documentation:	29
Annex 1: Instruments and supplies required for VIA testing:	29
Annex 2: CHECKLIST FOR FURNITURE, SUPPLIES AND EQUIPMENT	30
EXAMINATION ROOM.....	30
Annex 3: Infection prevention for VIA and cryotherapy	32
Annex 4: Handling and Care for Cryotherapy Equipment and Gas	37
Annex 5: Clinical Skills Checklists	41



Acronyms

- CDC: Centers for Disease and Control
- CO₂ :Carbon dioxide
- HPV: Human papilloma virus
- IUD: Intrauterine device
- LEEP: Loop Electrosurgical Excision Procedure
- SCJ: Squamocolumnar junction
- SOP: Standards of practice
- SPIRES: Stanford University Program for International Reproductive Education and Services
- STI: Sexually transmitted infection
- SVA: Single-visit approach
- VIA: Visual inspection with acetic acid
- VILI: Visual inspection with Lugo's iodine
- WHO: World Health Organization



1.0 Purpose of CCPST Guidelines

These clinical practice guidelines have been developed to provide clear guidance on cervical screening and preventative treatment for cervical precancer through early detection and treatment of precancer. The recommendation is to provide cervical pre-cancer screening services through a single-visit approach (SVA) which visual inspection of the cervix with 3-5% acetic acid (VIA) and treatment of precancerous lesions with cryotherapy. This is the internationally recognised and cost effective approach recommended by WHO for developing countries.

1.1 Source Evidence

The evidence for this guidance is obtained from the WHO guidelines and other studies.

1.2 Who Should Use CCPST Guidelines

These guidelines are designed to be used by physicians (Medical Doctors), clinical officers, nurses, and midwives, who provide cervical cancer prevention services. The guidelines are in alignment with standards of care adapted for resource constrained settings and aims to standardise quality of care among participating health care providers and their affiliated health facilities.



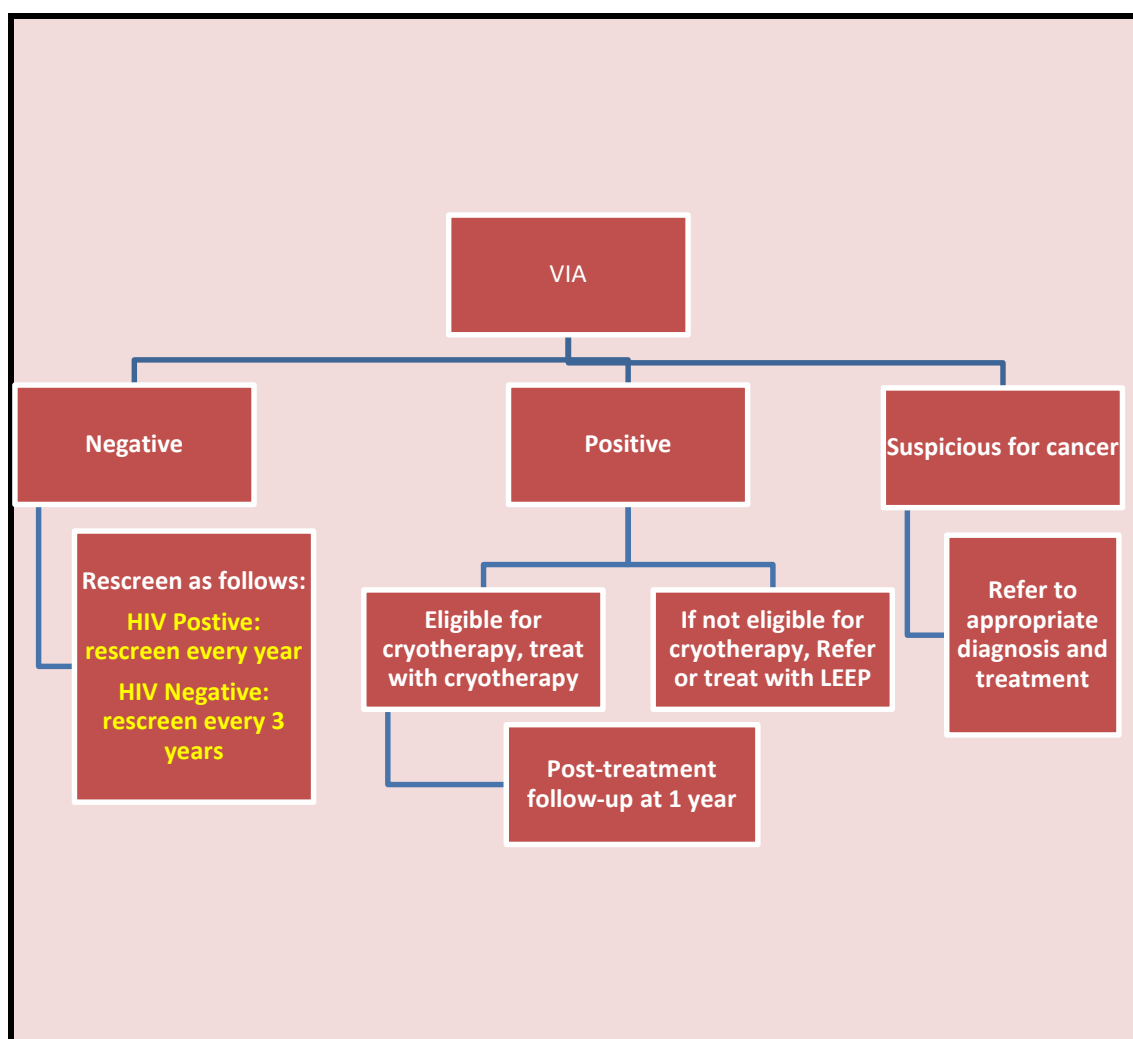
Below is the overview of steps in a single visit approach using VIA and cryotherapy

VIA TEST	Step 1:	Provide counselling on VIA test and obtain consent.
	Step 2:	Inspect and palpate the abdomen and external genitalia.
	Step 3:	Perform a speculum exam to view the cervix clearly.
	Step 4:	Apply a 3-5% acetic acid solution (vinegar) to the cervix.
	Step 5:	Observe for cervical change(s) after at least 1 minute.
	Step 6:	Discuss the results with the woman. If the results are positive and eligible for cryotherapy, counsel and offer cryotherapy
CRYOTHERAPY	Step 7:	Provide counselling on cryotherapy and obtain consent.
	Step 8:	Perform a speculum exam to view the cervix again (repeat VIA if necessary)
	Step 9:	Perform the double-freeze cryotherapy technique.
	Step 10:	Provide post-treatment and follow-up instructions to the woman.

Figure 1: Overview of steps in a single visit approach using VIA and cryotherapy



The VIA and Cryotherapy Protocol



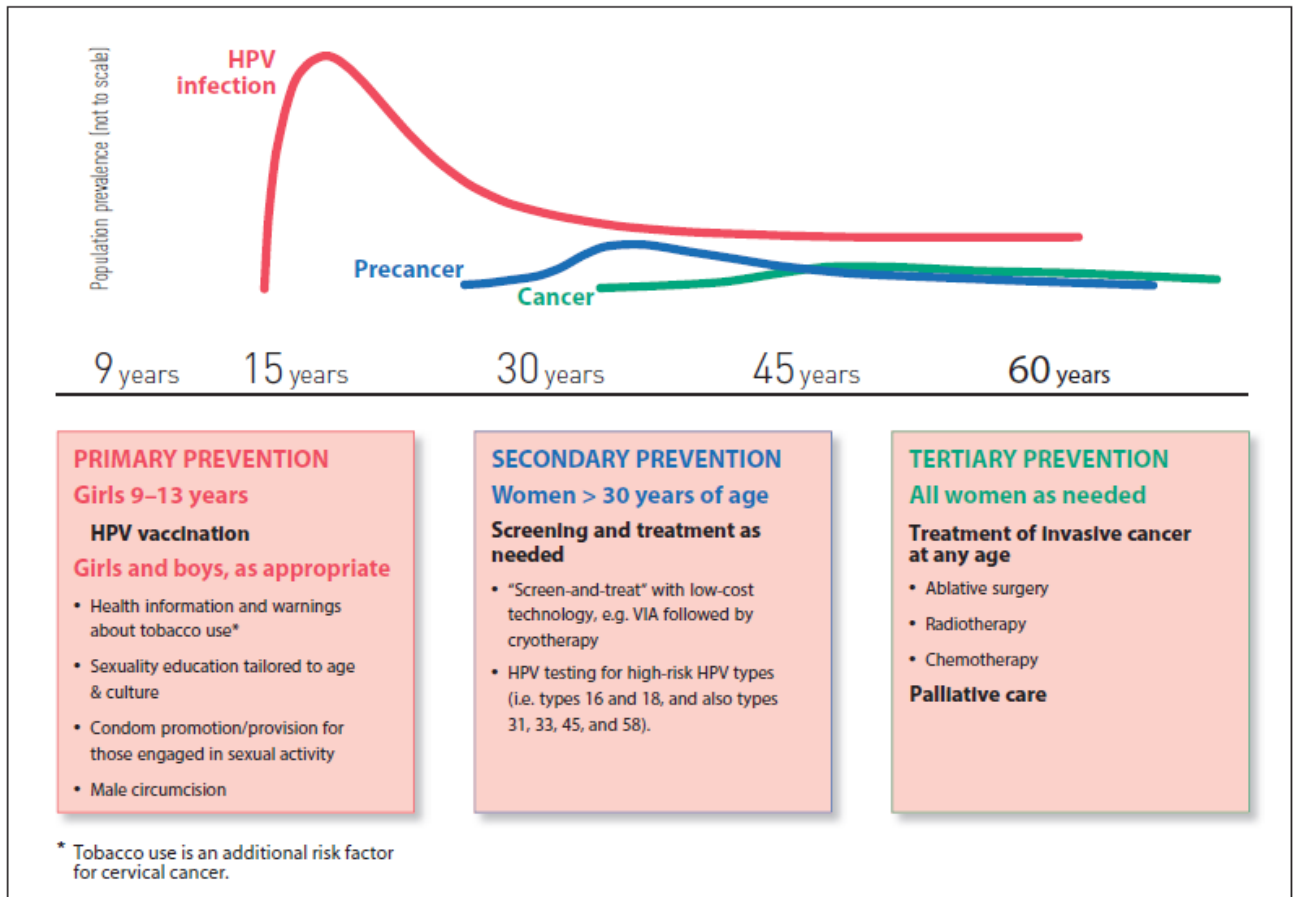
2.0 Background

- Cervical cancer is the second most common type of cancer among women. Nearly half a million women are diagnosed with it every year and just under half of these will die of the disease. It is estimated that approximately 80% of these deaths occur in developing countries. In Malawi; cervical cancer accounts for 45% of all cancer in women. Malawi has the highest burden of cervical cancer in the world at age standardised incidence rate (ASR) incidence 75.9/100,000 and ASR mortality 49.8/100,000 (Globocan 2015)
- Cervical cancer is preventable if detected early through screening. Precursor lesions can be detected and ablated long before development of invasive disease. Unfortunately, the majority of women in low and middle income countries still do not have easy access to screening programmes which detect and treat precancerous lesions.
- The consequence is that cervical cancer can remain undetected until it is too late for curative treatment and, as a result the death toll and disease burden from cervical cancer remain high in low-income countries in contrast to marked declines observed in high income countries where systematic screening programs have demonstrated dramatic reduction in incidence and mortality from this deadly disease.

2.1 The natural history of cervical cancer and HPV infection

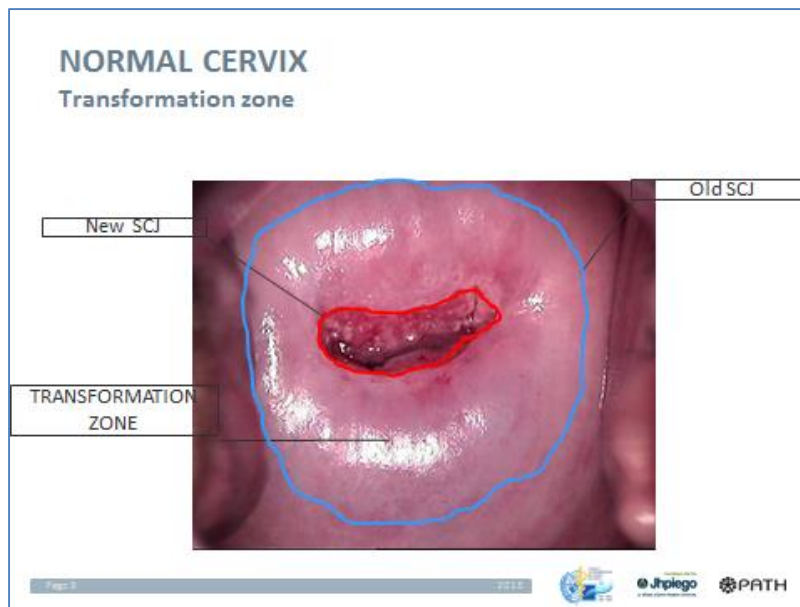
- The cervix is the lower end of the uterus that protrudes into the upper end of the vagina and contains squamous and columnar types of epithelium.





- The cells on the outside of the cervix are squamous epithelium. The cells on the inside of the cervix are columnar epithelium. The cells undergoing metaplastic change are on the area immediate outside the squamocolumnar junction called the transformational zone. HPV infects cervical epithelium and causes dysplastic change over several years that may result in to cervical precancer or cancer.





- Cervical cancer is an abnormal growth in the lower, narrow part of the womb—known as the cervix. Almost all cervical cancers are caused by virus—known as human papilloma virus (HPV). HPV is a common virus that is passed from one person to another through sexual intercourse.
- Usually the body fights off the HPV infection—however, over time there are few instances whereby it evolves into cancer.
- HPVs are a group of more than 100 related viruses. More than 30 subtypes are genital-area specific of which type 16 and 18 cause the majority of cervical cancers.
- The development of cervical cancer is very slow. It can take up to 20 years from infection with HPV to become cervical cancer. Most women get infected with HPV at least once in their lifetime. Usually women contract HPV during adolescence with peak infection coinciding with the onset of sexual activity.



- The initial infection of the cervix by HPV leads to a transient infection which can regress and be cleared or progress to a precancerous condition called dysplasia or Cervical Intraepithelial Neoplasia (CIN). Most HPV infections occur without any symptoms and go away without any treatment over the course of a few months to a few years.

2.2 Risk Factors for Cervical Cancer

The main cause of cervical cancer is HPV. HPV infection combined with other risk factors may further increase risk. Other risk factors for cervical cancer include:

- Sexual history: Women who have had many sexual partners or those who had intercourse with a man who has had many sexual partners may be at higher risk of developing cervical cancer.
- Weakened immune system: Infection with HIV or taking drugs that suppress the immune system increases the risk of cervical cancer.
- Smoking: Smoking increases the risk of cervical cancer.
- Lack of cervical screening: Cervical cancer is more common among women who do not have regular screening tests.
- Family history of cervical cancer: Cervical cancer may run in some families. If a woman's mother or sister had cervical cancer, her chances of developing the disease are 2 to 3 times higher than if no one in the family had it due to genetic predisposition.



2.3 Primary vs. Secondary Prevention

- Primary prevention: The goal of primary prevention is to prevent infection by reducing or eliminating exposure to cancer-causing factors. Primary prevention of cervical cancer includes delay of (sexual debut) intercourse, consistent condom use, monogamy, and HPV vaccines (Gardasil® and Cervarix®). HPV vaccination is recommended for girls before their sexual debut preferably at 9-13 years of age.
- Secondary prevention (cervical screening with precancer treatment) involves: Screening involves checking for disease when there are no symptoms. Progression of precancerous conditions to cervical cancer is slow; therefore screening has the potential to detect abnormal conditions before cancer develops. Screening tests for cervical cancer includes conventional or liquid-based cytology (Pap smear), HPV DNA testing, and visual inspection with acetic acid (VIA).

3.0 Visual Inspection with Acetic Acid test

3.1 Purpose

Visual Inspection of cervix using 3-5% acetic acid is the recommended screening option for low resource settings. The purpose of this guidance is to enable health workers to competently provide VIA to all eligible women within the 25 – 49 year age group.



3.2 VIA Screening Test

- VIA involves a standard vaginal speculum exam followed by visual inspection of the cervix 1 minute after washing it with a 3-5% acetic acid solution (ordinary table vinegar) using a cotton swab.
- The acetic acid solution application to the cervix shows any changes in the cells covering the cervix (epithelial cells) by producing the “acetowhite” reaction (white blotches). This allows the provider to identify if the woman has abnormal, precancerous cells to treat immediately with cryotherapy or refer her to further treatment if necessary.

3.3 General Counselling Guidelines

Counselling women prior, during, and after performing the VIA (screening) test alleviates anxiety, fear, and misunderstandings regarding the test, and helps the women to reach an informed decision. Counselling on the VIA test includes discussing the following topics:

Step by Step Guidance of Counselling for VIA:

- Describe the cervix and where it is located,
- Describe what cervical cancer is, how it is caused (by HPV) and effects of cancer,
- Outline the importance of cervical screening including early detection and treatment of precancer to prevent progression of precancerous lesions to cancer,



- Describe the VIA test (including the steps you will perform before you perform them), and
- Describe the Interpretation of VIA test results, treatment options, and follow-up.

When counselling women, make sure you:

- Explain the information in detail, in a non-threatening manner, and in language the woman understands best.
- To ensure confidentiality, do not share the woman's information with her companion(s) and/or other clinic staff unless she gives consent.
- Allow the woman time to consult with family members if she needs to prior to screening.
- Allow the woman to have someone in the room when she asks for it.
- Allow time for discussion; encourage the woman to ask questions and discuss her condition and findings.
- After you have provided counselling and information on VIA and the woman has no more questions or concerns, ask her to give consent for VIA testing.

3.4 Pre-Procedure Preparations

Step By Step Pre-VIA Guidance

1. Discuss the need for VIA, the procedure, likely findings, and management of abnormal lesions and follow-up options with the woman.



2. Confirm that the woman is eligible for VIA (sexually active and not menopausal).
3. Make sure that you have all necessary instruments and supplies required for VIA testing, as outlined in Annex 1
4. Arrange instruments and supplies on sterile or high-level disinfected (HLD) tray or container.
5. Ask the woman to empty her bladder (if she has not already done so in the last half hour) and verify that she has thoroughly washed and rinsed her abdominal and genital areas, where possible.
6. Help the woman to lie down on the examination table and place her heels on the couch. Ask her to move her lower part of the body toward the end of the examination table until her buttocks extend slightly beyond the edge of the table. Then ask her to fold her legs and let her knees fall apart and to relax her buttocks. Cover her abdomen up to the knees with a drape.
7. Wash hands thoroughly with soap and water and dry them with a clean, dry cloth/towel or air dry. Avoid sharing cloths/ hand towels to ensure proper infection prevention.
8. After your hands are washed and dried appropriately, perform examination of the lower abdomen and groin.

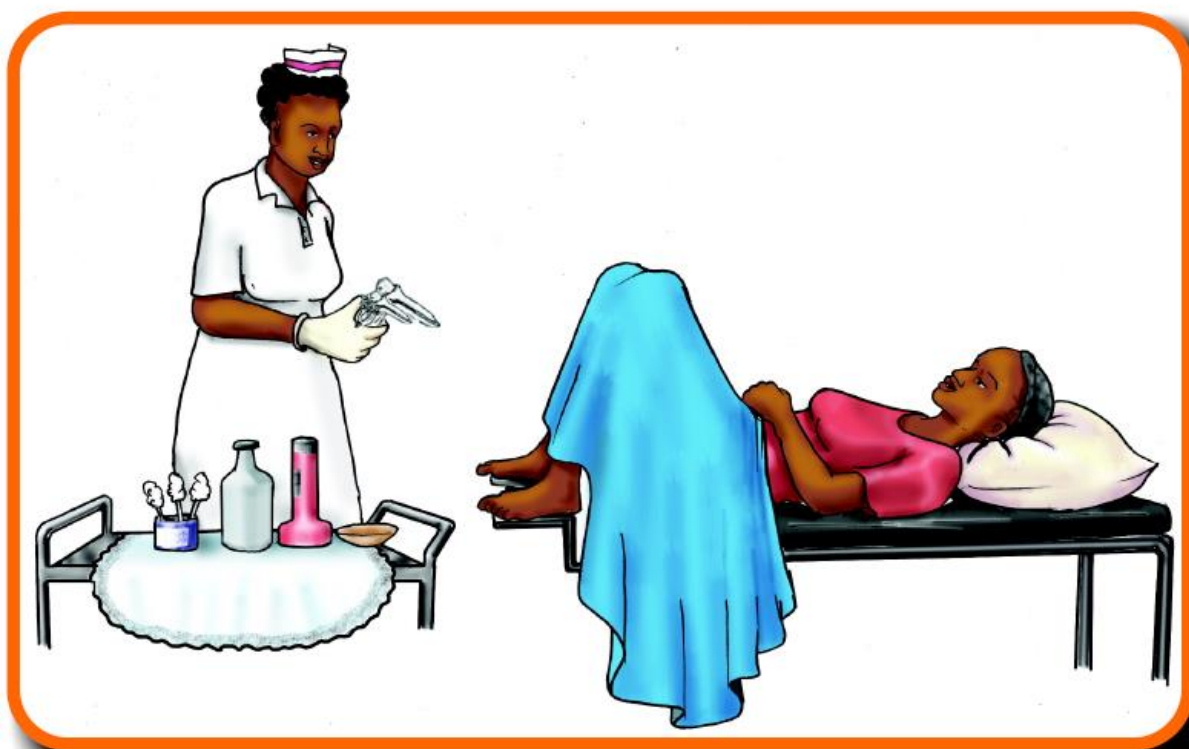


9. Point the light source toward the vagina.
10. Put new examination gloves on both hands.
11. Seat yourself comfortably so that you are as relaxed as possible and can look at the external genitalia easily.

3.5 Performing the VIA Test

Step By Step VIA Guidance

It is important to inform the woman about each of the VIA steps before performing them. This improves the woman's comfort during the examination.



1. Touch the inside of her thigh gently before touching any of the genital area so



that you do not startle her.

2. Inspect the external genitalia and check the urethral opening for discharge. Palpate the Skene's and Bartholin's glands.
3. Inform the woman that the speculum is about to be inserted and that she may feel some pressure.
4. Separate the labia minora with the right thumb and index finger,
5. Gently insert the speculum half way in to vagina or fully until resistance is felt and slowly open, adjust and fix the blades to clearly reveal the cervix.
6. Move the light source so that cervix can be seen clearly in its full entirety.
7. Check the cervix for cervicitis, ectropion (ectopy), tumours, Nabothian cysts, warts and ulcers.
8. Use a clean cotton swab to remove any discharge, blood, or mucus from the cervix and dispose of it in a leak-proof container or plastic bag. Check for contact bleeding.
9. Identify the cervical os and the squamocolumnar junction (SCJ).
10. Soak a clean swab in dilute acetic acid solution; apply it to the cervix; and dispose of swab. You may apply a second, fully soaked swab on the cervix



11. Wait at least 1 minute for the acetic acid to be absorbed and for any acetowhite reaction to appear.
12. Check if the cervix bleeds easily. Look for any raised acetowhitening areas on the cervix. These may be thickened, opaque or raised white plaques of acetowhite epithelium. Define the widths and make sure you are able to see the margins of acetowhite area. They have a clear or sharp margin/border and will usually originate at or very near the SCJ.
13. When visual inspection of the cervix has been completed, use a fresh cotton swab to remove any remaining acetic acid from the cervix and vagina.
14. Gently remove the speculum and place it in 0.5% chlorine solution for 10 minutes for decontamination.
15. If indicated, Perform a bimanual examination and a recto vaginal examination.

3.6 Post – VIA Tasks

1. Wipe the light source with 0.5% chlorine solution or alcohol to avoid cross-contamination.
2. Remove gloves by turning them inside out.
3. Wash your hands thoroughly with soap and water and dry them with a clean, dry cloth/towel or air dry. Avoid sharing cloths/towels to ensure proper infection prevention.

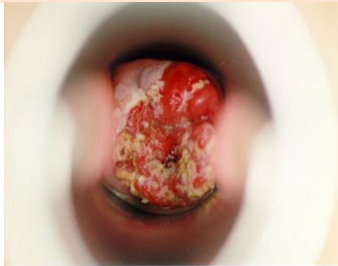


4. Ask the woman to move toward the head of the table and assist her to sit up.
Ask her to get dressed.
5. Wipe down the table with a 0.5% chlorine solution after the women gets off the examining table
6. Record the VIA test results and other findings in the records/chart and register.
7. Discuss the results of pelvic examination and VIA test with the woman.

3.7 Interpretation of Test Results and Management options

VIA Result	Clinical Criteria	Management	Image Sample
Negative VIA	Smooth, pink, uniform and featureless cervix; cervical ectropion; polyp; cervicitis; inflammation; and/or Nabothian cyst.	Treatment is not needed. The woman will probably not have increased risk of cervical cancer in the next 3 years. Therefore, recommend that she return in 3 years for re-testing.	
Positive VIA and eligible for cryotherapy	The VIA test showed acetowhite lesions that may be precancerous. The findings showed raised and thickened white plaques or acetowhite epithelium, usually near the squamocolumnar junction (SCJ); acetowhite lesion <75% of cervix; lesion does not extend onto the vaginal wall or endocervix; and lesion	Treat with cryotherapy.	



	extends <2 mm beyond the diameter of the cryoprobe.		
Positive VIA test and ineligible for cryotherapy	Findings showed raised and thickened white plaques or acetowhite epithelium, usually near the SCJ; acetowhite lesion >75% of cervix; lesion extends into the vaginal wall or endocervix; and lesion extends >2mm beyond the diameter of the cryotip.	VIA test detected acetowhite lesions that cannot be treated with cryotherapy. Provide the woman with a referral for further evaluation and appropriate management from a doctor who might have access to other forms of treatment such as Loop Electrosurgical Excision Procedure (LEEP), conization biopsy, or hysterectomy.	
Suspicious for cancer	Cauliflower-like growth or ulcer; fungating mass. Lesion is suspicious for cancer and appears to have moved beyond precancerous stage.	Cryotherapy cannot be used to treat suspicious cervical lesion(s). Refer the woman to seek further evaluation as soon as possible for diagnosis and appropriate treatment.	

Key Note to Provider: If the woman has cervicitis or inflammation and is eligible for cryotherapy, it is preferred that she is treated with antibiotics first, wait for 2 weeks, and then review and treat with cryotherapy if she is still VIA positive. However, if she cannot return to the facility within 2 weeks, you can give her antibiotic therapy and offer cryotherapy immediately.



4.0 Cryotherapy

4.1 Purpose:

The purpose of this guideline is to equip health workers with knowledge and skills to competently perform cryotherapy procedure for the treatment of cervical precancer in eligible women.

4.2 Who Can Perform Cryotherapy

All trained health workers are eligible to perform cryotherapy including; Medical officers, Nurses, Midwives, Clinical Officers.

4.3 Eligibility criteria

Cryotherapy should be offered to a woman if an acetowhite lesion was observed during the VIA test and she meets eligibility criteria. Eligibility criteria for cryotherapy include:

- Acetowhite lesions occupying <75% of surface area of the cervix,
- Lesion does not extend onto the vaginal wall,
- Lesion does not extend onto endocervix (cervical os)
- Lesion extends <2 mm beyond the diameter of the cryotip; lesion should not extend more than 2 mm into the canal.
- The lesion is not suspicious for cancer

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Step by Step Guidance of Counselling for Cryotherapy:

- Explain the cryotherapy procedure to the woman,
- Explain the benefits of the cryotherapy treatment procedure
- Highlight the likelihood of success and failure
- Potential risks; emphasize that there are hardly any risks associated with cryotherapy.
- Post treatment care and follow-up

What a woman can expect during or after being treated with cryotherapy

- *Some women experience abdominal cramps during the procedure and for 2-3 days after the procedure and may need analgesics.*
- *All women will experience watery vaginal discharge for 4–6 weeks.*
- *Some women will experience spotting/light bleeding.*

All women should be informed about these and not be alarmed

Care after cryotherapy

- *Women will need to be taught how to be responsible for self-care at home, which includes avoiding internal douching, avoiding use of vaginal tampons, and abstaining from sexual intercourse, or using condoms during intercourse if abstinence is not possible within 4 weeks after the cryotherapy procedure.*
- *If a woman experiences mild pain, she can take any analgesics*
- *If a woman experiences any of the symptoms and signs below, she should return to a facility:*
 - *Fever for more than 2 days*



- *Severe lower abdominal pain, especially if accompanied by fever*
- *Bleeding for more than 2 days that is heavier than her heaviest days of menstrual bleeding*
- *Foul smelling vaginal discharge*



- Allow time for discussion; encourage the woman to ask questions and discuss her condition. Focus on emphasizing abstinence post cryo and self-care after cryotherapy procedure is performed.
- After you have provided counselling and information cryotherapy and the woman: does not have any more questions or concerns; believes she will be able to abstain from sexual intercourse or use a condom during intercourse; and believes she can do self-care post- treatment, ask her if she gives consent for cryotherapy treatment.

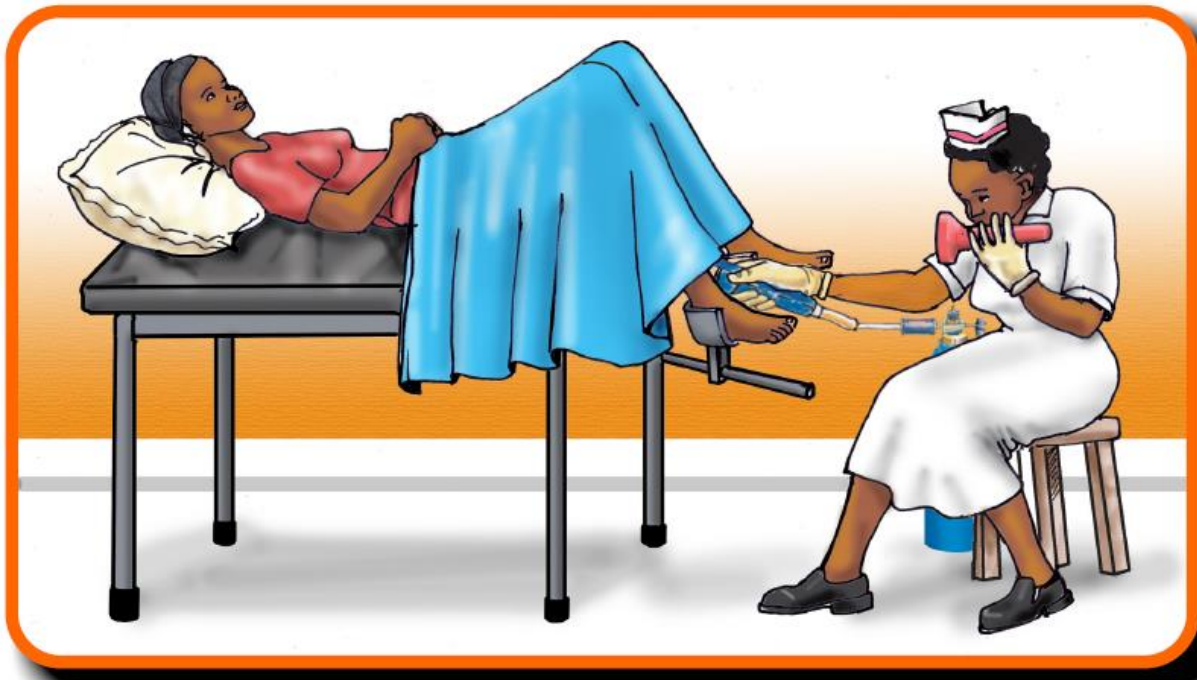


4.4 Pre-procedure preparations

Step By Step Pre-Cryotherapy Procedure Guidance

- Prior to performing cryotherapy, explain why treatment is recommended and the procedure to be used in treatment
- Encourage the woman to ask questions and provide accurate responses. Ensure she has understood the procedure and what to expect.
- Make sure that the cryotherapy machine is functional and refrigerant gas (CO2 or N2O) are available and ready to use.
- Remove or detach the protective cover placed on the (Cryoprobe) easily damageable part of the cryotherapy machine.
- Point the probe at the ceiling (but away from the patient). Pull the freeze “trigger” for 1 second and then put it on the defrost setting for 1 second to blow gas out through the thin metal tube and “clear the system.” Then affix a sterilized/high-level disinfected cryotip.
- Before bringing the woman into the examination room, be sure she has recently (within the past 30 minutes) emptied her bladder. Assist her onto the examining table and drape her.
- Wash your hands thoroughly with soap and water and dry them with a clean, dry cloth/towel or air dry. Avoid sharing cloths/towels to ensure proper infection prevention.
- Put on a pair of new examination gloves.
- Arrange instruments and supplies on high-level disinfected tray or container.





4.5 Performing the cryotherapy procedure

Step By Step Pre-Cryotherapy Procedure Guidance

- Inform the woman that the speculum is about to be inserted in her vagina and that she may feel some pressure or coldness.
- Gently insert the speculum fully, while opening the blades slowly, and fix them to see the entire cervix.
- Move the light source so you can see the cervix clearly.
- Clean discharges such as blood, or mucus from cervix with a swab. Identify the cervical os, SCJ, and site and size of lesion (apply dilute acetic acid if necessary). Dispose the swab in an infection prevention container.
- Apply the cryotip to the cervix, ensuring that the nipple is centered and placed securely on the os.
- Hold the cryoprobe perpendicular to the plane of the cervix, open the master



cylinder valve. Press the freeze trigger to start the freezing process. Set the timer for 3 minutes. Be sure to apply pressure to the cervix as the gas begins to flow to the cryoprobe. Watch as the ice ball develops at and around the cryotip.

- Ensure that the cryoprobe and tip does not touch the vaginal walls while freezing the cervix to avoid damage to the bladder or rectum. Use vaginal retractors or cut off the tip of a new condom and apply the latter on the speculum before inserting it in the vagina. The condom sheath will retract the vaginal walls and protect them from getting into contact with the cryotherapy tip.
- Use the double-freeze cryotherapy technique:
 - Freeze the cervix for 3 minutes then press the defrost valve, wait for tip to defrost and release itself from cervix (as it attaches with the ice).
 - Wait for 5 minutes to allow thawing to occur.
 - Repeat freezing for another 3 minutes again and defrost, then wait for tip to release from cervix.
- After removing the cryotip from the cervix, inspect cervix to verify that a hard, white, frozen “ice ball” is present.
- Inspect the cervix for any bleeding. If there is bleeding, apply pressure using a clean cotton swab or pack of gauze to achieve haemostasis. Then dispose the swab.
- Remove the speculum and place it in a 0.5% chlorine solution for 10 minutes for decontamination and further instrument processing steps to follow

4.6 Post-cryotherapy tasks

- Wipe the light source with 0.5% chlorine solution or alcohol.



- Remove gloves by turning inside out, and dispose of them in leak-proof container or plastic bag.
- Wash hands thoroughly with soap and water and dry with a clean, dry cloth, or air dry.
- Check if the woman is having excessive cramping before helping her sit up. If she is not experiencing excessive cramping, help her get down from the examination table and ask her to get dressed. If she is experiencing severe cramping after 5–10 minutes, give her an oral analgesic.
- Advise the woman regarding post-treatment care, potential side effects, and follow-up schedule.
- Record the results of treatment and follow-up plan.
- Observe the women for at least 15 minutes. Ask her how she feels before sending her home.
- Clean the cryotherapy unit.
- Separate the used cryotip from the probe and cover the thin metal tube part of the probe with a different cryotip or protective cover. Process the used cryotip according to the manufacturer's instructions and clean the probe with alcohol or chlorine bleach.
- Close the master cylinder valve.



5.0 Follow up of women who have had VIA or cryotherapy

Priority should be given to screening women aged 25 – 49 years.

- All clients should be given information on the test significance, possible side effects and follow-up schedules
- Women who test negative on their first screening test should be advised that the screening interval should not be more than 5 years. This will depend on the availability and recommendation from the national standards. Some countries and programmes will only have a once in a lifetime screening while other may recommend screening once every 3 years.
- The priority should be given to maximising coverage rather than maximising the number of tests in a woman's lifetime.
- Women who have been treated following a positive cervical screening test should receive a post treatment follow up at 1 year. Those still having a lesion eligible for cryotherapy should be treated immediately while those with ineligible lesions should be referred for appropriate evaluation and management. Women with a normal cervix, one year after cryotherapy should be seen in routine cervical screening clinic in 3 – 5 years depending on the country screening protocol.



Women who are HIV test positive should have the screening as soon as possible (at any age).

- Women, who test negative on their first screening test, should have a repeat screening within three years.

6.0 Guidelines For documentation:

All procedures conducted during cervical cancer screening should be documented in approved clinical records.

Client registers should be filled by the attending health worker at every step of service delivery.

Important records include; the clinic attendance register, the client form which contains screening record as well as cryotherapy treatment. The client referral form, where applicable should be filled.

Annex 1: Instruments and supplies required for VIA testing:

- Light source
- Instrument tray
- Bivalve speculums (of different sizes)
- Cotton swabs or cotton wool plus forceps
- New examination gloves or high-level disinfected surgical gloves
- Diluted (3-5%) acetic acid solution
- 0.5% chlorine solution
- Buckets with chlorine solution
- Clock/watch
- Record forms (e.g., VIA register, VIA client assessment form, etc.)



Annex 2: CHECKLIST FOR FURNITURE, SUPPLIES AND EQUIPMENT

EXAMINATION ROOM

- Locked cabinet for supplies and equipment
- Exam table with stool or chair for provider
- Macintosh on table
- Bed block/ chair to assist to get on table
- Chair for client
- Sink with running water or buckets with tap, soap or liquid hand sanitizer
- Table or Trolley for supplies
- Green Linen to put on the table or trolley for clean supplies and one over the supplies to keep supplies clean between clinic days
- Instrument trays for speculums and cotton swabs (if available)
- Wall clock
- Supplies for VIA:
 - Vaginal Speculums- reserve 20 per room (medium and large)
 - Exam gloves
 - Large cotton swabs
 - Vinegar in shallow container (gallipot)
 - Headlamps or torch
- Supplies for Cryotherapy:
 - Cryo units
 - 3 Tips in HLD container (plastic bowl with lid)



- 1-3 Bowls to decontaminate and HLD tips. One bowl of 70-90% alcohol or 2-4% cidex to high level disinfect (HLD) tips (after washing with soap and running water until visibly clean, soak for 20 min in solution and air dry)
- Sanitary napkins (if possible)
- CO2 tanks
- Hose to ventilate CO2 outside (duct (silicon) tape to adhere hose to outside)
- 12" spanner to attach CO2 tank to cry unit
- Paper taped to tank to record number of treatments
- M&E forms: MOH Register, Referral Log Book or forms, Client Cards
- HIV/AIDS testing: PITC register, HIV test kits, gloves, hand sanitizer, gauze for cleaning surfaces with chlorine solution
- FP methods: Offer everyone condoms and other methods if available.
- Infection Prevention Supplies:
 - Hand washing supplies
 - Spray bottle with chlorine solution (5%)
 - Gauze squares for washing table
 - Utility gloves/plastic apron
 - 4 buckets filled with
 - (1) plain water
 - (2) 5% chlorine solution
 - (3) soapy water
 - (4) rinse
- Place on Macintosh to dry instruments



- Sterilizer should be nearby
- 1 trash bin with cover (lined with plastic bag) for infectious material
- 1 trash bin without lid (lined with plastic bag) for non-infectious material

Annex 3: Infection prevention for VIA and cryotherapy

Hand washing

Hand washing is the single most important step in preventing infection, because we touch surfaces with our hands and then touch our face (eyes, nose, mouth) carrying microorganisms into the body. Hand washing removes many microorganisms from the skin, which helps to prevent transmission of infections from person to person.

Hand washing should be done:

- Before: the day's work; examining a client; performing any medical procedure (e.g., VIA, cryotherapy, insertion of an intrauterine device [IUD] or pelvic exam); handling clean, disinfected, or sterilized supplies for storage; putting on sterile gloves; going home.
- After: any situation in which the hands may be contaminated, such as handling instruments; touching bodily secretions or excretions; removing gloves; personal use of toilet; blowing nose, sneezing, or coughing.

Supplies needed for hand washing:

- Clean water (water may be running or from a bucket, but it must be clean)
- Soap



- Soap dish that drains and keeps the soap dry
- Clean, dry cloth/towel. Avoid sharing cloths/towels to ensure proper infection prevention.
- Bucket and dipper, or alcohol if no running water is available
- Soft sticks or brushes for nail cleaning, if available

Decontamination, Cleaning, and High-Level Disinfection

The three basic steps of the infection prevention processes recommended to reduce disease transmission from soiled instruments (speculum, forceps, cryotip, etc.) and other reusable items are: decontamination, cleaning, and sterilization or high-level disinfection.

General decontamination and cleaning

Equipment and instruments required for decontamination

Prior preparation of the following equipment and instruments is essential for proper decontamination:

- Liquid/powder soap
- Clean water
- Measuring jug/container
- Buckets for three different solutions.

Before any procedure, prepare different decontaminating solutions with recommended concentration in three buckets (one for chlorine solution; one for soap solution; and one for clean water). Always use plastic-type containers.

Decontamination and cleaning process after completing VIA procedure:



- Dispose of contaminated objects (swab and other waste) in a leak-proof container with cover while still wearing your glove.
- Fully submerge used speculum and forceps in the plastic container filled with 0.5% chlorine solution for only 10 minutes.
- Toothed or serrated instruments should be cleaned with a brush such as a toothbrush to dislodge debris.
- Immerse both gloved hands in the bucket containing 0.5% chlorine solution and remove by turning them the inside out and dispose of them in a leak-proof container.
- After 10 minutes, clean instruments with a brush and soapy water, then rinse at least three times with clean water and dry properly (use examination glove during cleaning).

Notes to provider:

Do not use abrasive cleaners (e.g., Vim) or steel wool because these products can scratch or pit metal or stainless steel. These scratches then become a nesting place for microorganisms, making cleaning more difficult.

Contaminated surface(s): If there is any surface (procedure table or instrument stand) that could have been contaminated by blood or other bodily fluid, you should decontaminate by wiping down with chlorine solution before you remove the glove or the surface should be cleaned after each procedure.



Decontamination and cleaning after completing cryotherapy procedure:

- Immerse both gloved hands in the bucket containing 0.5% chlorine solution and remove gloves by turning them inside out. Dispose of them in a leak-proof/plastic container.
- Before beginning the cleaning process, put new examination or utility gloves on both hands to protect you.
- Decontaminate the cryotherapy unit, hose, and regulator by wiping them with alcohol (70– 90%).
- Separate the cryotip from the probe, make sure the rubber stopper is placed in the opening, and cover the thin metal tube part of the probe with another cryotip or protective cover (if available).

Note to Provider:

Always protect the thin metal tube from damage because it is very sensitive and easily damaged.

Put the cryotherapy unit on the pre-prepared location or in the holder on the regulator.

Wash the cryotip with soap and water until visually clean and rinse it thoroughly with clean water.

Allow the cryotip to air dry.



Reminder to Provider:

Do not allow the cryotip to fall out during washing.

Do not submerge the cryotip in any chemical or disinfectant solution.

After washing, the cryotip can be sterilized with high-pressure steam sterilization (autoclave) or high-level disinfectant by boiling for 20 minutes before reuse (timing starts when the water starts to boil/bubble).

Sterilisation

- After decontamination and cleaning, and before sending to the central sterilization room, all instruments should be packed independently.
- The cryotip should be wrapped in a double thickness cotton cloth before sending for steam sterilization.
- Forceps, speculums, and all other jointed instruments should be in the open or unlocked position.
- Instruments should not be held tightly together in a way that will prevent steam contact with all surfaces.
- It is best to wrap clean instruments and other clean items in a double thickness of cotton cloth.
- Make sure a metal band around the drum is open before sterilization to allow steam into the drum through the perforated wall.



- After sterilization and before transporting to the VIA/cryotherapy procedure unit
- Make sure metal bands around all drums are closed.
- Make sure all packs with cotton cloth are dry. (Condensation might develop, which increases the probability of microorganism accumulation.)
- Transfer forceps and their holding containers should be cleaned and dried daily and whenever visibly contaminated (need sterilization).
- After sterilization, store the wrapped cryotip in a clean and dry place. It can be reassembled and reattached to the cryoprobe during cryotherapy procedure.

Annex 4: Handling and Care for Cryotherapy Equipment and Gas

Handling, Care, Transport, Storage, and Use of CO₂ Gas Cylinder and Cryotherapy Machine

Storage of CO₂ Gas Cylinders

- Gas cylinders should not be stored for excessive periods of time. Purchase only enough gas to meet short-term needs.
- Rotate stocks of gas cylinders to ensure that the first in are the first used.
- Store gas cylinder in a dry, safe place on a flat surface in the open air. If this is not possible, store in an adequately ventilated building.
- Protect gas cylinders from external heat sources that may adversely affect their mechanical integrity. This is particularly important in hot climates.
- Store gas cylinders at a temperature of 20–30° Celsius (68–86° Fahrenheit) and away from sunlight. Gas cylinders should be stored away from sources of ignition and other flammable materials. You could also post warning notices prohibiting smoking and unprotected electrical lighting devices or open flames.



- Ensure the valves on empty cylinders are closed to prevent contaminants from entering the cylinder.
- Store gas cylinders securely when they are not in use. They should be properly restrained, unless they are designed to be freestanding.
- Store cylinders where they are not vulnerable to hazards caused by impact (e.g., away from vehicles and human movement).

Transport of CO₂ Gas Cylinders

- Avoid the need for manual handling of gas cylinders whenever possible (e.g., by using cylinder trolleys).
- Do not use valves, shrouds, or caps for lifting cylinders
- Gas cylinders should not be raised or lowered unless adequate precautions are taken to prevent them from falling.

Fit suitable protective valve caps and covers to cylinder, when necessary, before transporting it. This helps prevent moisture and dirt from gathering in the valve of the cylinder, and provides protection during transport.

- Securely stow gas cylinders to prevent them from moving or falling. This is normally in the vertical position.
- Avoid transport them in vehicles where the load space is not separated from the driver's compartment.



- Disconnect regulators and hoses from cylinders before lifting and transport.

Handling, Care, and Use of CO2 Gas Cylinders

- Gas cylinders should always be stored in the upright position.
- Do not move cylinders unnecessarily and always keep them in a secure place by attaching them to the wall.
- Do not shake the gas inside the cylinders. However, if this occurs, allow time to pass before using them again. Do not use for at least 4 hours if you think the gas is not in stable condition. Do not use gas cylinders if they are hot to the touch; wait until they have cooled down.
- Do not over tighten when attaching a regulator to a gas cylinder. If possible, tighten by hand only. Always check for leakage
- Always make sure the gas pressure of the regulator is within the green-shaded operating range (40–70 kg/cm²).
- Do not forget to close the gas valve after completing the cryotherapy procedure.
- Remove the remaining gas from the cryotherapy system by deflating (this helps avoid the formulation of ice).



Handling, Care, and Use of Cryotherapy Machine

- Rings and washers need to be inspected every time the cylinder is changed and replaced.

All O-rings, washers, and gaskets must be compatible with the gas. Only use components recommended by the equipment suppliers.

- Always screw the fine end of the cryoprobe closed with the cryotip after use.
- Do not fit the cryotip into the cryoprobe against resistance as it will erode the screw.
- Never apply any kind of lubricant to the thread or the connected thread.

Make sure you have defrosted the cryotherapy machine and cleared the compressed CO₂ gas from the cryoprobe and the cryotherapy machine. (Leaving compressed gas in it creates pressure in the cryotherapy system and damages it.)

- Store the cryotherapy machine in a safe place by either hanging it on the cylinder or in an instrument trolley with the cryotip covered and in a place where people will not touch it.
 - When applying cryotherapy to the cervical lesion in “freeze” mode, squeeze the trigger gently until it latches. There is no need to maintain pressure on the trigger.
 - To defrost, squeeze the trigger against the handle and hold. In few seconds the tip will have ice/frost on it, look defrosted, and detach easily from the tissue. Do not attempt to withdraw the probe prior to defrosting, as the tissue will be torn.



Annex 5: Clinical Skills Checklists

CLINICAL ASSESSMENT TOOL FOR COUNSELING SKILLS IN VIA AND CRYOTHERAPY

(To be used by **Participant & Supervisor**)

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

- 1 Needs Improvement:** Step or task not performed correctly or out of sequence (if necessary) or is omitted
- 2 Competently Performed:** Step or task performed correctly in proper sequence (if necessary) but participant does not progress from step to step efficiently
- 3 Proficiently Performed:** Step or task efficiently and precisely performed in the proper sequence (if necessary)

CLINICAL ASSESSMENT TOOL FOR COUNSELING SKILLS IN VIA AND CRYOTHERAPY					
STEP/TASK	CLIENTS				
COUNSELING					
Clients	1 st	2 nd	3 rd	4 th	5 th
Initial Interview (Woman Reception Area)					
1. Greet the woman respectfully and with kindness.					
2. Establish purpose of the visit and answer questions.					
3. Provide general information about preventing cancer by early detection.					
4. Give the woman information about the pelvic examinations and the benefits and limitations of each in early detection of cancer. zExplain how the pelvic examination is done. zExplain how the VIA test and cryotherapy can prevent cervical cancer.					
5. Explain what to expect during the clinic visit.					
VIA-Specific Counseling (Counseling Area)					
1. Assure necessary privacy.					
2. Obtain biographic information (name, address, etc.)					
3. Ask the woman about her reproductive health history (Age at first sexual contact? Sexually transmitted diseases?)					
4. Give the woman additional information about VIA and cryotherapy: Explain the nature of cervical cancer and its relationship to HPV infection. Discuss the risk factors for the disease. Describe how the VIA test is done and the possible findings. Explain the treatment options if the VIA test is abnormal.					
5. Ask about any attitudes or religious beliefs that will affect the woman’s decision to have a VIA test.					
6. Discuss the woman’s needs, concerns and fears in a thorough and sympathetic manner.					
7. Help the woman begin to decide to have a VIA test.					
If woman chooses to have a VIA test:					



8. Ask the woman if she has any other questions about the VIA test.					
9. Describe the VIA test procedure and what she should expect during the pelvic examination and afterward.					

CLINICAL ASSESSMENT TOOL FOR COUNSELING SKILLS IN VIA AND CRYOTHERAPY					
STEP/TASK	CLIENTS				
Clients	1 st	2 nd	3 rd	4 th	5 th
If the VIA test is negative:					
1. Discuss with the woman the results of the VIA test and what it means to her reproductive health.					
2. Tell her when to return for future screening.					
3. Assure the woman she can return to the same clinic at any time to receive advice or medical attention.					
4. Provide follow-up visit instructions.					
COUNSELING (CRYOTHERAPY)					
If the VIA test is positive:					
1. After completing the pelvic examination, ask the woman if she is more comfortable discussing the results while lying on or sitting up on the table.					
2. Inform the woman about the VIA test findings.					
3. Ask the woman if she is pregnant. If she is pregnant, ask her the age of gestation.					
4. Give detailed information about the treatment option: Show how the cryotherapy procedure is used. Explain the cryotherapy steps. Describe the benefits and effectiveness of cryotherapy. Explain the potential side effects and ensure that the woman understands.					
5. Encourage the woman to ask questions and discuss her condition.					
6. Give the woman some time to decide.					
7. Ask the woman if she will give her consent for treatment.					
Post-Cryotherapy Counseling					
1. Provide the woman instructions for self-care at home.					
2. Advise the woman about warning signs.					
3. Discuss what to do if the woman experiences any problems (e.g., prolonged bleeding or abdominal or pelvic pain).					
4. Provide instructions for using the supplied condoms and feminine pads (if available).					
5. Ask the woman to repeat the instructions.					
6. Answer any questions.					
7. Schedule a follow-up visit.					



CLINICAL ASSESSMENT TOOL FOR VIA CLINICAL SKILLS

(To be used by **Participant & Supervisor**)

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

- 1 Needs Improvement:** Step or task not performed correctly or out of sequence (if necessary) or is omitted
- 2 Competently Performed:** Step or task performed correctly in proper sequence (if necessary) but participant does not progress from step to step efficiently
- 3 Proficiently Performed:** Step or task efficiently and precisely performed in the proper sequence (if necessary)

CLINICAL ASSESSMENT TOOL FOR VIA CLINICAL SKILLS					
STEP/TASK	CLIENTS				
CLIENT ASSESSMENT					
	1 st	2 nd	3 rd	4 th	5 th
1. Greet the woman respectfully and with kindness.					
2. Explain why the VIA test is recommended and describe the procedure.					
3. Tell what the findings might be and what follow up or treatment might be necessary.					
GETTING READY					
1. Check that the instruments and supplies are available.					
2. Ensure that the light source is available and ready to use.					
3. Check that the woman has emptied her bladder and washed and rinsed her genital area if necessary.					
4. Ask her to undress from the waist down.					
5. Help her onto the examining table and drape her.					
6. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry. Palpate the abdomen.					
7. Put one pair of new examination or surgical gloves on both hands.					
8. Arrange instruments and supplies on sterile tray or container, if not already done.					
VISUAL INSPECTION WITH ACETIC ACID					
1. Inspect external genitalia and check urethral opening for discharge.					
2. Palpate Skene's and Bartholin's glands.					
3. Insert speculum and adjust it so that the entire cervix can be seen.					
4. Fix the speculum blades in the open position so that the speculum will remain in place with the cervix in view.					



5.	Move the light source so that you can see the cervix clearly.				
6.	Examine the cervix for cervicitis, ectropion, tumours, Nabothian cysts or ulcers.				
7.	Use a clean cotton swab to remove any discharge, blood or mucus from the cervix. Dispose of swab in a leak-proof container or plastic bag.				
8.	Identify the cervical OS, squamo-columnar junction (SCJ) and transformation zone.				
9.	Soak a swab in 3–5% acetic acid and apply it to the cervix. Dispose of swab in a leak-proof container or plastic bag.				
10.	Wait at least 1 minute, and observe the cervix for acetowhite changes.				
11.	Inspect the SCJ carefully. Check whether cervix bleeds easily. Look for any raised and thickened white plaques or acetowhite epithelium.				
12.	As needed, reapply acetic acid or swab the cervix with a clean swab to remove mucus, blood or debris. Dispose of swab in a leak-proof container or plastic bag.				
13.	When visual inspection has been completed, use a fresh swab to remove any remaining acetic acid from the cervix and vagina. Dispose of swab in a leak-proof container or plastic bag.				
14.	Remove the speculum. If VIA test was negative, place in 0.5% chlorine solution for 10 minutes for decontamination.				
15.	Perform the bimanual examination and rectovaginal examination (if indicated).				
POST-VIA TASKS					
1.	Wipe light source with 0.5% chlorine solution or alcohol.				
2.	Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out. If disposing of gloves, place them in leak-proof container or plastic bag. Gloves must be disposed of if rectovaginal examination performed.				
3.	Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.				
4.	If VIA test is negative, ask woman to sit up, get down from the examining table and get dressed.				
5.	Record the VIA test results and other findings in woman's record. If acetowhite change is present, draw a map of the cervix and the diseased area on the record.				
6.	Discuss the results of the VIA test and pelvic examination with the woman and answer any questions. If VIA test is negative, tell her when to return for repeat VIA testing. If VIA test is positive or cancer is suspected, discuss recommended next steps. After counseling, provide treatment or refer.				



CLINICAL ASSESSMENT TOOL FOR CRYOTHERAPY CLINICAL SKILLS

(To be used by **Participant & Supervisor**)

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

- 1 Needs Improvement:** Step or task not performed correctly or out of sequence (if necessary) or is omitted
- 2 Competently Performed:** Step or task performed correctly in proper sequence (if necessary) but participant does not progress from step to step efficiently
- 3 Proficiently Performed:** Step or task efficiently and precisely performed in the proper sequence (if necessary)

CLINICAL ASSESSMENT TOOL FOR CRYOTHERAPY CLINICAL SKILLS					
STEP/TASK	CLIENTS				
CLIENT ASSESSMENT					
Clients	1 st	2 nd	3 rd	4 th	5 th
1. Explain why the treatment is recommended and describe the procedure.					
2. Check that if woman is pregnant, she is less than 20 weeks gestation.					
3. Tell her about the side effects to expect and the alternatives to cryotherapy.					
GETTING READY					
1. Check that instruments and supplies are available.					
2. Ensure that the light source is available and ready to use.					
3. Check that cryotherapy instrument is ready to use, that gas (CO ₂) is turned on at the cylinder and the pressure reads at least 40–70 kg/cm ² . Set timer to 0.					
4. Insert clean cryo-tip into protective sleeve. Remove protective cover from end of probe.					
5. Check that the woman has emptied her bladder if more than 30 minutes since VIA test.					
6. Help her onto examining table and drape her.					
7. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.					
8. Put one pair of new examination or sterile surgical gloves on both hands. If available, put a second glove on one hand.					
9. Arrange instruments and supplies on a sterile tray or container, if not already done.					
CRYOTHERAPY					
10. Insert speculum and fix blades so that entire cervix can be seen clearly. If using outer glove, remove it from left hand by turning inside out. If disposing of glove, place in leak-proof container or plastic bag.					
11. Fix the speculum blades in the open position so that the speculum will remain in place with the cervix in view.					
12. Move the light source so that you can see the cervix clearly.					
13. Use a clean cotton swab to remove any discharge, blood or mucus from the cervix. Dispose of swab in a leak-proof container or plastic bag.					



14. Identify the cervical OS, SCJ and site and size of the lesion. (If necessary, apply 3–5% acetic acid with a clean swab so that lesion can be seen. Dispose of swab.)					
15. Point probe at ceiling. Press freeze button for 1 second and then defrost button for 1 second.					
16. Screw cryotip with sleeve onto end of probe.					
17. Apply the cryotip to the cervix ensuring that the nipple is placed squarely onto the os. Check to be sure the cryotip is not touching the vaginal walls.					
18. Set timer for 3 minutes. Press freeze button. Apply pressure to the cervix as the gas begins to flow to the cryoprobe. Watch as the ice ball develops.					
19. Use “freeze-clear-freeze technique,” and freeze cervix for 3 minutes.					
20. Wait for the cryotip to detach from the cervix. Remove cryoprobe from vagina and place it on clean instrument tray.					
21. Wait 5 minutes and repeat the procedure (steps 8, 9 and 10) until freeze ball is 4 mm beyond edges of cryotip.					
22. Inspect the cervix carefully to ensure that a hard, white completely frozen ice ball is present.					
23. Close master cylinder valve.					
24. Inspect cervix for bleeding. If there is bleeding, apply pressure to area using clean cotton swab. Dispose of swab in a leak-proof container or plastic bag.					
25. Remove the speculum and place it in 0.5% chlorine solution for 10 minutes for decontamination.					
POSTCRYOTHERAPY TASKS					
1. Wipe light source with 0.5% chlorine solution or alcohol.					
2. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out. If disposing of gloves, place them in leak-proof container or plastic bag.					
3. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.					
4. Check to be sure woman is not having excessive cramping before she sits up, gets off the table and gets dressed.					
5. Advise the woman about post-treatment care, warning signs and follow-up instructions.					
6. Record the results of treatment and follow-up schedule in woman’s record.					
7. Observe the woman for at least 15 minutes. Ask her how she feels before sending her home.					

