Ministry of Community Development, Mother and Child Health



Ministry of Health



Visual Inspection with Acetic Acid (VIA) and Cryotherapy

A Reference Manual for Trainers and Health Care Providers

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Foreword

In order to improve the health of women and contribute to attaining MDG 5, a greater reduction in morbidity and mortality of women is imperative. When cervical cancer is detected early and treated, as many as 90% of the women who have it can be cured.

The VIA and cryotherapy clinical skills training course has been aligned with the projections of the National Cancer Control Strategic plan.

This clinical skills training course package will inform subsequent updates to the CECAP training materials and CECAP protocols and applicable at all levels of care. The course encompasses evidence-based clinical interventions for prevention of cervical cancer in a low-resource setting.

The components of the course include: anatomy of female sex organs, natural history of cervical cancer, prevention and control of cervical cancer, counseling and assessment of clients, performing VIA (visual inspection with acetic acid) with or without digital cervicography, performing cryotherapy, referral networks and mechanisms, monitoring and evaluation, and ensuring quality in the program. Adequate coverage of cervical cancer screening across the country will reduce cervical cancer incidence and deaths.

Honourable Emerine Kabanshi, MP
Ministry of Community Development, Mother and Child Health

Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CCPPZ	Cervical Cancer Prevention Program in Zambia
CECAP	Cervical Cancer Prevention
CHV	Community Health Volunteer
CIDRZ	Centre for Infectious Disease Research in Zambia
CIN	Cervical intraepithelial neoplasia
CO_2	Carbon Dioxide
DC	Digital Cervicography
FIGO	International Federation of Gynecology and Obstetrics
HAART	Highly Active Antiretroviral
HIV	Human Immunodeficiency Virus
HLD	High-Level Disinfected/Disinfection
HMIS	Health Management Information System
HPV	Human Papillomavirus
IARC	International Agency for Research on Cancer
LEEP	Loop Electrosurgical Excision Procedure
M & E	Monitoring and Evaluation
MOH	Ministry of Health
MC	Male Circumcision
N_2O	Nitrous Oxide
NCCCP	National Cervical Cancer Control Plan and Guidelines
PID	Pelvic Inflammatory Disease
PITC	Provider-Initiated Testing and Counseling
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
SCJ	Squamocolumnar Junction
SS	Supportive Supervision
STI	Sexually Transmitted Infection
SVA	Single Visit Approach
VIA	Visual Inspection with Acetic Acid
VILI	Visual inspection with Lugol's Iodine
WHO	World Health Organization

Acknowledgments

The development of the cervical cancer control program clinical skills training package by the Ministry of Community Development, Mother and Child Health, would not have been possible without the support of the following stakeholders:

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University Teaching Hospital (UTH) Department of Obstetrics and Gynaecology

Cancer Diseases Hospital (CDH)

Zambia Defence Forces (ZDF)

Jhpiego, an affiliate of Johns Hopkins University

Zambia Association of Gynaecology and Obstetrics (ZAGO)

Centre for Infectious Diseases Research in Zambia (CIDRZ)

Society for Family Health (SFH)

Project Concern International (PCI)

I am grateful to all the stakeholders for working tirelessly and ensuring successful compilation of the training package for cervical cancer screening. Scaling-up screening for pre-cancer lesions and treatment will reduce the incidence of cervical cancer in Zambia.

Dr. Davy M. Chikamata
Permanent Secretary
Ministry of Community Development, Mother and Child Health

Introduction

About the Reference Manual

This Reference Manual is designed for use by trainers and health care providers who are embarking on a cervical cancer prevention program that will focus on visual inspection with acetic acid (VIA) and cryotherapy as the core programmatic elements. It is intended to be used as an integral part of a comprehensive VIA and cryotherapy training package that includes a Participant's Guide, a Trainer's Guide, an interactive CD-ROM of cervical images, flashcards and other cervical images with questions, anatomic models, and a flash drive or CD-ROM of additional reference materials. While this reference manual does touch upon topics covered under service delivery guidelines, it does not go into the level of detail of those guidelines, and should not be viewed as a substitute for formal service delivery guidelines.

The information and guidelines contained in this manual were derived from a variety of sources, but draw heavily from Centre for Infectious Disease Research in Zambia (CIDRZ) and Jhpiego training materials. The reference manual contains "need-to-know" information for providing VIA and cryotherapy services in resource-constrained environments. That is, the reference manual contains core information in a more portable, easy-to-refer-to hard copy manual. This information is supplemented by providing each trainer and participant a flash drive or CD-ROM containing electronic versions of the CIDRZ Manual and other reference materials for easy reference. Throughout the reference manual, where indicated, specific areas are identified to direct the reader to other reference materials for more in-depth coverage of the topic.

Recommended Reading and Reference Materials

World Health Organization (WHO) Guidelines and Recommendations

World Health Organization. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition.* At:
http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/.

World Health Organization. 2013b. *WHO Guidelines: WHO Guidelines for Screening and Treatment of Precancerous Lesions for Cervical Cancer Prevention*. At:
http://apps.who.int/iris/bitstream/10665/94830/1/9789241548694_eng.pdf.

World Health Organization and Pan American Health Organization. 2013. *Monitoring National Cervical Cancer Prevention and Control Programmes: Quality Control and Quality Assurance for Visual Inspection with Acetic Acid (VIA)-Based Programmes*. At:
http://www.who.int/reproductivehealth/publications/cancers/9789241505260/en/

World Health Organization. 2012. *WHO Technical Specifications: Cryosurgical Equipment for the Treatment of Precancerous Lesions for Cervical Cancer Prevention*. At:
http://www.who.int/reproductivehealth/publications/cancers/9789241504560/en/

World Health Organization. 2011. *WHO Guidelines: Use of Cryotherapy for Cervical Intraepithelial Neoplasia*. At: http://whqlibdoc.who.int/publications/2011/9789241502856_eng.pdf.

World Health Organization. 2009. Human papillomavirus vaccines. WHO position paper. *World Health Organization Weekly Epidemiological Record*. At: http://www.who.int/wer/2009/wer8415/en/index.html.

The CIDRZ Manual

Screen-and-Treat Cervical Cancer Prevention Programmes in Resource-Constrained Environments: A Manual for Physicians, Nurse Practitioners and Managers, first ed. 2013. A Custom Publication of the African Centre of Excellence for Women's Cancer Control.

Jhpiego Resources

Cervical cancer prevention resource materials and country program documents. At: http://www.jhpiego.org and http://reprolineplus.org/

International Agency for Research on Cancer (IARC) Manuals

Sankaranarayanan R, Wesley RS. 2003. *A Practical Manual on Visual Screening for Cervical Neoplasia.* Lyon: International Agency for Research on Cancer: Lyon, France. At: http://screening.iarc.fr/doc/viavilimanual.pdf

Sellors J, Sankaranarayanan R. 2003. *Colposcopy and Treatment of Cervical Intraepithelial Neoplasia: A Beginner's Manual*. International Agency for Research on Cancer: Lyon, France. At: http://screening.iarc.fr/colpo.php

Virtual University for Cancer Control

A web-based learning course available at: http://elearning.vuccnet.net

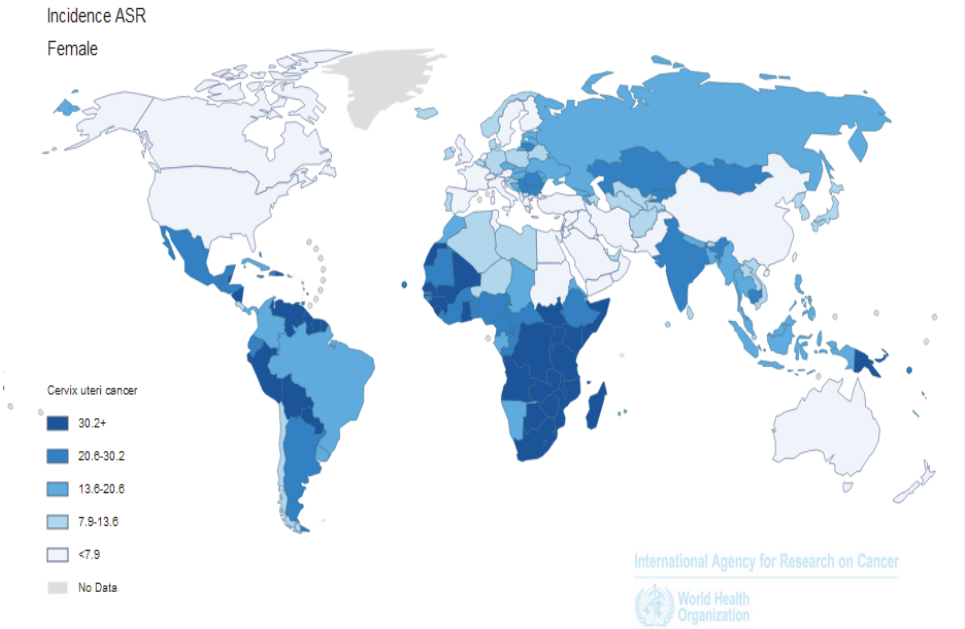
Chapter 1. Background

Importance of Cervical Cancer Prevention

Cervical cancer continues to be a major global public health problem for women. In 2012, it is estimated that nearly 530,000 new cases of cervical cancer and 266,000 deaths due to cervical cancer occurred worldwide (GLOBOCAN 2012a). Yet, when precancerous lesions are detected and treated, cervical cancer is almost completely preventable, with survival rates of nearly 100% (ACCP 2004; Castilaw and Wittet 2007). In high-income countries with high-quality, organized cervical cancer prevention programs, early diagnosis and treatment of precancerous lesions has led to significant reductions in burden of disease, with the incidence of cervical cancer decreased by a remarkable 70–80%. For example, in the United States, cervical cancer used to be one of the most common causes of cancer death for American woman, but between 1955 and 1992, cervical cancer mortality decreased nearly 70%. It has continued to decline by close to 3% per year since. Similar results have been seen in the United Kingdom (CCA 2012).

Due to poor access to high-quality screening and treatment services, though, approximately 85% of the global cervical cancer burden is borne by less-developed countries. The highest incidence and mortality rates are in Latin America and the Caribbean, sub-Saharan Africa, and South Asia (Figure 1.1). The trend of cervical cancer burden in less-developed countries is worsening, with increasing estimate of burden over time to the current 85% and an estimated 98% by 2030 (Ferlay et al. 2008).

Figure 1.1. Estimated age-standardized cervical cancer incidence rates



Source: GLOBOCAN 2012b. Cervical cancer estimated incidence, mortality and prevalence worldwide in 2012. At: http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp

As a result, cervical cancer is the most common cancer in women in the majority of developing countries and is also the most common cause of cancer deaths. It is the leading cause of years of life lost to cancer in low-resource settings and represents almost one-quarter of all cancers in women living in sub-Saharan Africa (CCA 2012). In Zambia, cervical cancer is by far the leading cause of cancer and cancer death among women. The cervical incidence and mortality age-

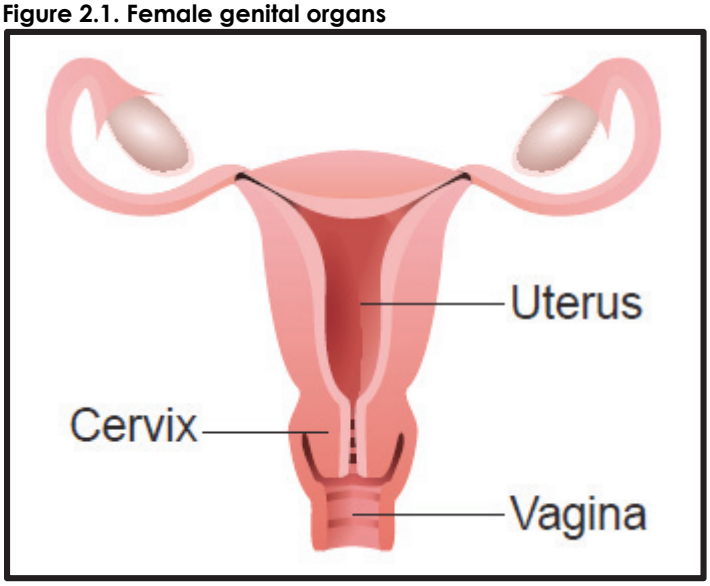
standardized rates of 58 per 100,000 and 36.2 per 100,000 women, respectively, are nearly three times higher than the second most common cause, breast, with incidence and mortality age-standardized rates of 22.4 and 11.1 per 100,000, respectively (GLOBOCAN 2012b).

Chapter 2. Anatomy and Physiology of the Cervix

Female Genital Organs

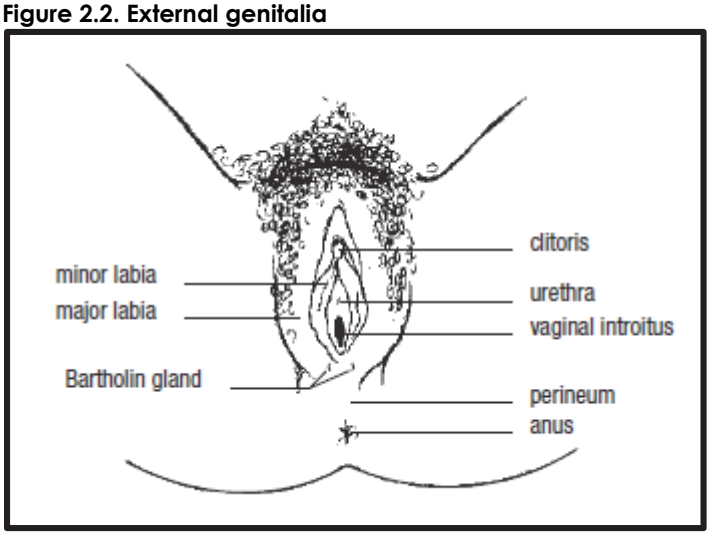
The primary components of the female genital organ system are the **ovaries, fallopian tubes, uterus, cervix, vagina, and external genitalia** (Figures 2.1 and 2.2).

Figure 2.1. Female genital organs



Source: CIDRZ 2013.

Figure 2.2. External genitalia



Source: WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figure 1.3, page 128. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

The **uterus, or womb**, is a thick-walled, smooth muscle organ with a cavity lined by endometrium that, under normal ovulatory cycles, is sloughed off monthly. The uterus expands during pregnancy to accommodate the growing fetus.

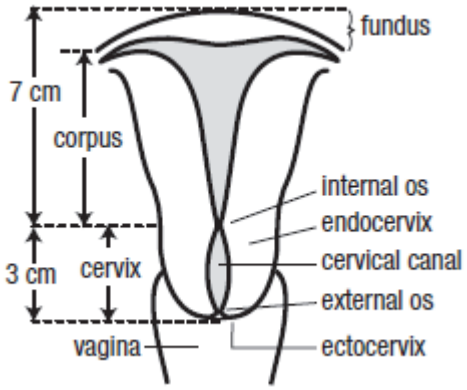
The **cervix, or mouth of the womb,** is the lower one-third of the uterus and is composed of dense fibromuscular tissue. The cervix progressively dilates during labor to allow passage of the fetus into the vagina. The cervix is described in more detail below (see Figure 2.3).

The **vagina**, **or birth canal,** is a muscular tube that creates a passage from the uterus and cervix to the outside of the body. It is this anatomical arrangement that allows direct visualization of the cervix with a speculum.

Anatomy and Physiology of the Normal Cervix

The **ectocervix** is the lower part of the cervix that lies within the vagina and is visible with a speculum. The **endocervix** is the upper part of the cervix that connects to the main body of the uterus. The **endocervical canal, or cervical canal,** runs through the center of the cervix from the **internal os**, where the endocervical canal opens into the uterine cavity, to the **external cervical os (or sometimes called the cervical os or just the os),** where the endocervical canal opens into the vagina. Typically, the external os is very easily seen in the center of the cervix when viewed with a speculum. In a woman who has never had a vaginal delivery, the external os is small and round; in women who have given birth vaginally, the external os can appear like a large, irregular slit (Figures 2.6 and 2.7, pages 8 and 9).

Figure 2.3. Uterus and cervix



Source: WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figure 1.5, page 30. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

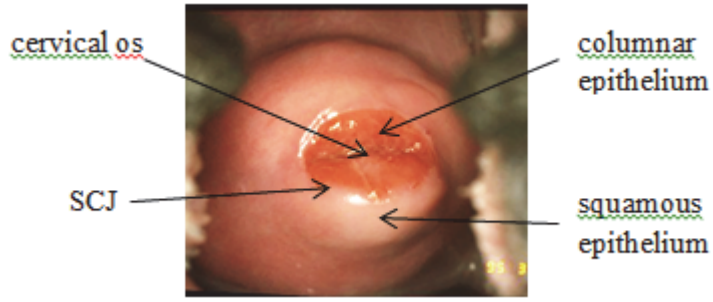
Cervical Epithelium

The cervix is covered by two types of epithelial cells: **squamous epithelium** and **columnar epithelium**. Squamous epithelium (which also makes up the skin) is composed of multiple layers of flat **squamous** cells. The squamous epithelium usually covers most of the vagina and the **ectocervix**. Columnar epithelium is composed of single layer of tall **columnar cells** (or glandular cells) and is responsible for producing cervical mucus. The columnar epithelium lines the **endocervical canal** and extends outward onto to the ectocervix to varying degrees. In Figure 2.4, note the difference in color of the **squamous epithelium** and columnar (glandular) epithelium. Normally, the ectocervix appears pink. The pink color is due to the blood that flows in the deeper cervical tissue, or stoma, beneath the multiple layers of squamous cells. The columnar epithelium appears more red due to the single layer of columnar cells that overlies the blood that flows in the cervical stroma.

Squamocolumnar Junction (SCJ)

Where the squamous epithelium meets the columnar epithelium is called the **squamocolumnar junction (or SCJ).**

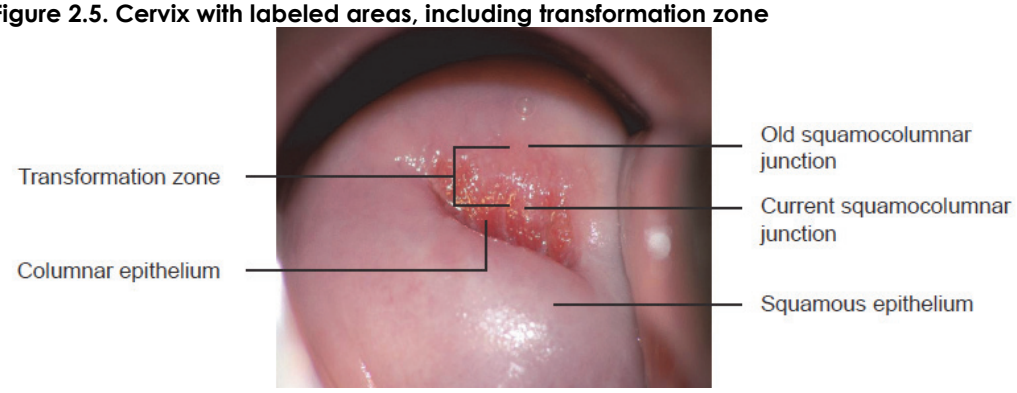
Figure 2.4. Cervix with labeled areas



Source: Jhpiego 2004.

With the onset of puberty and as a woman ages, with the accompanying changes in hormone levels (estrogen and progesterone), the columnar epithelium of the cervix is gradually replaced by squamous epithelium in a process referred to as **squamous metaplasia**. This normal replacement process gives rise to the **current SCJ**. Because this is an ongoing process, the location of the SCJ changes over time. The **transformation zone** is the area between the old SCJ and the current SCJ. While the old SCJ usually cannot be seen, the transformation zone may be seen, and usually appears pale pink-white in color (Figure 2.5).

Figure 2.5. Cervix with labeled areas, including transformation zone



Source: CIDRZ 2013.

Important Note: In the early years following puberty, most of cells within the transformation zone are columnar cells. With the rapid hormonal changes and active squamous metaplasia occurring at this time, the cells within the transformation zone, and especially those at the SCJ, are most vulnerable to the cancer-related changes induced by certain types of human papillomavirus (HPV) and other cofactors (Geng et al. 1999). Most adolescent girls do not understand that the younger they are when they become sexually active, the more chance there is that, if exposed to one or more of the cancer-inducing types of HPV, they will develop precancerous changes that ultimately could result in cancer as they get older. Using condoms helps protect these vulnerable cells, but delaying sexual intercourse until nearly age 20 is even more protective.

The transformation zone may be either a wide or a narrow area on the surface of the cervix, depending on several factors, such as age, parity, prior infections, and exposure to female hormones. Abnormal changes of the cervix, such as cervical intraepithelial neoplasia (CIN) or precancer and

cancer, almost always develop in this portion of the cervix. Thus, visual screening methods such as VIA are directed at examining the transformation zone and, especially, the SCJ. The SCJ changes location throughout a woman's lifetime. Typically, during a woman's early reproductive years, the SCJ can easily be seen on the ectocervix. As a woman ages and approaches menopause, though, the SCJ gradually moves into the endocervical canal and eventually cannot be seen.

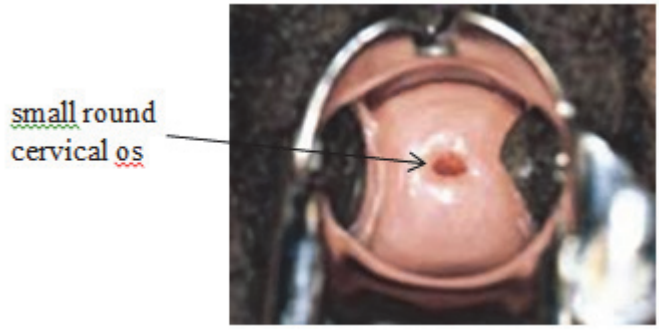
Normal Appearance of the Cervix

The detailed description of each cervix shown in this section is intended to supplement the cervical images in other areas of the resource materials (flashcards, CD-ROM, and flash drive). Therefore, when reading this section, please refer to those images to better understand the changes in each cervix being described.

Nulliparous

Note the smooth round opening (os) of the cervix (Figure 2.6). The normal trauma associated with the passage of a fetus through the cervix during birth (or late abortion) usually results in a more slit-like appearance of the cervix. The SCJ is visible as a faint, thin, white line just at the entrance to the cervical canal.

Figure 2.6. Nulliparous cervix



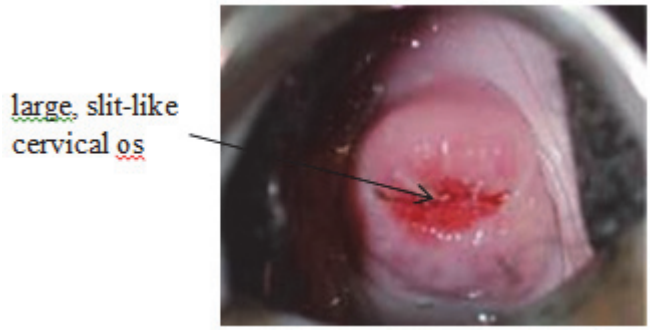
Source: Jhpiego 2004.

There is a small amount of glare visible, mainly on the squamous epithelium, which is an artifact caused by the photographic flash or light source. Clinically, glare can be differentiated from potential pathology by either moving the light source or changing position while viewing the cervix. Although the artifact due to glare will move with the change in light source or viewing angle, color changes indicative of diseased tissue will not.

Parous

Compare this parous cervix (Figure 2.7) with the nulliparous cervix. The cervical os is uneven, with a worn appearance. Such a cervix is often described as having a "fish mouth" appearance. At times, the many contours and surfaces of such a cervix may require that the health care provider manipulates the cervix with a swab in order to get as thorough a view of the SCJ as possible. This is perhaps best accomplished using a swab either on the cervix itself or by placing a swab in the cul-de-sac and pushing upward, thus bringing the cervix downward and into view. In large and patulous (spread apart) cervices, it may be necessary to open the bivalve speculum wider to better expose the SCJ.

Figure 2.7. Parous cervix

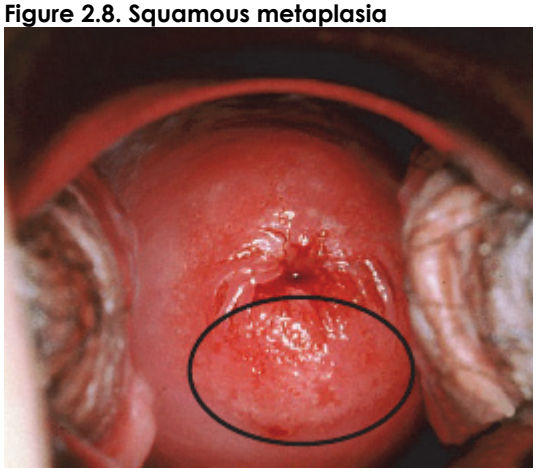


Source: Jhpiego 2004.

Squamous Metaplasia

Squamous metaplasia (Figure 2.8) is a physiologic process through which the columnar cells lining the endocervical canal near the SCJ are gradually replaced with squamous cells. This process is influenced by the level of female hormones and as a result of the cervix's exposure to the vaginal environment: the acidic nature of secretions, bacteria, viruses, and unclean foreign bodies. In the cervix shown here, there is a visible area of squamous metaplasia on the lower lip of the cervix, close to the SCJ. It has a faint white, translucent appearance, almost as if a thin, white veil were laid onto the cervix—most clearly seen following application of dilute acetic acid solution. Unlike mucus, it will not wipe away.

Figure 2.8. Squamous metaplasia



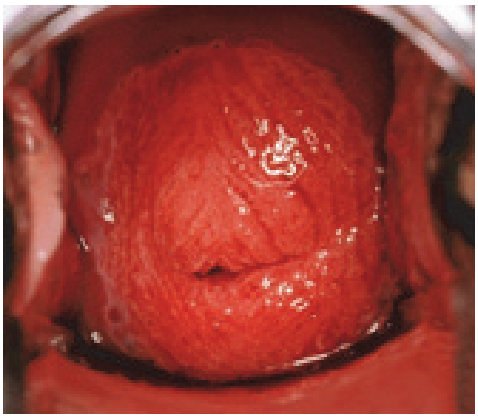
Source: Jhpiego 2004.

Benign Cervical Abnormalities

Ectropion/Ectopy

Exposure to hormones such as estrogen and progesterone (whether endogenous or synthetic) may affect the appearance of the cervix. This effect is typified by the increased presence of columnar cells on the outer surface of the cervix (Figure 2.9). This finding, often called ectropion or cervical ectopy, is not a pathological condition, but rather a normal variant of cervical appearance.

Figure 2.9. Cervical ectropion/ectopy

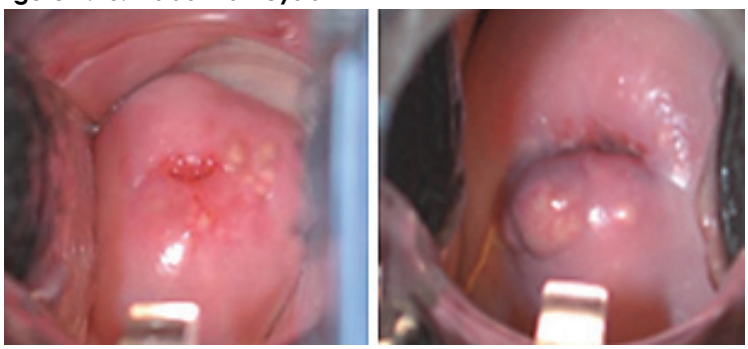


Source: Jhpiego 2004.

Nabothian Cysts

Nabothian cysts are mucus-filled cysts that look like yellowish, bluish, or white little balls just underneath the surface of the squamous epithelium (Figure 2.10). They are usually small in size (2–3 mm), but occasionally can grow to more than 1cm in size.

Figure 2.10. Nabothian cysts



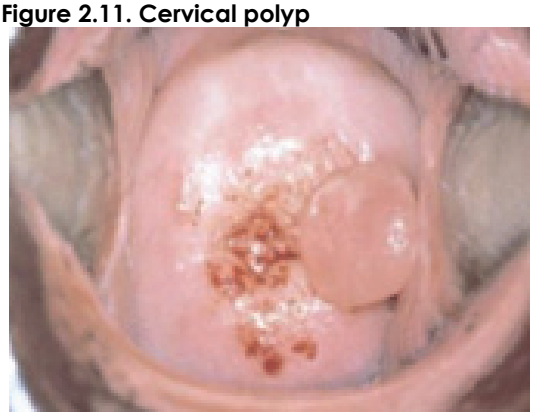
Source: Jhpiego 2004.

Nabothian cysts form when squamous epithelium grows on top of columnar epithelium, which often occurs during squamous metaplasia, and blocks the mucus from being secreted by these glandular cells. The mucus is trapped, and small cysts develop under the surface and often protrude outward. They are benign and do not cause pain. At times, though, the cervix can look very unusual due to the presence of a large number of nabothian cysts, or nabothian cysts that distort the cervix and may push blood vessels out over its surface.

Cervical Polyps

Cervical polyps are found fairly often and represent small segments of glandular tissue that arise from the columnar epithelium of the endocervical canal, but are attached by an elongated stalk. They vary in size and are often without symptoms, but some clients may present with postcoital bleeding, or, less commonly, prolonged or heavy menstrual bleeding. As in this picture (Figure 2.11), polyps are often very mobile and can be pushed in different directions in order to reveal the SCJ.

Figure 2.11. Cervical polyp



Source: Jhpiego 2004.

Chapter 3. Natural History of Cervical Cancer

HPV and Cervical Cancer

It is now clear that cervical cancer is caused by the human papillomavirus (HPV), a sexually transmitted infection (STI). HPV causes over 99% of invasive cervical cancers. HPV is highly transmissible and is the most common STI, with current evidence estimating that the majority of sexually active individuals will become infected at some point in their lives, some repeatedly, with one or more types of genital HPV. HPV causes almost all cases of genital warts. Though less common than cervical cancer, HPV can also cause cancer of the vagina, vulva, anus, penis, mouth, and throat (CDC 2012; WHO 2009; de Sanjose et al. 2010).

While most genital HPV infections are transient and benign, persistent infection with certain types of HPV can lead to the development of cervical precancer or cancer. More than 100 distinct HPV genotypes exist, but only a small subset (at least 13) are considered oncogenic or high-risk HPV and associated with development of cervical cancer. Globally, the most common HPV types associated with the development of cervical cancer are HPV 16 and 18, which account for approximately 70% of cervical cancer cases worldwide. Of all the HPV types, HPV 16 has the greatest oncogenic potential. While geographic distribution of high-risk HPV types varies among regions, HPV 16 is consistently the dominant high-risk HPV type. In addition to HPV 16 and 18, other high-risk HPVs include 31, 33, 35, 45, 52, and 58 (CDC 2012; WHO 2009; de Sanjose et al. 2010).

Natural History of HPV Infection and Cervical Cancer

As mentioned earlier, HPV infection is very common, and most HPV infections are transient and spontaneously resolve, posing little risk of progression. As a result, only a small percentage of women infected with HPV will develop significant cervical precancerous lesions or cancer. Persistent infection with high-risk HPV is the most important risk factor for developing cervical precancer or cancer. Important co-factors that increase the likelihood of HPV persistence are cigarette smoking and HIV infection (CDC 2012; ACOG 2012; WHO 2009; WHO 2013a).

The peak time of HPV infection is shortly after an individual becomes sexually active. While the peak time of HPV infection will vary depending on the local context, it tends to be most common in teenagers and women in their early 20s, with a decrease in prevalence as women age. Following initial HPV infection, most of these infections spontaneously clear. Most young women, especially those younger than 21 years, have an effective immune response that clears the infection quickly—in an average of 8 months. As a result, most women in this group do not have persistent HPV infection (CDC 2012; ACOG 2013; ASCCP 2013).

If HPV infection persists, however, cervical intraepithelial neoplasia may develop within a few years of infection. (See “A Note about Cervical Precancer Terminology” below for a description of CIN.) These low-grade lesions are not considered truly precancerous and often spontaneously resolve along with the HPV infection. This is often the case in young women (women in their early 20s or younger); if they do have persistent HPV infection that develops into CIN, most of the lesions will be mild and have a high rate of spontaneous regression to normal (CDC 2012; ACOG 2013; ASCCP 2013).

A Note about Cervical Precancer Terminology

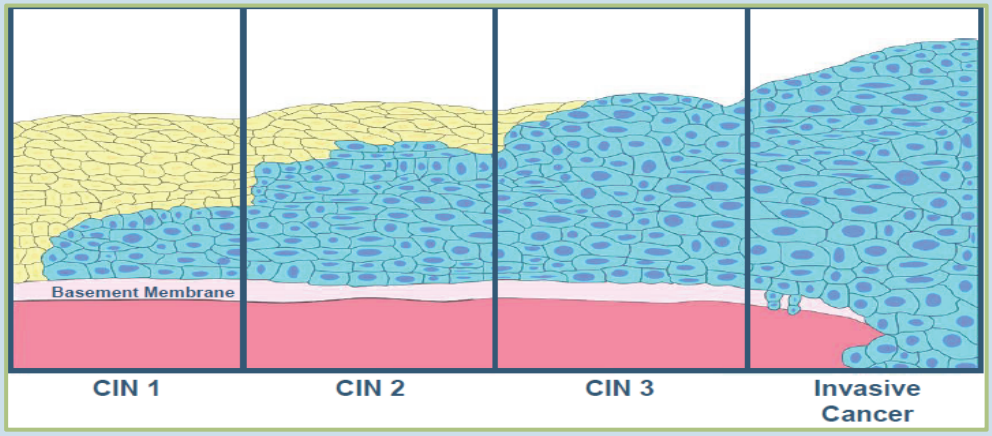
When Pap smear tests are used for screening, the cervical cytology results are usually reported using The Bethesda System terminology, which classifies squamous cervical epithelial cells according to their appearance. The following is a summary of this classification:

Interpretation/Result (for epithelial cells):

- **Negative** for intraepithelial lesion or malignancy
- **Atypical squamous cells (ASC):**
  - Of undetermined significance (ASC-US)
  - Cannot exclude high-grade squamous intraepithelial lesion (HSIL) (ASC-H)
- **Low-grade squamous intraepithelial lesion (LSIL):** encompassing HPV, mild dysplasia, and cervical intraepithelial neoplasia (CIN) 1
- **High-grade squamous intraepithelial lesion (HSIL):** encompassing moderate and severe dysplasia, carcinoma in situ, CIN 2 and CIN 3
  - With features suspicious for invasion (if invasion is suspected)
- **Squamous cell carcinoma**

The term cervical intraepithelial neoplasia (CIN) is often used interchangeably with cervical dysplasia, and the corresponding mild, moderate, and severe dysplasia histopathology classification (CDC 2012; ACOG 2013; WHO 2013b). However, CIN is the most commonly used terminology globally and uses internationally agreed-upon criteria for dividing cervical lesions into three grades based upon how many layers of the cervical epithelium are involved:

- **CIN 1**: The abnormal cells are confined to the bottom third of the cervical epithelium.
- **CIN 2**: The abnormal cells are confined to the bottom and middle third of the cervical epithelium
- **CIN 3**: The abnormal cells involve all three layers (bottom, middle, and upper) of the cervical epithelium.



CIN1 is considered a low-grade lesion, and CIN 2 and 3 collectively as high-grade lesions. This is clinically significant, because low-grade lesions tend to spontaneously regress, or clear without treatment, while high-grade lesions have a greater risk of progressing (see below for further discussion). As a result, CIN 1, or low-grade lesion, is not considered "precancerous" and CIN 2 and CIN 3 are considered precancerous. This is the reason that, when clinical studies are being compared where histopathology is used, they often refer to CIN 2+ lesions (detection or treatment), since these are considered cervical precancer.

When comparing CIN terminology with dysplasia terminology, CIN 1 corresponds to mild dysplasia, CIN 2 corresponds to moderate dysplasia, and CIN 3 corresponds to severe dysplasia and carcinoma in situ (CIS).

As previously noted, persistent HPV infection can develop into CIN 1, and from CIN 1 to CIN 2 and 3. However, persistent HPV infection can also progress directly to CIN 2 or CIN 3 (referred to as CIN 2+), which represent high-grade lesions and are considered cancer precursors, especially CIN 3. The rate of progression to CIN 2+ is variable, but usually takes at least a few

years. Approximately only 1% of CIN 1 progress to CIN 3 in a year, while 16% of CIN 2 progress to CIN 3 in a year. In contrast to infection in younger women, HPV infection detected in women older than 30 years is more likely to reflect persistent infection, and corresponds with increasing rates of more significant precancerous lesions (CIN2+), which are less likely to spontaneously regress. Although regression rates for CIN2+ lesions average near 50%, if left untreated, these lesions have a significant risk of progressing to invasive cervical cancer. This progression is usually still relatively slow, averaging 8–12 years to progress from CIN2+ to invasive cervical cancer. It is estimated that approximately 1–2% of women have CIN 2+ each year, with rates near 10% in HIV-infected women. This prolonged natural history of the precancerous stage offers excellent opportunities to detect the presence of precancerous lesions and to treat them to prevent progression to invasive cervical cancer. (Holowaty et al. 1999; ACOG 2013; ASCCP 2013; WHO 2014; WHO 2013b).

Ideally, treatment should be targeted at women with lesions at the highest risk of progression to invasive cervical cancer—CIN 2+. However, since confirmatory histopathology is not practical or feasible in many low-resource settings, it is recognized that a certain proportion of visual inspection with acetic acid (VIA)-positive women will have CIN 1 or less, and thus at lower risk of progression to invasive cervical cancer. In order to maximize impact, screening and treatment, especially in settings without confirmatory histopathology, should focus on age groups (or those with other risk factors, e.g., HIV) at higher risk for CIN 2+. Policies and guidelines must take this into account and weigh the advantages and disadvantages of overtreatment as compared to undertreatment when deciding age to start screening, as well as frequency of screening. The high risk of HPV infection shortly following onset of sexual activity, along with the slow progression from HPV infection to cervical precancer or cancer, offers many cervical cancer prevention opportunities.

Signs and Symptoms of Cervical Cancer

Cervical precancer, or CIN, does not cause any signs or symptoms. It does not cause abnormal discharge, abnormal bleeding, or pain; the woman feels well, which underlines the importance of cervical cancer screening in women who otherwise feel well. Cervical cancer, however, can cause signs and symptoms, especially as it becomes more advanced. Common signs and symptoms of cervical cancer include:

- **Postcoital or contact bleeding.** Bleeding following sexual intercourse or anything that contacts the cervix is often the first sign of cervical cancer. While other conditions can cause postcoital or contact bleeding (e.g., cervical polyps, severe cervicitis), cervical cancer must be considered in any woman who presents with these symptoms.
- **Abnormal vaginal bleeding.** Other types of abnormal vaginal bleeding, such as postmenopausal bleeding or bleeding in between menstrual periods, can be an indication of cervical cancer. There are multiple other potential underlying causes for abnormal vaginal bleeding, but cervical cancer should always be part of a differential diagnosis and be part of the evaluation of the woman.
- **Abnormal vaginal discharge.** Cervical cancer can produce abnormal vaginal discharge: blood-tinged, brown, foul-smelling, or purulent. Foul-smelling, bloody, purulent discharge is often a late sign of cervical cancer, and found in advanced cases with necrotic cervical tissue.

- **Discomfort or pain in pelvis, abdomen, back, legs, or following sexual intercourse.** Cervical cancer can cause these symptoms. If cervical cancer is causing these symptoms, the disease is often far advanced, and the woman will also have signs and symptoms of postcoital/contact bleeding and abnormal vaginal bleeding.

It is important, therefore, to ask women about the presence of these signs and symptoms. It is also important to examine women who present with these signs and symptoms, and not to turn them away believing that you cannot perform VIA on a woman who is bleeding. If the woman is having abnormal bleeding, she should be examined.

Stages of Cervical Cancer

If left untreated, cervical precancer can progress to invasive cervical cancer. This occurs when the abnormal cells spread through the basement membrane of the epithelial layer, and into the deeper cervical tissue (stroma). Cervical cancer is classified into stages according to the International Federation of Obstetrics and Gynaecology (FIGO), and is surgically staged (Pecorelli 2009) (Table 3.1; Figures 3.1–3.7).

Table 3.1. FIGO staging of cervical cancers

Stage	
I	The carcinoma is strictly confined to the cervix (extension to the corpus would be disregarded).
IA	Invasive carcinoma, which can be diagnosed only by microscopy with deepest invasion ≤ 5 mm and largest extension ≥ 7 mm.
IA1	Measured stromal invasion of ≤ 3.0 mm in depth and extension of ≤ 7.0 mm.
IA2	Measured stromal invasion of > 3.0 mm and not > 5.0 mm with an extension of not > 7.0 mm.
IB	Clinically visible lesions limited to the cervix uteri or preclinical cancers greater than stage IA.
IB1	Clinically visible lesion ≤ 4.0 cm in greatest dimension.
IB2	Clinically visible lesion > 4.0 cm in greatest dimension.
II	Cervical carcinoma invades beyond the uterus but not to the pelvic wall or to the lower third of the vagina.
IIA	Without parametrial invasion.
IIA1	Clinically visible lesion ≤ 4.0 cm in greatest dimension.
IIA2	Clinically visible lesion > 4.0 cm in greatest dimension.
IIB	With obvious parametrial invasion.
III	The tumor extends to the pelvic wall and/or involves lower third of the vagina and/or causes hydronephrosis or nonfunctioning kidney.
IIIA	Tumor involves lower third of the vagina with no extension to the pelvic wall.
IIIB	Extension to the pelvic wall and/or hydronephrosis or nonfunctioning kidney.
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 of the growth to adjacent organs.
IVB	Spread to distant organs.

Figure 3.1. Cervical cancer Stage IB

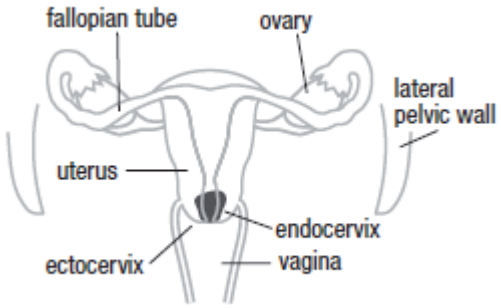
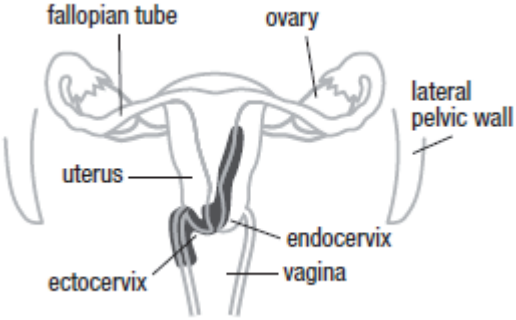


Figure 3.2. Cervical cancer Stage IIA



Source: WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figure 6.1, page 162. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

Figure 3.3. Cervical cancer Stage IIB

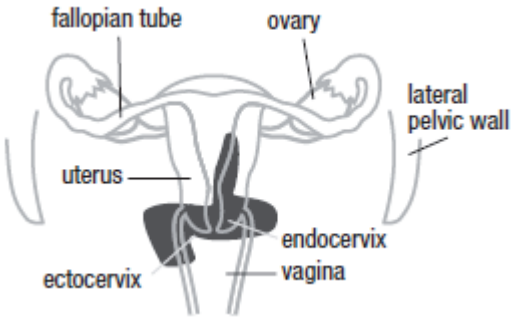
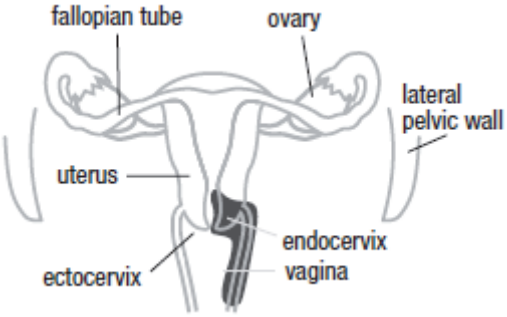


Figure 3.4. Cervical cancer Stage IIIA



Source: WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figures 6.1, page 162. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

Figure 3.5. Cervical cancer Stage IIIB

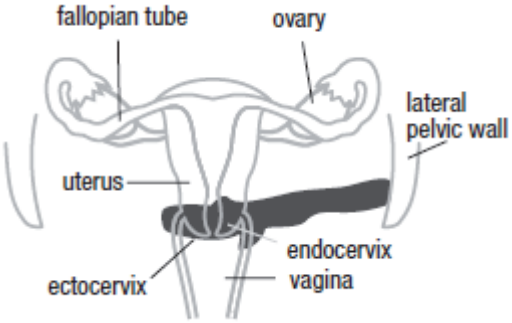
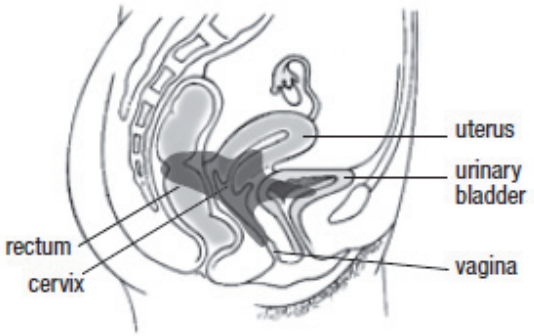
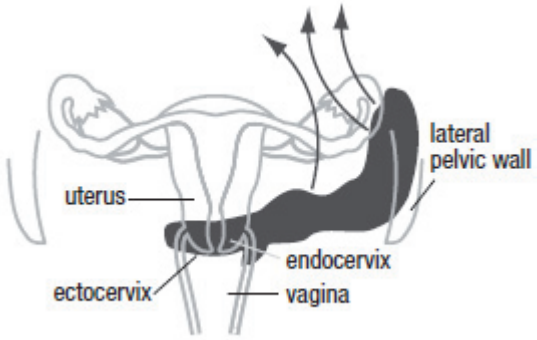


Figure 3.6. Cervical cancer Stage IVA



Source WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figures 6.1, page 162. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

Figure 3.7. Cervical cancer Stage IVB



Source: WHO. 2014. *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition,* Figure 6.1, page 162. At: http://www.who.int/reproductivehealth/publications/cancers/cervical-cancer-guide/en/, accessed January 15, 2015.

Relationship between HIV/AIDS and Cervical Cancer

Human immunodeficiency virus (HIV) suppress the body's natural defense mechanism, the immune system, making those infected with HIV more vulnerable to other types of infectious diseases, and making what would normally be mild diseases become more deadly. Globally, the HIV/AIDS epidemic continues to take its toll on men and women, with an estimated 35 million people living with HIV/AIDS in 2012, approximately 70% of whom are living in sub-Saharan Africa, and 95% of new infections occurring in low- and middle-income countries. Worldwide, over 50% of all those living with HIV are female, and in sub-Saharan Africa, women account for 60% of HIV infections. In addition, women account for over 70% of people age 15–24 years who are HIV-positive in sub-Saharan Africa (UNAIDS 2013).

A tremendous amount of success in the management of HIV and its common complications of opportunistic infections has led to improved care of HIV-positive women. Before antiretroviral therapy (ART) became common, HIV-positive women and men often died from opportunistic infections, such as tuberculosis and pneumonia, and died at young ages. However, with improved access to and management with ART, along with active screening and treatment of opportunistic infections, HIV-positive women are living much longer. Yet, while women are surviving longer following one type of viral infection, HIV, they are now living long enough to die from another type of viral infection, HPV and cervical cancer (De Vuyst et al. 2008). The regions where cervical cancer rates are highest also often tend to have high prevalence of HIV (Figure 3.8).

Figure 3.8. Cervical Cancer Incidence and HIV Prevalence in Africa (darker areas indicate higher rates)



Source: GLOBOCAN 2012b.
Cervical cancer estimated incidence, mortality and prevalence worldwide in 2012.
At: http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp



Source: UNAIDS 2013. At: http://www.unaids.org/en/dataanalysis/datatools/aidsinfo

That high prevalence of HIV infection correlates with high rates of cervical disease is consistent with the knowledge of how HIV influences the pathophysiology of HPV infection and cervical cancer, where the presence of HIV increases the risk of precancerous and cancerous changes on the cervix (WHO 2013b). Further, this increased risk is compounded by the general unavailability of effective cervical cancer prevention programs in these lower-resource settings, resulting in cervical cancer screening rates often being lowest where HIV prevalence is highest.

A normal, healthy, well-functioning immune system helps reduce the risk of developing cervical cancer. As noted earlier, while a large percentage of women will acquire cervical HPV infection at some point in their lives, a healthy immune system will help most women clear the infection. Because of their suppressed immune systems, HIV-infected women are at a higher risk for developing CIN and cancer than their HIV-uninfected counterparts (WHO 2013b; Adjorlolo-Johnson et al. 2010; Kahesa et al. 2008; Stein et al. 2008; Hawes et al. 2003, Gichangi et al. 2003; Chaturvedi et al. 2009; Denslow 2013). A number of factors may increase the risk of cervical cancer in HIV-positive women. Compared to HIV-negative women, HIV-positive women have the following:

- Higher rates of HPV infection, including high-risk HPV types
- Higher likelihood of multiple HPV types
- Higher HPV viral loads
- More rapid progression from HPV infection to cervical precancer and cervical cancer
- Higher rates of persistent HPV infection and CIN 2+

- A greater likelihood of having their HPV infection rapidly progress to cervical cancer, and a greater likelihood of getting cervical cancer at a much younger age
- Larger precancerous lesions that are more difficult to treat
- Higher recurrence rates of precancerous lesions following treatment

  (Branca et al. 2003; DeVuyst et al. 2008; Parham et al. 2006; Jamieson et al. 2002; Ahdieh et al. 2000; Firnhaber et al. 2009; Sahasrabuddhe et al. 2007; Minkoff et al. 1998; Uberti-Foppa et al. 1998; Tebeu et al. 2006, Gichangi et al. 2003)

Furthermore, in HIV-positive women, the rate and persistence of HPV infection, as well as the frequency of high-risk HPV types, increase with worsening or more advanced HIV disease (decreasing CD4 count and increasing HIV viral loads) (Palefsky et al. 1999; Denny et al. 2008; Luque, Demeter and Reichman 1999; Minkoff et al. 1998; Sahasrabuddhe et al. 2007; Denslow et al. 2013).

Not only may cervical cancer occur in HIV-positive women at younger ages, it tends to present at more advanced stages and have poorer responses to standard therapy, with higher recurrence and death rates, compared with HIV-negative women (Gichangi et al. 2003).

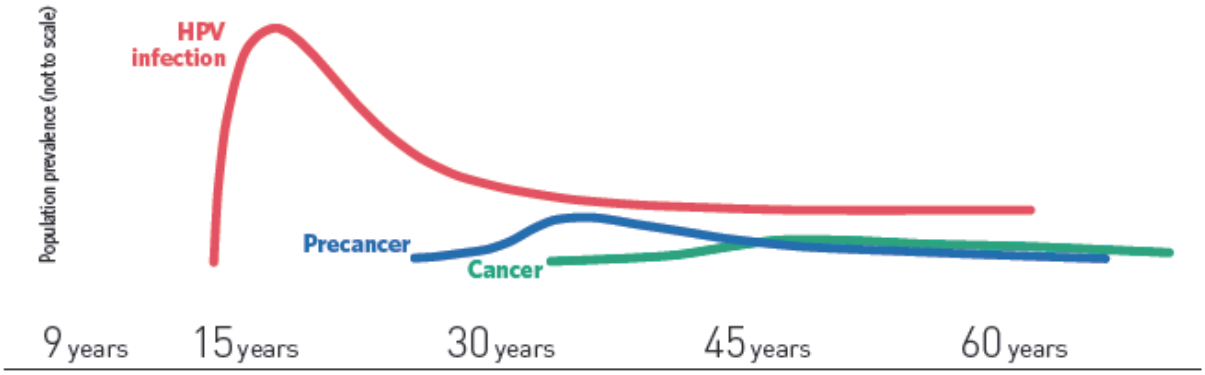
The role of highly active antiretroviral therapy (HAART) and improvement in immune function in reducing the development or progression of HPV infection and cervical disease remain unclear, with studies examining this issue having conflicting findings. Since HAART tends to improve the immune system to near-normal function, these results are unexpected (Adler 2010; De Vuyst et al. 2008). As a result, until evidence suggests otherwise, HIV-positive women should continue to be followed closely for evidence of cervical precancer, regardless of antiretroviral therapy or CD4 count.

Chapter 4. Cervical Cancer Prevention and Control

Continuum of Care

A comprehensive approach to cervical cancer prevention and control requires applying effective interventions along a continuum of care throughout the life cycle, and includes primary prevention, secondary prevention, and tertiary prevention, as well as palliative care, and all the activities that support these interventions (Figure 4.1).

Figure 4.1. Continuum of care to prevent HPV infection and cervical cancer



PRIMARY PREVENTION
Girls 9-13 years

- HPV vaccination

Girls and boys, as appropriate

- Health information and warnings about tobacco use*
- Sexuality education tailored to age & culture
- Condom promotion/provision for those engaged in sexual activity
- Male circumcision

SECONDARY PREVENTION
Women >30 years of age

Screening and treatment as needed

- "Screen and treat" with low cost technology VIA followed by cryotherapy
- HPV testing for high risk HPV types (e.g., types 16, 18 and others)

TERTIARY PREVENTION
All women as needed

Treatment of invasive cancer at any age

- Surgery
- Radiotherapy
- Chemotherapy

* Tobacco use is an additional risk factor for cervical cancer.

Adapted from: WHO. 2013a. *WHO Guidance Note: Comprehensive Cervical Cancer Prevention and Control: A Healthier Future for Girls and Women,* Figure 1, page 3. At: http://www.who.int/reproductivehealth/publications/cancers/9789241505147/en/, accessed January 15, 2015.

A detailed discussion of each of the interventions and their supporting activities is beyond the scope of this reference manual. Rather, what follows is a brief overview with a focus on secondary prevention using VIA and cryotherapy.

Primary Prevention

Because nearly all cervical cancer cases are caused by HPV, primary prevention of cervical cancer means preventing genital HPV infection from occurring in the first place. Complicating this task is that HPV is highly transmissible and is the most common STI. The majority of sexually active individuals will become infected with HPV at some point in their lives, with the peak incidence of infection occurring shortly after an individual becomes sexually active (WHO 2009; WHO 2013b; ACOG 2012; Vaccarella et al. 2006).

Prevention of HPV Infection Can Be Achieved Through:

HPV vaccination prior to exposure, i.e., before initiating sexual activity: Among the primary prevention approaches, HPV vaccination is the most effective and reliable method and holds the greatest promise for having a significant impact on cervical cancer rates. HPV vaccination does not treat HPV infection, precancer or cancer. Its effectiveness is based on the principle of vaccination prior to exposure and infection with HPV. WHO, therefore, recommends vaccinating girls in the target age group of 9–13 years, in the hope of reaching them before their first sexual contact (CDC 2012; WHO 2009; WHO 2013a; ACOG 2014).

Two types of HPV vaccines currently exist; the bivalent vaccine (Cervarix), which protects against HPV 16 and 18, and the quadrivalent vaccine (Gardasil), which protects against HPV 6, 11, 16, and 18. HPV 6 and 11 are associated with the development of benign anogenital warts, but not associated with the development of cervical cancer. Therefore, Gardasil protects against both cervical cancer and genital warts. Each of the vaccines is administered in 3 doses over a 6-month period. WHO estimates current market prices for the vaccines run from less than US$10 to more than US$100 per dose, while the total start-up and operational costs to deliver the three doses are estimated at US$7.20/girl (CDC 2012; WHO 2009; WHO 2013a; ACOG 2014).

The cumulative evidence to date is that these two vaccines are effective in preventing over 95% of clinical disease (CIN 2+) from HPV 16 and 18 for at least 5 years. The duration of protection following vaccination is unknown, but the study populations followed have not shown evidence of declining protection, either from clinical disease (CIN 2+) or antibody titers. The need for booster vaccination in the future has not been determined, but currently appears unnecessary. HIV-infected individuals can receive the HPV vaccine, but their immune response may be less than that seen in their HIV-uninfected counterparts. These vaccines also appear to provide limited cross-protection against other, less common, oncogenic HPV genotypes (CDC 2012; WHO 2009; WHO 2013a; ACOG 2014; CIDRZ 2013).

For further reading on HPV vaccination, see the WHO Guidance Note (WHO 2013a).

Behavior change approaches to reduce risk of exposure to HPV: Abstinence, delayed onset of sexual activity, reduced number of sexual partners (and partners' partners), and correct, consistent condom use can all decrease the risk of HPV exposure.

Delaying sexual activity, limiting the number of sexual partners: Since HPV is a sexually transmitted infection, it is not unexpected that key behavioral risk factors that increase the risk of HPV infection are related to sexual behavior and include: 1) early age of first sexual intercourse; 2) multiple sexual partners; 3) partners with multiple sexual partners; and 4) lack of correct and consistent condom use (WHO 2014). Early age of first sexual intercourse, though, is an important, distinct risk factor. The changes occurring in the cervix around menarche as described in Chapter 2 (the physiological immaturity of the cervix), make it particularly vulnerable to HPV infection. This vulnerability is believed to be due to relatively large areas of cervical ectopy with rapid metaplastic changes occurring at the SCJ, and these cells being particularly susceptible to HPV infection (Kahn et al. 2002).

Correct and consistent condom use: Since HPV can infect areas beyond those covered by condoms, condom use provides only partial protection against HPV infection. Even that partial protection, though, is important, especially because condoms provide additional benefits, such as protection against HIV and other STIs, as well as prevention of unwanted pregnancy (WHO 2014).

Prevention of HIV and other STIs: The interaction of HIV and HPV infection has been discussed earlier (see Chapter 3). Because HPV is a sexually transmitted infection, any effort to reduce the risk of STIs will also decrease the risk of HPV infection.

Stop smoking: Tobacco use is an important environmental risk factor for the development of cervical precancer and cancer, though its role in the pathogenesis is not well-understood. Some studies suggest a direct oncogenic effect of chemical carcinogens found in tobacco, while others suggest that smoking causes suppression of cell-mediated immunity against HPV infection, thus increasing the risk of cervical precancer and cancer. This effect appears to be related to current users and is dose-dependent, such that the longer and heavier the tobacco use, the greater the risk of cervical disease (Gadducci et al. 2011).

Use of oral contraceptives: The impact of long-term oral contraceptive (OC) use on the risk of developing cervical cancer continues to be debated. However, among long-term, continuous users of OCs, the risk of cervical cancer appears increased; for OC use of 5–9 years, 60% increase, for $\geq$10 years, double the risk. Cervical cancer risk decreases rapidly upon discontinuation of the OCs. Given the benefits of OCs, WHO and most providers do not recommend limiting the use of OCs (Gadducci et al. 2011, WHO 2014).

Male circumcision (MC): MC has long been associated with reduced risk of cervical cancer in the wives of circumcised men. Further study is warranted, however, because a study in Uganda demonstrated that MC was associated with a lower incidence in men of multiple high risk (HR)-HPV types and increased clearance of HR-HPVs as compared to controls (14.8% vs. 22.3%, respectively) (Gray et al. 2010). Yet, MC was not associated with decreased incidence or increased clearance of HR-HPV in the female partners of circumcised men 24 months after the procedure, as compared to partners of men in the control group (Tobian 2011).

Secondary Prevention

A successful secondary prevention pillar of a national cervical cancer prevention program requires the following elements to be present (WHO 2014):

- An accurate screening test
- Linkage to effective treatment
- High coverage (> 80%) of the population at highest risk for developing cervical cancer (target population)
- Effective linkages among all components of the program (primary prevention, secondary prevention, and tertiary care)
- Adequate resources (human, equipment, and supplies)
- Feasibility, acceptability, and cost-effectiveness

Screening Test Qualities and Their Interpretation

Sensitivity: the proportion of women testing positive among those who have cervical disease (true positive rate)

Specificity: the proportion of women testing negative among those who do not have cervical disease (true negative rate

Positive predictive value (PPV): Proportion of women having cervical disease among those with a positive test result

Negative predictive value (NPV): Proportion of women having no disease among those with a negative test result

Sensitivity and specificity are qualities that generally measure the intrinsic qualities of diagnostic tests. By definition, if accurately and validly calculated, these measures should not differ substantially across research studies. Because of this, they are good measures for comparing the relative value of different tests with regard to identifying true disease or non-disease.

Predictive values, on the other hand, are measures of the clinical utility of the test when applied to a specific population in a particular environment. Predictive values incorporate information on both the intrinsic qualities of the test and the prevalence of disease (i.e., probability of disease prior to testing) in the population being tested.

Reference Test

Clinical Test

	(+)	(-)	
(+)	a	b	a + b
(-)	c	d	c + d

a + c b + d

Sensitivity = a/a+c
Specificity = d/b+d

PPV = a/a+b
NPV = d/c+d

Screening Tests

See Table 4.1 for summary comparison of the quality of common screening tests.

Table 4.1. Screening test sensitivity and specificity in detecting cervical disease (CIN 2+ or Cancer)

Test	Sensitivity	Specificity
Pap smear	**38–83%[1]** **47–62%[2]**	**> 90%[1]** **60–95%[2]**
VIA	**80%[3]** **65–90%[2]**	**92%[3]** **64–98%[2]**
HPV testing **Clinician-collected** **Self-collected**	**93–98%[4]** **80–86%[4]**	**85%[4]** **85%[4]**

Sources: WHO 2014; FIGO 2009; Sauvaget et al. 2011; ACCP 2011.

Cytology

In high-income countries with high-quality, organized cervical cancer prevention programs, early diagnosis and treatment of precancerous lesions has led to significant reductions in burden of disease, with the incidence of cervical cancer decreased by a remarkable 70–80%. However, this requires substantial human resources, equipment, and supplies, as well as a multi-visit process. The process typically entails cytology screening or Pap smear, followed by a separate visit for colposcopy and confirmatory cervical biopsy if screen-positive, histopathology processing of the specimen, and finally another visit for treatment for confirmed CIN2+. Replicating the success of cytology-based screening programs seen in many high-income countries has proven difficult in resource-poor countries. This is due to many reasons, including (ACCP 2007; Sankaranarayanan et al. 2005; Anorlu 2008; WHO 2013b):

- competing health priorities such as HIV/AIDS, maternal mortality and malaria, among many others;
- substantial human resources, equipment, and supplies required, often lacking in many countries;
- a multi-visit process for screening and treatment, if indicated; and
- other bottlenecks associated with long wait times for cytology or histopathology results, and referral to distant health facilities for further management, creating barriers for women accessing services.

The terms **single visit-approach (SVA)** and **screen-and-treat** are often used interchangeably. Both approaches promote the linkage of screening with treatment by utilizing a point-of-care screening test, such as VIA. However, as the term implies, SVA uses a visual screening method coupled with immediate treatment in a single visit. Screen-and-treat, on the other hand, refers to an approach in which the treatment decision is based on the screening result and treatment is provided soon (in two visits), or ideally, immediately (single visit) following a positive screening test (WHO 2013b).

Default rates are a significant problem in a multi-step process, with 10–25% attrition for each step not unusual, and reports of up to 50–80% of women not receiving recommended treatment due to loss to follow-up (ACCP 2004; Bingham et al. 2003; Cronje 2004). Compounding this issue is that many of these settings lack a well-organized surveillance and recall system.

Visual Inspection of the Cervix

Visual Inspection with Acetic Acid (VIA)

Visual inspection with acetic acid (VIA) is a low-cost, low-tech point-of-care approach to cervical cancer prevention that promotes linkage of screening with immediate treatment of precancerous lesions, often with cryotherapy, in a single visit approach (SVA).

Linking screening with treatment in a SVA is programmatically important, as the SVA strategy minimizes the number of patients with abnormal screening results being lost to follow-up and not receiving appropriate treatment—a major cause for low program impact in developing countries. This linkage is not only clinically important—a safe, feasible, and acceptable alternative to cytology-based screening with comparable sensitivity—it is cost-effective (Goldie et al. 2005; Mandelblatt et al. 2002; Sankaranarayanan et al. 2007; Gaffikin, Lauterbach and Emerson 2003). In a cluster randomized trial in India, more than 31,000 women screened with VIA were compared to a similar number with no screening. Over 7 years, VIA with cryotherapy of abnormal lesions was associated with a 24% reduction in development of more advanced cervical cancer and 35% reduction in deaths due to cervical cancer (Sankaranarayanan et al. 2007). A recent review of published studies of VIA accuracy with histology as the standard and CIN 2 as the outcome measure found sensitivity 79–82%, specificity 91–92%, with positive predictive value (PPV) 9–10% (Sauvaget et al. 2011). VIA can also be task-shifted to non-physician health care providers, as evidenced by Jhpiego country program experience and CIDRZ, and is consistent with findings from other international organizations (WHO 2014; FIGO 2009).

Digital Cervicography (DC)

VIA can be combined with digital cervicography (DC) to magnify the cervix and view it in detail. With DC, after performing VIA, the provider takes a picture of the cervix using a high-magnification camera. DC allows the provider to magnify the cervix (up to 50 times) and see blood vessel abnormalities that cannot be seen with the naked eye, as well as store the image on the camera or on a computer. Lower-level magnification of the cervix (2–4X) does not increase VIA performance (Sankaranarayanan et al. 2004).

Conducting VIA and DC will be discussed in greater detail in Chapter 6.

Concerns Regarding Overtreatment

Because VIA and DC do not use confirmatory histopathology prior to treatment, there is a risk of overtreatment—women who are screen-positive undergo cryotherapy but do not actually have cervical precancer. WHO estimates that 1–2% of women in the general population have CIN 2+, and that this rate is estimated at 10% among HIV-positive women (WHO 2013b). These rates will vary by country and local context, but the underlying principle is the same: VIA-positive rates tend to run higher than this, often between 5–15%, with higher rates among HIV-positive women. As a result, a certain percentage of women will be receiving treatment who do not have CIN 2+. However, cryotherapy carries a very low risk of complications. The trade off with SVA or screen-and-treat is improving the rate of treatment with cervical precancer while accepting the risk of slight overtreatment with a proven, safe treatment. The multi-step process involving confirmatory histopathology risks losing women to follow-up who have cervical precancer, and thus not receiving treatment.

HPV Testing

HPV DNA testing for oncogenic or "high-risk" HPV subtypes shows significant promise for screening of women 30 years of age or older. The accumulating evidence of its accuracy, effectiveness, and reproducibility adds support for the use of HPV DNA testing as a primary cervical cancer screening tool. Clinician-collected HPV DNA testing has consistently demonstrated higher sensitivity to detect significant cervical disease (CIN 2+ or cancer) than VIA or cytology, along with good specificity. In addition, self-collection for HPV DNA testing shows only a slight decrease in accuracy, with sensitivities ranging from 80–86%, as compared to 92–98% for clinician-collected testing. Given the accuracy of HPV DNA testing, HPV-negative women are at an extremely low risk of developing cervical cancer in the 5–10 years following a negative test. As a result, the screening interval can be safely increased, to a minimum of 5 years, which adds to the cost-effectiveness of the test. A rapid HPV test has been developed but is not yet widely available, and feasibility and affordability remain significant barriers to widespread use of HPV DNA testing in low-resource settings (WHO 2013b).

Due to its accuracy and reproducibility, WHO recommends HPV testing over visual inspection methods or cytology, if resources are available. If using HPV testing, WHO recommends using it either as a single test or sequential testing, as follows (WHO 2013b):

- **Single test**: If HPV-positive, this indicates need for treatment. Visual inspection will still be necessary to determine if a woman can receive cryotherapy or requires loop electrosurgical excision procedure (LEEP). Even if no lesion is seen, the woman will still receive treatment (cryotherapy).
- **Sequential testing**: If HPV-positive, screen with a second test (e.g., VIA) and treat only if the second test is positive.

Treatment Options for Precancerous Lesions

The choice of treatment for precancerous lesions depends on the (WHO 2014; WHO 2013b):

- Availability and accessibility of the treatment method
- Training and experience of the provider
- Cost
- Location and extent of the lesion
- Relative advantages and disadvantages of each approach

Cryotherapy and LEEP are the most commonly recommended outpatient treatment options for precancerous lesions of the cervix (WHO 2014; WHO 2011; WHO 2012a; WHO 2013b; FIGO 2009). For screen-and-treat programs, WHO recommends cryotherapy as the first-choice treatment for women who are screen test-positive and eligible for cryotherapy. In women who have lesions not eligible for cryotherapy, WHO recommends LEEP, where available. WHO recommends against the use of cold knife conization in screen-and-treat programs (WHO 2013b) (see Table 4.2).

A third, relatively new procedure compared to cryotherapy and LEEP is cold coagulation. Cold coagulation uses a machine called a Semm cold coagulator to heat metal probes inserted into the cervical tissue to destroy precancerous lesions on the cervix. The heated probe can destroy tissue up to 4 mm deep in 30 seconds and 7 mm deep in 45 seconds. Due to its relatively recent use, less data exist on cold coagulation, though initial data suggest that cold coagulation and cryotherapy have comparable effectiveness in treating precancerous cervical lesions. In addition, both cryotherapy and cold coagulation do not require local anesthesia and can be performed by a wide range of health care workers.

Table 4.2. Comparison of cryotherapy and LEEP outpatient treatment options

	Cryotherapy	LEEP
Cure rate* **based on single treatment*	85–95%	90–95%
Other resources needed	CO_2 or N_2O gas and tanks Cryotherapy unit and tips	Electrosurgical unit and power Special instruments and supplies
Provider: **Technical difficulty**	Nurse or doctor Lowest	Generally reserved for doctor Intermediate
Complications **Minor side effects**	Lowest: generally minor 1–3%	Intermediate: generally minor 1–5%
Anesthesia	No	Yes – local
Pathology specimen	No	Yes
Cost	Lowest	Intermediate
Patient acceptability	High	High

* Cure rates (or effectiveness) refers to screen-negative 1 year following treatment. Figures cited are based on studies in general populations. In HIV-positive women, the effectiveness is expected to be lower for all procedures (Abha, Arthur, and Agarwal 2011; Chirenje et al. 2001; WHO 2011; WHO 2013b).

For program success, it is essential to link screening with treatment that is safe, effective, acceptable, and feasible. Cryotherapy does this, and, in most low-resource settings, is the main treatment method for precancerous lesions that meet cryotherapy eligibility criteria (see **Box: Eligibility criteria for cryotherapy**, page 29). Cryotherapy is the easiest and least costly method, with comparable effectiveness to LEEP when providers adhere to strict eligibility criteria. In addition, if one adheres to the eligibility criteria and uses the double-freeze technique, cure rates are 90% or higher (WHO 2011; WHO 2013b; Jhpiego). Precancerous lesions that do not meet cryotherapy eligibility are often collectively referred to as "large lesions" (see **Box: A word about terminology,** below) but actually consist of a number of different types of precancerous lesion: large precancerous lesions (covering > 75% of the cervix), lesions extending into the endocervical canal, or where the cryotherapy tip cannot cover the entire lesion. These large lesions should be treated in an outpatient setting with LEEP, if available and accessible (WHO 2011; WHO 2013b). In the general population, approximately 10–15% of precancerous lesions will fall into the category of a large lesion, while the rate is significantly higher, in some settings twice as high or more, in women who are HIV-positive (ACCP 2003; Pfaendler et al. 2008; Rema et al. 2008; WHO 2012b).

A word about terminology

Precancerous lesions that do not meet cryotherapy eligibility are often collectively referred to as ***large lesions.*** However, a number of categories of precancerous lesions exist that do not meet cryotherapy eligibility. For ease of reference, throughout this reference manual, *large lesion* will refer to all of the following types of precancerous lesions:

- Lesions covering > 75% of the cervix
- Lesions that extend into the endocervical canal and cannot be covered with the cryotherapy tip
- Lesions that cannot be completely covered by the cryotherapy tip
- An anatomic deformity of the cervix that prevents adequate application of the cryotherapy tip

Cryotherapy

Note: Performing cryotherapy will be discussed in greater detail in Chapter 7.

Cryotherapy is a relatively simple, safe, acceptable, and inexpensive method to destroy precancerous lesions by freezing. It is accomplished using a special instrument that delivers gas (carbon dioxide or nitrous oxide) to a cryotip applied to the cervix, and freezes the abnormal tissue. The procedure does not require electricity or anesthesia, and usually takes a total of approximately 10 minutes to perform. The woman may experience mild to moderate cramping, but adverse effects following cryotherapy are uncommon and generally minor. Discomfort usually resolves within a week after treatment. Following cryotherapy, a watery discharge generally continues for several weeks. Post-treatment infection (cervicitis) is uncommon (1%) and pelvic inflammatory disease (PID) is rare (< 1%).To maximize safety and effectiveness of cryotherapy, certain eligibility criteria should be met.

Eligibility criteria for cryotherapy

- Not suspicious for cancer
- Can see the entire extent of the lesion; lesion does not extend into the endocervical canal
- Lesion occupies < 75% of the cervix
- Cryotip covers the lesion (or < 2 mm of lesion extends beyond edge of cryotip)
- No anatomical deformity of the cervix that prevents good application of cryotip
- Client is not pregnant
- Client is more than 6 weeks postpartum
- Client does not have severe cervicitis

Cryotherapy cure rates following one treatment range from 86–95%, with rates of 90% or more when strict eligibility criteria are used (ACCP 2003; ACCP 2011; FIGO 2009; WHO 2011). Jhpiego country programs using VIA report VIA-negative rates of approximately 95% 1 year following cryotherapy, although because histologic examination was not performed before or after cryotherapy, actual "cure" rates cannot be verified (Jhpiego).

Studies and country experience have shown that a wide range of health care workers (nurses, midwives, and other clinicians) can be trained to perform cryotherapy competently (ACCP 2003; ACCP 2007; FIGO 2009). Cryotherapy is ideally suited to be linked with VIA screening in a SVA, without an intermediary diagnostic step of colposcopically directed biopsy, which is not considered necessary unless there is a suspicion of cervical cancer (ACCP 2007).

LEEP

LEEP stands for **L**oop **E**lectrosurgical **E**xcision **P**rocedure. The procedure uses a thin, wire loop heated with electricity produced by special electrosurgical generators. The aim of LEEP is to remove precancerous cervical lesions of the cervix and the transformation zone in their entirety. The excised tissue is sent for histopathology. As a result, LEEP can be used for both diagnosis and treatment. In skilled hands, LEEP is a relatively simple, safe, effective outpatient procedure for the excision of precancerous lesions of the cervix.

Advantages of LEEP compared to cryotherapy

- **More effective on large lesions.** The provider can adjust the loop size and technique in order to remove large lesions (with several passes if needed), tailoring the procedure to the size of the lesion on the ectocervix, as well as lesions that extend into the endocervical canal. This allows LEEP to be more effective than cryotherapy in treating large lesions, lesions that cannot be covered with the cryotherapy tip, and those that extend into the endocervical canal (WHO 2011).
- **Obtains tissue specimen for histologic examination.** Allows determination of the lesion's severity and extent.

Disadvantages of LEEP compared to cryotherapy

- **Requires more resources.** LEEP requires electricity, more expensive specialized equipment and instruments, and consumables.
- **Technically more difficult.** While LEEP is safe and effective in skilled hands, the level of training required is greater than with cryotherapy. It is a procedure primarily reserved for physicians, though some settings are expanding it to non-physicians with reportedly good success.
- **Risk of complications slightly higher.** When performed by competent providers, LEEP has a very low complication rate. However, the risks are slightly higher for LEEP compared to cryotherapy, especially severe bleeding.
- **Should be performed in a facility with an operating theater.** In the rare case of severe post-procedure bleeding that cannot be adequately controlled in the office, access to an operating theater and anesthesia is necessary.
- **Requires anesthesia.**
- **Often not available in a single visit approach.** Due to the additional requirements for LEEP, it is often not available as an immediate treatment option following a screening test-positive result.

For additional information on LEEP, see the CIDRZ Manual and Jhpiego LEEP Reference Manual.

Another treatment option that is receiving interest is cold coagulation, which uses a heated metal probe to destroy precancerous lesions on the cervix. Using a machine called a Semm cold coagulator, which is powered by electricity, the heated probe can destroy tissue up to 4 mm deep in 30 seconds and 7 mm deep in 45 seconds.

While cryotherapy as a treatment option is supported by a large amount of published data from many different contexts, cold coagulation, though promising, suffers from very limited data.

Advantages of cold coagulation include that it is a relatively simple technique, easy to learn and can be performed by a wide range of health care workers; does not require anesthesia; is well-tolerated by women; is very portable; and can treat a wider range of precancerous lesions than cryotherapy. The Semm coagulator requires an energy source (e.g., electricity or batteries), and is more expensive than a cryotherapy unit, though it makes up for that cost consideration by not requiring a continuous supply of gas. Due to the relative lack of a data and lack of recommendation from WHO, cold coagulation should be used only in research settings until further data become available.

Tertiary Prevention and Palliative Care

Tertiary prevention refers to the diagnosis and treatment of cervical cancer. Treatment consists of surgery and/or radiation therapy for earlier stages of cervical cancer, while later stages of cervical cancer are generally treated with radiation and chemotherapy (WHO 2014; *Zambia National Cervical Cancer Control Plan and Guidelines* (draft) 2014). Palliative care refers to relief of the pain and suffering (both physical and psychological) associated with life-threatening cervical cancer (WHO 2013a). As a result, palliative care is complementary of treatment and seeks to provide not only pain relief, but also emotional and spiritual support for women suffering from cervical cancer and their families.

Discussion of tertiary prevention and palliative care is beyond the scope of this reference manual. For additional information, see WHO's *Comprehensive Cervical Cancer Control: A Guide to Essential Practice, Second Edition* (2014).

Chapter 5. Counseling and Client Assessment

Counseling Women about Cervical Cancer Prevention

Background

An often overlooked component of providing cervical cancer prevention services is proper education and counseling of women. All women have the right to make an informed decision about undergoing cervical cancer screening. They have the right to accurate and up-to-date information about cervical cancer and precancer, and the screening tests and potential treatment procedures. Health care providers should offer information to and encourage all women, especially those between the ages of 25 and 50, to be screened.

Health care providers should be able to talk about the diagnosis of and possible treatment for cervical precancer and cancer using words the woman can understand. Unfortunately, it is often difficult for providers to talk with women about cervical cancer. It is equally difficult for women to talk openly about a disease that is sexually transmitted and that, if left undiagnosed and untreated, can lead to death. Talking about this sensitive issue will be easier if providers:

- have accurate, complete, and up-to-date technical information about cervical cancer screening tests, such as VIA, Pap smears, and HPV testing, and which tests are available;
- have accurate information about the types of treatment available for precancerous and cancerous lesions; and
- are able to build honest and understanding relationships with the women they counsel.

Health care providers should recognize that most precancerous lesions of the cervix do not have clinical symptoms. As a result, most women being tested will consider themselves completely healthy. Therefore, it is important to promote screening as a means of preventing cervical cancer. To help a woman make an informed decision about what to do, should treatment or referral be needed, important points to cover in this counseling are:

- Client's rights
- The cervix—what it is and where it is located
- Cervical cancer and precancer—what these conditions are and how they can be detected
- The cause of cervical cancer and the risk factors for developing it
- How to prevent cervical cancer, with emphasis on precancerous lesions or disease
- A brief description of the screening test used to examine the cervix and treat it, if indicated
- What to expect following the procedure and common side effects
- Self-care measures
- When to follow up or repeat screening

Basic Principles of VIA/Cryotherapy Counseling

Health care providers should know and be able to use basic counseling techniques. These techniques will help the provider establish a relationship with the client. If a woman believes in

the competence and honesty of the provider, she will be more likely to have the screening test performed and, if necessary, accept treatment and return for a follow-up as indicated. She will also be more likely to refer others who should get cervical cancer screening.

A woman may be very anxious or embarrassed about being examined or the procedure itself. It is important, therefore, to set the tone of the visit in a calm, non-pressured, non-threatening manner. Be sensitive to any cultural or religious considerations, respect her views, and ask if she would like a family member or friend present for the counseling. Other basic principles and tips for VIA and cryotherapy counseling include:

- Treat the client with respect: respect her cultural, religious, and individual views, fears, and concerns.
- Ensure confidentiality.
- Provide information and counseling in the local language, or use a translator, and use simple words and concepts that can be easily understood.
- Listen to what the woman has to say and encourage her to express her concerns; try not to interrupt her. Let the woman know that she is being listened to and understood.
- Provide accurate, up-to-date information needed to make a decision responsibly.
- Periodically assess understanding of the information given.
- Allow the client an opportunity to ask questions; answer her question directly and in a calm, reassuring manner.
- Do not pressure a client to make a particular choice, so that she feels empowered to exercise her basic rights.

If more than one woman is present for VIA services, group-based counseling may be given in that setting. Individual counseling for the client regarding post-procedure care and follow-up may be given along with pre-procedure counseling. If this is done, however, the health care provider should follow up after the procedure to reinforce key counseling messages and to answer any questions.

Client Rights

Every woman being tested for the presence of precancerous lesions or treated for abnormal findings has a right to information about her condition. Information should be given to her (and her family, where appropriate) in a supportive, confidential, and nonjudgmental manner, and it should include:

- results of the test;
- time frame for treatment, if any;
- procedure to be used, as well as the risks and benefits;
- her consent to the treatment; and
- need for referral to another facility, if necessary.

Every woman has the right to discuss her concerns and condition in an environment in which she feels confident. The client should be assured that her conversation with the counselor or health care provider will be private and confidential.

Women should know in advance the type of physical examination (e.g., pelvic examination, VIA) or procedure (e.g., cryotherapy) that is going to be performed.

When a woman is undergoing a physical examination or procedure, it should be carried out in an environment in which her right to privacy is respected, such as an examination or procedure room with a closed door or privacy screens. When receiving counseling or undergoing a physical examination or procedure, she should be informed about the role of each person in the room.

Women should be made as comfortable as possible when receiving services. To a certain extent, this is related to the adequacy of service delivery facilities (e.g., proper ventilation, lighting, seating, and toilet facilities). Moreover, the time she spends waiting to receive care should be reasonable and not require excessively long wait times.

Finally, women have a right to express their views about the services they receive. A woman's opinions about the quality of services, either gratitude or complaint, together with her suggestions for changes in service provision, should be viewed positively in a program's ongoing effort to monitor, evaluate, and improve its services. Regularly interviewing women about the services they have received and incorporating their suggestions for change will also improve the quality of care.

Confidentiality

All information that a woman provides should be treated confidentially. This includes information about her medical history and the reasons for her to seek care, the services provided to her, and any family planning decisions she makes. Confidentiality requires that the health care provider not discuss this information with the woman's partner, family, person accompanying her to the health care facility, or staff members not directly involved in her treatment without her consent (except where required in a life-threatening medical emergency). On the other hand, if the woman wants to involve a spouse or partner in decision-making, her wishes should be followed.

Privacy

Creating an atmosphere of privacy is critical to protecting the woman's confidentiality, sense of security and dignity, and willingness to communicate honestly. Often, simple changes in the physical setting where clients are treated or counseled will offer the woman more privacy. The following are some suggestions for maintaining privacy:

- Use a separate area, such as an office, closed treatment room, or curtained space, to encourage open communication when giving pre-procedure and post-procedure information or counseling.
- Draw curtains around the treatment area whenever the woman is undressed or, if curtains are not available, turn the treatment table so that the woman's feet are not facing a doorway or public space. Also provide a curtained area for changing clothes.

- Use drapes (or sheets, or even clothing if drapes are not available) to cover the woman's legs and body during examinations and procedures.
- During treatment, limit the number of people in the client care area to those involved in providing care. Even if the woman gives permission for a clinical training demonstration, limit the number of persons who are in the room during the demonstration. In addition, staff and trainees in the client care area should refrain from casual conversation among themselves.

Being a Good Counselor

A good counselor:

- encourages maximum participation and involvement by the woman (or couple) and helps her make her own decision;
- is an information giver, facilitator, and problem solver; suggests alternatives; helps the woman analyze and choose from known options; does not prescribe solutions; and helps her understand that she is making her own choice or decision;
- helps the woman to reveal her personality and life situation rather than make assumptions; and
- determines her concerns and other issues that could be barriers to effective learning.

General Advice When Counseling

A woman may become embarrassed when discussing testing for cervical cancer because it involves having a pelvic examination. Therefore, try to set the tone of the visit in a low-key, non-pressured manner, and assure her that the conversation is confidential. Finally, be sensitive to any cultural and religious considerations and respect her views. Additional tips for talking with a woman (or couple) include the following:

- Listen to what the woman has to say and encourage her to express her concerns; try not to interrupt her.
- Let the woman know that she is being listened to and understood.
- Use supportive nonverbal communication, such as nodding and smiling.
- Answer her questions directly in a calm, reassuring manner.
- Keep the message simple by using short sentences.
- Avoid sophisticated medical terms; instead, use words that the woman will understand.
- Give the woman written information (if available and appropriate) to remind her of instructions.
- Finally, ask her to repeat back to you the key points to ensure her understanding.

Some Key Messages include (Adapted from CIDRZ Manual 2013):

"The cervix is the mouth of the womb. Today, I will perform a test to see if your cervix is healthy. I will give you treatment if the cervix is not healthy. I want to make sure you understand and agree to the test and treatment."

"Let me tell you how the test is done. First, you will need to remove your clothes and lie on the examination table. I will place an instrument in your vagina so I can see the cervix. Your cervix will be washed with vinegar. You may feel a slight burning sensation. The vinegar is used to see if there are any unhealthy changes on your cervix."

"After I finish the test, I will discuss the findings with you (explain the different possible findings. Emphasize that a positive test often does not mean cancer is present, but means that the cervix has unhealthy changes which could become cancer in the future)."

"If your cervix is unhealthy, I will usually be able to perform treatment right here during the same visit. If I can't do the treatment here, I will send you to another clinic to see a doctor. Let me tell you how the treatment is done (discuss key messages for cryotherapy)."

"You don't have to have the test or treatment if you don't want to. Please feel free to leave. None of your regular health care will be affected by your decision to leave. If you decide to have the test or treatment, you may decide at any time to stop. You may come back later for the test or treatment if you want."

"Most of the time, the test and treatment work well. At this time, this is the best test and treatment available. The test and treatment is very safe and is used in many countries around the world. Problems may occur, but only very rarely."

"Please let me know if you have any questions (pause to allow time for questions)."

"Thank you for listening."

Test for understanding by asking the client to explain the importance of screening and what will occur during the examination. If she cannot tell you correctly, repeat the messages and show pictures until she understands.

Client Assessment

Target Population

Using risk and population coverage as a guide, WHO recommends the following for target population screening (WHO 2013b):

Among HIV-negative women:

- **Start screening in women 30 years of age and older,** because of their higher risk of cervical precancer and cancer. However, this should be adjusted based on prevalence of CIN 2+ among younger women in the population, as well as the peak incidence of cervical cancer in the population.
- **Prioritize cervical cancer screening in women aged 30–49 years of age.** Broader coverage of women in this age group is preferable to increasing the number of times a woman is screened in her lifetime. Even once in a lifetime screening is beneficial. Modeling studies have suggested that once-in-a-lifetime screening at age 35 linked with treatment will reduce cervical cancer incidence by approximately 25–36% (Goldie et al. 2005; Mandelblatt et al. 2002).
- **With VIA, screen every 3–5 years*.** Still, priority should be to broaden coverage with at least one screening per woman in the target population. As coverage improves and resources permit, programs should consider increasing the frequency of testing and/or expanding the target age group to younger and older women.

Among HIV-positive women:

- Start screening girls and women regardless of age once sexually exposed, due to their higher risk of cervical precancer and cancer.
- With VIA, screen within 3 years*.

*For details on WHO recommendations on incorporating HPV testing, see WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention (WHO 2013b).

Note: No woman seeking cervical cancer screening should be denied that service, even if she falls outside the target population.

In Zambia, 40% of cervical cancers are diagnosed in women younger than 35. These women have four times the rate of HIV than older women with cervical cancer (CIDRZ 2013). When determining target population and frequency of screening, consideration should be given to the local cervical cancer epidemiology, local HIV prevalence, and available resources.

Zambia has recently adopted a VIA screening guideline (Table 5.1).

Table 5.1. Zambia guidelines for VIA screening

HIV Negative Women		HIV Positive Women	
Age Range	**Re-Screening Interval**	**Age Range**	**Re-Screening Interval**
30–59	Every 5 years	25–59	Every 3 years

Source: Zambia National Cervical Cancer Control Plan and Guidelines 2014.

The guidelines also state the following:

"Importantly, these guidelines are not meant to be strictly enforced. Women—whether HIV positive or negative—who are outside the age ranges should be screened if there are reasons she is concerned about her risk of cervical cancer. Additionally, women with a family history of cancer or who have had a prior VIA-positive screening may wish to be re-screened on a more regular basis and should be accommodated."

When Can Screening Occur?

With very few exceptions, VIA can be performed in any woman, or at the very least can be attempted.

- **Menstrual cycle.** VIA can be performed at any point in the menstrual cycle, as long as bleeding is not so heavy as to prevent the provider from adequately visualizing the cervix. In this case, the provider should reschedule the woman for VIA screening after her menstrual cycle ends. However, before deciding to reschedule, the provider should ensure that the timing and amount of bleeding is consistent with the woman's menstrual cycle. Abnormal bleeding can be a sign of cervical cancer or other significant pathology that should be evaluated with a pelvic and speculum examination.
- **Recent sexual intercourse**. Recent sexual intercourse does not affect the ability to perform VIA.
- **Vaginal discharge**. Often, with mild vaginal or cervical infections, the discharge and inflammation are not so severe that VIA cannot be completed. If the woman has a severe infection, though, the discharge and accompanying inflammation may make it difficult to read the VIA result accurately. If obvious cervical cancer is not present and VIA cannot be completed due to the discharge and inflammation, the provider should reschedule the woman for VIA screening in 2 weeks, following antibiotic treatment.
- **Pregnancy.** VIA can be performed during pregnancy, but advanced pregnancy results in increased vascularity of the cervix and can sometimes cause confusion interpreting the VIA test. In addition, treatment of precancerous lesions is not recommended during pregnancy. Therefore, in general, it is preferable to have a woman return for screening 6–8 weeks after delivery, unless cervical cancer is suspected. If cervical cancer is suspected, a speculum exam should be performed and the client referred for further evaluation if the findings are suspicious for cancer.

Client Assessment

A targeted reproductive health and medical history should be obtained from each woman, as well as assessing for cervical cancer risk factors, before cervical cancer screening. The woman should be asked about her HIV status and offered HIV counseling and testing. Family planning should be discussed and services offered.

Targeted Reproductive Health and Medical History

- Age
- Parity
- Last menstrual period
- Menstrual history
- Family planning method
- HIV status
- Presence of abnormal bleeding, especially postcoital bleeding or contact bleeding
- History of sexually transmitted infections
- Presence of vaginal discharge
- Pertinent medical history (e.g., diabetes)
- Pertinent surgical history (cesarean section, hysterectomy, other pelvic surgery)

Cervical Cancer Risk Factors

- Early age of sexual intercourse; multiple sexual partners
- Previous abnormal cervical cancer screening
- HIV infection or other immunosuppression
- History of or current STI
- Other potential risk factors (e.g., tobacco use)

Remember! Counseling occurs before, during, and after the screening and/or treatment. While performing the VIA test, continually reassure the woman and inform her of the findings, including whether immediate treatment with cryotherapy may be needed. If the woman tests negative for VIA, counsel her about the meaning of the test results and when to return for future screening. The length of time until her next screening test should be consistent with national guidelines.

Chapter 6. Performing Visual Inspection with Acetic Acid (VIA) and Digital Cervicography (DC)

Pathophysiological Basis for VIA

When a provider looks at a cervix with a good, bright white light, before application of the acetic acid, normally the squamous epithelium will appear pink and the columnar epithelium appears red. This appearance is due to the reflection of light from the blood vessels in the underlying highly vascular stroma (deeper tissue) of the cervix. Since stratified non-keratinizing squamous epithelium is composed of multiple layers of cells, less light reaches the blood vessels to be reflected back, thus creating the pink color. In contrast, the columnar epithelium consists of a single layer of columnar cells, which allows the coloration of the vascular underlying stroma to be seen more clearly and appear red.

When 3–5% acetic acid is applied to the cervix, it causes reversible coagulation and precipitation of proteins within the cells. In a normal cervix, the cells in the superficial or top layer of the epithelium contain little protein. Abnormal epithelial cells, however, contain high levels of protein due to increased metabolic and nuclear activity. As a result, following application of acetic acid:

- Normal epithelium -> little protein, little coagulation -> light is able to pass through the epithelium -> cervix continues to look pink
- Abnormal epithelium (CIN) -> high levels of protein, much coagulation -> prevents light from passing through the epithelium -> acetowhitening occurs

While the acetowhite changes associated with CIN can appear rapidly, it can take at least 1 full minute for those changes to occur. In CIN, the thick, dense, opaque acetowhite is confined to the transformation zone, near the SCJ. In cancer, it can involve the entire cervix. Almost all precancerous and cancerous lesions develop in the transformation zone, close to the SCJ. Therefore, it is essential that the SCJ and transformation zone be seen in their entirety.

Not all acetowhitening is caused by CIN or early cancer. A number of other conditions, due to increased nuclear protein and metabolic activity, can cause acetowhite areas, such as:

- Immature squamous metaplasia—the area near the SCJ where columnar epithelium is rapidly undergoing change to squamous epithelium
- Healing and regenerating epithelium (e.g., inflammation)
- Leukoplakia (hyperkeratosis) or condyloma (genital warts), though these tend to appear white even before application of the acetic acid

The acetowhite changes associated with CIN and early cervical cancer are more dense, thick, and opaque with well demarcated margins from the surrounding normal epithelium (as if you can draw a line around the lesion). In contrast, the acetowhite changes associated with immature squamous epithelium and inflammation are pale, thin, often translucent, and patchy, with ill-defined margins.

Acetowhite changes due to CIN and early cervical cancer reverse much more slowly than immature squamous metaplasia and inflammation, with changes that may last 3–5 minutes following application of acetic acid, especially with more severe lesions. In contrast, acetowhite changes associated with immature squamous epithelium and inflammation tend to appear quickly, but also may quickly disappear, often within a minute. This underscores the importance of visualizing the cervix the entire time following application of acetic acid, and waiting at least 1 full minute by the clock before making a determination of the VIA reading.

Classification of VIA Results

Please refer to the many cervical images available for practice and review as part of the training package:

- **Jhpiego**: Interactive cervical image CD-ROM; set of flashcards; atlas
- **CIDRZ manual**
- **Trainers' cervical image portfolio**

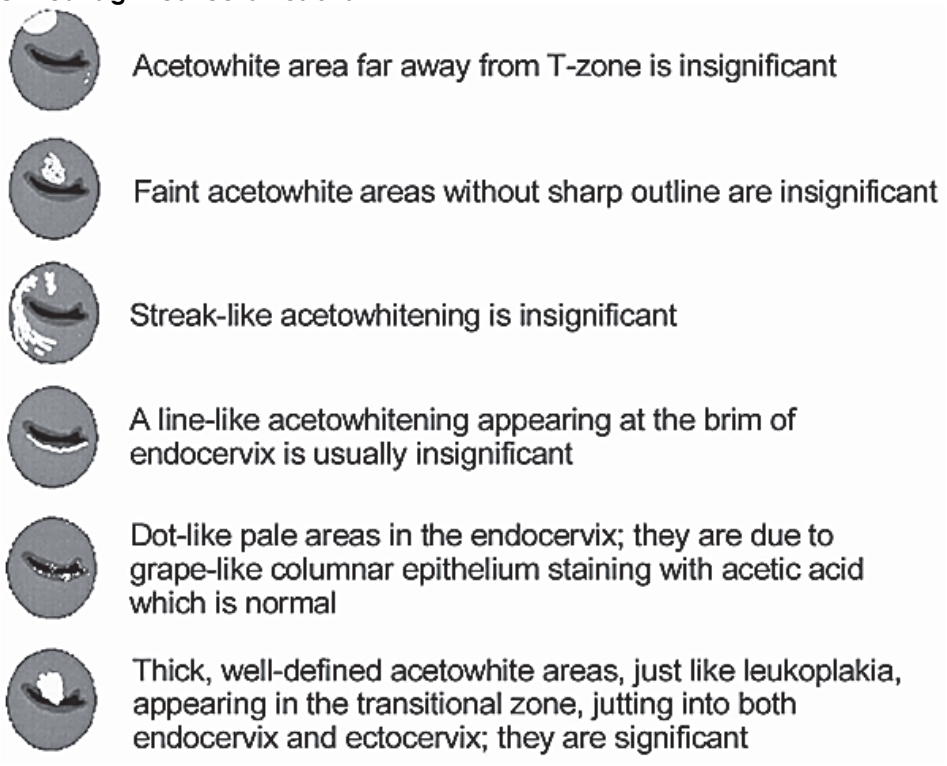
VIA results should be recorded using the following standardized categories (see Table 6.1):

- VIA-negative
- VIA-positive
- Suspicious for cancer

Table 6.1. Summary of VIA test results and clinical findings

VIA Result	Clinical Findings
Negative	No acetowhite lesions; non-significant acetowhite findings as described in Figure 6.1. Nabothian cysts, ectopy, polyps, and inflammation are all considered VIA-negative findings.
Positive	Thick, dense white lesion with distinct borders located within the transformation zone and close to or touching the SCJ.
Suspicious for Cancer	Fungating, friable mass that bleeds easily when touched; visible ulcers; acetowhite, cauliflower-like growths; highly atypical vessels.

Figure 6.1. Clinical significance of lesions



Adapted from: International Agency for Research on Cancer (IARC).

VIA-Negative

A VIA-negative result means the cervix appears smooth, pink, and uniform, with no acetowhite lesions or with non-significant acetowhite areas as described in Figure 6.1.

Nabothian cysts, polyps, ectopy, and inflammation are considered VIA-negative findings. Inflammation and regenerating epithelium may cause pale, translucent, and patchy acetowhite areas that do not have distinct margins, and tend to be diffuse/not restricted to the transformation zone.

Squamous metaplasia reacts to the acetic acid with a thin translucent acetowhite area that may cover the transformation zone near the SCJ. It is commonly mistaken by those early in the training as a VIA-positive finding, but it is a normal finding.

Openings around glands in the endocervix or in the transformation may appear as white, dot-like areas. Columnar epithelium and the mucus overlying it may react slightly and became slightly white. All of these reactions are normal and considered VIA-negative.

When performing DC, always perform VIA first and make a reading first, before completing DC. At times, the camera flash may generate a white glare on the photograph and be mistaken for an acetowhite lesion.

VIA-Positive

For clinical significance of possible lesions, consider:

- **Location:** Significant lesions occur in the transformation zone, close to or touching the SCJ.
- **Color and thickness:** Significant lesions are white, dense (opaque), and thick (often raised above surrounding tissue).
- **Borders:** Significant lesions have sharply demarcated/distinct borders (as if you could draw a line around them).

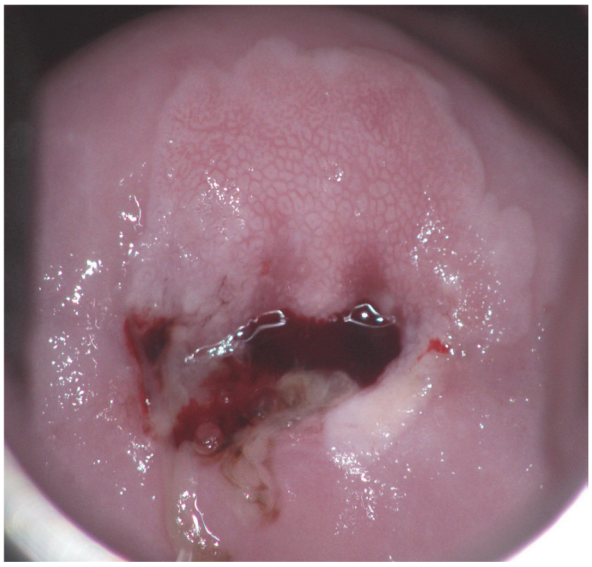
If the lesion has these characteristics, it is **VIA-positive.**

Mosaicism, Punctation, and Atypical Vessels

The presence of abnormal blood vessels (**mosaicism, punctation, and atypical vessels**), when associated with acetowhite areas on the cervix, may indicate CIN 2–3, microinvasive cancer, or invasive cancer. The following are short descriptions of these abnormal blood vessels and a photograph illustrating the finding of each (see flashdrive/CD-ROM) for additional photographs):

- **Mosaicism:** The abnormal blood vessels appear on the surface of the acetowhite lesion as a network of red lines intersecting thin red lines, appearing like tiles on a floor or cobblestones (Figure 6.2). The larger and thicker the area of mosaicism, the more severe the lesion.
- **Punctation:** The abnormal blood vessels appear within the acetowhite lesion as red dots on the surface of the acetowhite lesion (Figure 6.3). As with mosaicism, the larger and thicker the area of punctation, the more severe the lesion.
- **Atypical vessels:** Whereas normal blood vessels appear smooth and organized, atypical vessels appear jagged and disorganized, often with blood vessels of many different sizes and shapes going in different directions. They may appear as short curves and loops, sometimes described as "hairpins," "commas," or "apostrophes" (curves or loops). Highly atypical vessels tend to occur in invasive cervical cancer (Figure 6.4).

Figure 6.2. Photograph of cervix with mosaicism



Source: CIDRZ 2013.

Figure 6.3. Photograph of cervix with punctation



Source: CIDRZ 2013.

Figure 6.4. Photograph of cervix with atypical vessels



Source: CIDRZ 2013.

Suspicious for Cancer

A lesion is **suspicious for cancer** if it has the following characteristics:

- Fungating, friable mass that bleeds easily when touched
- Ulcers
- Acetowhite, cauliflower-like growths
- Highly atypical vessels

Note: If a VIA cannot be completed, there is no VIA result to be recorded and the test is described as indeterminate.

- If inflammation is so obscuring that the VIA cannot be interpreted, the woman should be treated with antibiotics according to national guidelines and asked to return in 2 weeks for rescreening.
- In menopausal women, if the transformation zone cannot be seen in its entirety, the VIA cannot be said to be completed.

If, however, the provider is unsure if the VIA is positive or negative, and cannot get an immediate second opinion, it is better to call the test VIA-positive and treat with immediate cryotherapy (if eligible for cryotherapy), rather than letting a potential VIA-positive case leave and miss treatment.

Equipment, Instruments and Supplies for VIA

- Examination table, preferably a gynecological examination table (with stirrups/footrests and a plastic cover that is easy to clean)
- Stool/chair, preferably movable and adjustable
- Privacy screens
- Instrument tray/trolley

- Specula: metal, bivalve (preferably Graves over Cusco), medium, and large
- Ring/sponge holding forceps
- Gallipots/other small metal dish
- Clean cotton balls/large cotton swabs
- Disposable wooden spatulas and/or condoms (to retract lax vaginal walls)
- Clean, disposable examination gloves
- 3–5% acetic acid (white table vinegar)
- Bright white light (gooseneck lamp or torchlight)
- Watch, clock, or timer that marks seconds and minutes
- Sheets/gowns to provide privacy
- Data management forms

Optional Items:

- A sterile individual pack for each client (speculum, ring/sponge holding forceps, gallipot, cotton balls)
- Kidney dishes

Note: Ensure that enough material is available to provide services for the maximum number of clients expected for the clinic that day.

Additional Materials for DC (*Adapted from CIDRZ 2013*)

- A digital camera with an optical zoom and automatic flash
- A macroconverter magnifying lens and lens adapter; despite the magnification of the camera, this lens is absolutely necessary to decrease the focal length and obtain a clear picture of the cervix
- Memory card(s) appropriate for the camera, 2 GB (gigabytes) or greater
- Camera charger or extra batteries; rechargeable AA batteries and a rechargeable compact charger

Optional Items:

- Extension cords and surge protectors
- Television or computer with external mouse and keyboard (to show the client the cervigram)
- Power cord for the television or computer
- Power source (electrical outlet or generator) for the television or computer
- Cable for connecting camera to television or computer (AV [audio/visual] cables)
- Internet source to share images and data electronically

Materials for Infection Prevention for VIA

- Autoclave/sterilizer
- Cloth (about 40 cm by 40 cm), pen, and autoclave tape (to package equipment to be autoclaved)
- Water source (to make solutions, wash instruments, and wash hands)
- Bar soap (to wash hands).
- Hand sanitizer
- Paper towels (to dry hands).
- Distilled water for autoclave machine
- Wash rags or mutton cloth (to clean the examination table)
- 10 L plastic container with soapy water (to hold used speculums)
- Detergent powder (to make soapy water)
- 10 L plastic container with 0.5% chlorine solution (to decontaminate the examination table and instruments)
- Chlorine granules or bleach (to make 0.5% chlorine solution)
- Scrub brush (to clean the instruments)
- Vinyl reusable or plastic disposable aprons (to protect the nurse and clinic assistants)
- A normal waste basket and waste bags (to dispose of paper waste)
- Hazardous waste bags and basket (to dispose of used gloves and cotton swabs)
- Two pairs of heavy-duty rubber cleaning gloves (to protect hands from the chlorine solution)
- Additional cleaning supplies, such as a mop, broom, dustpan, window cleaner, desk polish, and floor cleaner

Step-by-Step Guide for VIA

Step 1: Ensure Readiness of the Clinic

- Ensure the clinic is ready to conduct VIA/DC and cryotherapy.
- Ensure all necessary equipment, instruments, and supplies are available and ready for use (properly processed/cleaned), including cryotherapy equipment.

Step 2: Welcome the Client, Counsel Client, Take Targeted Reproductive Health History, and Obtain Informed Consent

- Greet the woman respectfully and with kindness. Introduce yourself.
- Counsel the client on the test and treatment, and obtain informed consent (see "Counseling Women on Cervical Cancer Prevention" in Chapter 5 and Appendix 3: Cervical Cancer Screening Form).
- Take a targeted reproductive health history (see "Client Assessment" in Chapter 5).

- Assess her HIV status. Perform counseling and testing for clients who do not know their status.
- Assess her family planning needs.
- Review and record client data on the Cervical Cancer Screening Form.

Step 3: Position the Client on the Examination Table; Prepare for Examination

- Make sure the client empties her bladder. A full bladder can make visualization of the cervix difficult, and may be uncomfortable for the woman during the exam.
- Ask her to remove her underwear, or to undress from the waist down and wrap a sheet around herself. Assist her onto the examination table.
- Ask the client to place her feet in the stirrups and move down until her buttocks reach the edge of the table. If the examination table lacks stirrups, she can place the bottoms of her feet on the end of the table. Place a sheet across her waist and thighs to preserve privacy.
- Check that instruments, supplies, and light source are available and ready for use.
- Sanitize your hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
- Inspect her abdomen; look for surgical scars and correlate with history taken earlier. Scars may indicate a previous surgery or hysterectomy. If the client has undergone a total hysterectomy, she does not have a cervix and should not be screened. If the client has undergone a partial hysterectomy, she has a cervix and should be screened. If any uncertainty exists about the presence of a cervix, this should be confirmed with a bimanual examination (see Step 4).
- Palpate her abdomen and assess for masses and tenderness. For completeness, combine this assessment with bimanual examination (see Step 4).
- Put on two pairs of new examination gloves on both hands.
- Arrange instruments and supplies on a clean tray or container, if not already done.

Step 4: Perform External Genitalia and Bimanual Examinations

- Be gentle during the exam. An inconsiderate or rough examination may cause the client to become uncomfortable or tense, and make the examination an unpleasant experience, as well as make the assessment more difficult. Always inform the client you are going to touch her before doing so.
- Inspect external genitalia for vulvar lesions, lichen sclerosus, and infectious disorders.

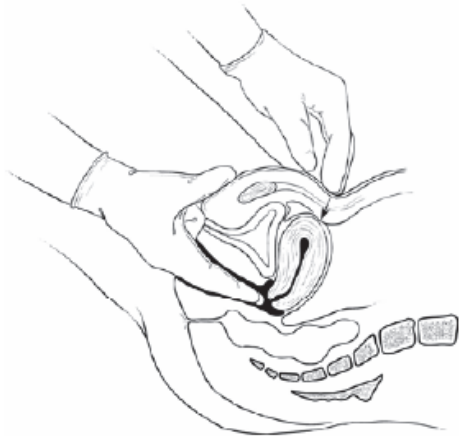
Vulvar Lesions and Cancer (For details, see the CIDRZ Manual 2013.)

- Compared to cervical cancer, vulvar cancer is rare. It occurs primarily among elderly women around age 70. Vulvar lesions and cancer occur more commonly in HIV-positive women.
- While vulvar lesions usually appear raised and may be fleshy, warty, or ulcerous, any lump or mass on the vulva may indicate vulvar cancer. Clients with possible vulvar lesions or cancer should be referred for further evaluation and biopsy.

Infectious Disorders

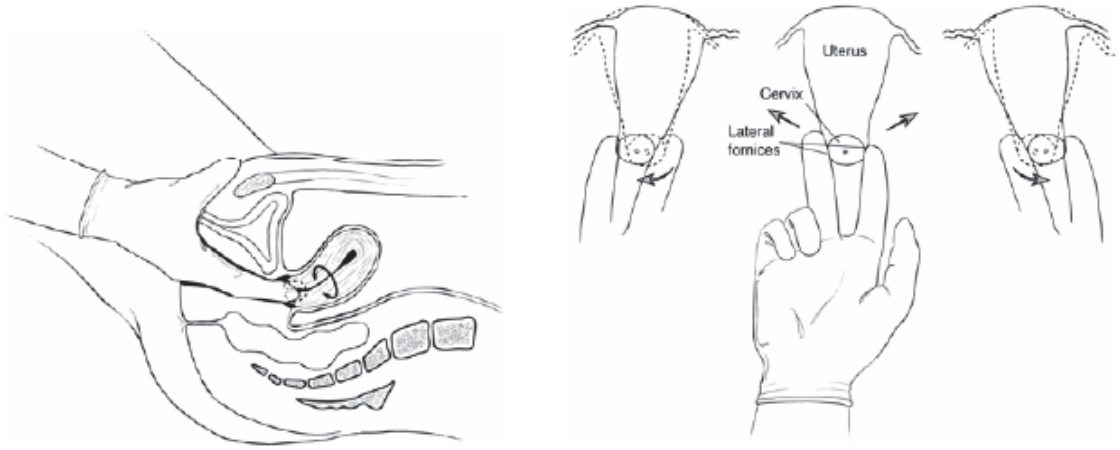
- Infectious disorders such as genital ulcers or discharge should be diagnosed and treated if necessary. (For details, see the CIDRZ Manual 2013.)
- Perform bimanual examination to assess the position of the cervix (this facilitates location of the cervix on speculum examination), cervical motion tenderness, size of uterus, presence of any pelvic/abdominal masses, and tenderness.
- To perform the bimanual exam, place two gloved, lubricated fingers in the vagina until you locate the cervix. Tell the woman what you are about to do and gently move the cervix to assess for cervical motion tenderness. Place your other hand on the abdomen just below the umbilicus and push down toward the two fingers in the vagina. Assess the size of the uterus and ovaries, as well as other pelvic/abdominal masses and tenderness (Figures 6.5–6.9).

Figure 6.5. Inserting the fingers into the vagina



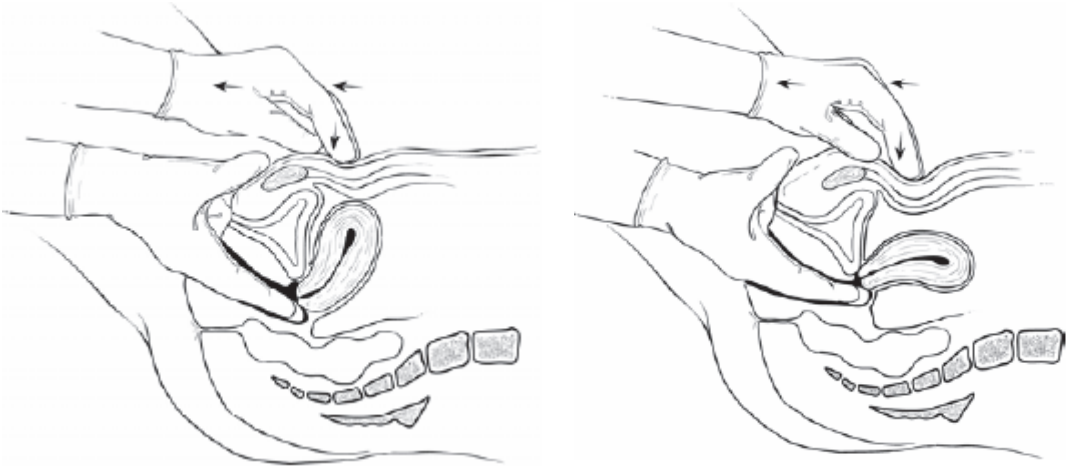
Source: Blumenthal and McIntosh 2005.

Figure 6.6. Checking for cervical movement and tenderness



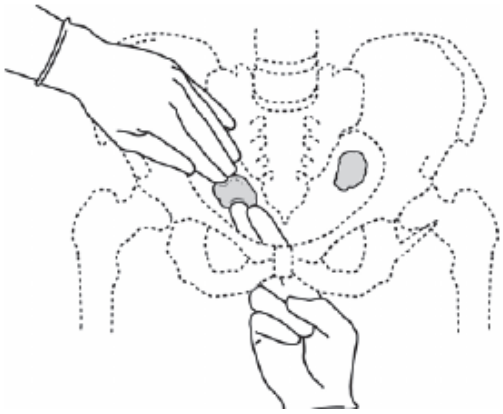
Source: Blumenthal and McIntosh 2005.

Figures 6.7 and 6.8. Palpation of anteriorly directed (anteverted) uterus and retroverted uterus



Source: Blumenthal and McIntosh 2005.

Figure 6.9. Locating and palpating the ovaries



Source: Blumenthal and McIntosh 2005.

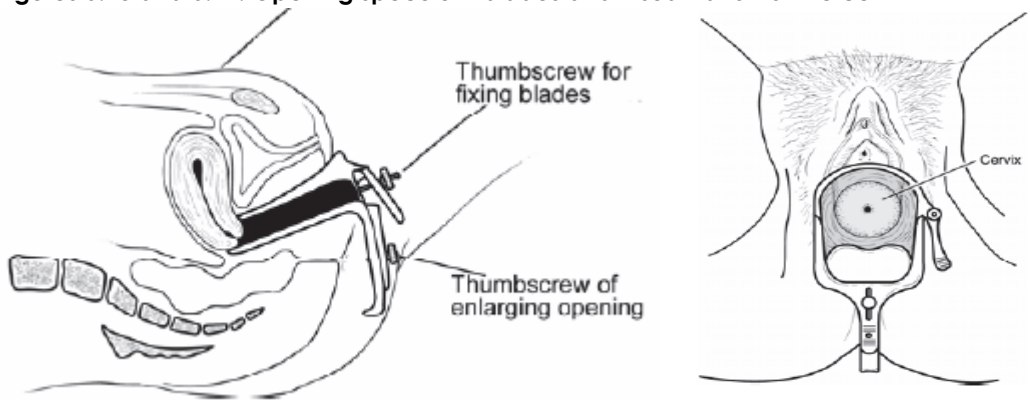
- Presence of an enlarged uterus may indicate pregnancy or fibroids. Presence of other pelvic/abdominal mass may indicate ovarian neoplasms.
- Pain and tenderness may indicate pelvic inflammatory disease (PID), appendicitis, or even ectopic pregnancy. (For details, see the CIDRZ Manual 2013.)

Step 5: Insert the Speculum

- Select a medium- or large-sized speculum, based on your assessment during the bimanual examination. Lubricate the speculum with clean, warm water or a small amount of water-soluble lubrication.
  - **Note:** Too much lubricant can interfere with the absorption of the acetic acid.
- Inform the client you are about to insert the speculum. Carefully separate the lips of the vagina (labia) with the fingers of your non-dominant hand and gently insert the speculum at a slight angle with the dominant hand, using a slight downward pressure to avoid touching the urethra. Insert the speculum gently and slowly, moving inward and posteriorly (or toward where you located the cervix on your bimanual examination) until slight resistance is felt. Slowly open the speculum until the cervix comes into view. Open the speculum as widely as possible without making the client uncomfortable (see Figure 6.10).

- Adjust the speculum so that the entire cervix and upper part of the vagina can be seen (see Figure 6.11). This may be difficult in cases where the cervix is very large or pointed extremely anterior or posterior. If necessary, use a clean cotton swab, wooden spatula, or other instrument to push the walls of the vagina outward or move the cervix up and down for a better view. Dispose of any used cotton swabs or wooden spatulas in the hazardous waste basket.

Figures 6.10 and 6.11. Opening speculum blades and visualization of the cervix



Source: Blumenthal and McIntosh 2005.

Note: If the walls of the vagina are very lax, first try using a cotton swab, wooden spatula, or other instrument to retract the vaginal walls and allow a clear view of the entire cervix. Alternatively, prior to insertion of the speculum, a condom can be rolled over the blades of the speculum and the tip of the condom cut off. When the speculum is inserted and the blades are opened, the condom will prevent the walls of the vagina from pushing into the space between the blades. This works best with non-lubricated condoms, which do not slide down the speculum blades as easily as regular, lubricated condoms.

Step 6: Inspect the Cervix

- Position the bright white light so the cervix can be easily seen. Identify the cervical os. Often by doing this simple step first, it helps orient you to the rest of the important cervical landmarks. Identify the columnar epithelium, the squamous epithelium, the squamocolumnar junction, and the transformation zone. Get a very good view of the cervix before applying acetic acid.
- Inspect the cervix for evidence of infection (cervicitis), STIs, ectopy, nabothian cysts, polyps, leukoplakia (hyperkeratosis), or condyloma:
- STIs should be identified and treated according to national guidelines. (For details on identification and treatment of STIs, see the CIDRZ Manual 2013.)
- If necessary, use a cotton swab to clean discharge, mucus, or blood away from the cervix. Dispose of the used cotton swab in the hazardous waste basket.

Step 7: Perform VIA (for DC, see following section)

- Soak a clean cotton swab in 3–5% acetic acid (vinegar), and using the forceps or other instrument, apply the swab to the cervix, thoroughly washing it. Make sure it is applied to the entire transformation zone. Dispose of the used cotton swab in the hazardous waste basket.
  - **Note:** 5% acetic acid solution is preferred. In addition, CIDRZ experience in Zambia suggests that in settings with questionable acetic acid strength, keeping the acetic acid-soaked swab in contact with the cervix for up to 3 minutes improves detection of abnormalities.
- **After removing the acetic acid soaked swab, wait at least 1 full minute,** using a watch, clock, or timer to keep track of the time. Keep the bright white light positioned to clearly see the cervix. Watch the cervix throughout this time for any characteristic changes as described above in **Pathophysiological Basis for VIA** and **Classification of VIA.**
- Determine VIA result – after at least 1 minute following application of acetic acid. Use the criteria and guidance as described above in **Pathophysiological Basis for VIA** and **Classification of VIA:**
  - VIA-negative;
  - VIA-positive; or
  - Suspicious for cancer.
- Discuss the results with the client.
  - If the VIA test was **negative**, proceed with post- VIA tasks.
  - If the VIA test was **positive**, determine eligibility for cryotherapy and discuss recommended next steps, with counseling and treatment as indicated. You may remove the speculum, but do not contaminate the instrument tray (see Chapter 7. Performing Cryotherapy).
  - If the VIA test requires **referral**, proceed with post-VIA tasks, discuss results, counsel, and refer as appropriate (see Chapter 8. Referral Networks and Mechanisms).

Step 8: Post-VIA Tasks

- Prior to removing the speculum, remove any excess acetic acid from the vagina with a cotton swab and dispose of the used swab in the hazardous waste basket. Inform the client that you are removing the speculum and gently remove it.
- Remove the speculum and place it in a container for decontamination. Decontamination with 0.5% chlorine solution for 10 minutes should be done either immediately or at a designated time during clinic.
- Wipe the couch, other equipment/instruments if used (e.g., camera), and the light source (if contaminated) with 0.5% chlorine solution or alcohol.
- Remove gloves and dispose of them in a leakproof container or plastic bag.
- Sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.

- If the VIA test is negative, have the woman get dressed. Record the VIA test results and other findings on the Cervical Cancer Screening Form.
- Review again the results of the VIA test and pelvic examination with the woman and answer any questions:
  - If the VIA test is negative, tell her when to return for repeat VIA testing.
  - If the VIA test is positive and she needs LEEP or cancer is suspected, discuss recommended next steps.
  - After counseling, provide treatment or refer.
  - Assure the woman that she can return for advice or medical attention at any time.
  - Provide follow-up instructions.

Step-by-Step Guide for DC (Adapted from CIDRZ Manual 2013)

Step 1: Photograph the Cervix (steps in addition to VIA)

Note: Refer to the camera user manual for specific instructions.

- Turn on the camera. Ensure that the flash is on and the batteries are functioning.
- Maneuver the camera, focus and zoom until only the cervix is seen and occupies the center of the picture.
- Hold the camera steady. Hold the shutter release button halfway down to focus the camera, then press the shutter release button all the way down to take the picture. Check photograph and ensure the cervix is not shadowed.
- If possible, connect the camera to a television or computer screen and position the screen so both the client and provider can see the cervix on the screen. The TV or computer screen enlarges the image and allows the client to watch as the provider photographs the cervix. This allows the provider to show the client her cervix and explain cervical health issues.

Step 2: Interpret the Results

- View the cervigram on the camera, computer, or television screen.
- Interpret VIA results as described previously. Zoom in on any suspicious areas to look for **abnormal vasculature** (for details and photographs, see IARC 2003 and CIDRZ Manual 2013).

The presence of abnormal vasculature patterns associated with areas of acetowhite may indicate CIN 2+, microinvasive cancer, or invasive cancer. Atypical vessels can also be caused by advanced pregnancy and inflammation, but these atypical vessels are not associated with acetowhite areas. The types of abnormal vasculature include:

Mosaicism: when interconnecting blood vessels occur over the surface of the acetowhite area to create the appearance of a cobbled area (sometimes called cobblestoning) or mosaic pattern, similar to tiles on a floor.

Punctation: when the terminating blood vessels appear as red dots or stipples on the acetowhite lesion surface:

- Typically, the thicker, the larger; and the more extensive the mosaicism or punctation, the more severe the lesion.

Atypical vessels: when blood vessels appear chaotic and jagged, with blood vessels of every size going in different directions. Atypical vessels may not even appear branched. Features of atypical vessels include "commas" (pools of blood) and "apostrophes" (curves or loops). Highly atypical vessels tend to occur in invasive cervical cancer.

Step 3: Discuss the Results with the Client

Show and explain the cervical image to the client. If necessary, show the client other cervigrams and compare her cervix to cervigrams of healthy and unhealthy cervices.

- Perform treatment or refer if necessary as outlined above.

Step 4 (Optional): Save the Cervigram as a Medical Record

- At the end of the clinic, transfer the images from the camera to the computer. Be sure to name the photos according to the client's number for easy identification.

Infection Prevention for VIA

Proper infection prevention (IP) is an essential component of providing cervical cancer prevention services. Good IP practices help:

- prevent the spread of HIV and other infections from one client to another, and between client and health care provider; and
- build trust among clients and staff that the instruments and clinical area are clean and safe.

Most infectious agents are transmitted by contact with blood and body fluids and most infections can be spread before symptoms are present. Therefore, it is essential that health care providers take universal precautions and treat all clients and patients as if they are infected. The following precautions should be used routinely by all health care providers:

- Wash hands before and after each client or patient contact—the single most practical procedure for preventing the spread of infection.
- Wear gloves when touching anything wet—broken skin, mucous membranes, blood or other body fluids (secretions or excretions), soiled instruments, soiled gloves, and medical waste.
- Use physical barriers (plastic aprons) if splashes and spills of any body fluids (secretions or excretions) are anticipated. A plastic apron also protects the health care providers' clothes from spillage of the acetic acid, which can stain clothes.
- Use safe work practices such as safely passing sharp instruments; properly disposing of medical waste; and not recapping, breaking, or bending needles or disassembling needles and syringes prior to disposal.

Infection protection tips for VIA

- Wash hands thoroughly with soap and water before each examination.
- When possible, have the client wash her genital area before the pelvic examination.
- Use new examination gloves during the procedure.
- Properly dispose of waste material (gauze, cotton, and disposable gloves).
- Wipe down the examination table/couch with 0.5% chlorine solution between each client; 70–90% ethyl or isopropyl alcohol can also be used, but is more expensive.
- Wipe down other contaminated surfaces (e.g., light source, camera) with 70-90% ethyl or isopropyl alcohol. Be especially careful with the camera not to damage the lens or internal components.
- Decontaminate instruments and reusable items after using them.
- Wash hands thoroughly with soap and water after removing gloves.

The three basic steps for processing instruments, surgical gloves, and other reusable items are:

- Decontamination;
- Cleaning; and either
- Sterilization or high-level disinfection (HLD).

Decontamination

Decontamination makes objects safer to handle by staff before cleaning. It is the first step in handling soiled surgical instruments and other items. It is important to decontaminate instruments and items that may have been in contact with blood or body fluids. Immediately after use, place instruments and other items in a 0.5% chlorine solution for 10 minutes (see Figures 6.12 and 6.13). This step rapidly inactivates HBV and HIV and makes items safer to handle. The 0.5% chlorine must be changed daily, or sooner if it becomes cloudy.

Figure 6.12. Formula for making dilute chlorine solution from concentrated solution

STEPS

- Determine concentration (% concentrate) of the chlorine solution you are using.
- Determine total parts water needed (use formula below or **Table C-3**).

$$\textbf{Total Parts (TP) water} = \left[\frac{\textbf{\% concentrate}}{\textbf{\% dilute}}\right] - 1$$

Mix 1 part bleach with the total parts water.

Example: Make a dilute solution (0.5%) from 5% concentrated solution.

1. Calculate TP water: $\left[\frac{5.0\%}{0.5\%}\right] - 1 = 10 - 1 = 9$
2. Add 1 part concentrated solution to 9 parts water.

Figure 6.13. Preparing a dilute chlorine solution from dry powder

AVAILABLE CHLORINE REQUIRED	GRAMS PER LITER OF WATER	
	0.5%	0.1%[a]
Calcium hypochlorite (70% available chlorine)	7.1	1.4
Calcium hypochlorite (35% available chlorine)	14.2	2.8
NaDCC (60% available chlorine)	8.3	1.5
Chloramine (25% available chlorine)	20	4
NaDCB-based **tablets** (1.5 g of available chlorine per tablet)	4 tablets/liter	1 tablets/liter

[a] Use **boiled** water when preparing a 0.1% chlorine solution for HLD because tap water contains microscopic organic matter which inactivates chlorine.

Cleaning

Cleaning is a crucial step in providing safe, infection-free equipment and instruments. A thorough cleaning with water and liquid soap or detergent physically removes organic material such as blood and body fluids. Dried organic material can trap microorganisms in a residue that protects them against sterilization or HLD. Organic matter also can partially inactivate disinfectants, rendering them less effective.

Utility gloves should be worn while cleaning instruments and equipment. Discard gloves if torn or damaged; otherwise, clean and leave to dry at the end of the day for use the following day. In addition to wearing gloves, extreme care must be taken to prevent needlesticks or cuts.

Staff should wear protective glasses, plastic visors or goggles, if available, while cleaning instruments and other items. This protects staff from splashing contaminated water into their eyes.

Clean instruments with a brush (old toothbrushes work well) and soapy water. Give special attention to instruments with teeth, joints, or screws where organic material can collect. After cleaning, rinse items thoroughly with water to remove detergent residue, which can interfere with chemical disinfection.

Practical Note: Soaking instruments in 0.5% chlorine solution for prolonged periods of time will lead to corrosive damage of the instruments, especially specula. Many busy VIA clinics have found that it is difficult and not practical to accurately time how long individual instruments have been soaking in the 0.5% chlorine solution prior to washing and cleaning them—some much longer than 10 minutes, others for a shorter time. Therefore, these clinics have opted to first place all instruments immediately after use in an empty bucket. As a batch, they are then decontaminated for 10 minutes in 0.5% chlorine solution, followed by cleaning with soapy water, rinsing, and high-level disinfection or sterilization.

High-Level Disinfection

When sterilization is not possible or not suitable, HLD is the only acceptable alternative for the final step in processing instruments. High-level disinfection destroys all microorganisms, including viruses causing hepatitis B and AIDS, but does not reliably kill all bacterial endospores. High-level disinfection can be achieved by boiling in water, steaming, or soaking in the chemical disinfectant 2–4% glutaraldehyde for **20 minutes**. Because boiling and steaming require only inexpensive equipment, which usually is readily available, they are the preferred methods for small clinics or those located in remote areas. Regardless of the method selected, however, HLD is effective only when instruments and other items are first thoroughly cleaned and rinsed before HLD.

Special Note on Cryotherapy Tips: An option for HLD of the cryotherapy tip is to soak in 70–90% ethyl or isopropyl alcohol for at least 20 minutes. See page 71 on Infection Prevention for Cryotherapy for further details.

Key Steps in Chemical High-Level Disinfection

- Decontaminate instruments that have been in contact with blood or body fluids.
- Thoroughly clean and dry all instruments.
- Cover all items completely with correct dilution of high-level disinfectant that has been properly stored.
- Soak for 20 minutes.
- Remove using high-level disinfected forceps or gloves.
- Rinse well with boiled water and air dry.
- Use promptly or store for up to 1 week in a high-level disinfected, covered container.

To prepare a high-level disinfected container, boil if small or (if large) fill a plastic container with 0.5% chlorine solution and soak for 20 minutes. (The chlorine solution can be transferred to a plastic container and reused.) Rinse the inside thoroughly with boiled water. Air dry before use.

Sterilization

Instruments and other items, such as needles or scalpels, which come into direct contact with tissues beneath the skin should be sterilized after first being decontaminated and thoroughly cleaned, rinsed, and dried. The sterilization process destroys all microorganisms, including bacterial endospores. Bacterial endospores are particularly difficult to kill because of their tough coating. (Bacteria that form endospores include Clostridium tetani, which causes tetanus.) Sterilization can be achieved by autoclave (high-pressure steam), dry heat, or chemicals ("cold sterilization").

High-Level Disinfection
High-level disinfection by boiling, steaming, or using chemicals is acceptable for final processing of instruments used for VIA or cryotherapy. Surgical (metal) instruments should be **steamed or boiled for 20 minutes** and allowed to dry. Instruments can be **soaked for 20 minutes in 2–4% glutaraldehyde, thoroughly rinsed in boiled water, and air dried.** **Note:** 2-4% glutaraldehyde must be prepared according to the manufacturer's guidelines and usually has a shelf-life of 14 days once activated, but check the manufacturer's information.

Sterilization
Instruments and surgical gloves can be sterilized by autoclaving. If necessary, metal instruments can be sterilized using dry heat. Steam sterilization: 121°C (250°F) at 106 kPa (15 lb/in^2) pressure for 20 minutes for unwrapped items; 30 minutes for wrapped items. Allow all items to dry thoroughly before removing. Dry heat: • 170°C (340°F) for 60 minutes (total cycle time—placing instruments in oven, heating to 170°C, timing for 1 hour and then cooling—is from 2 to 22 hours), or • 160°C (320°F) for 2 hours (total cycle time is from 3 to 32 hours). **Note:** Dry heat sterilization (170°C for 60 minutes) can be used only for metal instruments.

- One option for VIA clinics is to autoclave instruments and cotton swabs in one-per-client packets. The provider uses one VIA instrument packet per client, minimizing the chances of cross-contamination. Each packet to be autoclaved should consist of:
  - one speculum
  - one sponge-holding forceps
  - one gallipot
  - and several cotton swabs
- Wrap the packet in a cloth and secure with autoclave tape. Write the date of autoclaving on the tape. After autoclaving, allow time for drying and cooling of instruments prior to examination of clients. In general, it is best to autoclave equipment at the end of each day to allow for drying and cooling overnight.

Storage of Instruments

Store instruments in a covered, sterilized tray. Store them for no more than 21 days; otherwise repeat autoclaving.

For further reading on disinfection and sterilization guidelines, see WHO technical specifications: Cryosurgical equipment for the treatment of precancerous lesions for cervical cancer prevention (WHO 2012a), as well as CDC *Guidelines for Disinfection and Sterilization in Healthcare Facilities* (CDC 2008) and Chapter 14 of the IARC online colposcopy manual (Sellors and Sankaranarayanan 2003).

In addition, refer to the *Zambia Infection Prevention Guidelines, Second Edition,* May 2010.

Hazardous Waste must be disposed of according to national guidelines.

Chapter 7. Performing Cryotherapy

Overview of Cryotherapy

WHO states that in low-resource settings, cryotherapy is the treatment of choice for precancerous lesions eligible for cryotherapy because of the following advantages in its use (WHO 2011; WHO 2013b):

Advantages

- Safety—very low complication rate
- Effective (> 90% cure rate)
- Well-accepted by women
- Inexpensive compared to other treatment options
- Can be performed by a wide range of health care providers (nurses, midwives, doctors)
- Does not require electricity or anesthesia
- Can be readily used in a single visit approach

These characteristics of cryotherapy make it a valuable component of a cervical cancer prevention program. However, cryotherapy has some disadvantages that need to be noted (WHO 2011; WHO 2012a; WHO 2013b):

Disadvantages

- Cannot treat large lesions or those that extend into the endocervical canal
- Does not provide a tissue specimen for histopathology
- Requires a continuous supply of gas
- Tendency of cryotherapy units to break down if gas contains impurities/particulate matter
- Associated with temporary side effects such as cramping, watery discharge

Pathophysiological Basis for Cryotherapy

Cryotherapy is an ablative therapy that destroys the cervical precancerous tissue by using compressed gas delivered through a cryoprobe and cryotip to freeze and destroy the abnormal areas on the cervix. Cryotherapy destroys precancerous cells through two mechanisms: direct cell injury and vascular stasis (Hoffman and Bischof 2002). Direct cell injury occurs when intracellular ice forms, which requires very rapid freezing. Vascular stasis results in an indirect form of cellular injury, where the freezing damages the blood vessels supplying the cells and an ischemic, coagulative necrosis occurs over a period of approximately 3 days after initial injury (Hoffman and Bischof 2002; Gage and Baust1998).

These two mechanisms are governed by four key parameters during a single freeze-thaw cycle: freezing rate, minimum temperature achieved, hold time at minimum temperature, and thaw rate (Hoffman and Bischof 2002; Gage and Baust 1998; Baust and Gage 2004):

- Faster freezing rates result in more cell death.
- Colder minimum temperatures result in more cell death; however, the cold required for vascular stasis (-20°C) appears to be warmer than for direct cell injury (-40° to -50°C).
- Increasing the hold time at the minimum temperature increases cell death rate.
- A slower thaw rate increases the destructive effects of cryotherapy.

Repeating a freeze-thaw cycle increases overall tissue destruction, as each freeze-thaw cycle increases the thermal conductivity of the tissue for the next freeze. Therefore, each repeat of the freeze-thaw cycle freezes a larger volume of tissue (Gage and Baust 1998; Baust and Gage 2004).

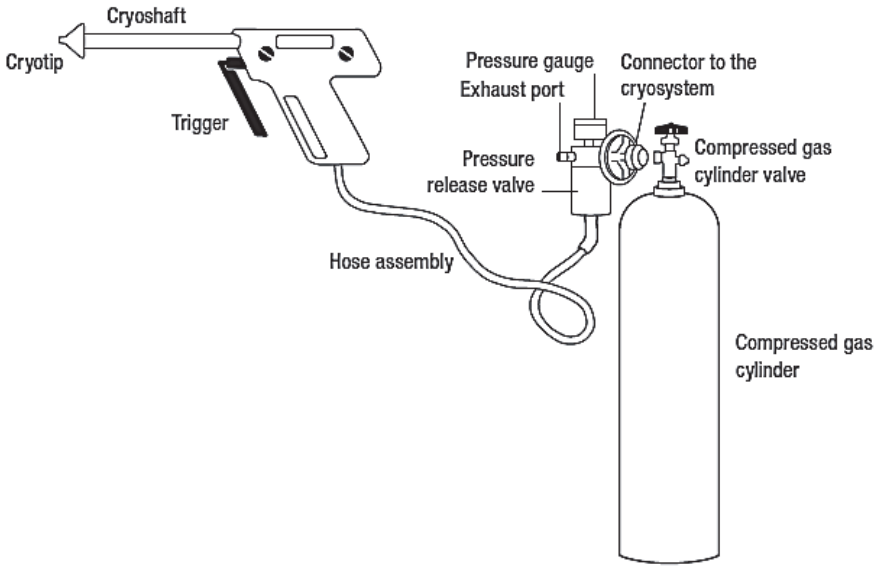
Special Cryotherapy Equipment

The following section provides an overview of the cryotherapy equipment. For more detailed information regarding the technical specifications of cryotherapy equipment, please see the reference *WHO Technical Specifications: Cryosurgical Equipment for the Treatment of Precancerous Cervical Lesions and the Prevention of Cervical Cancer* (WHO 2012a).

Cryotherapy Unit

The cryotherapy unit (Figure 7.1) refers to the equipment that enables high-pressure compressed gas to travel from the gas cylinder to the cervix via the cryoprobe and cryotip. It should be certified as capable of reaching and maintaining a cryotip temperature of at least -20°C and preferably -50°C (WHO 2012a).

Figure 7.1. Typical cryotherapy unit



Source: WHO. 2012a. *WHO Technical Specifications: Cryosurgical Equipment for the Treatment of Precancerous Lesions for Cervical Cancer Prevention,* Figure A1, page 31. At: http://www.who.int/reproductivehealth/publications/cancers/9789241504560/en/, accessed January 15, 2015.

The cryotherapy unit consists of:

- **Cryotip:** metal tip designed to fit up against and completely cover the precancerous lesions and induces freezing of the cervix.
- **Hand unit:** consists of the **cryoshaft** and **cryogun.**
- **Cryoshaft:** long, rigid tube that attaches the **cryotip** to the **cryogun**. The outer surface of the cryoshaft is insulated to prevent accidental freezing of any tissue it touches. Together, the cryotip and cryoshaft are sometimes called the **cryoprobe**.
- **Cryogun:** consists of a fiberglass handle (shaped like a gun), and freeze/defrost (thaw) triggers. The cryogun controls the flow of gas from the cylinder and **high-pressure hose** into the cryoprobe.
- **High-pressure hose:** flexible hose connecting the **connector/pressure gauge** to the **cryogun**. This hose assembly conducts gas to the cryogun, as well as back to the **exhaust port** for venting of the gas.
- **Connector/pressure gauge assembly:** connects the gas cylinder to the high-pressure hose. The **connector** is made of metal and has specific fittings for type of gas and where the cylinder was made (e.g., British fittings, U.S. fittings). It is essential to know this when ordering the cryotherapy units. The **pressure gauge** indicates the pressure within the system, as the gas leaves the cylinder. For safe and effective operating conditions, most pressure gauges have color-coded zones:
- **Red:** The pressure is too high, and it is unsafe to operate the equipment at this pressure. The cylinder needs to be cooled (if overheated) and/or gas released until pressure reading is in the green zone before operating the equipment.
- **Green:** Safe to use.
- **Yellow:** The pressure is too low for effective cryotherapy to be conducted. The cylinder should be exchanged for a full cylinder.
- **Pressure relief valve:** part of the **connector/pressure gauge** that is designed to protect the equipment, provider and client.
- **Exhaust port:** vents gas from the cryotherapy unit. As a result, cryotherapy should only be conducted in well ventilated rooms.

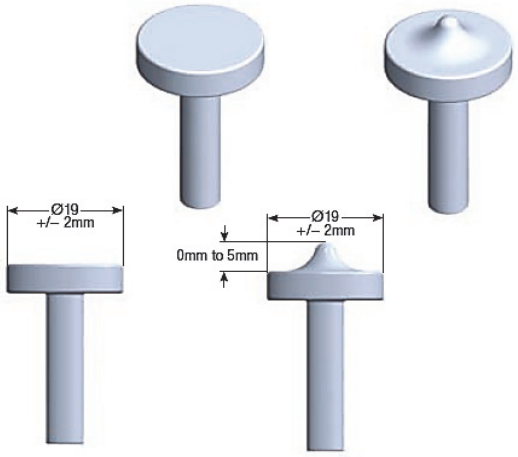
Note: Due to the specific characteristics of the compressed gas, the cryotherapy unit is manufactured according to the gas that will be used. Therefore, when ordering the cryotherapy units, not only must the cylinder fitting be specified, but the type of gas that will be used with it also needs to be specified.

Cryotherapy Tips

WHO recommends cryotips that are round in shape and 19 +/- 2 mm in diameter (Figure 7.2). The surface that contacts the cervix should be either flat or with a nipple-shaped small cone extension, not exceeding 5 mm. In practice, the nipple-shaped cryotips are preferable, because they are easier to position on the cervix. For flexibility in treating lesions, especially in a woman with a wide transformation zone, two different-sized cryotips should be considered: 19/20 mm and 25 mm (Jacob et al. 2005). However, it is slightly more difficult to use the 25 mm cryotip,

at least initially, and it may carry greater risk of accidental freezing of other tissue and potential complications. Therefore, if 25 mm cryotips will be used in a program, it is recommended that the provider become proficient in the use of the 19/20 mm cryotip first, before adding the 25 mm cryotip to the treatment options.

Figure 7.2. Illustration of recommended dimensions of cryotips



Source: WHO. 2012a. *WHO Technical Specifications: Cryosurgical Equipment for the Treatment of Precancerous Lesions for Cervical Cancer Prevention*, Figure 2, page 7. At http://www.who.int/reproductivehealth/publications/cancers/9789241504560/en/, accessed January 15, 2015.

Gas

WHO recommends using either carbon dioxide (CO_2) or nitrous oxide (N_2O), the most commonly used and studied compressed gases for cryotherapy, and most cryotherapy equipment manufacturers offer either option (WHO 2013b). In settings where both gases are available, WHO recommends CO_2 over N_2O because it tends to be much less expensive (often a quarter of the cost) and more readily available, and has fewer ventilation requirements (WHO 2012a; WHO 2013b). However, the choice of gas for a cervical cancer prevention program needs to take the local setting into consideration.

Both N_2O and CO_2 reliably achieve at least -20°C and closer to -50°C, though N_2O tends to achieve a colder minimum temperature at the cryotip and in the tissue than CO_2. However, and important, current evidence suggests no difference in clinical outcomes between the gases (WHO 2011; WHO 2013b).

Gas Quality

Gases are available in many different grades, such as medical, food, and industrial. While medical-grade gases are more expensive than other grade gases, they are very high quality and free of any potentially impurities that can cause equipment blockage, malfunctioning, and breakdown. Therefore, WHO recommends use of medical-grade gases if available and affordable. If medical-grade gases are not available, then food, beverage (for CO2), or equivalent grades can be considered, though industrial-grade is discouraged (WHO 2012a).

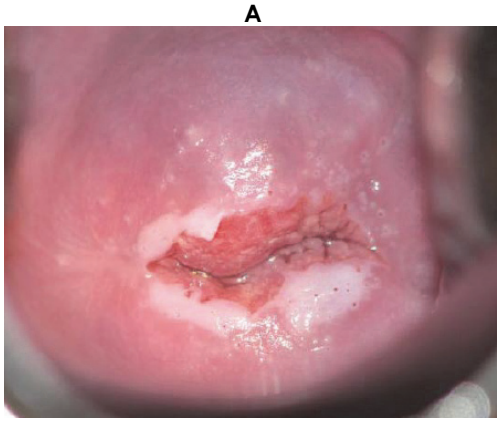
Client Assessment and Counseling for Cryotherapy

Eligibility criteria for cryotherapy (see Figure 7.3)

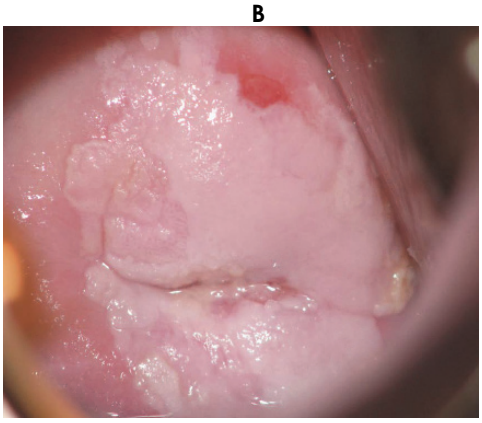
- Not suspicious for cancer
- Can see the entire extent of the lesion; lesion does not extend into the endocervical canal
- Lesion occupies < 75% of the cervix
- Cryotip fully covers the lesion
- No anatomical deformity of the cervix (e.g., polyps, large nabothian cysts) that prevents good application of the cryotip
- Client is not pregnant
- Client is more than 6 weeks postpartum
- Client does not have severe cervicitis

Figure 7.3. Lesion eligible for cryotherapy (A) and large lesion, not eligible for cryotherapy (B)

A



B



Source: CIDRZ 2013.

Counseling Prior to Cryotherapy

All women have the right to decide freely whether or not to receive treatment. Written consent is required for cryotherapy. The provider obtaining the woman's consent for cryotherapy should follow these steps:

- During counseling for screening, explain that if VIA discovers a precancerous lesion that can be treated with cryotherapy, the treatment can be done in the same visit. Explain in detail, in a nonthreatening manner and in language the woman can understand, the cryotherapy procedure, its risks, benefits, likelihood of success, and alternatives (Table 7.1).
- Allow time for and encourage the woman to ask questions and discuss her condition.
- Ask the woman if she gives consent for treatment, and obtain written consent (Appendix 3: Cervical Cancer Screening Form).

Table 7.1. Expected side effects from cryotherapy

Side Effect	Management
Cramping	• Counsel the patient before the procedure to expect some degree of cramping during and after the procedure and that cramping usually stops shortly after procedure. • Reduce cramping by pressing lightly on the cervix with the cryotherapy probe. • If cramping is severe, provide oral analgesic (acetaminophen or ibuprofen).
Vaginal discharge (profuse, watery)	• Counsel the patient to expect a discharge lasting up to 4–6 weeks. Provide the patient with undergarment and feminine pads*. • Counsel the patient to expect discharge to change color from a pink tint to clear white or a yellow tint (occasionally streaked with blood). • Counsel the patient to return if discharge changes to foul-smelling or is pus-colored (if so, evaluate for infection and treat with antibiotics). • Strongly advise abstinence from sexual intercourse for 6 weeks, primarily to prevent discomfort, bleeding, and infection the first 4 weeks, and primarily to prevent infection after 4 weeks. • If abstinence is unlikely, advise condom use for any sexual activity during the 6 weeks to prevent infection. *If undergarments or feminine pads are not available, cloth or other soft material may be used.
Spotting/light bleeding	• Counsel the patient to expect spotting/light bleeding for 1–2 weeks. • Counsel the patient to return for evaluation if there is heavy bleeding.

If not already covered in your counseling, following are some key questions and responses:

Q. What is cryotherapy?
A: Cryotherapy uses extremely cold gas to freeze and destroy the precancer/abnormal cells, which destroys the precancer. Cryotherapy uses an instrument to deliver the extremely cold gas to your cervix. The abnormal cells are frozen; once frozen, the cells will die and fall off the cervix. You will notice this in the form of a heavy, watery discharge that lasts up to 4–6 weeks after treatment.

Q: How effective is this treatment?
A: Cryotherapy is more than 90% effective in curing precancer lesions. Since the treatment is very effective, but not 100% effective, it is very important to follow up for re-screening as instructed.

Q: Will this treatment hurt?
A: During the treatment, you may feel some mild cramping and a cold sensation in the vagina and lower abdomen. The cramping will disappear quickly over the next 15 to 30 minutes. Usually it does not require pain medication, but if required, the cramping is easily treated with an oral pain medication. For the next few days, you may have some occasional mild cramping for which you may take whatever you might ordinarily take for menstrual cramps.

Q: What are the side effects of the treatment?
A: The most common side effect of the cryotherapy is a heavy, watery vaginal discharge for 4–6 weeks. Almost everyone who gets this treatment has this discharge. Some women also may have light bleeding or cramping. During this time, you should not put anything in your vagina. This means you cannot have sex, douche, or use tampons. If it is absolutely impossible to avoid sex over the 6 weeks following treatment, it is very important that you or your partner uses a condom.

Q: What could happen if I don't use a condom?
A: The freezing treatment creates a "wound" on the cervix, which needs time to heal. Any contact with the healing cervix may interfere with proper healing of the cervix. Also, you will be more susceptible to getting an infection or a sexually transmitted infection during this healing time. That's why it is so important to use a condom if you cannot abstain.

Equipment, Instruments, and Supplies for Cryotherapy

In addition to the equipment, instruments, and supplies required for VIA, cryotherapy requires the special equipment as described earlier:

- One cryotherapy unit
- At least two 19/20 mm cryotips with 5 mm nipple-shaped extensions
- Gas cylinder with either carbon dioxide or nitrous oxide gas. Should have at least two cylinders.
- High-level disinfected/sterile closed container for cryotip storage
- 70–90% ethyl or isopropyl alcohol
- Sanitary pads or suitable substitute
- Condoms

Optional Items:

- Different-size cryotips as described earlier in this chapter

Materials for Infection Prevention for Cryotherapy

In addition to the materials required for infection prevention for VIA, cryotherapy requires:

- 70–90% ethyl or isopropyl alcohol
- High-level disinfected/sterile closed container for cryotip storage, and processing (if in accordance with manufacturer recommendations)

Optional Items:

- 2–4% glutaraldehyde for HLD if not using other HLD method

Step-by-Step Guide for Cryotherapy

Step 1: Ensure Readiness of the Clinic

- Ensure the clinic is ready to conduct cryotherapy.
- Ensure all necessary equipment, instruments, and supplies are available and ready for use (properly processed/cleaned), including cryotherapy equipment, cryotips, and gas supply.
- Turn the gas on and ensure that the gauge is in the green zone.
- Without the cryotip on, point the cryoprobe toward the ceiling and pull the trigger to check the freeze and defrost function.
- **Note:** The following assumes that cryotherapy is being done as part of a single visit approach, that many of the steps performed for VIA (including counseling, history taking, and VIA) has already been performed, and that the same health care provider who performed VIA is performing cryotherapy. See a step-by-step guide for VIA for details leading up to this point.

Step 2: Counsel and Obtain Informed Consent

- Counsel the client on the test results and recommended treatment. Review previous counseling regarding cryotherapy. Explain why the treatment is recommended and describe the procedure. Encourage her to ask questions.
- Obtain her consent for treatment (written consent on the Cervical Cancer Screening Form, if not already done).

Step 3: Position the Client on the Examination Table; Prepare for Cryotherapy

- Ensure the client recently emptied her bladder (within 30 minutes) or ask if she wants to empty her bladder now. A full bladder can make visualization of the cervix difficult, and may be uncomfortable for the woman during the exam.
- Remove the contaminated gloves from the VIA examination and put on one pair of new examination gloves, if not already done.
- Arrange instruments and supplies on a clean tray or container, if not already done.
- Screw the high-level disinfected/sterile cryotip onto the end of the cryoprobe and hang it without contaminating (or hand to assistant, if available).

Step 4: Repeat the VIA

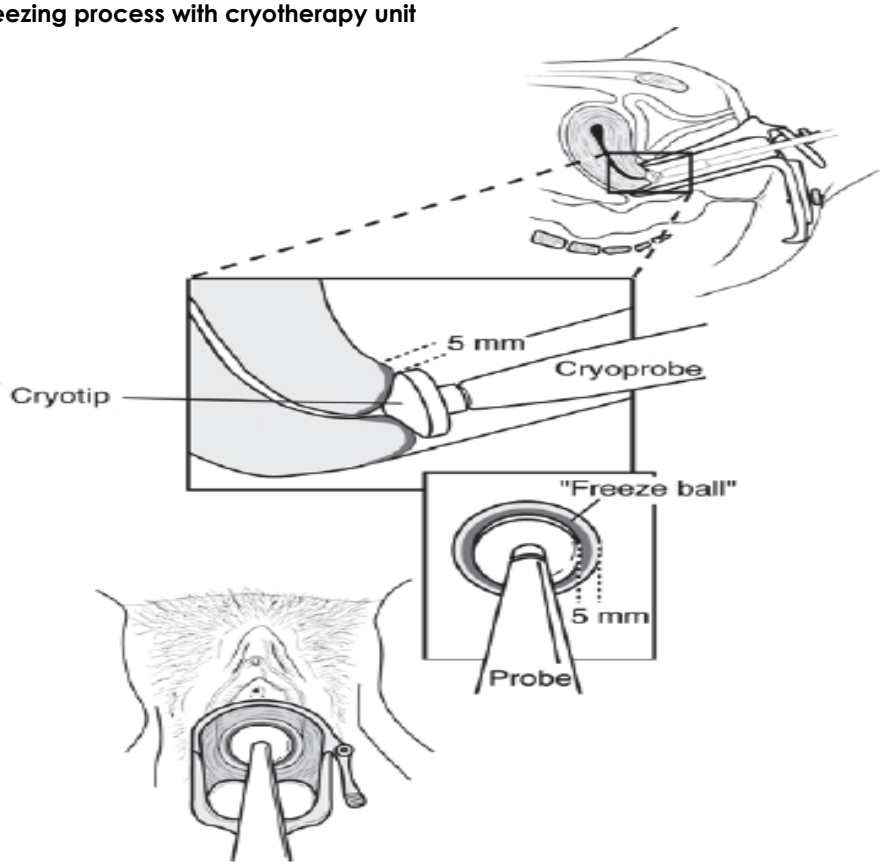
- Repeat VIA and determine eligibility for cryotherapy. If necessary, wipe away excess mucus or blood.
- Ensure good visualization of the cervix and lesion(s): use a bright white light, open the speculum wide (without creating too much discomfort), and ensure the vaginal walls will not obscure the cervix or create difficulty in performing cryotherapy and potential inadvertent freezing of the vaginal tissue. If necessary, use wooden spatulas, cotton swabs, a condom over the speculum, or other instrument to adequately retract the vaginal walls before proceeding.

Perform Cryotherapy Using the Double-Freeze Technique (Figure 7.4)

Step 5: Perform the First Freeze for 3 Minutes

- Apply the cryotip to the cervix, ensuring the entire acetowhite lesion is covered by the cryotip, and apply gentle pressure. Ensure the nipple is centered – it should be placed over or seated in the external os.
- Before starting, tell the client you are about to begin the treatment and that she will hear noise from the machine.
- Hold the cryogun perpendicular to the plane of the cervix. Press the freeze trigger to start the freezing process. Use a watch, clock, or timer to measure 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. Freeze for 3 minutes, ensuring a 4–5 mm ice ball has formed beyond the cryotip edge.

Figure 7.4. Freezing process with cryotherapy unit



Source: Blumenthal and McIntosh 2005.

Step 6: Defrost/Thaw for 5 Minutes

- After 3 minutes of freezing, the cryotip will be frosted and attached to the cervix by the ice ball. Press the unfreeze/defrost trigger. Wait for the cryotip to defrost (turn gold); this usually takes just a few seconds. However, do not use the active defrost too long, because rapid rewarming of the cervix can actually help the frozen tissue survive. It is better to gently rotate and gently pull to detach the cryotip as soon as you see the ice or frost start to disappear from the cryotip. This should occur very easily. Do not pull hard to detach the cryotip.

- If the cryotip does not separate, be patient and allow passive thawing to occur. Gently rotating the cryotip clockwise and counter-clockwise can assist in separation. However, if the cryotip is firmly attached, it will rotate the cervix also and may cause discomfort. Once the cryotip can be seen to spin without rotating the cervix also, it is ready to detach. Be careful not to touch the cryotip to the vaginal walls.
- Wait a total of 5 minutes, which starts at the time you stopped the first freeze.

Step 7: Perform the Second Freeze for 3 Minutes

- Refreeze for 3 minutes using the same technique. If an ice ball of 4–5 mm beyond the cryotip edge does not form, increase the freeze time to 5 minutes.
- Repeat the defrost/thaw technique as in Step 6, but once the cryotip detaches, the procedure has ended.
- Inspect the cervix to ensure that a hard, white, frozen ice ball is present (Figure 7.5). If not, then freeze at least one more time, putting more pressure on the cervix. Ensure that adequate pressure is displayed on the gauge attached to the cryotherapy unit. If pressure is inadequate, arrange for gas resupply and reschedule the procedure.
- Inspect the cervix for bleeding and, if needed, apply pressure with a clean cotton swab. Dispose of the swab.

Figure 7.5. Cervix before and after cryotherapy



Source: CIDRZ 2013.



Source: Jhpiego 2004.

Step 8: Post-Cryotherapy Tasks

- Remove the speculum and place in container for decontamination. Decontamination with 0.5% chlorine solution for 10 minutes should be done either immediately or at a designated time during the clinic.
- Check to be sure that the woman is not having excessive cramping before helping her sit up, get down from the table, and get dressed.
- Change gloves, and dispose of contaminated gloves in a proper waste bin.
- Close the master cylinder on gas cylinder. Wipe the light source (if contaminated during the procedure) and cryotherapy unit, including the cryotip, with alcohol. Empty the remaining gas from the cryotherapy tubing and ensure that the pressure gauge reads zero.
- Remove gloves and dispose of them in a leakproof container or plastic bag.

- Sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.
- Review post-cryotherapy and follow-up instructions (including written instructions). Observe the woman in the clinic area for at least 5 minutes (some recommend up to 15 minutes) following the procedure in case of severe cramping, bleeding, or feeling light-headed. Ask her how she feels before sending her home. Provide a sanitary pad or other suitable material.
- Record the treatment and follow-up plan on the Cervical Cancer Screening Form.

Cryotherapy Unit Job Aid – See Appendix 1.

Counseling Following Cryotherapy and Potential Complications

Before leaving the health facility, the client should receive counseling regarding:

- Details of self-care at home
- Conditions that might require coming to the clinic as soon as possible for care outside of the scheduled visits:
  - Vaginal discharge that smells extremely bad;
  - Bleeding heavier than a menstrual cycle;
  - Fever with or without chills; and
  - Severe lower abdominal pain
- When to return for her follow-up appointment and for re-screening
- Finally, the woman should be given a last opportunity to ask any questions she might have

Most women will not experience problems following cryotherapy. Advise the woman to expect some mild cramping and a clear, watery (sometimes pink or blood-tinged) discharge that usually lasts up to 4–6 weeks. If it becomes foul-smelling or pus-colored, or if she has pain, she should return to the clinic immediately to check for possible infection.

See Table 7.1 Expected Side Effects from Cryotherapy.

Advise the woman that she should not put anything inside her vagina—douche, use vaginal tampons, or have sexual intercourse—for 4 weeks, or until the discharge is completely gone. This helps promote healing of the cervix and reduces the risk of infection.

Note: If the woman will not be able to abstain from sexual intercourse, tell her to use condoms with every act of intercourse. Provide her with 15–20 condoms.

Severe complications following cryotherapy are very rare.

Types of Complications

Infection

Cervicitis: A localized infection of the cervix, without evidence of upper reproductive tract infections (e.g., PID, endometritis, salpingitis). Even mild cases are uncommon, with Jhpiego country programs reporting less than 1%. Cervicitis should be managed according to current national guidelines.

PID: An upper reproductive tract infection (e.g., PID, endometritis, salpingitis) that is a more serious complication than cervicitis and requires more intensive treatment. PID following cryotherapy is rare, occurring in less than 1% of women treated. Management should be with antibiotics according to national guidelines. Severe PID may require hospitalization for close monitoring and intravenous antibiotic therapy.

Bleeding

While very light bleeding or spotting is not uncommon, heavy bleeding is very rare, and is most often associated with sexual intercourse in a woman with severe cervicitis.

Cervical Stenosis

Severe pain and cramping, associated with little or no menstrual bleeding, is rare but can occur following cryotherapy due to necrotic plug syndrome. This uncommon condition presents at least 1 month following the procedure and is thought to be due to extensive destruction of tissue in the endocervical canal, resulting in scarring and obstruction of the endocervical canal. This obstruction may be caused by a necrotic plug of tissue, and is thought to occur more frequently when a cryotip with a long nipple extension is used. This complication can usually be immediately and easily managed by passing a small probe (e.g., a small cotton tip applicator, endocervical cytology brush, or metal uterine sound) or with cervical dilation, to facilitate drainage of menstrual blood.

Fistula

Vesicovaginal or rectovaginal fistula is a very rare, late-appearing major complication following cryotherapy. It occurs following accidental freezing of the vagina overlying the bladder or rectum, with subsequent breakdown of that tissue creating a fistula. Women will present with complaints of involuntary loss of urine or feces into their vagina, with or without pain, or signs of infection. Women with this condition require referral to an experienced gynecologic surgeon for evaluation and treatment.

Obstetrical Complications

Evidence suggests that obstetrical outcomes and fertility are not affected by cryotherapy.

Warning signs

If you have any of the following, you should return to this facility or the nearest health facility:

- Extremely foul-smelling or pus-colored vaginal discharge;
- Fever for more than 2 days, with or without chills;
- Severe lower abdominal pain, especially with a fever; or
- Bleeding heavier than the heaviest days of a menstrual cycle.

The health care provider must emphasize the importance of returning to the facility if any of these warning signs occur.

Infection Prevention for Cryotherapy

Infection prevention steps for cryotherapy are the same as with VIA except for the cryotherapy unit. **The key points in infection prevention of the cryotherapy unit are:**

- **Wipe down** the cryotherapy unit (handle, shaft, and cryotip, and also the hose and regulator if contaminated) with **70–90% ethyl or isopropyl alcohol**. Move from least contaminated to most contaminated area. Do **not** use chlorine solution due to its corrosive effect.
- **Wash** the cryotip (and plastic sleeve) with soap and water until visibly clean. Plug the open end of the cryotip with a rubber stopper to help prolong the life of the cryotip.
- **Rinse** the cryotip (and plastic sleeve) with clean water.
- **HLD the** cryotip (and plastic sleeve) using one of the following, according to WHO guidelines (WHO 2012a):
  - Boil in water for 20 minutes or steam for 20 minutes.
  - Soak in chemical disinfectant (2–4% glutaraldehyde or 0.1% chlorine solution) for 20 minutes, then rinse with boiled or sterile water.
  - If none of the above are available, soak in 70–90% ethyl or isopropyl alcohol for 20 minutes.
  - Allow to air dry and reassemble or store in HLD or sterile container.

Note: It is critical that the inside of the cryotip is completely dry before its next use, since water will freeze and potentially effect treatment or even crack the cryoprobe. A rubber stopper during the processing can help prevent this.

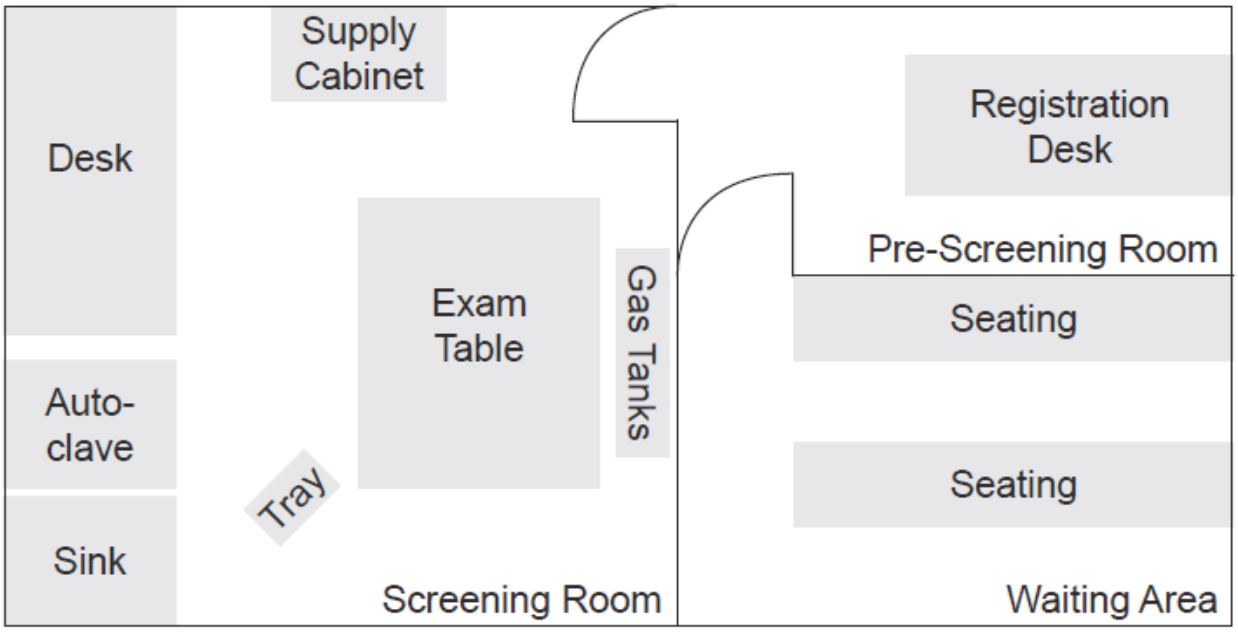
For additional details on disinfection for cryotherapy, see WHO Technical Specifications: Cryosurgical Equipment for the Treatment of Precancerous Lesions for Cervical Cancer Prevention (WHO 2012a), as well as the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (CDC 2008) and Chapter 14 of the IARC online colposcopy manual (Sellors and Sankaranarayanan 2003).

Facility Readiness and Clinic Set-Up

To ensure readiness of a facility to provide VIA/cryotherapy services, the facility must be assessed to determine its level of readiness and what gaps need to be addressed before launching services at that facility (see Appendix 2).

The VIA/cryotherapy room must be large enough for an examination table, instrument cart or tray, gas tank (and ventilation), adequate working space, sink, and supply cabinet (Figure 7.6). The gas tanks should be in a safe and secured location to prevent their being accidentally knocked over, and away from direct sunlight (to prevent overheating). Sterilizing equipment should be near, or even inside, the VIA/cryotherapy room. To ensure privacy, privacy screens should be used, and the examination table should be positioned so the client's head points toward the door.

Figure 7.6. Diagram of a model VIA/cryotherapy clinic room



Source: CIDRZ 2013.

Chapter 8. Referral Networks and Mechanisms

Integrating health services or establishing linkages with other health services is an important consideration for any cervical cancer prevention program. A well-functioning referral network includes linkages between the VIA/cryotherapy clinic and other services, if not provided at the clinic, as well as community sensitization activities. Examples of other clinics and services include: the Outpatient Department (OPD), Maternal and Child Health (MCH), the ART Clinic, the LEEP clinic, the oncology centers, as well as laboratory, pharmacy, and radiology services.

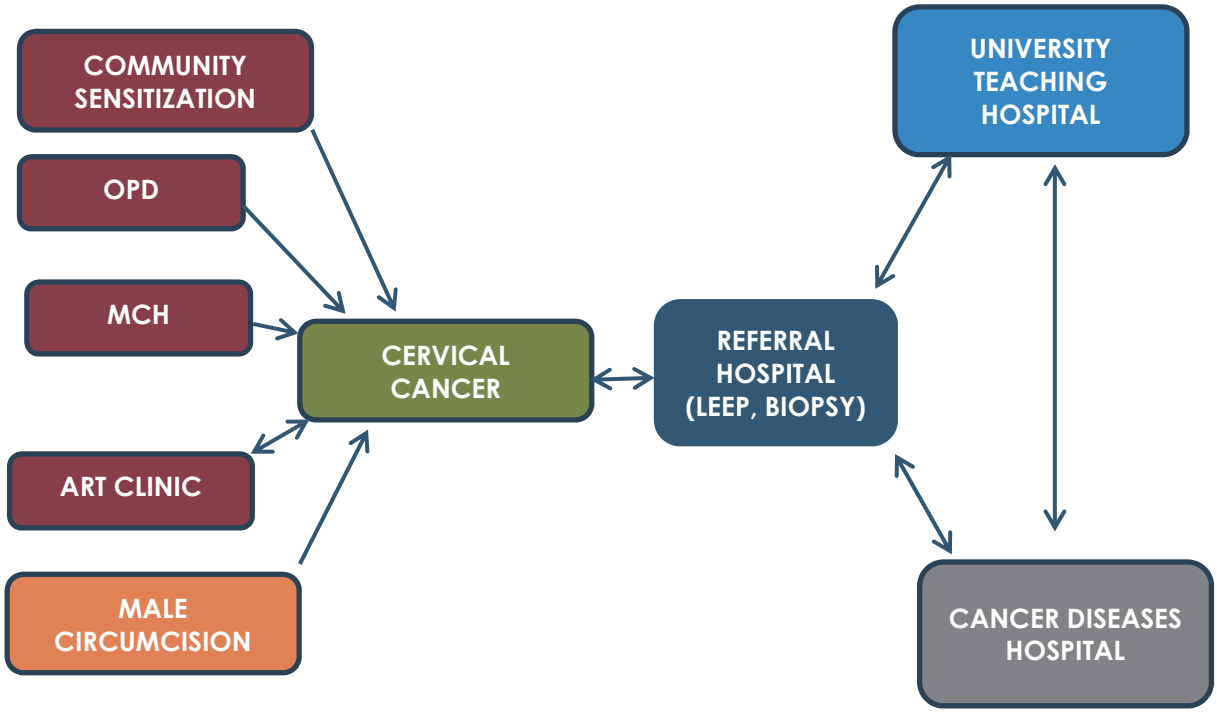
Developing a Referral Network

Two-way communication is a hallmark of an effective and efficient referral network. Two-way communication helps to ensure that a client receives the appropriate medical care without unnecessary delays, which can have a large impact on outcomes. To develop a referral network, it is essential to:

- Identify the services and facilities to include in the referral network.
- Ensure the referral facilities are capable of providing quality referral services as identified for that facility.
- Establish a communication system between the facilities using forms/letters, telephone, e-mail, or other distant means of communication.
- Develop referral protocols and guidelines, develop standardized referral and counter-referral forms, and ensure dissemination of these standardized protocols, guidelines, and referral forms.
- Monitor the referral network to ensure continuity and quality of care.

The Referral Network

Figure 8.1. Cervical cancer prevention and control referral network



Indications for Referral from the Screening Clinic

- Large lesions: the acetowhite lesion occupies more than 75% of the cervix, or the cryotip cannot cover the full extent of the lesion
- Lesion extends into the endocervical canal beyond the nipple of the cryotip
- Lesions with abnormal blood vessels: mosaicism, punctation or atypical vessels
- Abnormal vaginal bleeding
- Pelvic masses

Referral Mechanisms

Referral Forms

It is important for a program to have standardized referral forms. The referral form used will be the standard MOH Patient's Referral Form (Appendix 9: Referral Form). The form includes:

- Client name, age, sex, and contact information
- Present complaints or symptoms by the patient
- Findings and reason for referral
- Referral facility
- Drawing of the cervix (or cervigram), if indicated
- Name of provider making the referral

- Date of referral
- Counter-referral/Feedback space

The provider gives a referral form to the client at the time of the initial evaluation. The referral form serves two purposes: 1) it reminds the client to attend the referral appointment; and 2) it gives the consultant the client's details and reason for referral. The client then presents the referral form upon arrival at her appointment. The referral form should be copied and sent to the consultant for review prior to the appointment. It also serves as a backup in case the client forgets to bring the form to the appointment.

Counter-Referral Forms

After the visit, the consultant should communicate to the provider who made the referral the findings, recommendations, and treatment (if any) on the bottom of the MOH Referral Form.

To prevent loss to follow-up, the VIA/cryotherapy clinic should develop a mechanism to track referred clients so the clinic can actively follow up on clients to determine if they went to their referral appointments. This follow-up can take many forms, but should be active, not passive (i.e., the clinic should not wait to hear from the client about the results of the referral or just assume the client went to the referral appointment). A designated time interval referral list (weekly, every other week, or even monthly) can help track clients. The clinic should keep a list of referred clients and their contact information. At the designated time intervals, the clinic: 1) contacts the client to see if she has completed the referral appointment; and 2) contacts the consultant for results of pending referrals as well as to enable the consultant to follow up women who have not presented for their appointments.

Chapter 9. Monitoring and Evaluation

Background and M & E System Development

Monitoring and evaluation (M & E) of cervical cancer prevention programs helps determine which activities are effective and should be expanded further and which are not and should be stopped or would benefit from reworking. The continuous feedback mechanism provided by quality data and performance information, including identifying gaps and successes, finding solutions, and replicating best practices, ensures that programs can:

- prioritize services and activities supporting those services to ensure appropriate utilization of resources;
- demonstrate the program's effectiveness, coverage, and efficiency; and
- identify services that can be scaled up.

Reasons to Invest in and Improve Data Collection and Reporting:

- What gets measured, gets done.
- If you don't measure results, you can't tell success from failure and you can't identify gaps and find solutions.
- If you can't see success, you can't learn from it and share it.
- If you can't see success, you can't reward it.
- If you can't reward success, you probably are rewarding failure.
- If you can't recognize failure, you can't correct it.
- If you can demonstrate cost-effective results, you can scale up.

Monitoring and evaluation must be relevant, objective, transparent, and, most importantly, used as a management tool for implementing and tracking program progress.

This chapter of the reference manual will:

- introduce key monitoring and evaluation concepts;
- present simple and clear procedures for documenting cervical cancer screenings using VIA and DC for VIA-positive cases and treatments using cryotherapy;
- offer Zambia's performance indicators and the national data collection tools that support these indicators;
- provide examples of how to document unique patient cases; and
- discuss how data collected can be used to guide program improvement at the facility, district, and national levels.

Definitions:

Monitoring: Routine tracking of priority information about a program and its intended outcomes.

Are we doing the **right things**?

Evaluation: Measures changes over time in outcomes and the extent to which the changes can be attributed to the interventions.

Are we doing **things right?**

Monitoring and Evaluation Defined

There is a lot of confusion over the differences between monitoring and evaluation. **Monitoring** is the routine, daily, or monthly assessment of ongoing activities and progress. Trend-tracking over several time periods is part of the monitoring process. **Evaluation** is the periodic assessment of overall achievements. Monitoring looks at what is being done as it is being done; evaluation examines what has been achieved or what impact has been made over time.

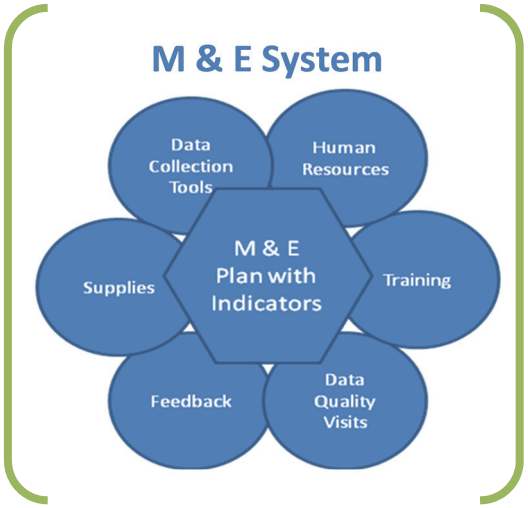
Within a cervical cancer prevention program, a lot can be learned about how well the program is being implemented by tracking a few key indicators related to routine service delivery, including screening, treatment, and referral results. These indicators are primarily related to the process, outputs, and outcomes leading toward the ultimate goal of reducing morbidity and mortality due to cervical cancer. Effective M & E is based on a clear, logical pathway of results in which one level is expected to lead to results at the next level, ultimately leading to the achievement of the overall goal.

When to Develop the M & E System?

Good monitoring and evaluation requires pre-planning as well as internal and external validation of results (i.e., checking for completeness and accuracy of the data collected). A standard data system, like a health management information system (HMIS), is essential to ensure that data can be analyzed, summarized, and compared in a standard and effective way across the program's lifecycle, and across the different health system levels, and compared to similar cervical cancer prevention programs in other countries through global reporting mechanisms. The need for a standardized global data system does not preclude individual country programs from collecting additional, situation-specific data, but all additional data should have justification for its collection so as not to waste the providers' time or diminish the value of the other essential data collected.

The cervical cancer prevention program's standard M & E core elements include: indicators, data collection tools, periodic supervisory (or monitoring) visits to clinics to assess data quality, analysis, and use and reporting tools (Figure 9.1). The data system, including the indicators and data collection tools for the cervical cancer prevention program, has been developed in collaboration with key stakeholders, including the Ministry of Health, to ensure that it is as simple as possible, only requiring data that will be useful to the implementation team's management of the program.

Figure 9.1. M & E system for CECAP



As mentioned previously, monitoring and evaluation must be built into the design and start-up of the program. M & E should be budgeted and be operational before any program activities like training or service delivery start. Key elements of M & E need to be decided upon **before** program start-up. These key elements include formative or preparatory research, baseline or endline surveys, key performance indicators and tools, a performance monitoring plan including targets by health facility or district for district and national reporting and incentives for the facility, and the human resources needed to implement the system. It is very difficult to design and carry out a monitoring and evaluation system after the program activities are under way, so it is best to do this planning in advance.

M & E System for Cervical Cancer Prevention Programming

Cervical cancer prevention programs use an M & E system to ensure effectiveness. This system has many components including:

- An **M & E plan** (with indicators and benchmarks or targets). This serves as a "road map" to identify results you want to measure, judge the success or shortfalls of the program, and guide what we want to be able to say about achievements of the program.
- **Data collection tools** including paper or computerized (for example, tablet or smartphone) forms, spreadsheets, and databases for capturing and analyzing the data.
- **Human resources** for data entry, analysis, synthesis, and interpretation of data. These personnel will put the data into context to uncover patterns or problem areas and transform the data into facts and information useful for programmatic decision-making and advocacy.
- **Training** for facility-based staff to standardize data collection, management, reporting practices, and how to use data for decision-making.
- **Ongoing supervision, monitoring, and data quality visits** to review and verify the quality of data.
- **Feedback** to sites on site-specific and program-specific performance.
- **Supplies** for managing paper forms including binders, cabinets, photocopies, registers, etc.

With stakeholders' participation, the flow of data, level by level—from the individual client being screened to the national information system—needs to be mapped to ensure completeness, accuracy, and timeliness of data collection activities. Integration of program data into existing data collection systems should be explored including the integration into the HMIS already reporting routine service delivery from facilities to national entities. Parallel systems are not ideal but may be necessary if cervical cancer screening and treatment is a relatively new phenomenon in the country and indicators do not already exist or if the system is not able to be modified in time for program start-up.

Roles, Responsibilities, and Timeframe

Ideally, a single point person will manage the cervical cancer program's M & E functions, with additional personnel tasked with other M & E-related responsibilities like data entry or site supervision for larger or more complex programs. This single point person will be responsible for the oversight of the M & E system, ensuring that M & E activities are carried out in a standard and systematic way including that procedures and protocols are in place for collection, reporting, analysis, use, and periodic data quality assessments. Table 9.1 highlights the roles and responsibilities of the various entities that are part of the cervical cancer prevention program.

Table 9.1. Roles and responsibilities in M & E for Zambia CECAP programs

Entity	M & E Role/Responsibility
Clients	Participates by providing data to providers. Receives feedback about the use of cervical cancer prevention services in their community.
Facility Staff: In-Charge, Providers, and Data Entry Clerks	Primary data collector on source documents (e.g., Cervical Cancer Screening Form). Completes collection and reporting tools on a daily and monthly basis. Uses data to guide implementation at the facility level. Agrees on annual targets and ensure they are reached.
District Staff: Supervisors and Staff	Ensure that data are checked and verified through periodic data quality assessments. Helps facility providers understand the data collected and implications for their activities. Helps facilities complete their monthly reporting and transfers this knowledge to the providers to carry out on their own.
National and Regional/Provincial Government	Uses aggregate data from facilities and districts to guide overall cervical cancer prevention programming. Budgets for activities. Identifies lessons learned and makes strategic recommendations and decisions.
Program Technical Staff	Collaborates with M & E team on indicators that are useful to guide implementation. End-user of the information for decision-making. Participates in monitoring visits.
M & E Point Person(s)	Coordination role. Provides training to facility providers and other program staff on standardized data collection. Leads analysis and synthesis of data at the district and national level. Provides results against targets to donors and the Ministry of Health as well as the individual facilities generating the data. Builds ownership and buy-in for the overall M & E system. Develops and updates manuals, guidelines, training materials, and reports for program M & E.

CECAP Indicators, Data Collection Tools, and Implementation Procedures

Cervical cancer programs worldwide have a set of standard indicators used to monitor the progress of the programs globally. This list of indicators can be adapted and expanded upon by individual programs to meet the countries' needs at facility, district, and national levels. Special care should be given to key pieces of information like VISIT TYPE and the cascade of indicators to ensure that these are collectable with each modification to the data collection tools. If information is omitted it may be difficult to understand how well the program is achieving its objectives and outcomes as well as to compare the results to other cervical cancer programs globally. This indicator set is linked

explicitly to Zambia's data collection and reporting tools included in this manual. Changes to the indicators will affect the data collection tools, and changes to the data collection tools will affect the indicators, so any changes should be reviewed carefully.

The M & E point person has access to indicator reference sheets. These sheets give more detail on each indicator's definition, data source, calculation, purpose, data requirements, analysis, and decision points. Table 9.2 below gives just the name of the indicator and reference number (to the indicator reference sheets) and key indicators to integrate into district and national HMIS systems.

Definitions:

Data: Raw numbers

Indicators: Markers that help to measure change by showing progress toward objectives. Indicators need to be observable, measurable, and agreed upon as valid. Indicators can be related to activities, service utilization, and outcomes/impact.

Information: The result of organizing, processing, and interpreting data in a way that puts the data into context, uncovers patterns or problem areas, and thus transforms data into useful information for decision-making.

Table 9.2. Matrix of CECAP program indicators with benchmarks and calculation guidance by health system level for the Cervical Cancer Prevention Program in Zambia (CCPPZ)

#	Indicator and Target/Benchmark	Numerator (Num, when numerator is calculated) and Denominator (Den)	Location Data Collected	Location Data Will Be Used			
				Facility (F)	District (D)	Province (P)	National (N)
Training, Facilities, and Awareness Raising Campaigns							
1	Number of people trained		D		X	X	X
2	Percentage of people trained still working in the content area 1 year later	Den: # of people trained in the previous year	% Calculated		X	X	
3	Number/Percentage of health facilities offering VIA and cryotherapy	Den: # of health facilities	D Calculated		X	X	X
4	Number of district-, province-, or national-level awareness-raising campaigns		DPN		X	X	X
5	Number of mass screening campaigns/Outreaches		FD	X	X		
Routine Service Delivery and Performance Indicators							
6	**KEY** – Number of new women who received VIA screening in the target age range (National Target: 1.2M)		F	X	X	X	X

#	Indicator and Target/Benchmark	Numerator (Num, when numerator is calculated) and Denominator (Den)	Location Data Collected	Location Data Will Be Used			
				Facility (F)	District (D)	Province (P)	National (N)
7	Percentage of new women who received VIA screening in the target age range (National Target: 85% by 5 years)	Den: # of women in the population aged: 1) 25 – 59 HIV+; 2) 30 – 59 HIV-; and 3) < 25 with > 59	Calculated		X	X	X
8	Number Percentage of new women screened with a VIA-negative result	Den: # of new women screened	F Calculated	X			
9	**KEY** - Number/Percentage of new women screened with a VIA-positive result (Benchmark: 5–10% / month)	Den: # of new women screened	F Calculated	X	X	X (% only)	X (% only)
10	Number/Percentage of new women referred to another site for advanced care and treatment (includes suspect cancer and referrals for large lesions): Overall Referral Rate	Num: Add together suspect cancers + referrals for large lesions, Den: # of new women screened	Calculated by district		X	X (% only)	
11	**KEY** - Number/Percentage of new women referred for suspect cancer (Benchmark: <1%/quarter)	Den: # of new women screened	F Calculated		X		X (% to cancer hospital)
12	**KEY** - Number /Percentage of new women referred for large lesions (Benchmark: ~ 10%/month)	Den: # of new women VIA+ women	F Calculated	X	X		
13	Number/Percentage of all new women who have confirmed cancer after referral	Den: # of new women referred for suspect cancer and present at referral site	D Calculated		X	X	X
14	Number/Percentage of new women who received treatment for large lesions after referral	Den: # of new women referred for large lesions and present at referral site	D Calculated		X	X	

#	Indicator and Target/Benchmark	Numerator (Num, when numerator is calculated) and Denominator (Den)	Location Data Collected	Location Data Will Be Used			
				Facility (F)	District (D)	Province (P)	National (N)
15	**KEY** – Number/Percentage of eligible cervical cancer screened new women screened and treated with cryotherapy on the same day (SVA) (Benchmark: 80% or above/mo)	Den: # of VIA+ new women minus # of new women referred for large lesions = # of new VIA+ women eligible for cryo treatment	F Calculated	X	X	X (% only)	X (% only)
16	Number/Percentage of new VIA-positive women who postpone cryotherapy	Den: # of new VIA+ women eligible for cryo treatment (see above)	F Calculated		X		
17	Number Percentage of new VIA-positive women who postponed cryotherapy and returned	Den: # of new VIA+ women eligible for cryo treatment (see above)	F Calculated		X		
18	Number/Percentage of new VIA-positive women who postponed cryotherapy and never returned (Lost to Treatment Follow-up)	Den: # of new VIA+ women Eligible for cryo treatment (see above)	F Calculated		X		
19	**KEY** – Number / Percentage of new VIA+ cryo eligible women who receive cryotherapy (incl. SVA and those who postponed and returned) – Overall Cryotherapy Treatment Rate (Benchmark: 90% month)	Num: SVA+ postponed and returned Den: # of new VIA+ women eligible for cryo treatment (see above)	F Calculated		X	X	X
20	Number/Percentage of new VIA-positive women that receive treatment that return with a post-treatment complication	Den: # of new VIA+ women treated with cryotherapy	F Calculated		X		
21	Number/Percentage of previously treated women (cryotherapy and LEEP) that return for 1-year follow-up visit	Den: # of women that received cryotherapy and LEEP in the previous 1 year	F Calculated		X		

#	Indicator and Target/Benchmark	Numerator (Num, when numerator is calculated) and Denominator (Den)	Location Data Collected	Location Data Will Be Used			
				Facility (F)	District (D)	Province (P)	National (N)
22	Number/Percentage of women who return for 1 year follow-up visit after treatment in previous year that now have a VIA-negative result (Cure rate. Benchmark: 95%/qtr).	Den: # of women that get screened 1 year post-treatment	F Calculated		X	X (% only)	X (% only)

Key Performance Indicators

Five key performance indicators, highlighted in yellow above and explained below, will help guide the program's implementation and tell you about various aspects of the program.

1. Number of new women screened

Monthly and annual targets should be set at the facility level and district level in line with the national targets for this indicator. If the screening number falls below the target, the facility team should brainstorm how to attract additional women to the site through word of mouth, TV/radio, group talks within other departments of the hospital, community talks, and outreach activities.

2. Percentage (number) of VIA-positive women

Tracking this indicator over time will help the program assess which facilities may be over- or under-diagnosing women. The expected VIA-positive rate in a previously unscreened general population is 5–10% (WHO 2013b). This rate is expected to be higher among women who are HIV-infected, often two times higher or more. If this number consistently is under 5% or over 10%, additional follow-up and exploration need to be done with the clinic to determine the underlying cause of the outlying rates and correct the problem if one is present.

3. Percentage (number) of eligible VIA-positive women who receive immediate cryotherapy on the day of the screening

This is the single visit approach (SVA) rate. All sites should be able to screen and treat on the same day at least 80% of the eligible women. By tracking this on a monthly and quarterly basis and watching the trends (above or below 80%), the program can identify which sites are performing well (SVA above 80%) and which sites need more assistance (SVA rates consistently below 80%). For example, facility X reports 60% of women received cryotherapy in January and 20% in February. If the SVA rate is consistently under 80%, the program staff should follow up with the site to determine why they are not able to screen and treat in the same day. The facility staff should also discuss this at their monthly data/program review meetings. The under-target results may be due to broken equipment, lack of supplies, cryotherapy trained provider not available, providers' workload (asked the patient to return on a different day because they are too busy), or lack of community awareness that if a patient is found to be VIA-positive she will be provided treatment on the same day.

4. Percentage (number) of new VIA-positive cryotherapy-eligible women who receive treatment

This indicator gives a picture of the overall cryotherapy rate within the program. It can help to highlight whether there is active or passive follow-up of those women needing treatment who have postponed and whether they have returned for treatment. This indicator should be at least 90% every month.

5. Percentage (number) of new VIA-positive women referred for large lesions

Providers should actively follow up with the women and the referral site to ensure that the women get the treatment that they need. Approximately, 10–15% of women should be referred for LEEP (large lesions) but this could be higher in HIV populations.

6. Percentage (number) of new women referred for suspect cancer

Providers should actively follow up with the referring site to ensure that the women get a biopsy completed and treatment as necessary for cancer. Less than 1% of women will be referred for suspect cancer.

The six key performance indicators are useful for the facilities to monitor on a monthly and quarterly basis. They can be monitored using graphs that are posted in the form of a poster on the wall of the facility. The staff at the facility would fill the poster out using the Monthly Facility Summary (see the "Data Use" section later in this chapter for more information).

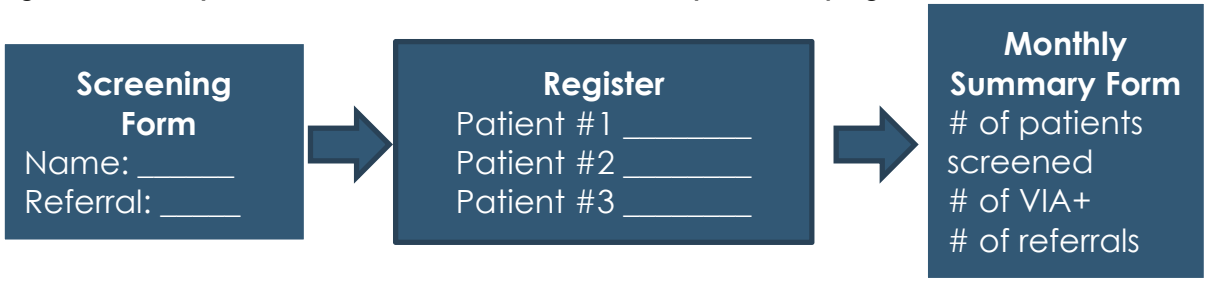
Data Collection Tools: Overview

There are three standard primary paper-based data collection tools (Figure 9.2) used to capture data necessary to calculate the indicators describe previously. These tools are:

- Cervical Cancer Screening Form
- Register
- Monthly Facility Summary Form

There are additional secondary forms including the Referral Form and Client Information Card.

Figure 9.2. Primary data collection tools for cervical cancer prevention program



Data Collection Tools: Cervical Cancer Screening Form

The Cervical Cancer Screening Form is the primary source of information about an individual patient (see Appendices 4 and 5 for the actual form and more information on the various variables on the form). This form is completed when the provider is seeing the client. It includes client/facility information, reproductive health history, HIV status, the visit type, drawing of the cervix using VIA and enhanced digital imaging, and screening and treatment results as well as referral information.

Tips:

- The latest version of the forms should be used. Older versions should be discarded.
- One Screening Form should be completed per visit. If a patient has to return to the site twice because she chooses to postpone cryotherapy, each visit should be documented separately on the Screening Form. This patient will have two forms.
- Complete all data fields on the form. Details are very important for the calculation of indicators. Completeness and accuracy should be a common practice.
- If there is a line (_____), complete it with more information.
- Ensure that if only one answer can be completed, you do not mark two (for example, a patient cannot be both VIA-positive and VIA-negative or both HIV-positive and HIV-negative).
- Make sure that a phone number for the screened woman is documented. If she does not have her own cell number, ask her to give you her husband's/neighbor's phone number and indicate whose number it is on the form. This number is useful in order to remind clients to return for treatment (after postponing) or to return for a 1-year post-treatment follow-up appointment.
- Completed Screening Forms should be kept in a binder in the order they were written into the Register. This binder as well as the Register and other forms should be stored in a locked cabinet to protect patient confidentiality.

Specific instructions on how to complete each field of the primary data collection tools are included in the appendix.

Data Collection Tools: Register

Special Note: Visit Type Section on Data Collection Tools

The Visit Type Section on the Cervical Cancer Screening Form is critically important for disaggregating (breaking down) the data into meaningful groups. Often we want to look at just new patients when calculating indicators like Percentage of New VIA-Positive Patients or just 1-year follow-up clients when we calculate the percentage of 1-year follow-up clients who previously had cryotherapy or LEEP and who now have a VIA-negative result (cure rate). There are six different Visit Types to choose from on the list. Each woman should be classified into one of the categories for each visit.

The definitions of each are below:
Initial VIA Completed: If this is the first VIA screening for the woman and she has not been seen elsewhere, mark this box.
Postponed Cryotherapy: If the VIA-positive woman is returning after previously postponing cryotherapy, the second Screening Form would have this box marked.
Post-Treatment Complication: Mark this box if a previously treated patient returns with a complication. Mark if it is related to LEEP or cryotherapy.
One-Year Follow-Up: When a previously treated patient returns around 1 year for a follow-up screening, this box should be marked.
Routine VIA Screening: When a previously screened women who was VIA-negative at the last visit returns for her next visit, it is marked as a Routine VIA Screening.
Referral From: If a patient was initially screened at another clinic and referred to your clinic for cryotherapy, this box gets marked. Fill in her previous diagnosis.

The Register information is transcribed from the completed Screening Forms. The Register should be completed at the end of the screening day. It should exactly match what is on the Screening Forms but is only a subset of the information on the Screening Forms. Some facilities may choose to complete the Register at the time of the patient visits along with the Screening Form. The Register is used to summarize the visits over the previous month and calculate the monthly indicators. It captures all of the patients screened with each patient given their own row on the document.

Tips:

- The bound Register should be divided into two sections. One section (in the front of the book) should be used to track the HIV negative or unknown patients and the back ½ of the book should be used to track the HIV positive patients. This will make it easier to complete the monthly summary indicators on the Monthly Summary Form. Alternatively, at the end of the month, HIV positive patients' rows can be highlighted on each page in order to differentiate them when you calculate the indicators.
- Do not leave any rows blank.
- Start a new page in the Register at the beginning of the new month.
- Only one column should be filled out for each section (example, do not mark that a patient was both a **new** patient and a **1-year follow-up** patient under the Visit Type Section).
- Each time a women comes to the clinic, a new row should be completed with the specific VISIT TYPE marked.

Data Collection Tools: Monthly Summary Form

At the end of each month, the site staff should review all Screening Forms against the entries made in the Register prior to completing the Monthly Summary Form. The Monthly Summary Form summarizes the various indicators by disaggregator (Visit Type, HIV Status and Age) for reporting. The data collected on the Monthly Summary Form can also be used to update the Data Use Poster for the three key performance indicators. The completed Monthly Summary Form should be signed and dated and sent to the appropriate person outlined in the data reporting section for Zambia.

Tips:

- Make sure the Screening Forms are compared to the Register and corrections made **before** completing the Monthly Summary Forms.
- Make sure to distinguish between the data captured for the different VISIT TYPES and the two categories for HIV status.
- All cells on the form should be completed. If there are no data for a particular indicator, for example, no suspect cancer cases, the cells should be marked with a zero (0).
- Make sure that the VIA-positive patients, VIA-negative patients, plus the suspect cancer cases equal the total number of women screened (with each visit type separated [new, routine, 1-year follow-up]).
- Make sure that the large lesion referrals, immediate cryotherapy cases, and postponed cryotherapy cases equal the total number of VIA-positive cases.
- Any corrections/clarifications to the forms by the facility staff should be done in **black or blue ink** and should be circled with the original response still legible.
- The site staff should conduct the data cleaning process after being trained in it by a program staff person.

Data Collection Tools: Secondary Data Collection Tools

There are a few tools that facilities can use to organize additional information for the smooth running of the program. These tools include: Referral Form and Client Information Card.

- **MOH Referral Form:** This form is completed by the site referring the patient for suspect cancer or a large lesion. It goes with the patient to the referral site. The additional information is completed at the referral site including the outcome of the referral (confirmed cancer case with result of the biopsy or LEEP performed). Referral information should be communicated back to the original site including the date the patient presented at the referral site and outcome of the referral.
- **Client Information Card:** This card should be completed by the provider and given to the woman at the end of her appointment. It should contain information relevant to her diagnosis, treatment, and referral as well as when she should return for her next VIA screening.

Documenting Unique Cases

1. Cervicitis:

Situation: Often women who are screened with VIA are found to have cervicitis, resulting in an incomplete VIA screening because the provider is unable to determine if the woman is VIA-positive or VIA-negative. According to clinical protocol, the provider will prescribe treatment and ask the woman to return for another VIA.

Documentation: For a VIA screening to count as a **completed** screening, a definitive diagnosis of VIA-positive or VIA-negative has to be determined. If it cannot be determined, this screening should **not** be counted toward your monthly screenings. This is very important, because we do not want to double-count this woman as having two **initial** VIA visits.

In terms of documentation:

First Visit:

- Complete a Screening Form. It needs to be marked as TEST RESULTS: NO, REASON: SEVERE CERVICITIS and should **not** be marked as an INITIAL VISIT under the visit type section. On the top of the form, it should be written in the right hand corner "NOT COUNTED" to remind you at the end of the month that this form should not be counted toward your monthly screenings on the Monthly Summary Form.
- Enter this information into the Register but make sure not to include a VISIT TYPE and clearly write in "treated for cervicitis" across the treatment section for this client's row. Make sure it is not counted toward your monthly screenings.

Second Visit after Completion of Cervicitis Treatment:

- If VIA was able to be completed with a definitive diagnosis, it should be documented both on the Screening Form and in the Register as an INITIAL VISIT. This screening should be counted toward the monthly totals.

2. VIA-positive women chooses to postpone cryotherapy and returns for treatment:

Situation: Occasionally a VIA-positive woman cannot get cryotherapy at the same time as her VIA screening for a variety of reasons.

Documentation: It is important to capture information about both visits (first visit where VIA screening was performed and the second visit where she had her cryotherapy). Important details will be different from one visit to the other, such as date of the visit, what was performed, when she should follow up, recommendations, etc. Each visit should be documented separately on a new Screening Form and two entries should be made into the Register in date order.

In terms of documentation:

First Visit:

- On the Screening Form and in the Register, it should be documented that this woman had an INITIAL VIA under visit type. It should be marked that she was VIA-positive under

Screening Result section, and CRYOTHERAPY POSTPONED under the Treatment Section along with the Reason for Postponing. Under the Follow-Up section, it should be documented when the woman plans on returning to the site.

- This woman should be documented in the Postponed Cryotherapy /Referral Tracking Log so that you make sure to follow up and encourage her to return.

Second Visit for Cryotherapy:

- In both the Screening Form and Register, it should be noted that this second visit was a POSTPONED CRYOTHERAPY visit under the VISIT TYPE. Under the Treatment Section, it should indicate that VIA WAS DONE TODAY.
- In the Register, it should be noted that this visit was a POSTPONED CRYOTHERAPY visit and PREVIOUSLY POSTPONED CRYO DONE TODAY under the Treatment section.

3. 1-Year Follow-Up Visit:

Situation: A woman returns after previously having VIA, being found VIA-positive and having cryotherapy treatment. The woman should be asked to present her Client Information Card. If she does not have it she should be asked if she has ever had VIA, what her result was, and if she had treatment (what kind of treatment).

Documentation: Again, this is a separate visit and should be documented separately from her first screening visit.

In terms of documentation:

First Visit:

- Documented normally.

Follow-Up Visit:

- On both the Screening Form and in the Register, it should be marked that this visit is a 1-YEAR FOLLOW-UP VISIT under the Visit Type section.

Monitoring Visits

Monitoring visits are used by the program staff to assess and ensure accuracy, integrity, and the quality of data being collected. It is also an opportunity to talk about the facility and overall program results. If gaps or deviations in practices are observed, it is also an opportunity to provide on-the-job training to the providers and answer questions. Monitoring visits should happen more frequently in the beginning of the program and less frequently once the site is fully operational and problems are at a minimum. Facilities will be informed in advance that a monitoring visit will take place. During the monitoring visit, the supervisors will review the screening and treatment activities, referrals, record-keeping, equipment, and supplies, as well as counseling and group education. All completed forms and registers should be available to the supervisors at the time of the visit. They may use a checklist to assess the facilities in a

standardized way. At the end of the visit, the supervisors will review with the providers their findings, answer any questions, and discuss next steps to rectify gaps/deviations.

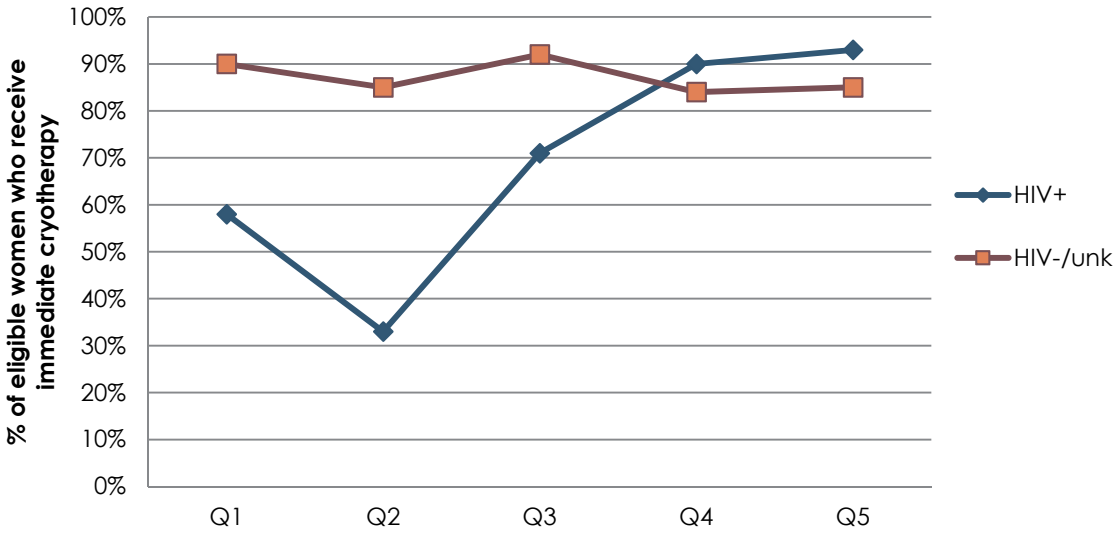
Data Use

Information derived from data has many uses depending on the level of the data user. The Ministry of Health may want to track screening coverage to get a sense of how many women have received screening across the country by district in order to hit a certain target, for example, 80% of all women screened in five years, for example. A facility in-charge may want to use data to better understand the demand for screening so he/she knows how many providers need to be assigned to the cervical cancer prevention program. When the numbers drop, he/she should investigate why women are not getting screened and what the perceptions are in the community. A facility provider may be interested in knowing the cure rate for 1-year follow-up patients for a sense of satisfaction that the services they are providing actually saves lives.

The indicators, data collection, and reporting forms all provide this sort of information in order to help make informed decisions. Unfortunately, incorrect decisions may be made if data collected are incomplete, late, or do not accurately reflect the patient population screened and treated. This is why it is critically important that data be of high quality, frequently assessed, and strengthened across all sites.

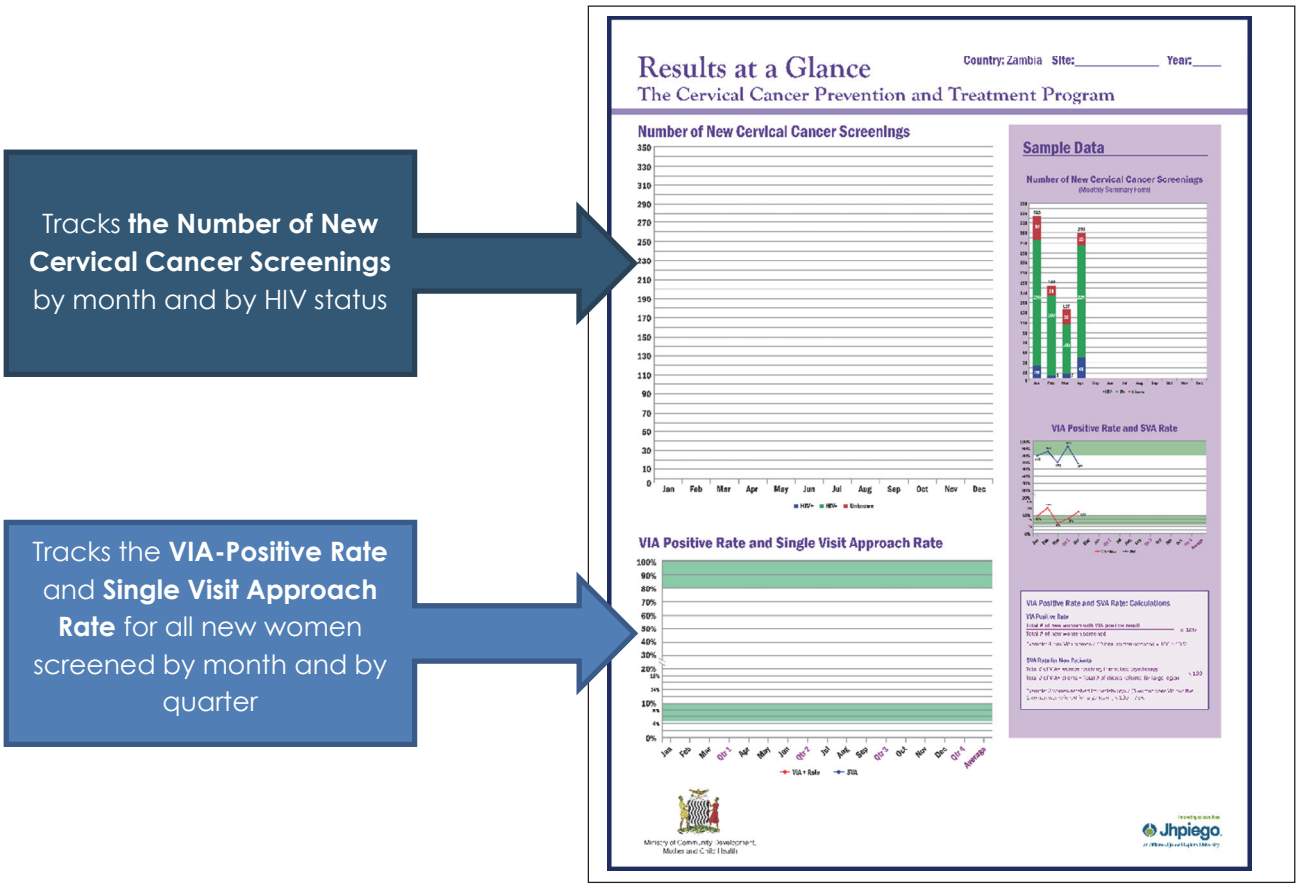
Figure 9.3 highlights data tracked over time for the percentage of eligible women who received immediate cryotherapy. You can see the dip from 58% to 32% and the continual low SVA rate of eligible women received cryotherapy between Quarter 1 and Quarter 2. When the facility documented this dip, they were in the position of exploring and identifying why some women were not able to obtain the services in the same day. In this particular case, there was a policy in the facility that HIV-positive women needed two screenings (one by the nurse/midwife and one by a physician) if they were found to be VIA-positive. Unfortunately, the physician was often away from the site, requiring the women to make a return appointment. This situation was rectified by Quarter 3 by providing additional training to the midwife so that the physician and facility in-charge were comfortable doing cryotherapy on their own.

Figure 9.3. Identification of implementation issues using data



A laminated Data Use Poster can help facilities track the three key performance indicators over time to identify gaps and times when they fall below or above the standard. This poster should be updated monthly once the Monthly Summary Form is completed. When the poster is updated, the cervical cancer prevention program staff, including the facility in-charge, should review the results as a team on a monthly basis. This discussion should include progress toward targets including the data that fall outside the standard, and any other trends and patterns presented. The team should brainstorm how they can improve their results for the next month (for example, doing more community outreach or group talks with women attending a non-cervical cancer prevention clinic to encourage them to come for a screening if they are below their target screenings). A Data Use Poster is shown in Figure 9.4.

Figure 9.4. Data use poster for facility level: Sample



Tips for Completing and Interpreting the Graphs on the Data Use Poster:

- Each facility, in conjunction with the program staff, should set a VIA screening target annually. The monthly target should be calculated from the annual target. This can be recorded as a line in a different color marked across from the corresponding number on the left axis on the first graph. Example, facility X's target is 200 screenings per month. The facility and program staff would draw a line at the 200 mark across all of the months of the year in the first graph.
- The calculations for each graph are highlighted in the pink box to the right of the empty graphs. These calculations directly relate to specific indicators on the Monthly Summary Form.
- The two green bands on the second graph represents the benchmarks for key indicators % VIA-positive and % Single Visit Approach (80% or above for single visit approach rate and 5–10% for VIA-positive rate). If the monthly results fall above or below the green bar, it means that they are outside of the benchmark. The team should investigate the reasons why and put an action plan in place to correct the problem, if one is found.
- The laminated poster can be wiped clean each year and re-used.

Data Management, Storage and Reporting

Data management refers to the collection, storage, processing, analysis and dissemination and efficient use of information in the context of monitoring and evaluation. Record keeping refers to the systematic recording of information in a standardized format and sometimes also understood as the storage of this information. Both data management and record keeping are essential for monitoring and evaluation.

Data collected is a valuable resource to be protected so ensure that all forms and registers are safe from damage and stored in a locked and secured cabinet or area. Unauthorized access should be discouraged to protect confidentiality.

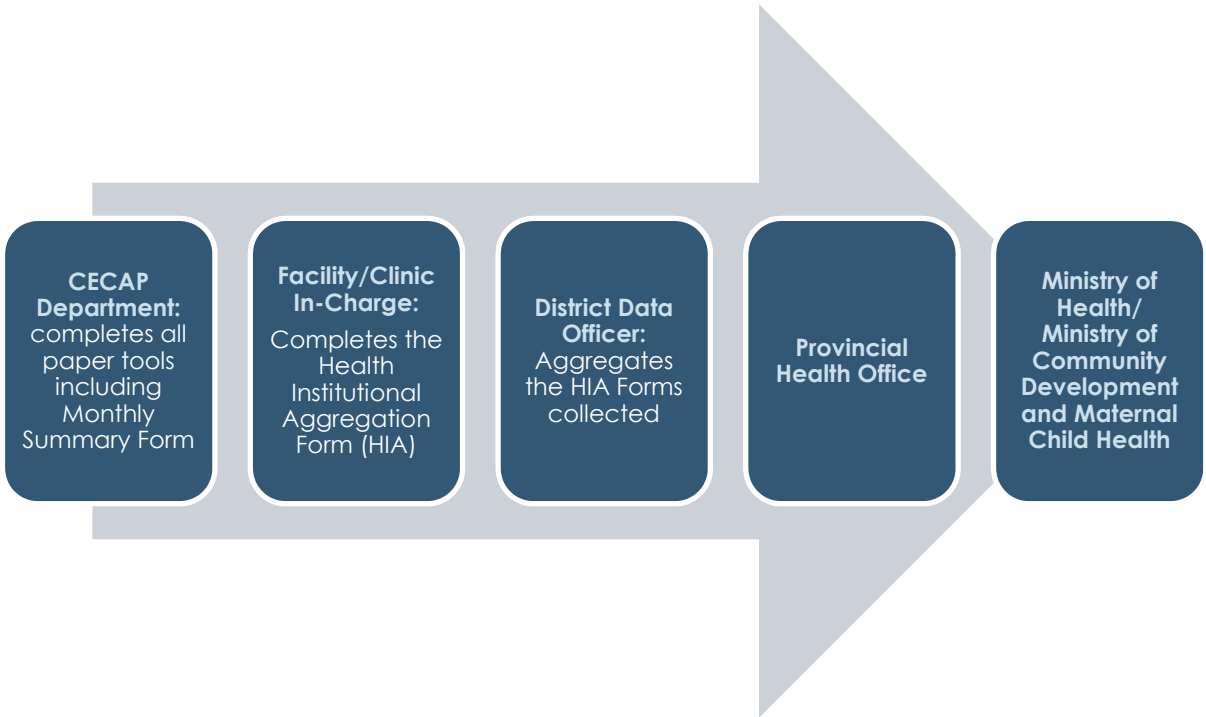
Screening Forms should be kept at the site in binders arranged by month in the same order that the clients appear in the Register. A separate notebook could be maintained to track clients that need to return for treatment and clients that were referred for large lesions or suspect cancer to ease follow-up.

The latest version of the Forms and Registers should be used at the site to ensure accurate data collection and reporting to calculate indicators. Registers should be bound.

Data Reporting

Monthly Summary Forms should be completed at the end of each month. These completed forms should be reported following the normal reporting practices at your facility. See the figure below for the reporting flow.

Figure 9.5. Suggested flow for CECAP data



Chapter 10. Ensuring Quality in the Program

The rationale for having quality assurance and quality control in a VIA-based program is that visual screening tests are subjective and dependent on health care provider competency, which can result in wide variability in their performance in different settings. VIA test characteristics (described in Chapter 4)—especially the suboptimal positive predictive value—may result in unnecessary referrals and/or treatment, which can offset the perceived savings associated with the low cost of the test. Quality assurance (QA) and quality control (QC) for VIA are, therefore, crucial in maintaining uniform and reproducible criteria for test positivity, and ensuring that the health care provider conducting the screening test accurately differentiates true positive and true negative cases.

Ensuring quality in the Cervical Cancer Prevention Program in Zambia (CCPPZ) includes ensuring that performance standards are being achieved. WHO and the Pan American Health Organization, in the *WHO Guidelines: Monitoring National Cervical Cancer Prevention and Control Programmes: Quality Control and Quality Assurance for Visual Inspection (VIA)-Based Programmes* (WHO/PAHO 2013) provide the following key definitions:

- **Performance standard:** Defines, in the clearest and most objective terms, the agreed-upon level of performance desired for a specific service, based on scientific evidence and best practices. It states what the health care service is expected to deliver.
- **Indicator:** A variable that measures one aspect of the program that is directly linked to the program's objectives. It specifically defines what to measure to determine whether the objectives or the standards have been achieved.
- **Quality assurance (QA)**: Refers to an overall management plan (the "system") that guarantees the provision for good-quality service.
- **Quality control (QC)**: Refers to the application of a series of measurements (the "tools") used to assess the quality of the services and facilities.
- **Quality improvement (QI):** A structured approach to analyzing performance and applying systematic efforts to improve it.

Defining the Core Indicators

For VIA and cryotherapy, WHO recommends five core indicators (WHO/PAHO 2013):

Performance Indicators

- **Screening rate of the target population (women aged 30–49 years):** Percentage of women aged 30–49 years who have been screened for the first time with VIA in the previous 12-month period.
- **Positivity rate:** Percentage of screened women aged 30–49 years with a positive VIA test result in the previous 12-month period.
- **Treatment rate:** Percentage of VIA-positive women receiving treatment in the previous 12-month period.

Result Indicator

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

Impact Indicator

- Cervical cancer age-specific incidence.

As noted in Chapter 9: Monitoring and Evaluation, the Zambia program has selected the following **key performance indicators:**

Note: All indicators should be **disaggregated by HIV status.**

Performance Indicators

1. Number of new women screened in the target population
   - 30–59 years of age for HIV-negative women
   - 25–59 years of age for HIV-positive women
2. Screen positivity:
   - VIA-positive rate
     - Percentage of VIA-positive women referred for large lesions
   - Suspect cancer rate
3. Treatment rate for VIA-positive precancerous lesions:
   - Single visit approach (SVA) rate for cryotherapy eligible lesions
   - Cryotherapy treatment rate (SVA + women who postponed cryotherapy and returned for treatment)

The Framework

Proper M&E allows a program to track progress, identify areas that are performing well, identify areas where a gap in quality exists and take corrective action. Evidence-based cervical cancer prevention policies and guidelines provide the overall programmatic framework essential to implementation of QA in a cervical screening program (WHO 2013c).

The QA/QC operational plan for a VIA-based screening program should be based on the following principles and guidance (WHO 2013c):

- The purpose of QA/QC is to ensure sustained, high quality of care.
- Measurable indicators must be clearly defined to facilitate assessment of program performance toward achieving the stated targets and goals.
- A supportive supervision framework should be implemented. Supportive supervision focuses on improving performance of service delivery to meet expected standards.
- Practical guidance and tools must be developed for health care providers and other stakeholders who play an active role in monitoring QA/QC.

Supportive Supervision

The supportive supervision (SS) visit is an essential component of QA/QC and improving quality of care. The objectives of the SS visit are to assess the quality of care at the facility, make recommendations for improving care, and develop an action plan. These SS visits should be conducted in teams with both a clinical/technical trainer/supervisor* and an M&E person to do the data quality assessment and data cleaning. During the SS visit, the trainer/supervisor and M&E person should use a SS tool as a guide to conduct the following tasks to achieve these objectives and documents them:

- Assesses provider performance using the performance standards (based on the clinical skills checklists used during training):
  - Assesses provider performing VIA and cryotherapy, with clients (ideally) or in simulation
  - Conducts an image review exercise (flashcard or computer-based, as appropriate) with each provider
  - Assesses client-provider interaction
- Assesses facility readiness;
- Reviews data management and the core indicators for the facility (see Monitoring Visit section in Chapter 9: Monitoring and Evaluation for more details); and
- Meets before and after with the providers and supervisor of the facility to discuss the purpose of the performance support visit and the visit findings.

***Note:** Trainer/supervisor refers to trainers, supervisors, or providers who have the knowledge, skills, and attitudes and who have been designated for the role of conducting the SS visit.

Timing of SS Visits

In an ideal arrangement, scheduled SS visits should occur as follows:

1. First week post-training for transfer of learning and facility set-up
2. 4–6 weeks post-training
3. Every quarter for the first year
4. Annually

Quarterly mentorship will be integrated with other programs by provincial health teams.

Note: Defaulting centers should have more visits planned until the trainer/supervisor is satisfied with the minimum quality of care and service provision. At local (district) level, quarterly update meetings should be arranged by the district community health office.

Sufficient time should be allocated for each SS visit, which should take a half to a full day to conduct. The action plan that was developed from the previous visit should be reviewed prior to the visit, and again during the visit the facility supervisor and designated staff. While it is not necessary, or feasible, to assess every provider at every SS visit, it is important to observe all aspects of service delivery—client registration, counseling, screening, treatment, infection

prevention, facility readiness, and documentation (including records and registers). This enables the trainer/supervisor to determine whether standards are being achieved. The SS visit also serves as an opportunity for trainers/supervisors to mentor and update VIA/cryotherapy providers and to work collaboratively with them to resolve any identified issues. During the SS visit and before its conclusion, the trainer/supervisor reviews the findings of the visit with the facility supervisor and VIA/cryotherapy providers, and works collaboratively with them to develop an action plan to address areas for improvement. After the visit, the trainer/supervisor writes up the SS evaluation report and shares it with the facility and appropriate district-level officials (see Table 10.1).

Table 10.1. Supportive supervision visit planning checklist

Activity	Checklist
Schedule visit with staff at facility to be visited	• Consult with the staff of the facility to establish an agreeable date for the visit. • Determine the amount of time the visit will take. • Ensure that the schedule of the visiting (external) trainer/supervisor is cleared for the visit. • The visiting trainer/supervisor should also inform staff at the facility of the aspects of the program that will be reviewed (e.g., counseling, VIA, infection prevention, data collected). • Ensure that the day of the visit is a screening day and that women are scheduled to receive services.

Ensure availability of all materials required	• Print copies of the agreed-upon program monitoring tools, including:
	  • Data collection tools
	  • Performance standards
	  • QC and QA plans and checklists

Review previous SS visit reports prior to the visit	• The visiting (external) trainer/supervisor should be familiar with the strengths and weaknesses in service provision previously identified at the facility as well as data on key performance indicators including progress toward targets and benchmarks.
Schedule adequate time for the visit	• There should be enough time to discuss the findings of the SS visit with the staff of the facility as well as time to review the facility's Screening Forms, registers, and monthly summary forms and/or computer database (to check whether they are available and up to date). • Time should also be set aside to discuss steps needed to address any identified gaps.
Communicate with facility staff regarding the visit	• Prepare staff for the visit and let them know what will be reviewed that day. • Schedule time at the end of the day for a discussion of the findings with the visiting trainer/supervisor.
Clean data collection tools and/or computer databases	• The person conducting the visit will want to review and clean the data collected in the data collection tools and/or computer databases. • Ensure that these are up to date and confirm calculations of the necessary indicators.

Adapted from: WHO/PAHO 2013. *Monitoring National Cervical Cancer Prevention and Control Programmes*: *Quality Control and Quality Assurance for Visual Inspection (VIA)-Based Programmes,* page 11. At: http://apps.who.int/iris/bitstream/10665/79316/1/9789241505260_eng.pdf?ua=1, accessed January 15, 2015.

Appendix 1. Cryotherapy Unit—Job Aid

First Use of the Day

1. With master cylinder valve in closed position, tightly attach regulator of cryotherapy unit (cryogun/shaft) to CO_2 or N_2O cylinder.
2. While holding cryogun pointed toward ceiling, slowly turn master cylinder valve to open position.
3. Check pressure on pressure gauge:
   - Green: approximately 40–74 kg/cm2. Appropriate pressure to operate.
   - Yellow: below 40 kg/cm2. Replace gas cylinder (see below).
   - Red: above 74 kg/cm2. Unsafe to operate (see below).

Gauge in "green zone"

1. Point cryogun to ceiling. Check freeze function for 1 second, then check defrost function for 1 second.
2. Screw high-level disinfected (HLD) cryotip onto end of probe.
3. 3-5-3 technique. Freeze 3 minutes – defrost 5 minutes – freeze 3 minutes.
4. Set timer for 3 minutes. Apply cryotip to cervix and initiate the freeze. Watch as ice ball develops and freezes for 3 minutes:
   - 3 minutes is a guideline. Most important, look for a 4–5 mm ice ball beyond the cryotip edges.
5. After the freeze step, start defrost and detach cryotip from the cervix as soon as it is able. Stop defrost function and wait for a 5-minute thaw.
6. Repeat Steps 4 and 5.
7. Inspect cervix to ensure that ice ball is present, covers appropriate area of cervix, and there is no injury to surrounding tissues.
8. Remove cryogun from vagina and either hand to assistant or place on clean tray.
9. After caring for the patient, turn master cylinder valve to closed position and release pressure inside the hose by activating the defrost mechanism until the pressure reads zero.
10. Wipe the cryogun handle, shaft, and tip with ethyl or isopropyl alcohol-soaked cotton swabs (three separate swabs), unscrew cryotip from end of probe, rinse in clean water, and soak in Cidex or 70–90% ethyl or isopropyl alcohol for 20 minutes for high-level disinfection (HLD). Cryotip can also be autoclaved.

11. Protect cryoshaft tip by putting protective plastic sleeve or covering on cryoshaft when a cryotip is not in place.
12. At end of HLD, if using alcohol, simply remove and allow to air dry in HLD container. If using Cidex, rinse thoroughly with boiled or sterile water, tap all water out of cryotip, and air dry in HLD container.

Repeat use during clinic session

13. Screw HLD cryotip onto end of probe.
14. Turn master cylinder valve to open position.
15. Proceed with steps 3–12 as above.

At end of the day

16. Assuming steps 9–12 have been done, either: 1) keep cryotherapy unit attached to gas cylinder, or 2) disconnect regulator of cryotherapy unit from CO2 or N2O cylinder and store in box with cryotips.
17. Ensure that gas cylinder is in a safe, cool place for storage.

Gauge in "red zone"

18. **Do not operate** – could ruin cryotherapy unit or rupture hose and cause injury. Turn master cylinder valve to closed position, release pressure by pulling trigger to freeze (one click). When pressure reads zero, pull trigger all the way (second click) and release.
19. Unscrew regulator of cryotherapy unit from gas cylinder.
20. In well-ventilated area, ensure that all is clear from tank. Turn master cylinder valve to slightly open position and vent large cylinder for 30 seconds, small (20 lb) cylinder for 15 seconds. Recheck pressure—if still red, repeat steps. If green, ready to operate. If still red after repeated ventings, do not use cylinder—return to manufacturer or gas company for further evaluation.
21. Note: If cylinder is warm to touch, do not use. Store in cool place or wrap in cool, wet cloths to reduce temperature.

Gauge in "yellow zone"

22. Replace cylinder. Turn master cylinder valve to closed position, release pressure by activating the defrost mechanism until the pressure reads zero.
23. Unscrew regulator of cryotherapy unit from gas cylinder.
24. Proceed with steps as outlined under "First use of the day."

Appendix 2. Cervical Cancer Prevention Program in Zambia – Facility Readiness Assessment Tool

I. Background Information

Facility Name and Location:	
Type of Facility (GRZ, *NGO, ZDF, Other*)	
Level of Facility (*Health Center, Hospital*)	
Date of Visit	
Name and Contact Information of Primary Contact Person	
Names of Other Key Staff	
Names of Assessment Team Members	
Is VIA currently being offered? Is cryotherapy currently being offered?	YES NO Yes No

Census

1. What is the population size of women in the catchment area of this facility?	
2. If available, what is the cervical cancer screening target population size for the area? If not available, what is the next closest age group (e.g., 15–49) where these data are available?	
3. Is there HIV prevalence data for the catchment area? If Yes, what is the percentage?	YES NO

II. Client Volume and Selected Health Services Offered

Check (√) if service is offered. For each service offered, collect data to record the following statistics.

√		Number of Clients Served in Past Month	Number Clients Served in Past Year	Comments
	HIV Services: • PICT • ART • PMTCT • CD4 testing			
	Family Planning			
	STI Services			
	Antenatal Care Labor and Delivery Postnatal			
	Current Cervical Cancer Prevention			

III. Relevant Facility Personnel

For the proposed department/unit where CECAP services will occur, list names, titles, training/experience, and past pelvic exam experience of health facility staff members. It is important to know how many staff are available to conduct/supervise a CECAP program, given existing workload.

Name	Sex	Title	Type of Training/Experience (see codes below)	Pelvic Exam Experience? (Y/N)	Does the provider meet selection criteria for providing VIA and cryotherapy?* (Y/N) *See selection criteria below

Training/Experience Codes:

1 = Pelvic Exams
2 = VIA/Cryotherapy
3 = Family Planning
4 = Counseling
5 = Group Health Education
6 = STI Testing and Treatment
7 = Infection Prevention
8 = HIV services (specify)
9 = TB Services
10 = Other (specify)

VIA/Cryotherapy Provider Selection Criteria

- Professionally trained provider, e.g., Nurse, Midwife, Clinical Officer, Doctor
- Clinically active; experience with pelvic exams
- Job description includes working directly with potential clients
- Motivated to provide CECAP services
- Position security – will remain attached to site for at least 24 months
- Has good vision (eyesight); Does not have tremors

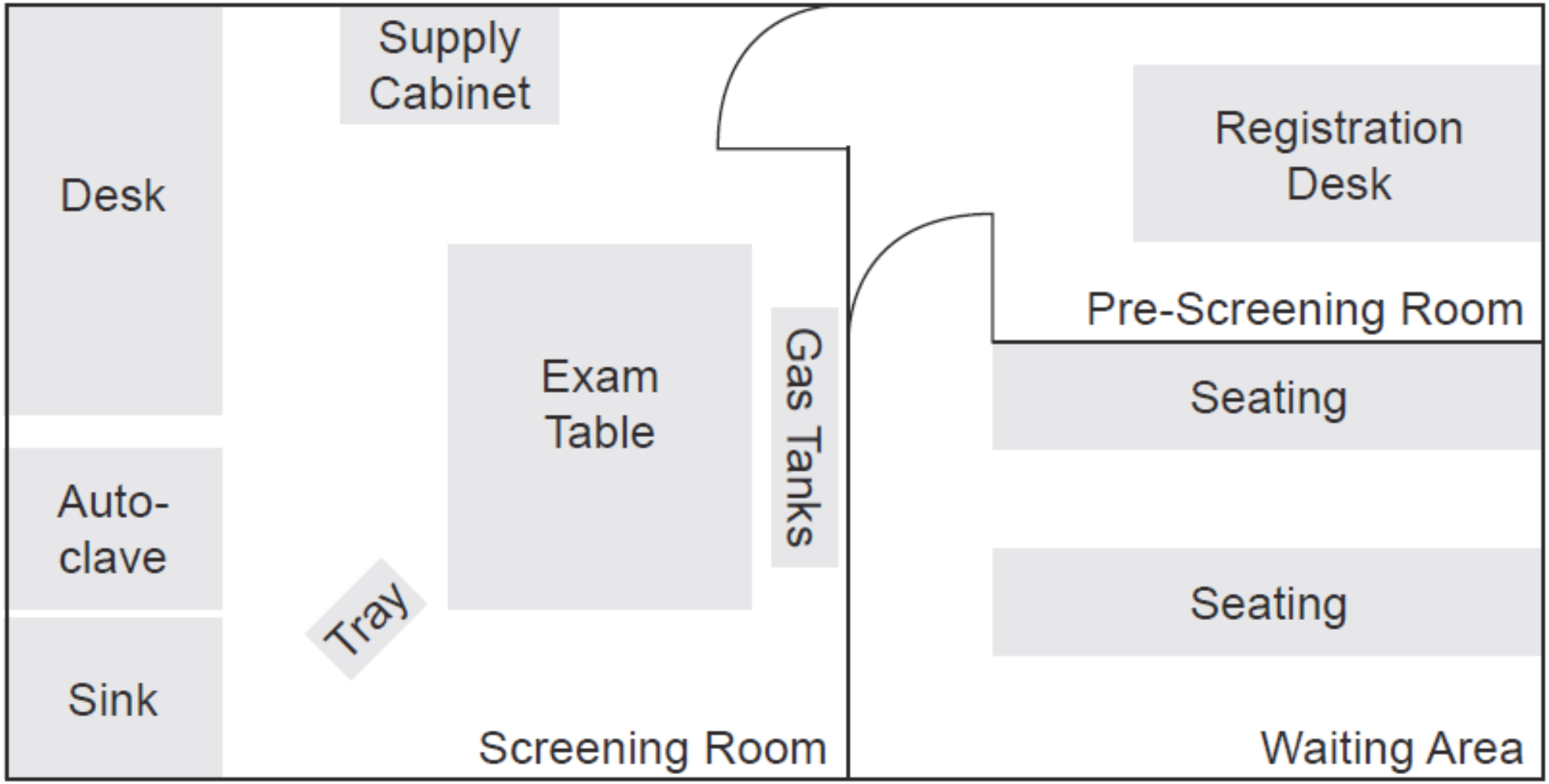
IV. Assessment of Facility as Appropriate Cervical Cancer Prevention Service Delivery Site

Instructions: Check (√) all criteria met. If NOT APPLICABLE, then cross out the item. In the last column, indicate YES if all criteria are met. If one or more are not met, indicate NO.

Standard	Verification Criteria	Comments	Standard Met?
1. Clinic is clean and comfortable.	**Observe the absence of dust, litter, cobwebs, dirt, and spillage (blood) in the following:** ☐ Common areas (Open space, Waiting rooms) ☐ Consultation/examination rooms ☐ Toilets ☐ Treatment room (if available)		
2. Clinic provides female clients sufficient privacy to clean and dress themselves.	**Observe if clinic has private space where female clients can clean and dress themselves. Examples include:** ☐ Exam Room ☐ Curtained Area ☐ Bathroom ☐ YES (Describe: _____)		
3. Clinic has at least one private exam area in which pelvic exams can be performed.	**Observe if exam area is sufficiently private with either:** ☐ Separate exam and procedure rooms **OR** ☐ Large room with privacy screen/curtains		
4. Clinic's private exam area is adequately furnished for pelvic exam procedure. **See page 106: Diagram of a model VIA/cryotherapy clinic room**	**Observe if exam area has the following furnishings:** ☐ Table for pelvic exams with stirrups ☐ Adjustable stool with wheels or chair ☐ Instrument table or trolley ☐ Sink with tap/running water **OR** Bucket with spigot **OR** Pitcher ☐ Soap or alcohol-based antiseptic ☐ Supply of towels for individual hand drying ☐ Sufficient space for provider to sit and perform exam ☐ Sufficient space for stand-alone CO_2 or N_2O tank		
5. Checklist of supplies and instruments necessary for VIA/Cryotherapy is available. *(NOTE: Instruments can be purchased and provided to the*	**Observe if the following supplies and instruments are available on site:** ☐ Examination gloves ☐ Camera ☐ Specula: Total of 20 – 12 Medium, 5 Large, 3 Small (long and narrow) ☐ Gallipots (20)		

Standard	Verification Criteria	Comments	Standard Met?
facility if needed.)	☐ Sponge forceps (20) ☐ Drapes/sheets ☐ Cotton or cotton swabs—large ☐ 3–5% acetic acid (Vinegar with documented strength 3–5) ☐ Bright white light source (if torchlight, also have spare batteries) ☐ Camera (if conducting DC) ☐ Television screen (not essential, but mark if present) ☐ Chlorine ☐ Plastic bucket with lid for decontamination ☐ Plastic bucket with lid for waste ☐ Plastic bucket with lid for scrubbing specula		
6. Clinic has gas cylinders available (CO_2 or N_2O).	**Observe if the following are available and functioning on site:** ☐ Cryotherapy unit (1) ☐ Cryotips (minimum 2) ☐ 70–90% ethyl or isopropyl alcohol for HLD of cryotips, and HLD containers for storage. If no, comment on how cryotips are HLD or sterilized ☐ Compressed gas cylinders (CO_2 or N_2O) ☐ Special fittings, if needed ☐ Indicate type of fitting (British or American) _____ ☐ Cold coagulation unit (not an essential item, but mark if available)		
7. Clinic has available waiting area.	**Observe if clinic has:** ☐ Designated area for patient waiting and/or group education		
8. Clinic has necessary forms and storage capability for cervical cancer prevention data.	**Observe if clinic has:** ☐ Cervical Cancer Screening Register ☐ Cervical Cancer Screening Monthly Summary ☐ Cervical Cancer Screening Forms ☐ Cervical Cancer Screening Card ☐ Facility-level Data Use Poster ☐ Locked storage for individual forms and register ☐ Computer – desktop (not essential, but mark if present) ☐ Internet (not essential, but mark if present and if available most times)		

Diagram of a model VIA/cryotherapy clinic room



Standard	Verification Criteria	Comments	Standard Met?
9. Clinic organizes individual medical records (if collected).	**Observe if individualized medical records are:** ☐ Stored in cabinets or binders in a locked room ☐ Retained in the clinic near where clients are screened ☐ Easily retrievable if need to be found at a later time ☐ Computerized **OR** Arranged: ☐ Alphabetically **OR** ☐ Chronologically **OR** ☐ ID# (Type of ID# used: _____)		
10. Clinic has a culture of collection, reporting, managing, and using data well.	**Observe/or ask providers if:** ☐ There is a designated person responsible for recording and reporting data ☐ Posters or charts are on the walls highlighting updated data trends for various service delivery areas ☐ Observe if forms are legible, complete, accurate, and well-maintained ☐ Monthly report forms are cross-checked with registers or other source documents before report is submitted ☐ Staff have been trained in how to collect data ☐ There are no stock-outs of data collection tools ☐ Monthly reports are submitted on time and are complete ☐ Providers can report last month's screening numbers and know their targets for a particular service delivery area		

V. Assessment of Infection Prevention Practices

Instructions: Check (√) all criteria met. If NOT APPLICABLE, then cross out the item. In the last column, indicate YES if all criteria are met. If one or more are not met, indicate NO.

Standard	Verification Criteria	Comments	Standard Met?
11. Staff use appropriate handwashing technique.	**If possible, observe if health care provider:** ☐ Washes hands with soap prior to each client contact and before putting on gloves ☐ Washes hands with soap after each client contact and after removing gloves ☐ Wash hands with soap after any contact with blood or mucous membranes ☐ Washes hands with soap after handling objects that might be contaminated **OR** ☐ Uses alcohol-based antiseptic between clients as appropriate (if hands NOT visibly soiled) ☐ Dries hands using clean towel or air dries		
12. Clinical staff use Personal Protective Equipment (PPE) when performing clinical procedures, according to standard practice.	**Observe if staff wear the following PPE during indicated procedures, if applicable:** ☐ Gloves (exam, sterile, utility) ☐ Gowns/aprons ☐ Closed shoes/boots		
13. Clinic staff properly dispose of waste.	**Observe if staff properly dispose of waste materials according to the following:** ☐ Yellow: infectious waste (anything that comes into contact with body fluids or human body parts) ☐ Black: domestic waste (e.g., food waste) ☐ Sharp box		
14. Staff decontaminate pelvic exam and family planning instruments appropriately.	**Observe if staff:** ☐ Place instruments in decontamination bucket immediately after use ☐ Leave instruments in decontamination bucket for 10 minutes ☐ Move instruments into bucket of soapy water and scrub while wearing PPE		

Standard	Verification Criteria	Comments	Standard Met?
15. Staff appropriately sterilize instruments.	**Observe if staff perform sterilization by:** ☐ Autoclave ☐ For cryotip and cold coagulation tip, HLD or sterilize according to manufacturers' instructions ☐ Immediately use or store instruments in appropriate HLD or sterilized covered containers		

VI. Monitoring and Evaluation

1. Does someone come to your facility to review the quality of your data including accuracy and completeness (including to check what you have reported against the data collection forms retained at your clinic)? If yes, describe.	
2. Do you have annual targets for any of your service delivery areas? If yes, can you describe some targets? How often are you able to reach these targets?	
3. How do you currently use the data you collect? Describe any decisions you made based on the data that were collected at your facility.	
4. Do you receive feedback on the quality of your data or what you have reported?	

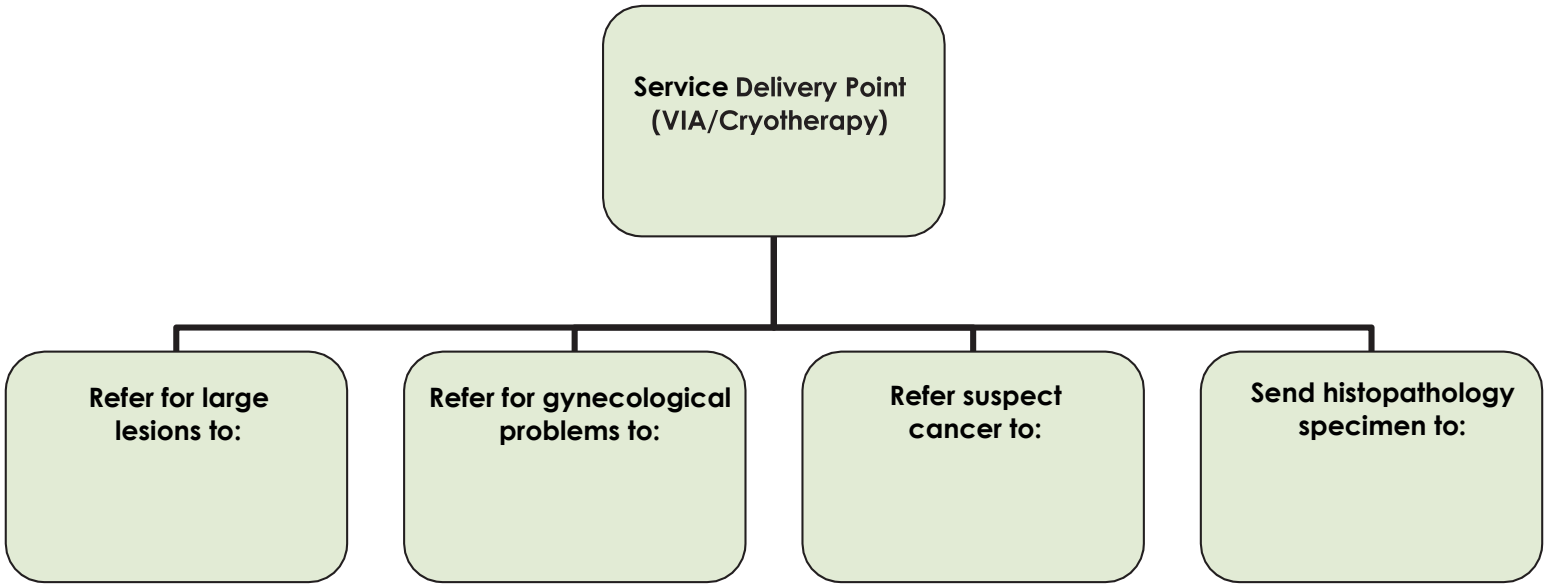
VII. Equipment and Supplies

1. Where would the clinic purchase and refill CO_2 or N_2O gas tanks? How much would it cost? Who is responsible for ensuring that these are ordered in a timely manner?	
2. Does the clinic have a repair and maintenance technician? Who is responsible for fixing the clinic equipment? If minor repairs were required for the cryotherapy unit, who is available to assist?	
3. Does the clinic have frequent stock-outs of basic supplies such as gloves, infection prevention supplies, etc.?	

VIII. Referral System

1. Where is the closest referral site for treatment that cannot be offered at this facility? Complete the information in the column at right for each facility. Use the back of this sheet if more space is needed.	Site Name: Public/Private: Distance in KM: Cost of transport:
3. What is the system in place to process referrals (are there forms; is there feedback to the referring site about the treatment offered)?	
4. Where are the following services offered? How far away from this service delivery point?	
a. Pap smear	
b. Colposcopy, biopsy	
c. LEEP	
d. Gynecological surgery	
e. Radiation/Chemotherapy	

5. Diagram how the referral system would operate, assuming that VIA and cryotherapy would be offered at one site:



IX. Community Mobilization

A. Community Health Volunteers (CHVs)

1. Are there community health volunteers?	**YES NO**
2. If YES, how many are there?	
3. How is the CHV selected?	
4. What is the role of the CHV?	
5. How is the CHV oriented? Supervised?	
6. What type of reporting is the CHV expected to do? How often?	
7. Could the CHV educate women about cervical cancer prevention and help recruit women in the target age group to be screened?	

B. Health Education

1. What type of health education is offered at the health facility? What are the topics? Who gives the health talks? How often? Is there a schedule?	
2. What type of health education is offered in the community? How often? How is this organized?	
4. Please provide 1–2 examples of successful health awareness-raising campaigns in this area.	

D. Outreach programs

1. Are outreach health services offered in the community?	YES NO
2. If YES, then: What services are offered?	
3. What type of vehicle is used?	
5. How often do the outreach services operate?	
6. Who conducts the outreach?	
7. Are there health records of outreach services?	

Additional Comments:

Appendix 3: Cervical Cancer Screening Form



Cervical Cancer Screening Form

Client/Facility Information	Reproductive Health History
District:_____ Facility Name: _____ Provider Name: _____ Client ID: _____ VIA Screening Date:___ ___ / ___ ___ / ___ ___ ___ ___ D D M M Y Y Y Y Client Name: _____ Age: _____ Phone #: _____ Contact Details: (House Number, Village): _____ _____	Parity:_____ Last Menstrual Period:_____ FP Method: _____ Any abnormal vaginal bleeding/contact bleeding ☐ Yes ☐ No Previous Cervical Cancer Screening & Treatment: Date/Result_____ History of STDs: ☐ Yes ☐ No Any other pertinent medical/surgical history: ____ _____ _____ _____

Treatment Consent Form

I hereby consent to the procedure cryotherapy to be performed on me, the effect and nature of which has been explained to me. I understand that an assurance has not been given that the operation will be performed by a particular person.

Signed_____Witness_____

Visit Type *(Pick Only One Visit Type)*	HIV Status
☐ Initial VIA ☐ Postponed Cryotherapy ☐ Post-Treatment Complication Related to Cryotherapy ☐ One-Year Follow Up *One year follow up appointment after cryotherapy treatment at last visit (not dependent on HIV status)* ☐ Routine VIA Screening *Returning patient with a VIA negative result at last screening visit (not dependent on HIV status)* ☐ Referral for Cryotherapy from: _____ (referring VIA screening site name)	☐ Positive → ☐ On ART ☐ Not on ART ☐ Negative (within the last 3 months) ☐ Unknown: → Reasons:_____ PICT Accepted: ☐ Yes ☐ No Result: ☐ Positive ☐ Negative Newly diagnosed HIV-positive referred? ☐ Yes ☐ No

V1

Physical Exam

Pelvic exam done? ☐ Yes ☐ No Abnormal vaginal discharge? ☐ Yes ☐ No

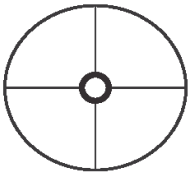
Vulva/Perineum_____ Cervix_____

Vagina_____ Lower Abdomen_____

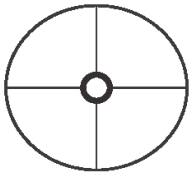
Clinical Diagnosis_____

VISUAL INSPECTION WITH ACETIC ACID (VIA) **OR** **ENHANCED DIGITAL IMAGING (EDI)**

☐ Yes ☐ No



☐ Yes ☐ No



Test Results

☐ No → ☐ Reason (e.g. severe cervicitis): _____

Screening Results?

☐ Yes →
- ☐ VIA Negative
- ☐ VIA Positive → Eligible for Cryotherapy? ☐ Yes ☐ No
- ☐ Suspect Cancer

Entire lesion seen	☐ Yes ☐ No	Extends into cervical os	☐ Yes ☐ No
Covers <75% of cervix	☐ Yes ☐ No	Covers >75% of cervix	☐ Yes ☐ No
Atypical vessel	☐ Yes ☐ No	Mosaicism/Punctation	☐ Yes ☐ No

Treatment and Prescription(s)

☐ Cryotherapy performed today

☐ Cryotherapy postponed

Reason: _____

_____

_____

Prescription(s):_____

_____

_____

Referral

Referred to:

_____

☐ Suspect cancer

☐ Large / Severe lesion

☐ Other Gyn. Referral:_____

_____

Notes/Recommendations/Follow up Dates

Appendix 4: Instructions for Completing Cervical Cancer Screening Form by Variable

Variable	Description	Data Source
Client/Facility Information		
Instruction: This section can be completed by the health care provider conducting the screening or by a data assistant during registration. Some of the information will need to be gathered from the client.		
District	Name of the district where the facility is located	Provider
Facility name	Name of the health facility where the VIA screening was conducted	Provider
Provider name	Name of the health care provider who conducted the VIA screening	Provider
Client ID	The Client ID recorded should follow the Client ID structure established by the facility	Provider
VIA screening date	Date of when the VIA screening was conducted in day/month/year format	Provider
Client name	Include the full client name including middle/ maiden name	Client
Age	Age at last birthday in years	Client
Phone number	The cellphone or home phone number of the screened woman. If she does not have a phone number, then the phone number for her partner, neighbor, or community health worker. Indicate below the line whose number is recorded. If no phone number is available, mark "not available" or "NA" on the line.	Client
Contact details	Include information for the screened women in order to follow up with her in person. This information could include the house number and village or nearest landmark.	Client
Reproductive Health History		
Instruction: This section should be completed by the health care provider in consultation with the client. The first section should be discussed prior to the examination and the rest of this section should record the pelvic exam findings.		
Parity	Number of pregnancies carried to beyond 20 weeks (includes stillbirths)	Client
Last menstrual period	Date of the first day of the last menstrual period	Client
Family planning method	Current family planning method used by the client	Client
Any abnormal vaginal bleeding/ Contact bleeding	Mark YES or NO when the client is asked about any abnormal vaginal bleeding or contact bleeding during intercourse.	Client

Variable	Description	Data Source
Previous cervical cancer screening and treatment: Date/Result	Record if the client has ever had a previous cervical cancer screening, the date, and whether she was VIA-negative, VIA-positive, or suspect cancer. If she was VIA-positive, record whether she received treatment and what type of treatment. If the client has never had a screening before, write NONE on the line.	Client
History of STDs	Mark YES or NO depending on the client's response about her history of sexually transmitted diseases.	Client
Any other pertinent medical/surgical history	Document any other relevant medical or surgical history in the space provided.	Client
HIV Status		
Instruction: This section should be completed by the health care provider in private. Information can be by self-report of the client, viewing an HIV Care and Treatment Card (C & T card) or Voluntary Counseling and Testing Card, or by viewing the HIV Care and Treatment (C & T) records.		
HIV status: Positive	Mark box with an **X** if the screened woman has an HIV-positive result on her last HIV test.	Client, C & T Card, C & T records
On ART	Mark box with an **X** if the screened woman is currently on HIV antiretroviral drugs (ART).	
Not on ART	Mark box with an **X** if the screened HIV-positive woman is <u>not</u> currently taking ART.	Client, C & T Card, C & T records
HIV status: Negative	Mark box with an **X** if client's last HIV test was negative and less than 3 months old. If HIV test result is more than 3 months old, refer client to get tested and return with result.	Client, VCT result card
HIV status: Unknown and reason	Mark box with an **X** if client has never had an HIV test and refuses to take the test after offered testing. Write the reason the client is unknown HIV status.	Client
PICT accepted: Yes or no	If the client has an HIV-negative test older than 3 months or unknown HIV status, PICT should be offered and the box marked with an **X** if she accepts or declines	Provider
PICT Result: Positive or negative	Mark box with an **X** with the result of the HIV test conducted by the provider.	Provider
Newly diagnosed HIV-positive referred?	If a client undergoes provider-initiated testing and counseling (PITC) or has recently found out she is HIV-positive, the provider should offer a referral to the HIV care and treatment center and mark the appropriate box.	Provider

Variable	Description	Data Source
Visit Type		
Instruction: The provider should determine the reason for the VIA screening by talking with the woman. Only one answer can be selected and is critically important to document correctly in order to calculate the indicators.		
Initial VIA completed	Mark box with an **X** if this is the first VIA screening ever completed. If a Pap was performed previously, but no VIA, mark this box. Either a VIA-positive or a VIA-negative result has to be determined in order to mark this box. If the client has cervicitis and the VIA diagnosis cannot be determined, the form VISIT TYPE should be left blank and not counted toward the month totals until the women returns after completing the medication prescribed. At that point, a new form should be completed and marked as an INITIAL VIA COMPLETED.	Provider
Postponed cryotherapy	Mark box with an **X** if a VIA-positive woman who had previously postponed cryotherapy returns for cryotherapy. This VISIT TYPE only applies to the documentation for a second visit.	Provider
Post-treatment complication: Related to cryotherapy	If a previously treated client returns to the facility with a problem, mark this box with an **X**.	Provider
1-year follow-up	When a previously treated with cryotherapy or LEEP client returns for follow-up after 1 year, this box should be marked with an **X**.	Provider
Routine VIA screening	If a previously screened client who was found to be VIA-negative at her last screening returns for her routine screening, this box should be marked with an **X**.	Provider
Referral from: _____	If a women comes to your facility to be screened and was referred from another facility after completing a VIA screening at that facility, mark this box with an **X**. Also indicate the previous diagnosis at the other facility as VIA-positive or determined to have a large lesion that needs advanced care.	Provider
Physical Exam		
Pelvic exam done?	Mark YES or NO after you complete the screening whether it included a pelvic exam.	Provider
Abnormal vaginal discharge	Mark YES or NO if vaginal discharge is noted during the pelvic exam and client remarks that it is abnormal or it looks abnormal during the exam.	Provider/Client
Vulva/Perineum	Mark any abnormalities discovered during the pelvic exam.	Provider
Vagina		
Cervix		
Lower abdomen		
Clinical diagnosis	Document the clinical diagnosis from the pelvic exam.	Provider

Variable	Description	Data Source
Prescription	If the client needs a prescription based on the findings from the pelvic exam, document the name and dosage of the prescription here.	Provider
Visual Inspection with Acetic Acid and Enhanced Digital Imaging		
Instruction: The provider who visualizes the cervix after acetic acid or after Enhanced Digital Imaging is used should draw what is seen including the outline of the SCJ, the acetowhite lesion (if there is one), the cervical os, and suspect cancer (if seen).		
Test Results		
Instruction: This section should be completed to document whether screening was completed and the result. Only one screening result should be documented per form.		
Test results?	If VIA was not completed, mark NO and include the reason why VIA was not completed (including severe cervicitis).	Provider
Screening results: Yes		
Screening result: VIA-negative	Mark the box with an **X** if the VIA screening was negative (showed no acetowhite lesion).	Provider
Screening result: VIA-positive	Mark the box with an **X** if the VIA screening was positive (showed an acetowhite lesion).	Provider
Eligible for cryotherapy?	If the client with a VIA-positive result has a lesion meeting the qualifications for cryotherapy, mark YES; if not, mark NO.	Provider
Suspect cancer	Mark the box with an **X** if cervical cancer is suspected prior to VIA being conducted.	Provider
Entire lesion seen	Mark YES if you can visualize the entire lesion on the cervix. Mark NO if the lesion cannot completely be visualized. Refer if NO is marked.	Provider
Covers <75% of the cervix	Mark YES if the lesion covers less than 75% of the cervix. Mark NO if it covers more than 75% of the cervix. Refer if it covers more than 75% of the cervix.	Provider
Atypical vessels	Mark YES or NO.	Provider
Extends into cervical os	Mark YES if it extends into the cervical os. Mark NO if it does not extend. Refer those clients marked YES.	Provider
Covers >75% of cervix	Mark YES if it covers more than 75% of the cervix and refer. Mark NO if it does not cover more than 75% of the cervix.	Provider
Mosaicism/ Punctation	Mark YES or NO.	Provider
Treatment		
Instruction: This section should be completed if the VIA screened woman was found to be VIA-positive. Only one box should be marked.		
Cryotherapy performed today	Mark the box with an **X** if the screened woman with a VIA-positive result agreed and had cryotherapy performed during this visit.	Provider

Variable	Description	Data Source
Cryotherapy postponed/Reason: _____	Mark the box with an **X** if the screened woman with a VIA-positive result was not able to get cryotherapy today and was postponed (this could be due to the provider or the client's decision). Include the reason why cryotherapy was postponed on the line provided.	Provider
Referral		
Instruction: This section should be completed for all screened women with a VIA-positive result who need to be referred to another facility or another department at the same facility for advanced care. Only one box should be marked.		
Referred to: _____	Mark the site to which the screened woman is being referred to for advanced care.	Provider
Suspect cancer	Mark an **X** in the box if the screened woman is being referred to another site because the provider suspects cancer. Make sure to fill out a Referral Form and track her information in the Referral Tracking Log.	Provider
Large lesions	Mark an **X** in the box if the screened woman is being referred to another site because the acetowhite lesion was large or extended into the canal. Make sure to fill out a Referral Form and track her information in the Referral Tracking Log.	Provider
Other gynecological problem referral (specify)	Mark an **X** in the box if there was another gynecological problem identified during the screening, the woman cannot get the treatment necessary during this appointment, and she needs to be referred to another department within the same facility or another facility. Make sure to fill out a Referral Form.	Provider
Notes/Recommendations/ Follow-up dates	Write in any additional notes and recommendations, as well as when the woman should return for a repeat screening.	Provider

Appendix 5: Register

ZAMBIA CERVICAL CANCER SCREENING AND TREATMENT PROGRAM — **VIA/CRYOTHERAPY REGISTER - v1**

FACILITY NAME: _____ **MONTH:** _____ **YEAR:** _____ HIV STATUS (+, -, or unknown - for entire page): _____

	INTAKE																					
	CLIENT INFORMATION					VISIT TYPE						SCREENING					REFERRAL		TREATMENT or PROCEDURE			
No.	Screening Date	Client ID No	Client Name	Contact Information (e.g., Address/Phone Number)	Age	Initial VIA Completed Visit	Previously Post-poned Cryo Visit	Post-Treatment Complication related to Cryotherapy	1-year Follow Up Visit	Routine VIA Screening Visit	Referred Patient Visit	VIA Done Today	VIA Negative	VIA Positive	Suspect Cancer	Screening Provider Initials	Large Lesions	Suspect Cancer	VIA today / Cryo done today	VIA today/ Cryo postponed	Postponed Cryo done today	Treatment Provider Initials
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O		P	Q	R	S	T	
1																						
2																						
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20																						
COLUMN TOTALS																						

Appendix 6: Instructions for Completing the Register

Variable	Column Letter	Description	Data Source
Top Margin			
Instructions: On each new page, complete the information requested on the top of the page. The Register should reflect all of the screenings that took place at the facility. A new page should be started for each new month. The Register should be divided into sections with the front section for the screenings of HIV-negative or HIV-unknown women and the back section for HIV-positive women.			
Facility name	None	Write in the name of the facility that completed the screening.	Provider, Nurse, Midwife, or Registrar
Month	None	Write the name of the month in which the screenings documented on this page took place.	
Year	None	Write the name of the year in which the screenings documented on this page took place.	
Row 1, 2, 3…. 20	None	Each individual client visit should be tracked in order of screening date/time. If a client visits the clinic more than once, more than one row should be used to document each visit.	
Column totals	None	At the bottom of the Register, there is a row to track the tally totals for each column. This should be completed during the Review and Reconciliation process at the end of the month. Zeros (0) should be placed in columns with no tally marks.	Provider/ Supervisor
Intake: Client Information			
Instructions: All information related to client information should be documented. Only one answer should be marked with an **X** under Visit Type. All information should be transcribed from the completed Cervical Cancer Screening Forms.			
Screening date	A	Write in the date of the screening in day/month/year format.	Provider, Nurse, Midwife, or Registrar
Client ID number	B	Write the client ID.	
Client name	C	Write in the full name of the woman screened including middle/maiden name.	
Contact information	D	Write the address and phone number for the client.	

Variable	Column Letter	Description	Data Source
Age	E	Record the age at last birthday of the screened woman as it appears on the Cervical Cancer Screening Form.	Provider or others
Intake: Visit Type			
Instructions: Only one answer should be marked with an **X** under Visit Type. All information should be transcribed from the completed Cervical Cancer Screening Forms.			
Initial VIA completed visit	F	Mark an **X** in the square if this was the first VIA screening for the woman.	Provider, Nurse, Midwife, or Registrar
Previously postponed cryo visit	G	Mark an **X** in the square if the previously screened VIA-positive client returns for cryotherapy. Do not fill in the VIA diagnosis section since she was previously diagnosed during her last visit.	
Post-treatment complication related to cryotherapy	H	Mark an **X** in the square if a client returned after cryotherapy with a complication.	
1-year follow-up visit	I	Mark an **X** in the square if the women returned for a follow-up screening after her previous screening that resulted in a VIA-positive diagnosis as well as treatment with either cryotherapy or LEEP.	
Routine VIA screening visit	J	Mark an **X** in the square if the woman returned for her 2nd, 3rd…. xth screening after her previous screening diagnosis was VIA-negative.	
Referred client visit	K	Mark an **X** in the square if the woman was referred from another screening site for cryotherapy	
Screening, Referral, and Treatment: Screening			
Instructions: Only one answer should be marked with an **X** under the Screening section. All information should be transcribed from the completed Cervical Cancer Screening Forms.			
VIA done today	L	Mark if the VIA was completed today with a diagnosis reached (Suspect Cancer, VIA-positive or VIA-negative).	Provider
VIA-negative	M	Mark an X if the VIA had a negative result.	
VIA-positive	N	Mark an X if the VIA had a positive result.	
Suspect cancer	O	Mark an X if client is suspicious for cancer.	
Screening provider initials		Write the initials of the Provider who actually carried out the screening and determined the diagnosis.	Provider

Variable	Column Letter	Description	Data Source
Screening, Referral, and Treatment: Referral			
Instructions: Only one answer should be marked with an **X** under the Referral section. All information should be transcribed from the completednCervical Cancer Screening Forms.			
Large lesions	P	Mark an **X** in the square if the screened woman was referred to another site due to a large lesion or a lesion that extended into the cervical canal.	Provider, Nurse, Midwife, or Registrar
Suspect cancer	Q	Mark an **X** in the square if the screened woman was referred to another site or another department within the same site. If this cell is marked, there should also be an X in Column O.	
Screening, Referral, and Treatment: Cryotherapy and Other Treatment			
Instructions: Only one answer should be marked with an **X** under the Cryotherapy and Other Treatment section. All information should be transcribed from the completed Cervical Cancer Screening Forms.			
VIA today/Cryo done today	R	Mark an **X** in the square if VIA was completed today (diagnosis made) and cryotherapy was performed on the same day as the screening.	Provider, Nurse, Midwife, or Registrar
VIA today/Cryo postponed	S	Mark an **X** in the square if VIA was conducted today (diagnosis made) and the cryotherapy treatment was postponed (per provider or client's preference).	
Postponed cryo done today	T	Mark an **X** in the square if a previously diagnosed VIA-positive client returns for cryotherapy treatment.	
Treatment provider initials	X	Write in the provider who completed the treatment.	Provider

Appendix 7: Monthly Summary Form

ZAMBIA CERVICAL CANCER SCREENING AND TREATMENT PROGRAM
MONTHLY REGISTER SUMMARY

Facility Name: _____ **Month:** _____ **Year: 20**_____

N°	INDICATOR	CALCULATION FROM LOGBOOK COLUMNS		HIV+ (A)	HIV – (B)	HIV STATUS UNKNOWN (C)	TOTAL (A+B + C)
1	Number of clients with suspected cancer	**Initial VIA**	Both F and O marked				
		1 YR Follow-Up	Both I and O marked				
		Routine Visit	Both J and O marked				
2	Number of clients who received a VIA screening	**Initial VIA**	Both F and L marked				
		1 YR Follow-Up	Both I and L marked				
		Routine Visit	Both J and L marked				
3	Total number of unique clients seen this month	**Initial VIA**	(F and O) + (F and L)				
		1 YR Follow-Up	(I and O) + (I and L)				
		Routine Visit	(J and O) + (J and L)				
4	Number of clients with NEGATIVE VIA result	**Initial VIA**	Both F and M marked				
		1 YR Follow-Up	Both I and M marked				
		Routine Visit	Both J and M marked				
5	Number of clients with POSITIVE VIA result	**Initial VIA**	Both F and N marked				
		1 YR Follow-Up	Both I and N marked				
		Routine Visit	Both J and N marked				
6	Number of clients referred for large lesions	**Initial VIA**	Both F and P marked				
		1 YR Follow-Up	Both I and P marked				
		Routine Visit	Both J and P marked				
7	Number of clients with VIA today **AND** cryotherapy performed **today** (single visit approach)	**Initial VIA**	Both F and R marked				
		1 YR Follow-Up	Both I and R marked				
		Routine Visit	Both J and R marked				
8	Number of clients with VIA today **AND** cryotherapy **postponed**	**Initial VIA**	Both F and S marked				
		1 YR Follow-Up	Both I and S marked				
		Routine Visit	Both J and S marked				
9	Number of clients with previously postponed cryotherapy performed today	TOTAL	Both F and T marked				
10	Number of clients with a post-treatment complication	Cryotherapy	H				

VIA Positive Rate for Initial VIA _____ / _____ = %
Calculation: # VIA positive for initial VIA / # of Initial VIA screenings

Single Visit Approach for Initial VIA: _____ / _____-_____ = %
Calculation: # new clients with cryo on the same day as screening / # new clients VIA positive (-) # of new clients referred for large lesions

Completed By : (signature, print, and date) : _____ Feb 2015 – v1

ZAMBIA CERVICAL CANCER SCREENING AND TREATMENT PROGRAM
MONTHLY REGISTER SUMMARY

N°	INDICATOR	CALCULATION FROM REGISTER COLUMNS		TOTAL
11	Number of women screened using VIA (total)	TOTAL		
		Age <20	Both E and L marked	
		Age 20-29		
		Age 30-39		
		Age 40-49		
		Age 50+		
12	Number treated with cryotherapy	TOTAL		
		Age 20-29	Both F and R + T marked	
		Age 30-39		
		Age 40-49		
		Age 50+		

Appendix 8: Referral Form



PATIENT'S REFERRAL FORM

Health Centre: _____

Phone: _____

Patient's Name: _____ **Referral/File No.** _____

Age: _____ **Sex:** _____

Address: _____

_____

Present Complaint(s) by the Patient:

- _____
- _____
- _____

Provisional Diagnosis: _____

_____

_____

Reason(s) for Referring: _____

_____

_____

Name of Referring Officer: _____

Title: _____

Signature: _____

Date: _____ **Time:** _____

Feedback Remarks by Hospital / Health Centre Staff

_____

_____

_____

_____

Appendix 9: Client Information Card

Ministry of Health

DISTRICT: …….

FACILITY NAME: …….

NAME: …….

DATE OF BIRTH: ……

Date	Screening/Treatment Performed	Name of Health Care Provider	Next Appointment Date

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