innovating to save lives

Jhpiego

an affiliate of Johns Hopkins University

Loop Electrosurgical Excision Procedure (LEEP) Services:

A Reference Manual for Providers

Jhpiego is an international, non-profit health organization affiliated with The Johns Hopkins University. For more than 40 years, Jhpiego has empowered frontline health workers by designing and implementing effective, low-cost, hands-on solutions to strengthen the delivery of health care services for women and their families. By putting evidence-based health innovations into everyday practice, Jhpiego works to break down barriers to high-quality health care for the world's most vulnerable populations.

Published by:
Jhpiego Corporation
Brown's Wharf
1615 Thames Street
Baltimore, Maryland 21231-3492, USA
www.jhpiego.org

Contributors: Dr. John E. Varallo and Dr. Jean Anderson
Editor: Dana Lewison
Desktop Publishing: Jamie Wolfe, Trudy Conley, and Bekah Walsh

TABLE OF CONTENTS

PREFACE

Loop Electrosurgical Excision Procedure (LEEP) is an important component of a comprehensive cervical cancer prevention (CECAP) program. While visual inspection with acetic acid (VIA) combined with immediate cryotherapy in the single visit approach (SVA) is effective and possible in the majority of VIA-positive cases, approximately 15% of VIA-positive cases will not be eligible for cryotherapy—and this percentage will be higher among HIV-infected women (ACCP 2003; Pfaendler 2008; Rema 2008; WHO 2012). Without treatment, these women are at significant risk of having these precancerous lesions progress to invasive cervical cancer. LEEP helps fill the gap where cryotherapy is not an appropriate treatment method for precancerous lesions.

The LEEP reference manual expands upon and complements Jhpiego's learning resource package for VIA and cryotherapy, and represents our ongoing commitment to prepare health care providers to provide high-quality CECAP services. This reference manual focuses on the training and provision of LEEP services. It assumes that the trainers and those being trained are competent in VIA and cryotherapy and have a good understanding of cervical cancer and its prevention. Therefore, **Chapters 1 and 2** of this manual will provide a review, rather than a detailed description, of the cause and natural history of cervical cancer, the relationship between HIV/AIDS and cervical cancer, primary prevention of cervical cancer, screening for precancerous lesions, and cryotherapy treatment of precancerous lesions.

The LEEP reference manual, while a resource in itself, is intended to be used as an integral part of a comprehensive learning resource package that includes:

- LEEP Reference Manual
- Guide for Participants
- Guide for Trainers
- PowerPoint presentations and job aids
- Anatomic models for practicing LEEP

A model course schedule is provided in the Trainer's Guide, but the design of the learning resource package allows flexibility in how the training is conducted—whether through a structured course or through a more modular or on-the-job/mentoring training approach. Regardless of the approach, the objective is the same: to develop competent LEEP providers who can provide high-quality LEEP services as part of a high-quality comprehensive CECAP program.

ABBREVIATIONS

ART	Antiretroviral therapy
CECAP	Cervical cancer prevention
CIN	Cervical intraepithelial neoplasia
FIGO	International Federation of Gynecology and Obstetrics
HLD	High-level disinfected/disinfection
HPV	Human papillomavirus
HR	High-risk
LEEP	Loop Electrosurgical Excision Procedure
PID	Pelvic inflammatory disease
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 contributors wish to thank the following for the leadership, vision, and feedback on the LEEP training materials and course design as they were implementing the LEEP program in their countries:

- Guyana: Dr. Leslie Ramsammy (Ministry of Health), Dr. Madan Rambaran (Medical Director, Georgetown Public Hospital), and Mr. Michael Khan (CEO, Georgetown Public Hospital);
- Tanzania: Dr. Robert Kamala and Dr. Safina Yuma (Reproductive Health Cancer Unit, Ministry of Health and Social Welfare), Dr. Gaudence Komba (Peramiho Mission Hospital), and Dr. Mary Rose Giattas (Technical Advisor, Jhpiego Tanzania Cervical Cancer Prevention Programme);
- Burkina Faso: Professor Jean Lankoande (CHU Yalgado); and
- Dr. Ricky Lu (Director, Family Planning and Reproductive Health, Jhpiego) from Jhpiego headquarters in Baltimore, Maryland.

We also send an enormous thank you to all of the LEEP providers, nurses, and clinical staff at the LEEP sites in the three countries, without whose dedication and tireless efforts these programs would not be possible.

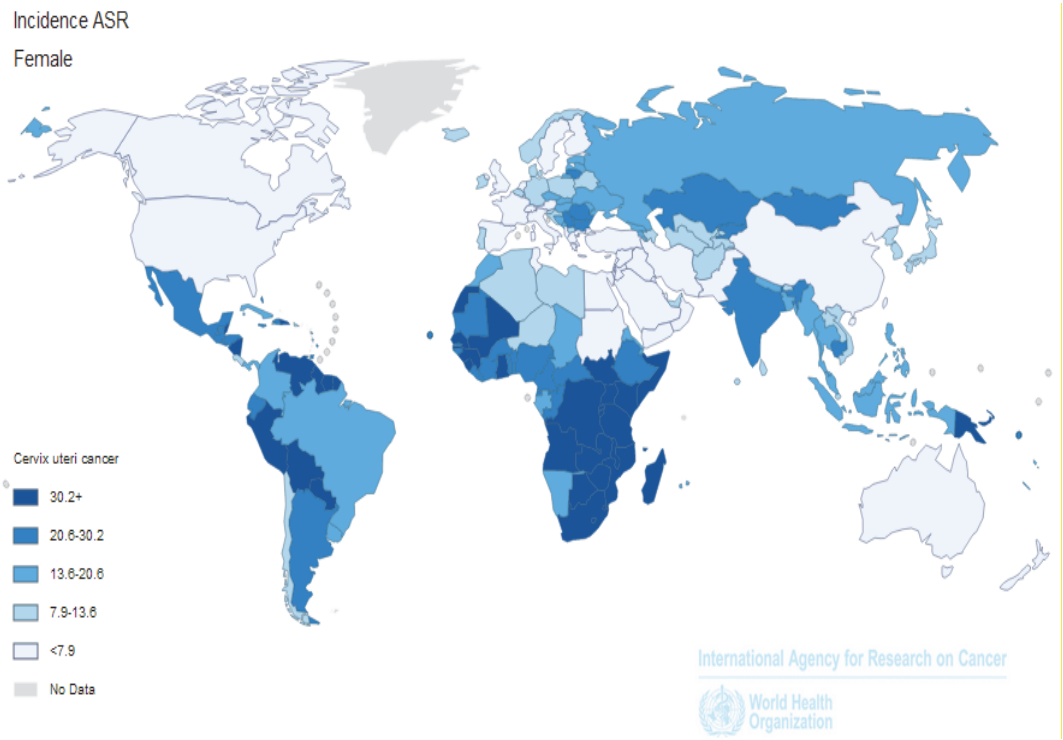
1. INTRODUCTION

IMPORTANCE OF CERVICAL CANCER PREVENTION

Cervical cancer continues to be a major global public health problem for women. Each year, nearly 530,000 new cases of cervical cancer and 266,000 deaths due to cervical cancer occur 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 have led to significant reductions in burden of disease, with the incidence of cervical cancer decreased by a remarkable 70–80%. For example, in the U.S., 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 (see **Figure 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. 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).

HPV AND CERVICAL CANCER

It is now clear that cervical cancer is caused by the human papillomavirus (HPV), a sexually transmitted infection (STI). Through use of the most sensitive assays, over 99% of invasive cervical cancers have been found to be HPV-positive. 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. 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 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 (HR 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 HR HPV types varies among regions, HPV 16 is consistently the dominant HR HPV type. In addition to HPV 16 and 18, other HR 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

While HPV infection is common, 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 HR 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 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. 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. The most important clinical evidence of persistent HPV infection is cervical intraepithelial neoplasia, or CIN, which is classified as CIN 1 (low-grade), CIN 2, and CIN 3 (collectively referred to as high-grade). Note: The term CIN is often used interchangeably with

cervical dysplasia, and the corresponding mild, moderate, and severe dysplasia histopathology classification (CDC 2012; ACOG 2013; ASCCP 2013; WHO 2013b).

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, WHO 2013b).

A Note about Cervical Precancer Terminology

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; it uses internationally agreed-upon criterion for dividing cervical lesions into three grades based upon how many layers of the cervical epithelium are involved:

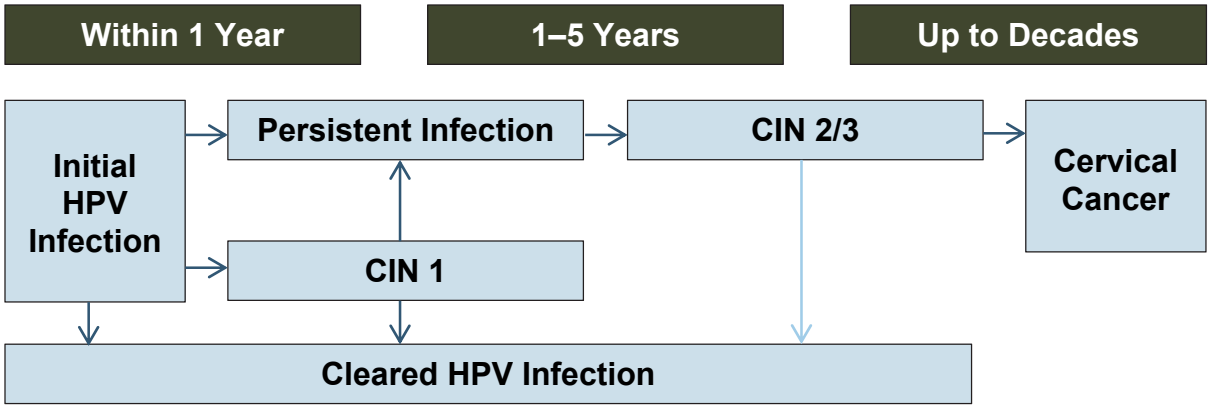
- **CIN 1**: The abnormal cells are confined to the bottom third of the cervical epithelium.
- **CIN 2**: The abnormal cells are confined to the bottom and middle third of the cervical epithelium.
- **CIN 3**: The abnormal cells involve all three layers (bottom, middle, and upper) of the cervical epithelium.

CIN 1 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.

In a comparison of 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).

Cervical cancer generally takes a long time to develop: the time from initial HPV infection to the development of cervical cancer is usually at least 10–20 years (average 20 years) (see **Figure 2**) (CDC 2012; ACOG 2013; WHO 2006; WHO 2009).

Figure 2. Natural History of HPV Infection and Cervical Cancer



Following initial HPV infection, most HPV infections spontaneously clear in an average of 8 months. If HPV infection persists, however, CIN 1 may develop within a few years of infection. These low-grade lesions are not considered truly precancerous and often spontaneously resolve as well as clear 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).

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 progress through CIN 1, but 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 (CIN 2+), which are less likely to spontaneously regress. Although regression rates for CIN 2+ 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 CIN 2+ 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 2006; 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.

RELATIONSHIP BETWEEN HIV/AIDS AND CERVICAL CANCER

Human immunodeficiency virus (HIV) suppresses 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 (UNAIDS 2012). In addition, women account for over 70% of people ages 15–24 years who are HIV-positive in sub-Saharan Africa (UNAIDS 2013).

The regions where cervical cancer rates are highest also often tend to have high prevalence of HIV (see **Figure 3**).

Figure 3. Incidence of Cervical Cancer and HIV in Africa (darker areas indicate higher incidence)

Cervical Cancer Incidence in Africa

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

HIV Incidence in Africa

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

This situation 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). This increased risk is compounded by the general

unavailability of effective cervical cancer screening programs in these lower-resource settings. As a result, while HIV-infected women may live longer with improved HIV care and treatment, including antiretroviral therapy (ART), they may end up dying from another virus—HPV—if they do not have access to cervical cancer prevention services.

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 depressed 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 et al. 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 with regard to HPV and cervical precancer:

- Higher rates of HPV infection, including HR 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 likelihood of persistent HPV infection and CIN 2+
- Larger precancerous lesions that are more difficult to treat
- Higher recurrence rates of precancerous lesions following treatment

(Branca 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)

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 RNA levels) (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).

When invasive cervical cancer does develop in HIV-positive women, it may occur at younger ages and 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).

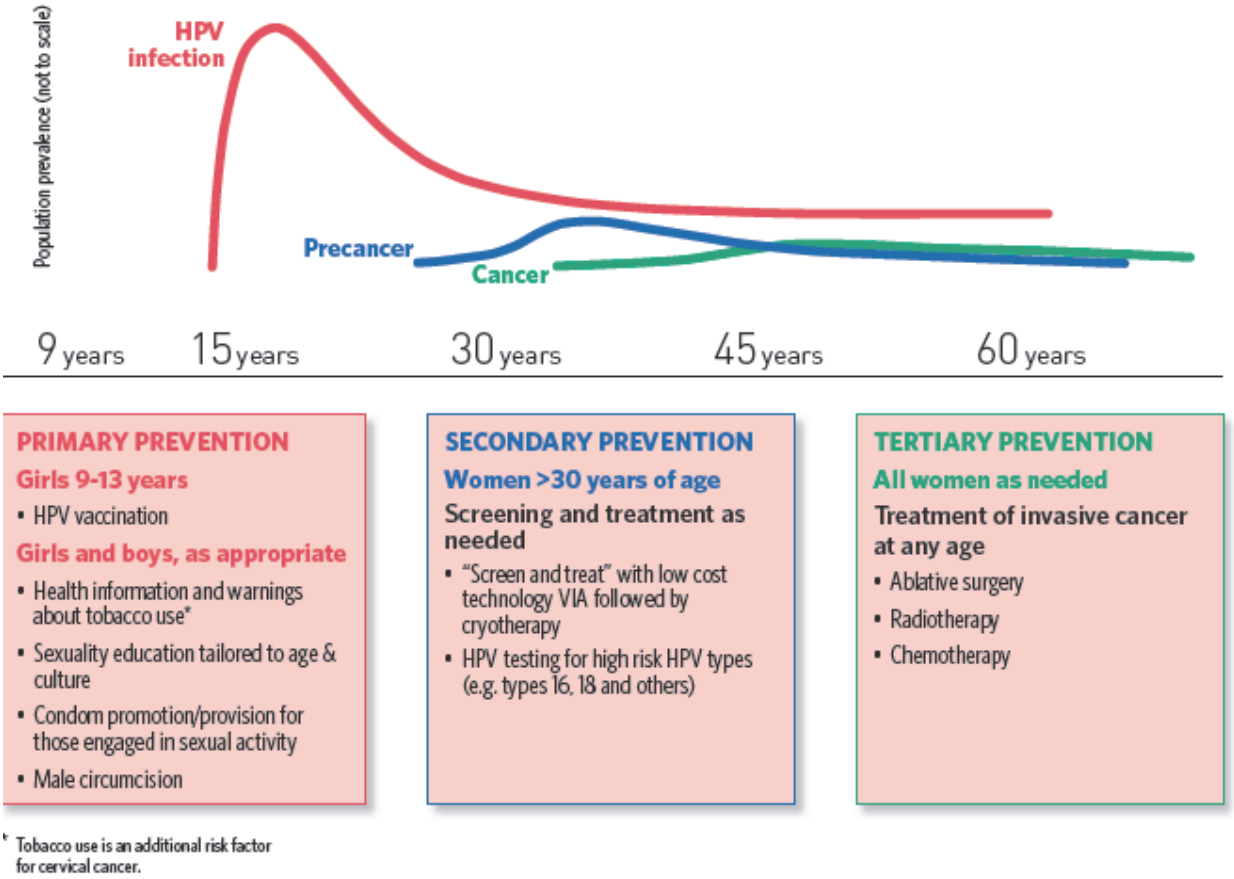
The role of effective ART and improvement in immune function in reducing the development or progression of HPV infection and cervical dysplasia remains unclear, with studies examining this issue having conflicting findings. As a result, until evidence suggests otherwise, HIV-positive women should continue to be followed closely for evidence of cervical dysplasia, regardless of antiretroviral therapy or CD4 count.

2. PREVENTION OF CERVICAL CANCER

CONTINUUM OF CARE

A comprehensive approach to cervical cancer prevention requires applying effective interventions along a continuum of care throughout the life cycle, and includes primary prevention, secondary prevention, and tertiary care, as well as palliative care, and all the activities that support these interventions (see **Figure 4**).

Figure 4. Continuum of Care to Prevent HPV Infection and Cervical Cancer



Source: World Health Organization. 2013a. *WHO Guidance Note: Comprehensive Cervical Cancer Prevention and Control: A Healthier Future for Girls and Women,* p. 3. Accessed January 22, 2015. Available at: http://www.who.int/reproductivehealth/publications/cancers/9789241505147/en/

Discussion of each of the interventions and their supporting activities is beyond the scope of this LEEP Reference Manual. Rather, what follows is a brief overview of primary prevention and secondary prevention, with a focus on LEEP.

PRIMARY PREVENTION

Because nearly all cervical cancer cases are caused by HPV, primary prevention of cervical cancer involves preventing genital HPV infection from occurring in the first place. What complicates 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. 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 2010).

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 three 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 2010).

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 2010).

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), consistent, correct condom use, and stopping smoking can all decrease the risk of HPV exposure:

- **Delaying sexual activity, limiting the number of sexual partners:** Because 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 2006). 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:** Because 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 2006).
- **Stop smoking:** Tobacco use is an important environmental risk factor for the development of cervical precancer and cancer, although 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).

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 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 et al. 2011).

SECONDARY PREVENTION

A successful secondary prevention pillar of a national cervical cancer prevention program requires the following elements to be present (WHO 2006):

- 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 TESTS

(See Table 1 for summary comparison of screening tests.)

Cytology

Replicating the success of cytology-based screening programs in high-income countries has proven difficult in resource-poor countries. This is largely because the resources required to sustain resource-intensive, cytology-based, multi-visit approach programs—trained personnel, supplies, laboratory infrastructure, equipment, and a well-organized surveillance and recall system—are limited (ACCP 2007; Sankaranarayanan et al. 2005). However, in low-resource settings, many or most women reside at some distance from health centers, have little access to or cannot afford effective transportation, and there is a lack of effective recall mechanisms for abnormal results (Anorlu 2008). 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).

Visual Inspection of the Cervix

Visual inspection of the cervix with acetic acid (VIA) is a low-cost and low-tech approach to cervical cancer screening that allows immediate treatment of precancerous lesions with ablative (e.g., cryotherapy) or excisional (e.g. LEEP) methods in a single visit approach (SVA). Linking screening to 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 is consistent with findings from other international organizations (WHO 2006; FIGO 2009).

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. 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 (WHO 2013b). 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.

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

- **Single test:** If HPV-positive, this indicates the need for treatment. Visual inspection will still be necessary to determine if a woman can receive cryotherapy or requires 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.

Table 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]

Source: WHO 2006[1]; FIGO 2009[2]; Sauvaget et al. 2011[3]; ACCP 2011[4].

HOW CAN PRECANCEROUS LESIONS BE TREATED?

The choice of treatment for precancerous lesions depends on the following (WHO 2006, 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 (WHO 2006)

Cryotherapy and LEEP are the most commonly recommended outpatient treatment options for precancerous lesions of the cervix (WHO 2006; WHO 2011; WHO 2012; WHO 2013b; FIGO 2009). For screen-and-treat programs, WHO recommends cryotherapy as the first-choice treatment for women who have 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).

Table 2 summarizes the key characteristics of each treatment option.

Table 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).

Cryotherapy and LEEP are the recommended outpatient treatment options for precancerous lesions of the cervix (WHO 2006; WHO 2011; WHO 2012; WHO 2013b; FIGO 2009). 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** on page 14). It 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). Precancerous lesions that do not meet cryotherapy eligibility are often collectively referred to as "large lesions" (see **Terminology** box on next page) 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 should be treated in an outpatient setting

with LEEP, if available and accessible (WHO2011; 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 2012).

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

Cold knife cervical conization is another treatment option, but is technically more difficult to perform, requires hospitalization, requires more resources, and has higher rates of complications. As a result, it is recommended only when outpatient treatment options are not available or when the eligibility criteria for outpatient treatment methods such as cryotherapy or LEEP cannot be met (WHO 2006).

Given the focus of the training course, this reference manual will, following a brief review of cryotherapy, describe LEEP in detail.

CRYOTHERAPY

Cryotherapy is a relatively simple, safe, acceptable, and inexpensive method to destroy precancerous lesions by freezing. This 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%).

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 12 weeks postpartum

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, these rates cannot be verified.

Studies 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).

3. LEEP—LOOP ELECTROSURGICAL EXCISION PROCEDURE

INTRODUCTION

LEEP stands for **L**oop **E**lectrosurgical **E**xcision **P**rocedure, and may also be referred to as Large Loop Excision of the Transformation Zone (LLETZ). The objective of LEEP is the complete excision of precancerous lesions of the cervix and the transformation zone. In skilled hands, LEEP is a relatively simple, safe, effective outpatient procedure. To perform LEEP, following injection of an anesthetic into the cervix, the provider uses a thin wire loop heated with electricity produced by special electrosurgical generators to completely excise the cervical tissue and entire transformation zone—cutting and coagulating at the same time. This is followed by control of bleeding with cauterization and application of Monsel's paste.

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.** LEEP allows determination of the lesion's severity and extent. However, in areas with limited resources, pathological evaluation is usually not available, which diminishes the advantage of LEEP for the purposes of histological examination of the cervical tissue.

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, although 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.

OBJECTIVE OF LEEP

The primary objective of LEEP is to treat precancerous lesions of the cervix by excising them completely, along with the entire transformation zone. It is important to excise the entire transformation zone along with the identified lesion, because the transformation zone may be harboring HPV even if part of it does not appear to be involved with the lesion. The tissue specimen obtained can then undergo histological examination, if available—for presence and degree of CIN or unsuspected invasive cervical cancer, as well as if the cervical lesion was removed in its entirety. As a result, LEEP can be used for **both diagnosis and treatment.**

Note: In some cases, LEEP may be used as a method of biopsy to **diagnose invasive cervical cancer,** where the intent is not to try to remove the entire suspicious lesion on the cervix, but merely to obtain a sample for histological examination. However, **extreme caution** must be used in these cases, because hemorrhage may occur, and only small biopsies should be performed.

CURE RATES

While cryotherapy is reported to have cure rates (absence of persistent or recurrent disease 1 year following treatment) comparable to that of LEEP, especially if strict cryotherapy eligibility criteria are used, studies have generally found LEEP to be associated with somewhat higher cure rates than cryotherapy. A randomized clinical trial of cryotherapy and LEEP for treatment of histologically confirmed, high-grade cervical dysplasia found that LEEP had a higher overall cure rate of 96.4% as compared to 88.3% for cryotherapy (Chirenje et al. 2001).

In addition, cryotherapy cannot treat all precancerous lesions encountered. Approximately 10–15% of VIA-positive women will require LEEP due to the presence of a large lesion, with large lesion rates higher among HIV-positive women (Bradley et al. 2005; Gaffikin, Lauterbach, and Emerson 2003; WHO 2012). Field reports also suggest that LEEP referral rates are higher in HIV-positive women because more large lesions are seen in this population. It is important, therefore, for a comprehensive national cervical cancer prevention and control program to have high-quality LEEP services available.

ELIGIBILITY CRITERIA FOR LEEP

While LEEP can be used for both large and "small" (cryotherapy-eligible) lesions, in most low-resource settings, it is generally reserved for large precancerous lesions. LEEP can be performed only by providers who have demonstrated clinical competence in performing LEEP, or under the direct supervision of a competent LEEP provider. LEEP may be used in cases suspicious for cancer, but only as a diagnostic tool, not as a means of treatment.

LEEP requires local anesthesia and is to be performed only in settings that have a functioning operating theater to handle potential urgent complications related to the procedure (e.g., heavy bleeding).

Eligibility Criteria for LEEP

- Lesion is VIA-positive (or by visual inspection with Lugol's iodine [VILI] or colposcopy).
- Lesion is not suspicious for cancer (unless LEEP is being performed as a biopsy and not treatment).
- The full extent of the external lesion can be identified. If the lesion extends into the endocervical canal, attempts should be made to visualize its extent, and a multiple pass procedure should be utilized to get deeper into the endocervical canal.
- There is no evidence of pelvic infection, severe cervicitis, severe vaginal infection, anogenital ulcer, or a bleeding disorder.
- The client is not pregnant (unless there is a concern for invasive cancer).
- The client is more than 12 weeks postpartum.
- If the client is hypertensive, hypertension should be well-controlled, or use local anesthetic without epinephrine (similarly in women with cardiovascular disease).

EXPECTATIONS FOLLOWING LEEP AND ROUTINE SELF-CARE

LEEP has a low rate of complications, especially serious complications, when performed by a trained, competent provider. However, a small proportion of women will develop complications, generally minor (ACCP 2003; ACCP 2007; Charmot et al. 2010; Jacob et al. 2005; WHO 2006). It is important that women be counseled about what to expect, what is normal, self-care, potential complications, and the warning signs, and that providers have the knowledge and skills to manage these complications, or know when to refer appropriately.

Vaginal discharge, bleeding, and infection are the most common reported side effects or complications associated with LEEP. It is common to have a brown, grayish-black discharge, sometimes with some spotting lasting from a few days to 2–3 weeks. This is often followed by a thin, watery or non-purulent discharge for another 2–3 weeks as the cervix heals. These side effects usually resolve without intervention, and are not worrisome.

Importantly, HIV viral shedding appears increased during this time and up to 3–4 months (Wright et al. 2001), though a recent study suggested that this may be less of a problem if the woman is on ART (Chung et al. 2011). Therefore, abstinence or condom use is strongly recommended during this time.

It is recommended that women receive both verbal and written instructions. They should be advised of the following:

- Expect a grayish/black discharge, possibly with a small amount of bleeding, for a few days and up to 2 weeks. A small amount of discharge can last up to 4 weeks and is considered normal.
- Discharge that is yellow and malodorous, or associated with abdominal pain or fever, may be a sign of infection. If this occurs, the woman should be seen promptly.
- Heavy bleeding (heavier than a menstrual period) is not normal. If this occurs, the woman should be seen promptly.
- Do not have sex and do not put anything in vagina (douching, tampons, fingers) for 6 weeks after treatment. This helps prevent infection, prevent bleeding, and lets healing occur. In addition, the risk of HIV transmission appears increased during this time. Therefore abstinence (or at least the use of condoms, if abstinence is not possible) is critically important during this time period. Further, condoms are recommended for 12 weeks following LEEP in order to reduce the risk of HIV transmission.
- Follow up in 6 weeks, if possible, and let the woman know when and how to get her pathology results if the tissue was sent for histological examination.
- Repeat screening in 1 year.

See **Appendix A** for the **Job Aid on Loop Electrosurgical Procedure (LEEP),** which covers indications, eligibility criteria, and what the provider should do before and after the procedure.

COMPLICATIONS AND THEIR MANAGEMENT FOLLOWING LEEP

More severe signs and symptoms should be evaluated for the occurrence of minor or severe complications related to treatment. The following are early and late warning signs of potential complications. Women should be counseled to look for and to seek care if any of these occur:

Early Warning Signs (usually within the first 2–4 weeks)

- Fever for more than 2 days
- Severe lower abdominal pain, especially if fever is present
- Foul-smelling or pus-colored discharge
- Bleeding heavier than heaviest days of menstrual bleeding for more than 2 days
- Bleeding with clots

Late Warning Signs (usually 1–3 months following the procedure)

- Later onset of lower abdominal pain with fever
- Severe menstrual cramping with minimal or no menstrual bleeding
- Leaking of urine or feces through vagina

Types of Complications

Infection

Cervicitis: A localized infection of the cervix, without evidence of upper reproductive tract infections (e.g. PID, endometritis, salpingitis). Rates are slightly higher for LEEP compared to cryotherapy, but still generally less than 5%. Program data have shown that less than 1% of women who have LEEP develop infection following the procedure. 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 rates following cryotherapy and LEEP are equivalent, typically involving 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 the frequency and severity of prolonged or moderate to heavy bleeding that requires intervention following LEEP vary according to reports, in general it occurs in less than 2% of LEEP cases. Most immediate post-LEEP bleeding can be managed through the use of proper coagulation using the ball electrode as described in **Chapter 5: Performing LEEP.**

Rarely, bleeding is severe (immediate or delayed) and uncontrollable with the above measures. In these cases, bleeding can be controlled with: 1) suturing of the bleeding site—this can often be done in the clinic, but occasionally requires better anesthesia and visualization and must be done in the operating theater, or 2) packing for 24 hours (or for stabilization for transport).

Cervical Stenosis

Severe pain and cramping, associated with little or no menstrual bleeding, can occur following LEEP due to necrotic plug syndrome. This uncommon condition presents at least 1 month following the procedure and is thought to be due to extensive cauterization of the LEEP excisional crater near the endocervical canal, resulting in scarring and obstruction of the endocervical canal. This obstruction may be caused by a necrotic plug of tissue. 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 LEEP treatment. It occurs following inadvertent burning 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

Preterm delivery risk following LEEP is a somewhat controversial and unresolved issue, with some evidence of increased risk (Jakkobsen et al. 2009), while a recent study demonstrated no increased risk (Werner 2010). The difference in outcomes from the studies may be related to the amount of tissue removed during LEEP—the deeper the LEEP and more tissue removed, the higher the risk (Noehr et al. 2009; Jakkobsen et al. 2009). However, the evidence is clearer that women who have LEEP performed two or more times are at an increased risk of preterm delivery. Infertility due to cervical stenosis or pregnancy loss due to cervical incompetence is rare following LEEP.

4. COUNSELING AND SCREENING OF POTENTIAL LEEP CLIENTS

OVERVIEW

All women have the right to make an informed decision about the management of an abnormal screening test result. They have the right to accurate and up-to-date information they need to make decisions responsibly. It is important that all LEEP providers, or assistants trained to provide this counseling, are able to counsel potential clients appropriately. If a trained assistant provides counseling, it is still the responsibility of the LEEP provider to review this information with the woman before proceeding with the decision for LEEP. (See the **LEEP Counseling and Client Assessment Job Aid** in **Appendix B.)** This counseling consists of ensuring that the woman understands:

- The benefits of treating precancerous lesions of the cervix
- Why LEEP is recommended in her case, and what her management options are
- How the procedure is performed and what to expect during the procedure
- What to expect following the procedure and common side effects
- Self-care measures
- Potential complications associated with LEEP, the warning signs, and when to call or return for further evaluation, and how to access that care
- When and how to follow up after the procedure (for pathology results, if obtained, and routine post-LEEP)
- When to repeat screening

BASIC PRINCIPLES OF LEEP COUNSELING

A woman may be very anxious or embarrassed that she has been referred for LEEP, or about 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 LEEP 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 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 LEEP services, group-based counseling may be given in that setting. Individual counseling for the patient regarding post-procedure care and follow-up may be given along with pre-procedure counseling, although if this is done, the provider should follow up after the procedure to reinforce key counseling messages and to answer any questions.

WHAT ARE THE STEPS INVOLVED IN LEEP COUNSELING AND CLIENT ASSESSMENT?

Pre-Procedure Individual LEEP Counseling and Client Assessment:

- **Review the reason LEEP has been recommended:** In most cases, a woman presenting for LEEP has been referred from another site or provider. It is important, therefore, before proceeding with the examination and LEEP to review the referral information to determine the purpose of referral, and ask the woman if she understands why she has been referred.
- **Take a targeted reproductive and medical history:** Assess for risk factors for treatment complications and to ensure no contraindications exist for treatment. Ask specific questions that may reveal information that would require a change in management or that would identify women at increased risk for complications from the procedure, including:
  - Recent or current pregnancy: LEEP should not be performed during pregnancy and not until at least 12 weeks postpartum.
  - Current abnormal vaginal/cervical discharge and/or pelvic pain or anogenital ulcer: evaluate for PID or other genital tract infection. These should be treated according to national guidelines before LEEP is performed.
  - Current heavy vaginal bleeding: It is advisable not to attempt to perform LEEP when a woman has heavy bleeding. If it is menstrual bleeding, ask her to return after menses is completed: If abnormal bleeding, evaluate or refer for evaluation, as indicated (rule out pregnancy!). At a minimum, a pelvic and speculum examination should be conducted to assess for cervical cancer, or other obvious causes (e.g., large endocervical polyp, prolapsed fibroid).
  - HIV status: HIV-positive women are at increased risk of recurrence, and should be followed more closely than their HIV-negative counterparts.
  - History of STIs: a recent history of STI indicates a higher risk for infection following LEEP.
  - Hypertension or other cardiovascular disease: If poorly controlled chronic hypertension, the use of adrenaline or epinephrine with the local anesthetic (lignocaine/lidocaine) is contraindicated.

- Bleeding disorder: Presence of a bleeding disorder with a history of easy bleeding should alert the LEEP provider to consider a change in management, e.g., perform LEEP in the operating theater or use a slower technique with more coagulation during the excision.

- **Take the client's blood pressure and pulse:** If blood pressure is > 160/110 or if pulse is > 100, consider postponing the procedure until the woman has been further evaluated. If the decision is made to proceed with LEEP, use local anesthetic without adrenaline or epinephrine.

- **Explain the purpose of LEEP:**
  - LEEP is performed to excise/remove the precancerous lesion in its entirety to prevent it from developing into invasive cervical cancer. The reason most women are referred for LEEP is because the size of the lesion or its extension into the endocervical canal reduces the effectiveness of cryotherapy. LEEP is able to adjust to the size of the precancerous lesion, and thus maintain high effectiveness in most cases (90–95% or even higher cure rates).
  - Management options should be briefly covered: 1) no treatment—precancerous could spontaneously regress, but significant chance of lesion progressing, possibly to cancer; 2) cryotherapy—some benefit, but effectiveness is reduced with large lesions or lesions that extend into the endocervical canal, with failure rates two to three times higher, or even more, in these cases (ACCP 2003; WHO 2011); and 3) cold knife cervical conization or simple hysterectomy—cure rates are high (96–100%), but lack of accessibility to these services, greater resources required, increased risks, and much longer recovery are major disadvantages to this approach.

- **Describe LEEP:**
  REMEMBER—USE SIMPLE, EASY-TO-UNDERSTAND LANGUAGE!
  - **What is LEEP?** LEEP is a procedure that uses an electrically heated wire loop to excise/remove the abnormal tissue. It is performed after numbing the cervix with a local anesthetic. Following the excision portion of the procedure, any bleeding is controlled using an electrically heated small metal ball, often followed by placement of a paste to the cervix (showing the Monsel's paste and describing what type of vaginal discharge to expect is useful).
  - What to expect during the procedure:
    - **Describe the set-up:** Describe the placement of the dispersive/grounding pad on her leg; the need to repeat the pelvic examination and VIA; the need to use a special speculum (one attached to smoke evacuator tubing); and that it may be a little more uncomfortable than her previous VIA examination because you need to open the speculum a little wider to ensure you can see the cervix very clearly and perform the LEEP well and safely.
    - **Describe establishing local anesthesia:** Explain that local anesthesia is established using a local injection and therefore the woman will likely feel a sting from the needle. Epinephrine/adrenaline often causes an increase in heart rate, as well as blood pressure. Prepare the woman to expect the sensation of her heart beating fast or "racing" following injection of the local anesthetic. This feeling is usually transient, lasting 1–2 minutes. If

this does occur, encourage the woman to take slow, deep breaths, which can help minimize the sensation. Rarely palpitations may occur.

- **Describe the sounds** from the LEEP unit and smoke evacuator.
- **Describe expected sensations during the actual procedure, and the length of time LEEP will take:** Explain the possibility of minor discomfort during the procedure (e.g., pressure, heat), but that sharp pain or very hot sensation is not normal. More local anesthesia is required if significant discomfort occurs.

Key point: The woman **should not be told** that she will have ***no*** **discomfort.** Encourage communication between the provider and the woman throughout the procedure.

- Describe expected normal recovery, side effects, possible complications (short- and long-term), warning signs, self-care, and when to return for follow-up:
  - Provide accurate information, but be aware of causing undue alarm in the woman by emphasizing potential complications.
  - Tell the woman that this information will be reviewed again following treatment and before she leaves.
- Encourage the woman to ask questions or to express any concerns she has. Respond to these in a direct, calm, and reassuring manner.
- Ask for consent for treatment: Document according to local requirements.

Key point: Type of consent will depend on local requirements and laws; this may be oral or written consent.

Post-Procedure LEEP Counseling

- **Review what the woman can expect:** The woman should expect to have a brown, grayish-black discharge, sometimes with some spotting lasting from a few days to 2–3 weeks. This is often followed by a thin, watery or non-purulent discharge for another 2–3 weeks as the cervix heals. These side effects usually resolve without intervention, and are not worrisome.
- **Give instructions for self-care at home:** Abstinence should be emphasized until complete healing has occurred following LEEP—at least 6 weeks. During this time, nothing should be put into the vagina (no douching, tampons, or fingers). This helps prevent infection and bleeding and helps promote healing. Furthermore, LEEP has been shown to dramatically increase genital tract HIV shedding during the period of healing and may increase risk of sexual transmission of HIV. During the healing period, women who are HIV-negative may be more vulnerable to becoming infected, as well as have an increased risk of HIV transmission to an uninfected male partner if the woman is HIV-positive. Condom use should be emphasized for all women, regardless of HIV status, who do have intercourse during the healing period. Further, continued condom use beyond the healing period should be strongly encouraged for HIV-positive women and for HIV-negative women if they are in a serodiscordant relationship.

- **Review warnings signs of possible complications:**
  - Discharge that is yellow and malodorous, or associated with abdominal pain or fever, may be a sign of infection. If this occurs, the woman should be seen promptly.
  - Heavy bleeding (heavier than a menstrual period) is not normal. If this occurs, the woman should be seen promptly.
- **Discuss what the woman should do if warning signs occur:** Give the client ways to contact the clinic or provider, times when the clinic is open for walk-in evaluation, or let her know how to contact her local VIA provider who referred her.

Key point: Initial follow-up evaluation. Since many women will have traveled a long distance for treatment and will have limited access to transportation, it is important to **consider initial evaluation locally** with the woman's VIA provider at the site where she was initially evaluated. This visit should occur **6 weeks following the procedure. Communication between LEEP and referring VIA providers,** and agreement on how these cases will be managed, **is essential** for high-quality services. The woman should never suffer due to lack of communication between providers.

- **Discuss recommended follow-up:** 1-year follow-up for repeat VIA screening, regardless of HIV status.
- **Encourage and answer any questions.**
- **Following post-LEEP counseling, provide a sanitary pad and condoms.**

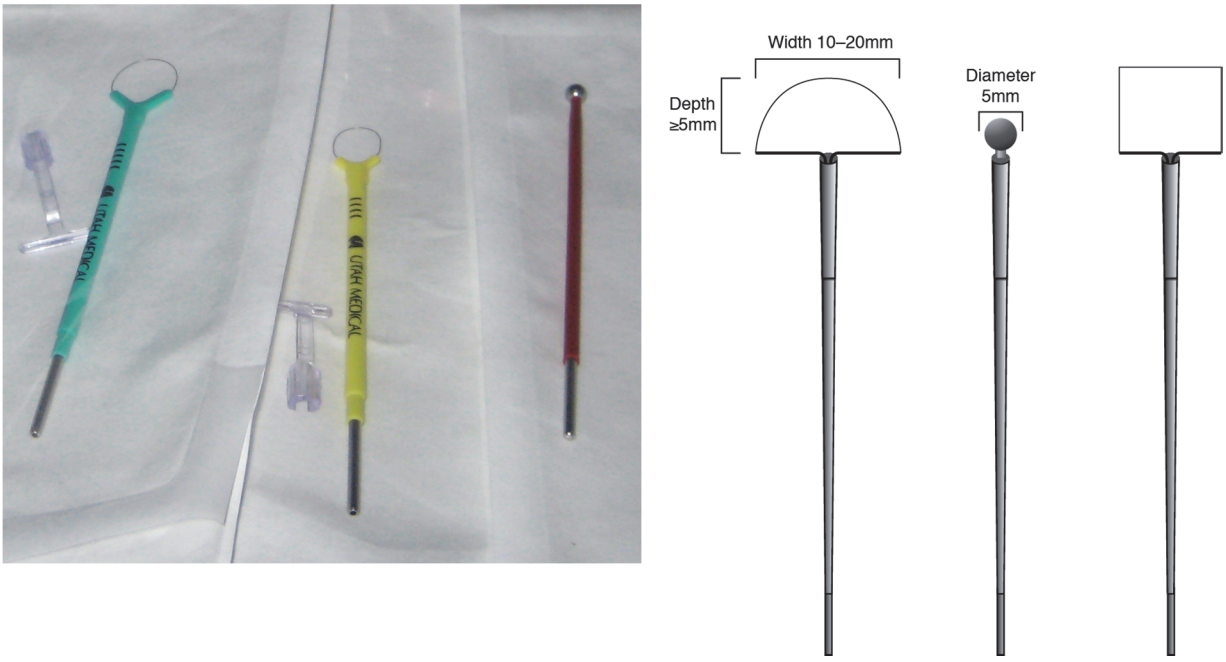
5. PERFORMING LEEP

ELECTROSURGERY BASICS FOR LEEP

Electrosurgery involves the use of electric current to cut through tissue (by vaporizing at 100° C) or to coagulate in order to achieve hemostasis (by dehydrating tissue at above 100° C). **Electrosurgical cutting** results in the least thermal damage to tissue, but does not achieve hemostasis, while **electrosurgical coagulation** causes the most thermal damage to tissue and achieves hemostasis. Since the cervix is vascular and it is essential to minimize bleeding during the excision of the cervical tissue, LEEP uses an electrosurgical cutting setting that achieves some coagulation while cutting by blending both cutting and coagulation electrical currents. This combination of electrical currents is called **blended cutting**, and is the type of cutting electrical current referred to in this learning resource package unless otherwise noted**.** The type of coagulation used in LEEP is called **fulguration**. Fulguration is achieved using a 5 mm ball electrode. With the ball electrode not actually touching the tissue, the activated current "sprays" or "arcs" multiple sparks between the ball electrode and the tissue. For optimal effect, the tissue must be as free of blood, or "dry" as possible.

LEEP: 1) cuts tissue using very fine (0.2 mm) loop wires (tungsten or stainless steel) of varying widths, depths, and configurations, and 2) coagulates using a 5 mm ball electrode (see **Figure 5**).

Figure 5. Loops and Ball Electrode



IMPORTANT

- To minimize bleeding while cutting during LEEP, move the loop electrode very slowly but continuously (providing directional guidance) through the tissue.
- Never use pure cutting electrical current during LEEP.

EQUIPMENT, INSTRUMENTS, AND SUPPLIES

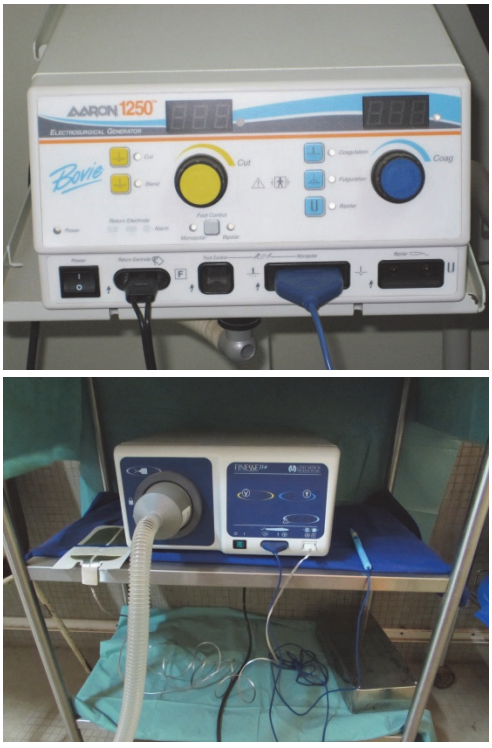
Note: The **details** about the LEEP electrosurgical unit, smoke evacuator, and filter **will vary depending on the manufacturer.** This will affect details of equipment set-up, current settings, use, care, and maintenance, **but many of the principles are the same.**

In addition to the VIA supplies, the following LEEP equipment and supplies are required:

Equipment

- **LEEP electrosurgery unit and power source:** The LEEP electrosurgery unit (or "LEEP unit") provides the power and different waveforms for cutting and coagulation. The LEEP unit has inputs for the dispersive pad and electrosurgery pen, and the unit will not function without these being properly attached. Most LEEP units also have a smoke evacuator and filter as part of the unit; if not, these are separate components. Even if the smoke evacuator is part of the LEEP unit, it often has a separate power switch and must be turned on before proceeding with LEEP.
- **Smoke evacuator and filter:** The smoke evacuator has a filter that should be changed at an interval according to the manufacturer's specifications—some units have both external and internal filters. Suction tubing is connected from the smoke evacuator to the LEEP speculum tubing. The smoke evacuation system has a high flow rate and is essential in order to remove smoke during the procedure for satisfactory visualization, and to protect persons in the room from potential exposure to aerosolized HPV particles (see **Figure 6**).

Figure 6. LEEP Units and Smoke Evacuators

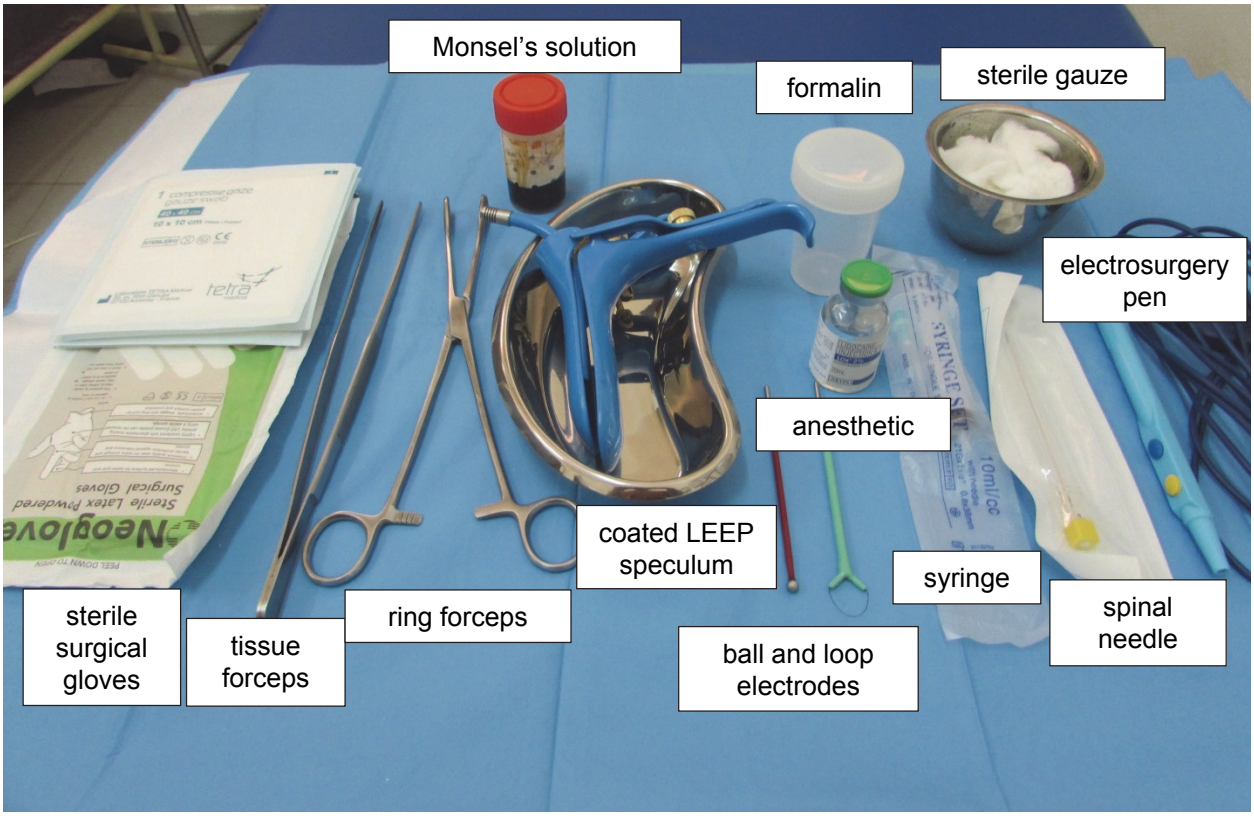


- **Large instrument trolley:** Ideally with two shelves.
- **Examination table with stirrups:** The examination table should allow the provider to insert the speculum and visualize the cervix and be at a comfortable height to perform the procedure well. While this can be accomplished without a gynecological examination table with stirrups, it is more difficult to do so. The examination table in LEEP is more important than in VIA or cryotherapy.
- **Light:** Good-quality light is essential throughout the procedure. This can be accomplished with a quality gooseneck lamp or a torchlight held by an assistant.

Instruments (see Figure 7)

- **LEEP speculum (medium and large):** The LEEP speculum is different from regular vaginal specula because it is coated with non-conductive material and has a metal tube that can be attached to tubing and a smoke evacuator. The coated speculum helps avoid conducting an electrical shock or injury if an activated loop or ball electrode inadvertently contacts the speculum. Alternatively, a regular metal speculum covered with a condom can be used, but since these specula rarely have an attachment for the smoke evacuator tube, an assistant will need to hold the tubing to keep a clear operative field. While inadvertent contact of a non-coated speculum (and not covered with a condom) with an activated loop or ball electrode will cause a painful shock, it rarely causes significant tissue damage because the energy is dispersed over a relatively large area of contact.
- Using special coated/insulated (similar to LEEP speculum) **vaginal wall retractors, wooden spatulas, or a condom/finger of a glove over the speculum** can help improve visualization if the vaginal walls bulge into the operative field, as well as reduce the risk of inadvertent contact of an activated loop or ball electrode with the vagina.
- **Tenaculum:** Sometimes used to manipulate the cervix for better visualization and/or move the cervix away from the vaginal sidewall to protect it against inadvertent contact with the loop or ball electrode.
- **Long tissue forceps and/or ring forceps:** Used to pick up excised LEEP specimen(s). Also used to apply cotton balls or gauze to the cervix during VIA/VILI, and during LEEP as noted below.
- **Long needle driver:** In the rare case that bleeding cannot be controlled with coagulation, it is important to be prepared to suture to achieve adequate hemostasis.
- **Long surgical scissors:** To cut the suture.

Figure 7. A Typical LEEP Instrument Tray with Necessary Instruments and Supplies



Supplies

These include disposable items, although some can be reused for several procedures; assume one per procedure unless otherwise noted.

- **Loop and ball electrodes:** available in varying sizes and configurations. (See **Figure 5**.)
  - **Depth: should be at least 5 mm**, but range from 5–15 mm.
  - Width: recommended width of the loop electrodes includes 10 mm, 15 mm, and 20 mm.

SPECIAL TIP: The most useful, versatile, and safe size loop is the **15 mm x 8–12 mm** (width x depth), especially early in your experience as a LEEP provider. The 15-mm loop can remove any size lesion, even very large ones, by utilizing multiple passes. Unless the LEEP provider has extensive experience, **larger loops increase the risk of injury or excessive bleeding** due to inadvertently removing too much tissue at once (e.g., larger and deeper tissue specimens excised, with greater problems with bleeding; more inadvertent injury to vaginal sidewall). The **10 mm x 10 mm loop** is useful for lesions that primarily extend into the **endocervical canal.**

- The 5-mm ball electrodes are used for coagulation.

The required power settings for the different size loop electrodes and ball electrode are described in Table 3.

Table 3. Power Settings for Loops and Ball Electrodes

Type/Size Loop and Ball Electrode	Power Setting
10 x 10 mm loop	30 watts – blended
15 x 5 mm loop	35 watts – blended
15 x 8 mm loop	35–40 watts – blended
15 x 12 mm loop	40 watts – blended
20 x 8 mm loop	45–50 watts – blended
20 x 12 mm loop	50 watts – blended
5 mm ball	35–40 watts – coagulation

Note: Most LEEP electrosurgical units come with settings recommended by the manufacturer. These are good baseline settings and can be adjusted according to provider experience and preference.

KEY POINT: When using the loop electrodes for excision, ensure that the power setting is **blended** and not pure cutting. The blended setting combines cutting and coagulation to help minimize bleeding during the excision.

- **Electrosurgery pen:** Electrosurgery pens hold the loop and ball electrodes and are connected to the LEEP unit. The pens will have either hand control (cut and coagulation buttons on the pen) or foot control (cut and coagulation pedals) to activate the electrodes. The operator must depress the button or foot pedal to activate the electrodes, but care must be taken not to inadvertently activate the electrode early, as this may lead to electrical burns of the patient if the electrode is touching the vaginal wall as the operator advances the electrode through the vagina to the cervix.
- **Dispersive (grounding) pad or plate:** For patient safety and optimal effect, a dispersive (grounding) pad or plate must be used to allow the electrical circuit to be completed. The dispersive pad should be placed on the thigh, or if a plate is used, under the buttocks. This contact must be maintained over a large area or the patient is at risk for suffering an electrical burn at the site. Most LEEP electrosurgical units have an internal system that monitors the circuitry. If a problem is encountered, the unit will alert the operator and prevents operation until the problem is corrected. In addition, the dispersive pad site should be dry and there should not be any fluids pooling underneath the patient. LEEP should not be performed around any flammable gases or liquids (such as those containing alcohol) or other flammable objects.
- **Suction tubing:** Attaches to the speculum and smoke evacuator to keep the operative area clear of smoke, and moves smoke to the external and internal filters.
- **Local anesthetic:**
  - 1% or 2% lidocaine (or similar agent) with 1:100,000 to 1:200,000 epinephrine (see Special Tip below regarding dilution).
  - 1% or 2% lidocaine (or similar agent) without epinephrine: for those with contraindications for use of epinephrine.

- **Spinal needles:** 22-, 25-, or 27-gauge, 3.5 inches long. These needles are used to inject the cervix with local anesthetic. The length of the needle is important in order to reach the cervix while maintaining good visualization. Needle extenders or dental syringes can also be used, if available. Of note, if the spinal needles are not good quality, the 25- or 27-gauge needles bend easily and make injection into the cervix difficult.

- **Syringes:** 5- and 10-mL.
- **Needles:** 18- or 20-gauge for drawing up local anesthetic.
- **Exam gloves:** Can use non-sterile gloves for practice; use sterile gloves for the procedure. Will need a range of sizes depending on the LEEP provider and assistant.
- **Wooden tongue depressors or spatula:** To act as a vaginal wall retractor or to help manipulate cervix.
- **Condoms/finger of a glove:** When placed on the speculum and the tip cut, the condom/finger of a glove acts as a vaginal wall retractor. Non-lubricated work best (if available), since they do not slip down the speculum as much. If a coated LEEP speculum is not available, a condom can be used to prevent electrical shock from inadvertent contact of the loop/ball electrode with the speculum.
- **Large, tight cotton swabs or small gauze sponges:** For VIA/VILI, but mostly to maintain a clean field of vision. A clean field of vision is very important, especially following removal of the LEEP specimen. The bed or base from where the tissue was removed can bleed heavily at times. To accurately determine the exact area of bleeding and for the ball coagulation to work effectively, the bed of the LEEP biopsy must be as dry as possible. This requires firm pressure on the bed followed by a quick look. Large, firmly made cotton swabs or ring forceps/long tissue forceps with cotton balls or small squares of cut gauze work well. Loosely made cotton swabs do not work well in this situation, as they cannot apply the appropriate amount of pressure and the loose cotton will often stick and obscure the field. Coagulation does not work as effectively if it needs to traverse a small collection of blood; it works most effectively with a dry field and where it can "arc" across to the tissue.
- **3–5% acetic acid:** To perform VIA prior to the LEEP. Alternatively, Lugol's iodine can be used to identify the abnormal area to be excised.
- **Monsel's solution/paste:** To ensure hemostasis.
- **Sterile kidney basin:** For surgical field. Alternatively, can use the cloth(s) the speculum and ring forceps were processed in as a sterile surgical field.
- **Drapes:** These are primarily to cover the woman's genital area as much as possible. They do not have to be sterile.
- **Gauze or vaginal pack:** For bleeding that is difficult to control following LEEP—to be used in place for 24 hours, or as a temporizing measure until the patient is taken to the operating theater.
- **Condoms and sanitary pads:** Provided to the woman following the procedure.

- **Suture—O or # 1-polysorb on a CT-needle (or similar suture and needle):** Needed only if bleeding does not stop with other measures.
- **Formalin and specimen cup (if specimen is to be sent for pathology).**
- **Cidex (2–4% glutaraldehyde):** For chemical high-level disinfection (HLD) or sterilization of loop and ball electrodes.

Note: For the insulated instruments (speculum)**,** once 2–4% glutaraldehyde is used for HLD or sterilization, the instrument should not be autoclaved in the future. Use of both techniques can lead to damage of the insulation, leading to increased risk of electrical shock or burn.

- **Meat:** for practice. Fresh, firm sausages, beef tongue, or chicken is preferable.
- **PVC tubing/pipe:** For practice, to simulate a speculum and vaginal walls.

SPECIAL TIP: Preparing Monsel's Paste

First, prepare glycerol starch – an ingredient of Monsel's paste

Ingredients

- Starch (30 g)
- Sterile water (30 mL)
- Glycerine (390 g)

Preparation

- In a crucible, dissolve the starch in the sterile water.
- Add the glycerine and shake or stir well.
- Heat the crucible and its contents over a bunsen burner, mixing constantly with a spatula until the mixture becomes thick and swells.

Note: Do not overheat the mixture to the point that it turns yellow.

- Store in a labeled container (Glycerol Starch; use by date) in a cool place for up to 1 year.

Next, Prepare Monsel's Paste

Ingredients

- Ferric sulfate base (15 g)
- Ferrous sulfate powder (a few grains)
- Sterile water (10 mL)
- Glycerol starch (12 g)

Preparation

Note: The reaction during this preparation emits heat.

- Add a few grains of ferrous sulfate powder to 10 mL of sterile water in a glass beaker. Shake or stir well.
- Dissolve the ferric sulfate base in the solution by stirring with a glass rod. The solution should become crystal clear.
- Place the glycerol starch in a glass mortar and slowly add ferric sulfate solution to glycerol starch, constantly mixing to get a homogeneous mixture.
- Place in a 25 mL brown glass bottle.
- If a paste-like consistency is preferred (the color of mustard), allow enough evaporation to occur before securing the top. This may take 2–3 weeks, depending on the environment.
- Secure the top and store in a labeled container (Monsel's Paste; use by date) for up to 6 months. If desired, sterile water can be added to the paste and stirred to thin it.

SPECIAL TIP: Preparing Adrenaline with Lidocaine/Lignocaine Mixture

Many sites do not have lidocaine/lignocaine with epinephrine. In these cases, the provider should mix the adrenaline. This can safely be done by adhering to the following principles:

One ampoule of 1:1,000 adrenaline in 1 mL volume.

- This equals 1mg adrenaline in 1 mL.
- This equals adrenaline 1,000 µg/mL.

If one ampoule is diluted to 10 mL:

- This equals adrenaline 0.1 mg/mL.
- This equals adrenaline 100 µg/mL.
- This is 1:10,000 adrenaline.

If one ampoule is diluted to 100 mL:

- This equals adrenaline 0.01 mg/mL.
- This equals adrenaline 10 µg/mL.
- This is 1:100,000 adrenaline.

1:200,000 adrenaline equals 5 µg/mL:

In order to achieve 1:200,000 adrenaline, use an insulin syringe to draw 0.1 mL from the ampoule of 1:1,000 adrenaline (this equals 100 µg; 0.1 x 1,000 µg) and add this to 20 mL vial of 1% lidocaine /lignocaine (100 µg/20 mL = 5 µg/mL).

UPKEEP AND MAINTENANCE

Follow manufacturer's specifications for upkeep and maintenance of equipment. Appropriate infection prevention processes should be employed after each procedure (see **Chapter 6: Infection Prevention for LEEP**).

STORAGE

All equipment, instruments, and supplies should be stored securely. After sterilization, reusable instruments should be stored in sterile containers or packaging.

RE-STOCKING

It is critical to have sufficient instruments and supplies prior to performance of LEEP. One person should be designated as responsible for managing and tracking supplies, including developing a system to track the number/amount of each item and expiration dates (when applicable) and to re-order when necessary.

CLINICAL TECHNIQUE FOR LEEP: STEP-BY-STEP INSTRUCTIONS

Counseling and Client Assessment

See **Chapter 4** for details.

1. Establish the purpose of the visit.
2. Take a targeted reproductive and medical history. Assess for risk factors to treatment and ensure no contraindications exist for treatment.
3. Take and record blood pressure and pulse.

4. Based on the above assessment, decide if it is safe to proceed with LEEP and if any change in type of local anesthetic is needed.
5. Explain why the treatment is recommended and describe LEEP, including what to expect during and following treatment, as well as self-care measures.
6. Ask the woman for her consent to perform LEEP.

Note: Some of the following steps may be performed by either the provider or an assistant. In the list below, it is noted specifically when one or the other should perform the task.

Getting Ready

1. Ensure that all equipment, instruments, and supplies (see Equipment and Supplies above) are available, ready, and in working condition.
2. Ensure that a reliable power source is available.
3. PROVIDER AND ASSISTANT: If not already done, sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
4. ASSISTANT: Ensure that the woman has recently emptied her bladder.
5. ASSISTANT: Ask the woman to undress only from the waist down, help her onto the examining table, and drape her. Note: Drapes are primarily to cover the woman's genital area as much as possible and do not have to be sterile.
6. Take her blood pressure and pulse, if not already done:
   - If blood pressure is > 160/110 or if pulse is > 100 (especially in presence of cardiovascular disease), use local anesthetic without epinephrine or adrenaline, or consider postponing procedure until her the woman has been further evaluated.
7. Help the woman place her feet onto foot rest/stirrups or her legs into stirrups.

KEY SAFETY POINT: With stirrups, **ensure that the woman's legs are padded and not in contact with metal.**

KEY SAFETY POINT: LEEP should **not** be **performed around any flammable gases or liquids (such as those containing alcohol)** or other flammable objects. Also, ensure that the **surface** the woman is lying on is **dry**, that she is not lying in a collection of fluid.

Visualizing the Cervix and the Lesion

1. PROVIDER: Perform bimanual examination followed by VIA (VILI or colposcopy can also be used) with a regular speculum to confirm the presence of a large lesion. If a large lesion is present, determine eligibility for LEEP and the size loops that will be required. Remove the speculum and proceed as outlined next.

NOTE: Ensure that the acetic acid used for VIA is of proper concentration (3–5%). If too dilute, it may be difficult to visualize the lesion. VILI may be an alternative, if Lugol's iodine is available.

2. ASSISTANT: Attach dispersive (grounding) pad to woman's thigh.
3. PROVIDER: Put one pair of new examination gloves on hands and connect suction tubing to LEEP speculum (being careful to not contaminate speculum blades) and place near edge of HLD/sterile tray or field.
4. PROVIDER OR ASSISTANT: Put on a new pair of sterile examination gloves and arrange instruments and supplies on a HLD/sterile tray, kidney dish, or towel on the trolley, if not already done.
5. PROVIDER: Gently insert the speculum in the vagina, and visualize the cervix. Open the speculum as wide as possible without creating discomfort. It is essential to have optimal visualization and exposure of the cervix in order to: 1) see the lesion in its entirety, and 2) perform LEEP without injury to the vaginal walls. If necessary, use coated vaginal wall retractors, wooden spatulas, or a speculum covered by a condom for better exposure and to protect the vaginal walls.

NOTE: To minimize the woman's discomfort, **be mindful and gentle** when inserting, moving, and opening the speculum to minimize patient discomfort.

Establish Local Anesthesia (Provider performs all of the following tasks):

1. Local anesthesia is achieved using 1% or 2% lidocaine (or similar agent) with 1:100,000 to 1:200,000 epinephrine (or adrenaline). The epinephrine causes vasoconstriction and helps reduce the amount of bleeding, as well as improving visualization and facilitating coagulation of the LEEP bed using the 5 mm ball electrode.

NOTE: Epinephrine or adrenaline often causes an increase in heart rate, as well as blood pressure**,** and can cause the **woman to become worried if** she is **not prepared for the sensation of her heart beating fast or "racing."** This feeling is usually transient, lasting 1–2 minutes, and the sensation can be minimized by encouraging the woman to take slow, deep breaths. Rarely, palpitations may occur.

KEY SAFETY POINT: To minimize the risk of intravascular injection, ensure infiltration is subepithelial, and infiltrate only after aspiration (pull back on the syringe plunger); if blood returns with aspiration, you must move the needle and aspirate again before infiltrating to ensure you do not inject into a blood vessel. **Injection of epinephrine/adrenaline** containing local anesthetic **into a blood vessel can cause blood pressure to increase to dangerous levels or cause arrhythmia. Use lidocaine without epinephrine/adrenaline if the woman is hypertensive, has a cardiac condition, or is elderly.**

2. Draw up 3–5 mL of local anesthetic using an 18- or 20-gauge needle on a 5- or 10-mL syringe. Discard the needle in a sharps container.

3. Withdraw the stylet from a 25- or 27-gauge spinal needle, discard it in a sharps container, and attach the spinal needle on the 5-mL syringe containing local anesthetic.
4. Before infiltrating, warn the woman that she may feel a little stick and then shortly after she may feel her hear starting to beat fast, as noted above. Then, using a total of approximately 3–4 mL of local anesthetic (using more for larger lesions), infiltrate equal amounts (approximately 1 mL) of local anesthetic in quadrants (3, 6, 9, and 12 o'clock) at 1–4 mm depth and near the periphery of the lesion. Good anesthetic placement is assured when local blanching is seen. If a deeper excision into the endocervical canal (e.g., LEEP cone) is planned, local anesthetic should also be infiltrated into the endocervical canal anteriorly and posteriorly.
5. Allow the anesthetic to take effect—wait 1 minute before proceeding with LEEP.

SPECIAL TIP: Remember to **infiltrate local anesthetic all around the cervix** even if the lesion is only on one side because the objective of LEEP is to remove the transformation zone along with the precancerous lesions.

SPECIAL TIP: Because the cervical tissue is dense, in some cases it may be difficult to puncture. In these cases, use a **stab-like motion to puncture the cervix** to the desired depth. Because of the dense cervical stroma, it may also be difficult to infiltrate and may take additional force, after you ensure that there is no blood upon aspiration. It is normal to have a small amount of bleeding at infiltration sites.

SPECIAL TIP: Infiltrate at the surgical site, not at some distance from it—this is because you want both the anesthetic action and the hemostasis. It is often helpful to use the infiltration sites to outline the area to be removed. **It is more difficult to see VIA-positive lesions after infiltration of local anesthetic,** so be clear where your lesion is before infiltrating.

Excision of the Lesion (Provider performs all of the following tasks):

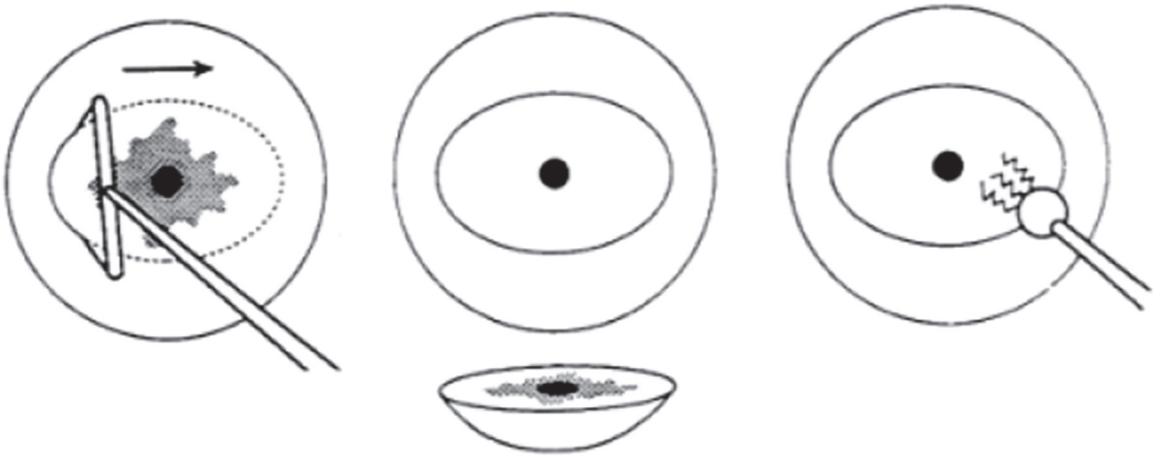
1. Visualize the lesion/identify landmarks where you visualized the lesion. If necessary, repeat VIA, but remember, after infiltrating local anesthetic, seeing a VIA-positive lesion may be more difficult.
2. To minimize risk to the woman's normal cervical tissue, as well as to minimize the cautery effect in the specimen, the least amount of power that will effectively perform LEEP should be used. (See **Table 3** for recommended power setting.)
3. Choose a loop that is wider than the lesion, if possible—ideally to perform the procedure in a single pass (see **Figure 8**), but given that most of the referrals are for large lesions, these often need to be done with two or more passes.

KEY POINT: The objective of the procedure is not only to **remove the entire lesion with a 5-mm margin,** but **also to remove the entire transformation zone.**

4. Place the loop in the electrosurgery pen.

5. Warn the woman that she will hear the smoke evacuator come on, then test that the unit is ready by briefly depressing the hand button or foot pedal.

Figure 8. Excision of an Ectocervical Lesion in a Single Pass



Source: Sellors JW and Sankaranarayanan R. 2003. *Colposcopy and Treatment of Cervical Intraepithelial Neoplasia: A Beginners' Manual,* p. 107. International Agency for Research on Cancer (IARC), World Health Organization. Accessed January 22, 2015. Available at: http://screening.iarc.fr/doc/Colposcopymanual.pdf.

6. Check again that the unit is set to the appropriate blended cutting and coagulation settings.

NOTE: Before starting the procedure, make sure the current is set for a blended setting and not cutting current.

7. Ensure adequate visualization of the cervix and lesion, that the vaginal walls are well-retracted, and that good light is positioned well for the procedure.

SPECIAL TIP: Use a wooden tongue blade, other retractor, or condom over the speculum to protect the vaginal wall if it is close to the cervix. In addition, a **large cotton swab** can be placed in the vaginal fornix and pressure applied in order to move the cervix into better view.

8. Plan the excision and practice the entry and exit points with the loop (NOT activated) to ensure that the entire lesion can be removed without hitting the vaginal wall. The starting point for excision is 5 mm outside the outer boundary of the lesion, and 3–5 mm outside the transformation zone. Orient the loop perpendicular to the surface of the ectocervix above the starting point (See **Figures 7, 8, and 9**). Tell the woman that the procedure is about to start.

KEY SAFETY POINT: Many lesions are quite large and may even extend onto the vaginal wall, particularly if the woman is HIV-positive. **Do NOT extend the excision on to the vaginal wall—** this will result in an increased risk of serious complications, such as hemorrhage and fistula. Also, remember that no anesthetic has been injected into the vaginal wall.

KEY SAFETY POINT: Do not inadvertently activate the electrode early, as this may lead to electrical burns to the patient if the electrode is touching the vulva or vaginal wall, or as the electrode is being advanced through the vagina to the cervix.

9. When the loop is ready just above the starting point, but not touching the tissue, activate the loop electrode/start the current by depressing the cutting button or foot pedal.

SPECIAL TIP: Activate the loop electrode before touching the tissue and finish the excision/cutting (loop exits the tissue) before deactivating the loop electrode.

10. Introduce the loop into the tissue, letting the loop cut its path, and not pushing it in.
11. Provide directional guidance to the loop, moving it very slowly but continuously, until a **depth of at least 5 mm** is reached**, but not more than 10 mm.**
12. Once the appropriate depth is reached, gradually guide the loop parallel to the surface of the ectocervix until it **reaches a point 5 mm outside the opposite outer boundary of the lesion.** Then withdraw the loop, **keeping it perpendicular to the surface of the ectocervix**. Stop the current/deactivate the loop electrode (release the button or foot pedal) as soon as the loop exits the cervix.

SPECIAL TIP: Maintaining proper orientation throughout the procedure and **appropriate speed are critical** to obtaining a good tissue specimen, minimizing bleeding, and promoting better healing. Jagged wound edges bleed more and do not heal as well as clean edges. **Passing the loop too quickly** does not allow the blended cutting to coagulate as it cuts, resulting in **poor hemostasis.** It also can produce drag and an **uneven cut,** which tends to bleed more and results in less optimal healing.

SPECIAL TIP: Do not stop activation of the loop while it is within the substance of the cervix. In order to activate the loop effectively and consistently, it must not be touching tissue. Therefore, if this happens, withdraw the loop and start from the opposite end and attempt to meet up where the previous excision ended.

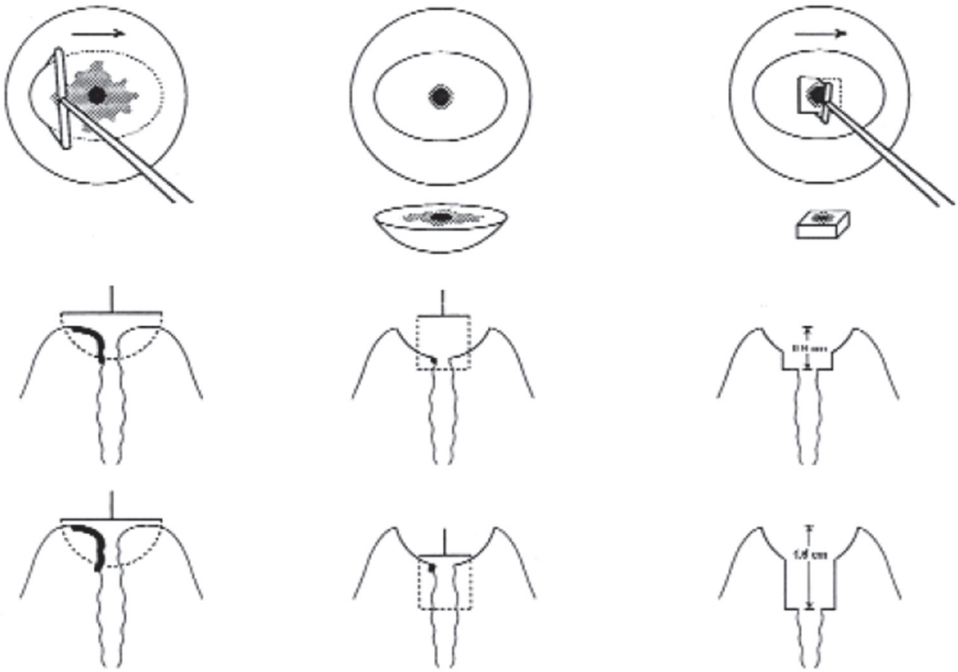
SPECIAL TIP: Direction of the pass is not important (left-to-right, right-to-left) and is **based on provider preference. However, a posterior-to-anterior pass is much more preferable than an anterior-to-posterior pass.** With an anterior-to-posterior pass, if bleeding occurs during the excision, it may trickle down and obscure the field as you are trying to complete the excision.

SPECIAL TIP: If multiple passes are required, it is **preferable to remove the posterior portion first, followed by the anterior portion.** In this way, if bleeding occurs from the cut edges (e.g., from the posterior pass), it will not flow into the surgical site of the second pass (anterior pass) and obscure the field.

13. Remove specimen(s) with a long tissue forceps and place in appropriately marked specimen containers with formalin.
14. If there is bleeding in the excisional crater, apply pressure with a large cotton swab or ring forceps/long tissue forceps with cotton ball or gauze.
15. Remove the loop and place it, along with tissue forceps, on the sterile surgical field for processing following the procedure. (See **Chapter 6, Infection Prevention for LEEP**.)

Endocervical Lesions: If a lesion extends into the endocervical canal and is unlikely to be removed with the typical ectocervical excision maneuvers as described above, a **two-layer** excisional method should be used. In this case, the ectocervical portion of the lesion is excised as previously described. **This is followed by a smaller loop, usually 10 mm x 10 mm** (see **Figure 9**) to excise the endocervical lesion. These types of excisions can extend to a total depth of 1.5 cm or more. Because this type of excision carries more risk (bleeding, stenosis, obstetrical complications), it should be performed only when necessary, and only by more experienced LEEP providers. If the lesion extends more than 1 cm into the endocervical canal, the woman should be referred for cold-knife cervical conization, if possible.

Figure 9. Two-Layer Excision of Ectocervical and Endocervical Lesions



Source: Sellors JW and Sankaranarayanan R. 2003. *Colposcopy and Treatment of Cervical Intraepithelial Neoplasia: A Beginners' Manual,* p.109 . International Agency for Research on Cancer (IARC), World Health Organization. Accessed January 22, 2015. Available at: http://screening.iarc.fr/doc/Colposcopymanual.pdf.

NOTE: If it is very hot with little ventilation, **the LEEP unit can overheat following repeated procedures.** This is a safety mechanism and the unit will shut down for about 15 minutes. If you have a fan, keep it blowing on the unit to keep it relatively cool.

SPECIAL TIP: If the woman complains of pain during the procedure, stop and inject more local anesthetic.

Hemostasis (Provider performs all of the following tasks):

Achieving hemostasis after excision of the LEEP specimen is critical to avoid excessive blood loss and can generally be accomplished by careful use of electrical coagulation. **A greater amount of bleeding is associated with larger specimens, deeper excisions, too little (or no) epinephrine, and by moving the loop too quickly during excision,** which does not allow enough time for the blended coagulation to occur.

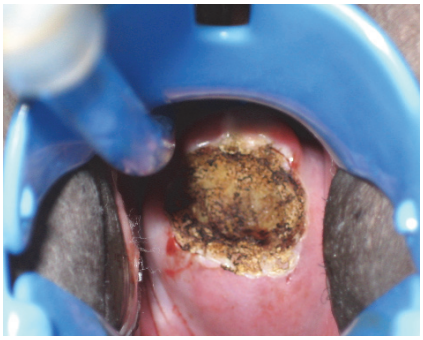
It is very important to be able to maintain a "clean" field of vision, especially following removal of the LEEP specimen. The bed or base where the tissue was removed can bleed heavily at times. To accurately determine the exact area of bleeding and for the ball coagulation to work effectively, the bed of the LEEP biopsy must be as dry as possible. This requires firm pressure on the bed followed by a quick look. Large, firmly made cotton swabs or ring forceps/long tissue forceps with small squares of cut gauze work well. Loosely made cotton swabs do not work well in this situation, as they cannot apply the appropriate amount of pressure and the loose cotton will often stick and obscure the field. **Coagulation does not work well when it is attempted through blood;** it works most effectively with a dry field.

1. Change the LEEP unit setting to coagulation and insert the 5-mm ball electrode into the electrosurgery pen.
2. **Coagulate bleeding areas first.** If no bleeding is present, starting with the edges of the crater, coagulate using the ball electrode. Remember that coagulation (or fulguration) works best when the ball electrode does not actually touch the tissue. The activated current "sprays" or "arcs" multiple sparks between the ball electrode and the tissue. For optimal effect, keep the area as dry as possible during this time (see **Figure 10**).

SPECIAL TIP: Coagulate every time. Even if an area does not have active bleeding, coagulate it because vasospasm (especially if epinephrine was used) may resolve and lead to delayed bleeding.

SPECIAL TIP: Start coagulation anteriorly, holding compression posteriorly and move downward once bleeding is controlled anteriorly; otherwise, blood will keep accumulating in the operative field. When coagulating, **blot, do not rub, tissue.**

Figure 10. Coagulation of Excisional Crater



3. If adequate hemostasis is achieved, **coat the base of the excisional crater with Monsel's solution or paste.** For particularly stubborn bleeding cases, apply a liberal amount of Monsel's with a large cotton swab and apply pressure for 1–2 minutes.
4. Remove the ball electrode and place it, along with the loop electrode, in a small basin/container for contaminated loop and ball electrode instruments. Hand the electrosurgery pen to the assistant.

5. Swab out from the vagina any remaining blood, clot, or excess Monsel's and dispose of in a leakproof container or plastic bag.

6. Gently remove the speculum. Wipe blood or Monsel's from blades, disconnect suction tubing from the speculum and hand tubing to the assistant, and place the speculum, along with the ring forceps/tissue forceps, in the basin/container for contaminated instruments.

Post-LEEP Tasks (Provider performs all of the following tasks, unless otherwise noted):

1. Remove gloves and place in leakproof container or plastic bag.
2. Put on new pair of non-sterile examination gloves.
3. Ensure that the woman is not having headaches, chest pain, nausea, excessive bleeding, or cramping, and that she feels well enough to get up. If not, allow her to rest, or take other appropriate steps as necessary.
4. PROVIDER OR ASSISTANT: If the woman feels well, give her a pad, and assist her in sitting up, getting off the examination table, and getting dressed. Ask her not to leave the clinic until she receives further instructions regarding self-care, warning signs, and follow-up.
5. PROVIDER OR ASSISTANT: Turn off power to the LEEP unit.
6. PROVIDER OR ASSISTANT: Wipe suction tubing, electrosurgery pen, and light source with 60–90% alcohol. Wipe the examination table or Macintosh cloth, and other contaminated surfaces, with alcohol or 0.5% chlorine solution.
7. PROVIDER AND ASSISTANT: Sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
8. PROVIDER: Advise the woman regarding post-treatment self-care, warning signs, and follow-up (see **Chapters 3 and 4**). Review post-LEEP instructions with the woman (including giving written instructions). Record treatment and follow-up on her client card.
9. PROVIDER: Record results on the proper forms and register/logbook. Fill out appropriate referral forms and pathology forms.

6. INFECTION PREVENTION FOR LEEP

INFECTION PREVENTION DURING LEEP AND PROCESSING OF LEEP EQUIPMENT AND INSTRUMENTS

The key objectives of infection prevention during LEEP and proper processing of LEEP equipment and supplies are to: 1) reduce the risk of infectious complications associated with LEEP, 2) prevent facility-related transmission of HIV or other blood-borne infections between LEEP clients, and 3) protect health care workers at all levels from exposure to disease. To achieve these objectives, LEEP providers and health care staff must:

- Apply **standard precautions** (previously known as universal precautions) with all LEEP clients.
- Use sterile gloves during LEEP.
- Use HLD/sterilized instruments, with appropriate handling and processing of LEEP equipment and supplies (see below for details), as well as soiled linen.
- Ensure appropriate handling/disposal of waste after each procedure.

INFECTION PREVENTION DURING LEEP

Standard precautions (WHO 2007) are the minimum infection prevention measures to be used with all clients. The key elements of standard precautions with LEEP include:

- **Hand hygiene** (handwashing, hand sanitizing). Perform before and after each procedure.
- **Gloves.** Use sterile surgical gloves during LEEP or if handling sterilized equipment, instruments, and supplies. Use clean, non-sterile examination gloves during bimanual examination and handling of non-sterile supplies. The assistant can wear clean, non-sterile examination gloves during the procedure if she/he will be handling only contaminated or non-sterile items.
- **Facial protection** (eyes, nose, mouth). Because LEEP is very unlikely to generate splashes or sprays of blood or body fluids, eye protection and a surgical mask are not necessary. In addition, a surgical cap is not required.
- **Gown**. Again, since LEEP is very unlikely to generate splashes or sprays of blood or body fluids, a gown is not necessary. However, in the process of performing VIA (or colposcopy) before LEEP, with swabbing blood from the vagina, or with the application of Monsel's solution, a plastic/rubber apron may be worn to protect clothing from spillage of blood or solutions. Remove a soiled gown or clean and disinfect a soiled apron following the procedure.
- **Prevent needle sticks and injuries from sharp instruments.** Use care when handling needles, and dispose of needles and other sharps in a properly labeled puncture-proof container.
- **Linens and drapes.** The linens and drapes are primarily to cover the genital area and provide privacy for the woman and they do not need to be sterile or HLD. However, they should be handled and processed appropriately to prevent transfer of pathogens to other clients or to providers and assistants.

- **Waste.** Treat waste contaminated with blood, body fluids, secretions, or excretions as clinical waste and handle/dispose of in accordance with local regulations.
- **Equipment, instruments, and supplies.** The handling and processing of LEEP equipment, instruments, and supplies will be detailed later in this chapter.

INFECTION PREVENTION STEPS FOR LEEP

NOTE: The following steps do not describe the LEEP technique in detail, which was covered in **Chapter 5**. However, pay attention to the numerous areas where IP practices occur during LEEP, and how a breakdown in any of these steps increases the risk of infection to the client, provider, and health facility staff.

IMMEDIATELY BEFORE LEEP

- PROVIDER AND ASSISTANT: Perform hand hygiene—sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
- PROVIDER AND ASSISTANT: Ensure that properly processed and stored LEEP equipment, instruments, and supplies are available and ready to use.
- ASSISTANT: Ensure that a table or stand with a sterile field (drape/towel or metal kidney dishes or basins) is ready for use.
- PROVIDER: Put on new examination gloves and perform bimanual examination, and remove and discard gloves appropriately.
- PROVIDER OR ASSISTANT: Put on sterile examination gloves and arrange instruments and supplies on the dry sterile field, if not already done.

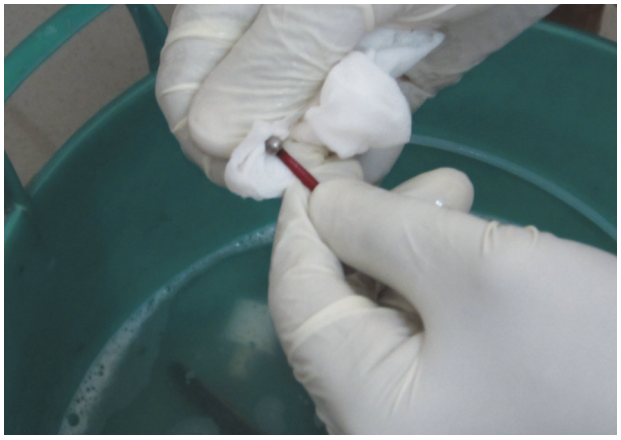
DURING LEEP

- PROVIDER: Put on new sterile examination gloves, if not already done.
- PROVIDER: Perform LEEP. Dispose of contaminated swabs/gauze appropriately throughout procedure.
- PROVIDER: Once excisions with the loop electrode and coagulation with the ball electrode are completed, remove the electrodes and place in a small basin/container for contaminated loop and ball electrode instruments.
- PROVIDER: Hand the electrosurgery pen to the assistant or place on the sterile field.
- PROVIDER: Using large swabs or gauze, swab out from vagina any remaining blood, clot, or excess Monsel's and dispose of appropriately.
- PROVIDER: Gently remove the speculum. Using gauze, wipe blood and/or Monsel's from blades, discard gauze appropriately, disconnect suction tubing from the speculum and hand tubing to assistant, and place the speculum, along with the ring forceps/tissue forceps, in the basin/container for contaminated instruments.

- PROVIDER: Remove gloves, dispose of appropriately, and put on new pair of non-sterile examination gloves.
- PROVIDER OR ASSISTANT: Wipe suction tubing, electrosurgery pen, and light source with 60–90% alcohol. Wipe the examination table or Macintosh cloth, and other contaminated surfaces, with alcohol or 0.5% chlorine solution. Dispose of gauze appropriately.
- PROVIDER AND ASSISTANT: Remove gloves and dispose of them appropriately.
- PROVIDER AND ASSISTANT: Sanitize hands with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry.
- PROVIDER AND ASSISTANT: Process and sterilize the loop and ball electrodes. Process and either HLD or sterilize the LEEP speculum (see **Figures 11A and 11B**).
- PROVIDER AND ASSISTANT: Ensure that the LEEP set-up is ready for the next procedure or stored properly until the next clinic.

Figure 11A. Cleaning the LEEP Speculum (including the smoke evacuator tubing, which can become clogged over time, prior to sterilization)

Figure 11B. Cleaning the Ball Electrode prior to Sterilization



Processing of LEEP Equipment, Instruments, and Supplies

(See **Appendix C: Job Aid for the Basic Care and Maintenance of LEEP Equipment, Instruments and Supplies and Appendix D: Summary of Steps Used for Processing Instruments and Other Items Used in LEEP Services**.)

Loop and Ball Electrodes – Chemical Sterilize

Proper sterilization and post-sterilization handling of the loop and ball electrodes are essential. These are the instruments that come in direct contact with the broken epithelial barrier of the client. Improper sterilization, improper post-sterilization handling and storage, or a breakdown in sterile surgical technique can increase the risk of infection for the woman undergoing LEEP.

NOTE: Typically, **loop and ball electrodes** are considered single-use and disposable. However, with proper handling and processing, these electrodes **can be autoclaved or chemically sterilized and reused—**a minimum of five times. Country experience has shown that with special care, the electrodes can be reused more than 20 times. The limiting factor in the number of times they can be used is that the loop wire does not cut as well, or it becomes brittle and breaks. The ball electrode coagulation effectiveness decreases with time, but with proper cleaning of debris from the ball electrode prior to sterilization, the life of the ball electrode can be extended similar to, or longer than, the life of the loop electrodes (see **Figure 12**).

Figure 12. Loop and Ball Electrodes in Separate Packaging for Sterilization and Storage

1. Following the procedure, put on new examination or utility gloves.
2. Gently wash the loop and ball electrodes with soapy water. Make sure all tissue and char are removed—do this ***gently*** with the loop, or it will break. A soft brush or gauze works well for this.
3. Rinse the loop and ball electrodes in water, then autoclave or chemically sterilize:
   - **Autoclave:** Autoclave loop and ball electrodes separately from other metal instruments. This reduces the risk of breaking the wire loop with heavier instruments, and with loops that have plastic shafts, reduces the risk of melting the shaft from contact with heated metal.

- **Chemical sterilization:** A good option for the electrodes is 2–4% glutaraldehyde (Cidex), if available. Make sure to follow the manufacturer's instructions regarding time for sterilization (generally 8–10 hours) and activated shelf-life (14 or 28 days, sooner if solution becomes cloudy). After sterilization, remove the electrodes with a sterile grasper, hold the electrodes with a sterile gloved hand, and rinse with sterile water.

4. Store sterilized instruments in sterilized packing or in a covered sterile container.

LEEP Speculum – High-Level Disinfection (HLD) or Sterilize

Because blood and other fluids/solutions will get on the speculum, special attention must be paid to the cleaning and sterilization process. Do **not** allow the speculum to soak in 0.5% chlorine solution for more than 10 minutes, as this will corrode this relatively expensive instrument.

1. Unscrew the speculum so that the blades come apart; put the screw back on its thread. This allows for more thorough cleaning.
2. Wash and scrub with soapy water. Gauze and/or a toothbrush are effective in getting blood and Monsel's off. Rinse in water. Put the blades back together.
3. The speculum can be either sterilized (autoclaved) in the usual manner or high-level disinfected (HLD). HLD options include:
   - 2–4% glutaraldehyde (Cidex) for 20 minutes

   Note: For the insulated instruments (speculum), it is preferable that one method or the other (heat or chemical) for HLD or sterilization be used consistently. Use of both techniques increases the risk of damage to the insulation, leading to increased risk of electrical shock or burn. **Regardless of the method used**, before each use, the LEEP speculum should be **inspected for breaks (cracked, worn, or exposed areas) in the insulation material** covering the speculum.

   - Boil or steam for 20 minutes.
   - Chlorine (0.1% solution—must use sterile or boiled water) for 20 minutes. Change solution daily or sooner if it becomes cloudy. Due to the risk of corrosion of this expensive speculum, chlorine is the least preferable of these methods.
4. Handle and store consistent with sterile or HLD principles.

Ring (Sponge Holder) Forceps, Tissue Forceps – HLD or Sterilize

Wash the ring forceps/long tissue forceps (if used) with soapy water.
Process similarly to the LEEP speculum (above).

Electrosurgery Pen – Disinfect

This is considered a disposable instrument but can be reused multiple times with proper care. Once the fitting of the electrode becomes loose or there is a poor connection and flow of the current, the pen should be changed.

- Following the procedure and with new examination gloves on, wipe down the electrosurgery pen with 60–90% alcohol or 0.5% chlorine solution, starting from the cord to the handle. Make sure fluid does not get into the electrode holder. If blood or Monsel's gets on the pen, remove it first with soapy gauze and wipe dry.
- Alternatively, decontaminate by soaking in 0.5% chlorine solution for 10 minutes. However, this risks decreasing the life of the electrosurgery pen by corroding the electrical connections.
- Store on a clean tray on the trolley.

Suction Tubing – Disinfect

Suction tubing is also considered disposable but can be reused multiple times. The outside of the tubing should be wiped with 60–90% alcohol or 0.5% chlorine solution. If the inside of the suction tubing becomes contaminated with blood or other body fluids, decontaminate by soaking the tubing (but not the filter if attached) in 0.5% chlorine solution for 10 minutes followed by thorough rinsing with clean water.

Dispersive Pad – Disinfect if Contaminated

It is reusable until good adhesion to the woman's thigh cannot be maintained.

Light Source, Examination Table – Disinfect

Wipe with 60–90% alcohol or 0.5% chlorine solution.

LEEP Electrosurgical Unit and Smoke Evacuator: Disinfect if Contaminated.

Wipe surfaces with 60–90% alcohol or 0.5% chlorine solution after disconnecting from the electrical source.

Disposable Supplies

- Dispose of needles and other sharps in a properly labeled, puncture-proof container.
- Ensure appropriate disposal of other non-reusable supplies after each procedure

7. IDENTIFICATION AND MANAGEMENT OF COMMON SIDE EFFECTS AND POTENTIAL COMPLICATIONS

COMMON SIDE EFFECTS AND POTENTIAL COMPLICATIONS

LEEP has a low rate of complications, especially serious complications, when performed by a trained, competent provider. However, a small proportion of women will develop complications, generally minor.

Most side effects associated with LEEP are not serious and will resolve without intervention. Most LEEP-related complications can be avoided, and side effects minimized, through:

- Carefully screening clients
- Strictly adhering to correct infection prevention techniques
- Performing LEEP with close attention to technical detail
- Properly counseling clients regarding self-care

Most side effects require only reassurance, while some problems or complications will require specific management. **Table 4** offers guidance to assist health care providers in reassuring patients or managing specific complications that may occur.

Table 4. Identification and Management of Common Side Effects and Complications Encountered at Follow-Up

Side Effects or Complications (Signs/Symptoms)	Explanation	Management
Vaginal Discharge: Side Effect Brown, grayish-black discharge, sometimes with some spotting lasting from a few days to 2–3 weeks. This is often followed by a thin, watery or non-purulent discharge for another 2–3 weeks. **Vaginal Discharge: Complication** Discharge that is yellow and malodorous, or associated with abdominal pain or fever	It is a common side effect to have a vaginal discharge as described. The brown, grayish-black discharge with some spotting is due to old blood/ fresh blood admixed with the cautery effect from LEEP and the Monsel's solution. The subsequent thin, watery or non-purulent discharge is the cervix undergoing the healing process. These types of vaginal discharges are normal and do not require intervention. Discharge that changes color to yellow or green, and has a foul odor, or is accompanied by pelvic/ abdominal pain +/- fever, is a sign of infection. The woman should be seen immediately for evaluation.	**History:** Determine severity and duration of symptoms: how much discharge is the woman having; what does it look like; is there foul odor associated with it; is it accompanied by other symptoms (e.g., pain, fever); when was the LEEP; did the woman have discharge immediately prior to LEEP; has the woman had sexual intercourse since the LEEP (and, if so, were condoms used) or put anything inside her vagina; is she HIV-positive? **Examination:** Perform an appropriate physical assessment: vital signs – temperature and pulse, abdominal examination; speculum and bimanual exam to assess possible cervicitis (localized cervical infection) and PID (upper genital tract infection) –cervical motion tenderness, uterine, and adnexal tenderness. Get laboratory studies as appropriate, e.g., complete blood count (CBC), cultures (if available). If the discharge is consistent with that expected following LEEP, provide reassurance. If cervicitis or PID is present, treat with antibiotics according to national guidelines and record the complication in the LEEP register/logbook. Severe PID may require hospitalization for close monitoring and intravenous antibiotic therapy.
Bleeding: Side Effect A small amount of bleeding (from spotting to no heavier than menses) for a few days up to 2 weeks **Bleeding: Complication** Bleeding heavier than the heaviest day of menses for 2 days and especially if bleeding is bright red and/or with clots	A small amount of bleeding or spotting from the LEEP site is not uncommon the first 2 weeks, and can even occur after a period of no bleeding at all. It usually resolves without intervention. In a small percentage of cases, spotting can last for up to 4 weeks. As long as the bleeding is not heavy and no other warning signs accompany it, no intervention is required. Heavy bleeding from LEEP is	**History:** Determine severity and duration of the signs and symptoms: how much bleeding is the woman having; when was the LEEP; when did bleeding start; has it changed; is the bleeding accompanied by other symptoms (e.g., pain, fever); and how well is the woman tolerating the bleeding, is she light-headed or weak? **Examination:** Vital signs: pulse, blood pressure, temperature; abdominal exam: tenderness; pelvic exam: speculum exam; active bleeding from LEEP site; clots; abnormal discharge; bimanual exam: cervical motion/uterine/or adnexal tenderness. If small amount of bleeding, no active bleeding site, or abnormal discharge or tenderness suggestive of infection: provide reassurance; reinforce need to avoid sexual intercourse until healing is complete. If the cervix is friable but no specific area of active bleeding, and there is abnormal cervical discharge and/or pelvic tenderness, treat for cervicitis or pelvic inflammatory

Side Effects or Complications (Signs/Symptoms)	Explanation	Management
	uncommon and usually occurs early following LEEP – usually within the first 24–48 hours; it is usually due to either: 1) inadequate hemostasis at time of LEEP, or 2) the hemostatic "plug" on the cervix came off. Heavy bleeding can also occur with cervical infection after LEEP.	disease according to national guidelines. If active bleeding from LEEP site: apply Monsel's solution; if bleeding is not controlled, consider exam under anesthesia with electrocautery and/or suture.

Side-Effects or Complications (Signs/Symptoms)	Explanation	Management

Infection
• Lower abdominal/pelvic pain
• Fever
• Abnormal vaginal discharge
• Friable cervix
	Cervicitis and/or pelvic inflammatory disease is uncommon after LEEP (0–2%). It is more likely if the woman has an infection at the time of the procedure, if sterile technique is not used, or if sexual activity is resumed before complete healing occurs. It is important that any existing infection be treated prior to LEEP.	**History:** What symptoms are present (e.g., pain, discharge, fever) and how long after the LEEP did they occur? What is their severity? Were any symptoms present when LEEP was performed? Are there other symptoms (e.g., nausea, vomiting, diarrhea, dysuria) that might suggest urinary or gastrointestinal infection? Has the woman had sexual intercourse since the LEEP (and, if so, were condoms used)? Is she HIV-positive?
		
		Examination: Perform an appropriate physical assessment, including: vital signs (temperature, pulse); abdominal exam: assess for tenderness; pelvic examination (speculum and bimanual): assess for abnormal vaginal/cervical discharge, cervical friability, cervical motion/uterine/adnexal tenderness.
		• Appropriate laboratory studies: pregnancy test, CBC, urinalysis, cultures (if available) to help rule out other problems, such as: appendicitis, pregnancy/ectopic pregnancy, or urinary tract infection.
		• If suspect cervicitis with friable cervix, abnormal or foul-smelling discharge, but without cervical/uterine/adnexal tenderness – Treat according to national guidelines:
		  • If suspect PID due to the following signs/symptoms found and no other causes can be identified:
		  – Lower abdominal, uterine, or adnexal tenderness (tenderness in the ovaries or fallopian tubes) +/- fever
		  – Evidence of cervical infection: yellow cervical discharge containing mucus and pus, cervical bleeding when it is touched with a swab
		  – Tenderness or pain when moving the cervix and uterus during bimanual exam (cervical motion tenderness)
		• Treat PID according to national standards; if PID is severe, hospitalization for IV antibiotics may be needed.

Side-Effects or Complications (Signs/Symptoms)	Explanation	Management
Cervical Stenosis **Presents as lack of menses (or very light flow), usually associated with severe cramping at expected time of menses**	Occurs in 4–8% of women after LEEP due to scarring over of cervical opening. More likely to occur with removal of larger and deeper specimens.	• **History**: Menstrual pattern and flow since LEEP; presence of pelvic pain or cramping. • **Examination**: Vital signs: temperature, pulse (should be normal in absence of infection); abdominal exam: assess for tenderness or mass; pelvic exam/speculum: assess for healed cervix with cervical opening scarred over or very small and does not admit small cotton tip or uterine sound; discharge should be normal in absence of infection; bimanual exam: assess for uterus that may be slightly enlarged and tender. • Laboratory tests: pregnancy test. • May attempt to probe with sound, small wire probe, or Pap smear cytobrush (may require counter-traction with tenaculum on cervix); if this is not possible or is unsuccessful, refer to higher level of care.
Fistula **(Leakage of urine or stool through vagina)**	Very rare occurrence; can occur with electrocautery damage to vaginal mucosa.	• **History**: Leakage of urine or stool or both through the vagina; onset and duration; type of leakage (if urine): continuous or with cough, or urgency; dysuria, blood in urine. • **Examination**: Vital signs: temperature, pulse; abdominal exam: tenderness, distention; pelvic exam: speculum: urine or stool in the vagina, defect in vaginal wall; bimanual exam: mass or tenderness. • Laboratory tests: urinalysis/culture to rule out infection. • Refer to higher level of care.
Pregnancy Complications (Preterm delivery)	Some studies show risk is increased, especially associated with deeper specimens, and repeat procedures.	• Women who have had LEEP (and especially if the LEEP was deep, or if a repeat LEEP), should be counseled about the risk and followed more closely in pregnancy for preterm labor

8. LEEP CLINICAL SERVICES

CLINICAL TEAM APPROACH

LEEP clinical services involve coordinated efforts by the members of a team. This includes a provider and an assistant. Some of the duties may be performed by either the provider or assistant, others will be the responsibility of one or the other. The provider is the person with overall responsibility for quality services. Depending on the setting, there may also be a supervisor on site or responsible for several sites. From the outset, it is very important to establish the individual responsibilities and lines of authority.

PREREQUISITES FOR LEEP SERVICE PROVISION

- Site staff and supervisors committed to providing LEEP services
- Adequate space to provide services, including privacy considerations
- Presence of staff who have been trained in VIA, VILI, or colposcopy and LEEP
- Adequate supplies, instruments, and equipment to perform LEEP
- Linkages with other sites performing VIA/cryotherapy so that women who require LEEP can be referred
- Linkages with sites providing pathology services: ideally provided for all LEEP specimens, but particularly important for cases with suspicion for invasive cancer

PRACTICE AND DEMONSTRATING COMPETENCE

LEEP should be performed only by those who have demonstrated clinical competence in the procedure. Prior to performing LEEP on a client, providers must demonstrate competence in:

1. Identifying precancerous lesions (with VIA, VILI, or colposcopy).
2. Using correct infection prevention practices.
3. Performing simulated LEEP on models, such as meat (chicken breast or beef tongue works well) or sausage. Ideally, practice should include using PVC tubing, with ability to evacuate smoke, to simulate actual performance of LEEP on a client as closely as possible.
4. Using the LEEP checklist.
5. Managing potential side effects and complications associated with LEEP.
6. Pre- and post-procedure counseling of clients.
7. Keeping accurate records and performing quality assurance procedures.

PROVISION OF SERVICES

The following are necessary components of service provision. It is helpful to start with an action plan to identify individual issues, an implementation plan, the person responsible and the completion date.

- Identification of the days/hours when services will be provided
- System for monitoring supplies:
  - Order supplies based on anticipated volume of clients; reassess on regular basis.
  - Develop a system for tracking expiration dates, when applicable.
- Maintenance plan for equipment with schedule
- Infection prevention protocol in place
- Communications between sites performing VIA/cryotherapy and those performing LEEP:
  - VIA/cryotherapy sites: should provide written or electronic communication about referrals (generally using a standardized form): name, reason for referral
  - Mechanisms for making appointments
  - LEEP sites: should provide written, oral or electronic communication about the procedure, any complications, and recommended follow-up
- Established responsibilities and line of authority
- Monitoring and evaluation plan
- Quality assurance plan

RECORD KEEPING

Good record keeping is an essential part of high-quality LEEP services. The following are key components of record keeping (written or electronic):

- Confidentiality: client information should be accessible only to providers and assistants and should be held by them to be strictly confidential
- Client name, identification number (if applicable), age, and address or other contact information
- Date of service
- Provider of services
- Complications, if any
- Other comments: e.g., pathology (if sent), etc.
- Follow-up
- HIV information: if possible, the following minimum information should be obtained:
  - HIV status
  - Most recent CD4 count
  - ART (Y/N)

Monitoring, Evaluation, and Quality Assurance:

The rationale for having monitoring, evaluation, and quality assurance/quality control in a VIA-based LEEP program is to ensure high-quality services. Ensuring quality in a cervical cancer prevention program includes ensuring that performance standards are being achieved. Program monitoring and evaluation should generally be performed on a monthly, quarterly, and yearly basis. The Ministry of Health and/or other funders may require official reports at other intervals. 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* (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 of 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 LEEP, recommended core performance indicators include the following, **all disaggregated by HIV status:**

- **Treatment rate:** Number and percentage of women referred for LEEP who complete treatment in a defined period.
  - Treatment rate should be at least 90%.
- **Complication Rate:** Number and percentage of LEEP-related complications (e.g., post-LEEP infection, hemorrhage) in a defined period. This is a safety indicator.
  - Complication rate should be less than 2%.
- **Effectiveness:** Percentage of women who are screen-negative for cervical disease 12 months following LEEP.
  - Screen-negative rate at 1-year post-LEEP should be at least 90%.

In addition, where pathology services are available and feasible to obtain, there should be **correlation of pathology with pre-LEEP diagnosis.**

The Framework

Proper monitoring and evaluation allows a program to track progress, identify areas that are performing well, and identify areas where a gap in quality exists and corrective action should be taken.

Evidence-based cervical cancer prevention policies and guidelines provide the overall programmatic framework essential to implementation of QA in a cervical screening program (WHO/PAHO 2013).

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

- 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, to make recommendations for improving care, and to develop an action plan. During the SS visit, the **trainer/supervisor*** should use an **SS tool** as a guide to conduct the following tasks to achieve these objectives and document them:

- Assesses provider performance using the performance standards (based on the clinical skills checklists used during training):
  - Assesses the provider performing LEEP with clients (ideally) or in simulation;
  - Assesses client-provider interaction;
- Assesses facility readiness;
- Reviews data management and the core indicators for the facility; 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 requisite 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

Note: Defaulting LEEP sites should have more visits planned until the trainer/supervisor is satisfied with the minimum quality of care and service provision.

Table 5. 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, LEEP, infection prevention, data management). • Ensure that the day of the visit is a LEEP service day and that women are scheduled to receive services.

Ensure availability of all materials required	• Print copies of the agreed 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.
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 logbooks 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.
Communication 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.
Update logbooks and/or computer databases	• The person conducting the visit will want to review the data collected in the logbooks and/or computer databases. • Ensure that these are up-to-date and, if possible, calculate the necessary indicators.

Adapted from: 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 (VIA)-Based Programmes,* p. 11. Accessed January 22, 2015.Available at: http://apps.who.int/iris/bitstream/10665/79316/1/9789241505260_eng.pdf?ua=1

Sufficient time should be allocated for each LEEP SS visit, which should take 1–2 days to conduct. The action plan that was developed from the previous visit should be reviewed prior to the visit, and again during the visit with the facility supervisor and designated staff. While it may not be necessary, or feasible, to assess every LEEP provider at every LEEP 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 LEEP SS visit also serves as an opportunity for trainers/supervisors to mentor and update LEEP providers and to work

collaboratively with them to resolve any identified issues. During the LEEP SS visit and before its conclusion, the trainer/supervisor reviews the findings of the visit with the facility supervisor and LEEP 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 LEEP SS evaluation report and shares it with the facility and appropriate district-level officials.

APPENDIX A. JOB AID FOR LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP)

Indications for Using LEEP

• Treatment of precancerous lesions determined by one of the following:
  ◦ Colposcopy or cervical biopsy
  ◦ VIA-positive
  ◦ VILI-positive
• LEEP is generally reserved for **large precancerous lesions not eligible for cryotherapy,** but can be used for smaller, cryotherapy eligible lesions also.
• **Biopsy, not treatment, of cervical lesions suspicious for cancer**

Eligibility Criteria for LEEP
• Lesion is **VIA-positive** (or by VILI or colposcopy/biopsy). • **Lesion is not suspicious for cancer** (unless LEEP is being done as a biopsy and not treatment). • **The full extent of the external lesion can be identified.** If the lesion extends into the endocervical canal, attempts should be made to visualize its extent, and a multiple pass procedure should be utilized to get deeper into the endocervical canal. • **No evidence of PID, cervicitis, vaginal infection, anogenital ulcer, or a bleeding disorder.** • Client is **not pregnant**. • Client is **more than 12 weeks postpartum.** • **If client is hypertensive, hypertension should be well-controlled, and use local anesthetic without epinephrine (similarly in women with cardiovascular disease).**

Before LEEP
1. **Establish purpose of visit –** *Provider* 2. **Explain why the treatment is recommended and describe LEEP –** *Provider* 3. **Assess for risk factors to treatment** (including checking blood pressure), and based on history, ensure no contraindications exist for treatment – *Provider* *4.* **Counsel regarding LEEP:** what to expect, potential complications, self-care, and follow-up – *Provider and Assistant* *5.* Ask the woman if she has any questions and **obtain her consent** for treatment – *Provider and Assistant* 6. If not already done, **sanitize hands** with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with clean, dry cloth or air dry – *Provider and Assistant* 7. **Check that LEEP equipment, instruments, supplies, light source, and power source are available and ready to use –** *Provider and Assistant* 8. Check that the woman has **recently emptied her bladder** (within 30 minutes), help her onto examining table, and drape her – *Assistant*

During LEEP
1. **Perform bimanual examination followed by VIA/VILI/colposcopy.** Determine if the woman meets eligibility criteria for LEEP, or if some other management is more appropriate. **Determine size loop(s) needed, anticipated number of passes**, and ensure that loops and ball electrode are ready on the table. Remove speculum – *Provider* 2. **Attach suction tubing** to the coated LEEP speculum (do not contaminate speculum blades) and place near edge of HLD/sterile tray or field. – *Assistant* (Alternatively, this step can be performed by the *Provider* during the next step, prior to performing abdominal and bimanual examination.) 3. **Attach dispersive (grounding) pad** to woman's thigh. – *Assistant* 4. Put on a new pair of **sterile examination gloves and arrange instruments and supplies on a high-level disinfected/sterile tray, kidney dish, or towel on the trolley**, if not already done. – *Provider or Assistant* 5. Gently **insert speculum** and fix blades in the open position, as wide as possible without creating discomfort. If necessary, use coated vaginal wall retractors, wooden spatulas, or a condom for better exposure and to protect the vaginal walls. – *Provider* 6. **Establish local anesthesia.** Do not use lignocaine with epinephrine if the woman has high blood pressure or cardiac disease. – *Provider* 7. **Insert appropriate-sized loop** in electrosurgery pen and **set on blended cutting** at appropriate power**.** Briefly depress button on pen or depress foot pedal to ensure that LEEP unit, including smoke evacuator, is working properly. – *Provider* 8. **Ensure adequate visualization and vaginal wall retraction**. – *Provider* 9. **Excise entire lesion and transformation zone. Orient loop correctly and just above starting point. Activate electrode and introduce the loop into the tissue,** providing directional guidance, maintaining correct orientation throughout the procedure. **Excise 5 mm outside outer boundary of lesion and to a depth of at least 5 mm but not more than 10 mm. Maintain activated loop until loop exits the cervix tissue.** – *Provider* 10. **Remove specimen(s)** with long tissue forceps and place in appropriately marked specimen containers with formalin. – *Provider* 11. Apply pressure to cervix if necessary to control bleeding. **Perform additional passes if necessary.** Once excisions are completed, **remove loop and place on sterile surgical field, along with long tissue forceps, for processing following the procedure.** – *Provider* 12. **Change** LEEP unit setting to **coagulation and insert 5-mm ball electrode** into electrosurgery pen. – *Provider* 13. **Achieve hemostasis. Coagulate bleeding areas first.** If no bleeding is present, start with the edges of the crater, **coagulate using the ball electrode** with proper technique (keeping area dry and arcing the current). – *Provider* 14. If adequate hemostasis is noted, coat the base of the excisional crater with Monsel's solution or paste.). – *Provider* 15. **Remove ball electrode and place** it, along with ring forceps/tissue forceps, if used, **in basin/container for contaminated instruments.** Hand the electrosurgery pen to the assistant. – *Provider* 16. Gently **remove speculum**. **Wipe blood or Monsel's from blades** (discard in leakproof container or plastic bag), **disconnect suction tubing** from speculum and hand tubing to assistant, and **place speculum in basin/container for contaminated instruments.** – *Provider*

After LEEP

1. **Remove gloves, dispose of properly, and put on new pair of non-sterile examination gloves.** – *Provider*
2. **Check to be sure woman is doing well** before helping her sit up, get down from table, and get dressed. – *Provider or Assistant*
3. **Turn off power to LEEP unit.** – *Provider or Assistant*
4. **Disinfect suction tubing, electrosurgery pen, light source, examination table or Macintosh cloth, and other contaminated surfaces** with 60–90% alcohol or 0.5% chlorine solution. – *Provider or Assistant*
5. **Remove gloves and dispose of them in leakproof container or plastic bag.** – *Provider or Assistant*
6. **Sanitize hands** with alcohol-based sanitizer, or wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry. – *Provider or Assistant*

Post-LEEP counseling

7. **Advise the woman regarding post-treatment self-care, warning signs, and follow-up. Review post-LEEP instructions with the woman (including giving written instructions).** – *Provider and Assistant*
   - **Self-care:**
     - Provide a sanitary pad.
     - It is normal to have a brown, grayish-black discharge, sometimes with a small amount of spotting lasting from several days to 2 weeks following LEEP. This is often followed by thin, watery or non-purulent discharge for another couple of weeks while the cervix heals.
     - Do not put anything in the vagina for 4 weeks (no sexual intercourse, no tampons, no fingers); provide condoms if she cannot abstain from sexual intercourse.
   - **Advise the woman to seek care immediately if any of the following early warning signs occur (usually within the first 2–4 weeks):**
     - Fever for more than 2 days
     - Severe lower abdominal pain, especially if fever is present
     - Foul-smelling or pus-colored discharge
     - Bleeding heavier than heaviest days of menstrual bleeding for more than 2 days
     - Bleeding with clots
8. **Record treatment in her client card** and advise her to follow up in the clinic in 6 weeks. – *Provider*
9. **Process and sterilize loop and ball electrodes. Process and either HLD or sterilize LEEP speculum. –** *Provider and Assistant*
10. **Fill out appropriate pathology forms and process specimens.** – *Provider*
11. **Ensure LEEP set-up is ready for next procedure or stored properly** until the next clinic. – *Provider and Assistant*

APPENDIX B. JOB AID FOR LEEP COUNSELING AND CLIENT ASSESSMENT

Step	Objective
Review referral form and information **Ask woman if she understands why she was referred for LEEP**	• To determine reason the woman was referred for LEEP • To determine the woman's level of understanding before proceeding with counseling

Step	Objective	Ask about/Evaluate for	Client Assessment/Considerations
Take a targeted reproductive and medical history	• To assess for risk factors for treatment complications and to ensure no contraindications exist for treatment. Ask specific questions that may reveal information that would require a change in management, including:	• Recent or current pregnancy	• LEEP should not be performed during pregnancy and not until at least 3 months postpartum.
		• Current abnormal vaginal/cervical discharge and/or pelvic pain or anogenital ulcer; evaluate for cervicitis, PID, or other genital tract infection	• Genital and pelvic infections should be treated according to national guidelines before LEEP is performed. LEEP can be performed 4 weeks following treatment.
		• Current vaginal bleeding (unless only spotting)	• It is advisable not to attempt to perform LEEP when a woman has bleeding heavier than just some spotting. If it is menstrual bleeding, ask her to return after menses is completed. If abnormal bleeding, evaluate or refer for evaluation, as indicated (rule out pregnancy!). At a minimum, a pelvic and speculum examination should be conducted to assess for cervical cancer, or other obvious causes (e.g., large endocervical polyp, prolapsed fibroid).
		• HIV status	• HIV status: HIV-positive women are at increased risk of recurrence, and should be followed more closely than their HIV-negative counterparts.

Step	Objective	Ask about/Evaluate for	Client Assessment/Considerations
Take a targeted reproductive and medical history	• To assess for risk factors for treatment complications and to ensure no contraindications exist for treatment. Ask specific questions that may reveal information that would require a change in management, including:	• History of STIs (e.g., chlamydia, gonorrhea)	• If recent and not treated (or high risk for re-infection following treatment), post-LEEP infection risk increased significantly. Screen for and counsel regarding high-risk behaviors before deciding to proceed with LEEP.
		• Hypertension or other cardiovascular disease	• Hypertension or other cardiovascular disease: If poorly controlled chronic hypertension, the use of adrenaline or epinephrine with the local anesthetic (lignocaine/lidocaine) is contraindicated. The woman should also be referred for treatment and ongoing care for her hypertension.
		• Presence of bleeding disorder	• Presence of a bleeding disorder with a history of easy bleeding should alert the LEEP provider to consider a change in management, e.g., perform LEEP in the operating theater or use a slower technique with more coagulation during the excision.
Step		**Advantages**	**Limitations**
Explain purpose of LEEP	• Removes precancerous lesions and prevents progression to invasive cancer: • Can help diagnose cancer if present so that appropriate treatment can be arranged	• More effective with larger lesions or lesions that extend into the cervical canal • Provides pathology specimen, when pathology is available • Effectiveness (cure rate): In general, 96% or higher	• Recurrence or persistence rates are higher in women with HIV infection. • Possibility of complications but rates are low and most side effects minor.
Step	**Points to cover in steps of LEEP and what to expect**		
Describe LEEP	• Set-up • Sounds client will hear • Local anesthesia • Expected sensations during LEEP • Length of time for LEEP • Expected side effects • Self-care • Possible complications • Warning signs • When to return for follow-up		

Step	Consent	
Obtain consent	Oral or written, according to local standards, guidelines, and legal requirements	
Step	**Points to cover**	
Provide post-LEEP counseling	• Review how LEEP went • Review expected side effects • Review self-care • Review possible complications • Review warning signs and what to do if she develops any • When to return for follow-up • Provide written instructions	

APPENDIX C. JOB AID FOR BASIC CARE AND MAINTENANCE OF LEEP EQUIPMENT, INSTRUMENTS, AND SUPPLIES

LEEP ELECTROSURGERY UNIT

The LEEP electrosurgery unit (or "LEEP unit") provides the power and different waveforms for cutting and coagulation. Refer to the specific manufacturer's manual for details on settings for blended cutting and coagulation. The LEEP unit has inputs for the dispersive pad and electrosurgery pen, and the unit will not function without these being properly attached. Most LEEP units also have a smoke evacuator and filter as part of the unit; if not, these are small, separate components. Even if the smoke evacuator is part of the LEEP unit, it often has a separate power switch and the provider must turn it on before proceeding with LEEP.

SPECIAL TIP. If it is very hot with little ventilation in the room, the LEEP unit can overheat following repeated procedures. It's a safety mechanism and the unit will shut down for about 15 minutes. If you have a fan, keep it blowing on the unit to keep it relatively cool.

The LEEP unit is subject to corrosion from environmental elements and fluids. Therefore, do not place liquids directly on the unit, and do not store where water may drip onto it (leaky ceilings/near open windows). When it is not in use, it is recommended that it be covered with a water-resistant sheet, or at least a cloth sheet, especially in high-humidity areas.

Some LEEP units have internal filters that need to be replaced annually. Refer to the manufacturer's manual for details on the recommended frequency for all filter replacement.

LOOPS AND BALL ELECTRODES

Proper sterilization and post-sterilization handling and storage decrease the risk of infection for the woman undergoing LEEP. In addition, proper handling increases the number of times a loop or ball electrode can be effectively used, resulting in decreased cost of providing LEEP services.

1. Gently wash the loop and ball electrodes with soapy water. Make sure all tissue and char are removed—do this ***gently*** with the loop, or it will break. A soft brush or gauze works well for this.
2. Rinse the loop and ball electrodes in water, then autoclave or chemically sterilize.
   - **Autoclave:** Autoclave loop and ball electrodes separately from other metal instruments. This reduces the risk of breaking the wire loop with heavier instruments, and with loops that have plastic shafts, reduces the risk of melting the shaft from contact with heated metal.
   - **Chemical sterilization:** A good option for the electrodes is 2–4% glutaraldehyde (Cidex), if available. Make sure to follow the manufacturer's instructions regarding time for sterilization (generally 8–10 hours) and activated shelf-life (14 or 28 days, sooner if solution becomes cloudy). After sterilization, remove the electrodes with a sterile grasper, hold the electrodes with a sterile gloved hand, and rinse with sterile water.

3. Store sterilized instruments in sterilized packing or in a covered, sterile container.

LEEP Speculum – High-Level Disinfect (HLD) or Sterilize

Since blood and other fluids/solutions will get on the speculum, special attention must be paid to the cleaning and sterilization process. Before soaking the speculum, the provider should use gauze to wipe off as much blood and/or Monsel's from the speculum as possible. If decontaminating before HLD, do not allow the speculum to soak in 0.5% chlorine solution for more than 10 minutes, as this will corrode this relatively expensive instrument.

1. Following the procedure, put on new examination or utility gloves.
2. Unscrew the speculum so that the blades come apart; put the screw back on its thread. This allows more thorough cleaning.
3. Wash and scrub with soapy water. Gauze and/or a toothbrush are effective in getting blood and Monsel's off. Rinse in water. Put the blades back together.
4. The speculum can be either sterilized (autoclaved) in the usual manner or high-level disinfected (HLD). HLD options include:
   - 2–4% glutaraldehyde (Cidex) for 20 minutes

     Note: For the insulated instruments (speculum), once 2–4% glutaraldehyde is used for HLD or sterilization, the instrument should not be autoclaved in the future. Use of both techniques can lead to damage of the insulation, leading to increased risk of electrical shock or burn.

   - Boil or steam for 20 minutes
   - Chlorine (0.1% solution—must use sterile or boiled water) for 20 minutes. Change solution daily or sooner if it becomes cloudy. Due to the risk of corrosion of this expensive speculum, chlorine is the least preferable of these methods.
5. Handle and store consistently with sterile or HLD principles.

Ring (Sponge Holder) Forceps, Tissue Forceps – HLD or Sterilize

Process similarly to LEEP speculum above.

Electrosurgery Pen – Disinfect

This is considered a disposable instrument but can be reused multiple times (between 20 and 50 times) with proper care. Once the fitting of the electrode becomes loose or there is a poor connection and flow of the current, the pen should be changed.

1. Following the procedure and with new examination gloves on, wipe down the electrosurgery pen with 60–90% alcohol or 0.5% chlorine solution, starting from the cord to the handle. Make sure fluid does not get into the electrode holder. If blood or Monsel's gets on the pen, remove it first with a piece of soapy gauze and wipe dry.

2. Alternatively, decontaminate by soaking in 0.5% chlorine solution for 10 minutes. However, this risks decreasing the life of the electrosurgery pen by corroding the electrical connections.
3. Store on a clean tray on the trolley.

Suction Tubing – Disinfect

Suction tubing is also considered disposable but can be reused multiple times. The outside of the tubing should be wiped with 60–90% alcohol or 0.5% chlorine solution. If the inside of the suction tubing becomes contaminated with blood or other body fluids, decontaminate by soaking the tubing (but not the filter if attached) in 0.5% chlorine solution for 10 minutes, followed by thorough rinsing with clean water.

Dispersive Pad – Disinfect if Contaminated

The pad is reusable until good adhesion to the woman's thigh cannot be maintained.

APPENDIX D. SUMMARY OF STEPS FOR PROCESSING INSTRUMENTS AND OTHER ITEMS USED IN LEEP SERVICES

Item	Surface Disinfection	Decontamination	Cleaning	HLD	Sterilization
	• Reduces microbial contamination of noncritical surfaces (i.e., those that come in contact with intact skin) with short contact times	• Makes objects safer to handle before cleaning; rapidly inactivates HIV and hepatitis B virus: →reduces risk of hepatitis B and HIV transmission	• Removes all visible blood, body fluids, tissue, and dirt • Makes HLD and sterilization more effective	• If sterilization is not practical or possible (except loop and ball electrodes must be sterilized); destroys all viruses, bacteria, parasites, fungi, but not reliably all bacterial endospores	• Alternative method of final processing; destroys all microorganisms including endospores
Examination table top, light source, and other large surface areas	Wipe off with: • 0.5% chlorine solution, or • 60–90% isopropyl or ethyl alcohol.	• Not practical in most cases. • May consider for certain items, such as smoke evacuation tubing/connectors that become visibly contaminated with blood on the interior of the tubing.	Wash with soap and water if organic material remains after surface disinfection.	Not necessary	Not necessary
Certain instruments used for LEEP: • Speculum • Ring/ tissue forceps • Retractor (metal)	Carefully wipe off excess blood and body fluids with gauze (not with chlorine or alcohol solution) before decontamination. This will make decontamination process more effective, and will prolong the time between needing to make a new basin of 0.5% chlorine solution.	Soak in 0.5% chlorine solution for 10 minutes before cleaning. Rinse or wash immediately.* Note: The LEEP speculum is susceptible to corrosion. Do not let it soak in 0.5% chlorine solution for more than 10 minutes. Alternatively, it can be soaked in soapy water before cleaning.	Using a soft brush, wash with soap and water. Rinse with clean water. If they will be sterilized, air or towel dry and package. Note: Pay special attention to speculum joints and screws. When the speculum is heavily soiled, it is often easier to take the speculum apart to facilitate cleaning.	• Steam or boil for 20 minutes. • Chemically HLD by soaking in 2–4% glutaraldehyde (Cidex) solution for 20 minutes. Rinse well with boiled water and air dry before use or storage. • Change solution every 14–28 days (read manufacturer's instructions) – sooner if solution becomes cloudy.	• Dry heat for 1 hour after reaching 170°C (340°F), or • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in2) for 20 minutes(30 minutes, if wrapped).

Item	Surface Disinfection	Decontamination	Cleaning	HLD	Sterilization
Loop and ball electrodes	Not necessary	The loop and ball electrodes are especially susceptible to corrosion. Therefore, **do not** soak them in 0.5% chlorine solution.	Prior to cleaning, the loop and ball electrodes can be soaked in soapy solution for a short period of time (10–20 minutes) to help loosen any adhered blood or tissue. Using a toothbrush or gauze, ***gently*** wash with soap and water. Rinse with clean water.	• HLD is not appropriate. • These items must be sterilized.	• Chemical sterilize by soaking in 2–4% glutaraldehyde (Cidex) solution for 8–10 hours (read manufacturer's instructions). Rinse well with sterile water or normal saline solution and air dry before use or storage. • Change solution every 14–28 days (read manufacturer's instructions) – sooner if solution becomes cloudy. **NOTE:** Do not autoclave the LEEP speculum if it has undergone chemical sterilization previously, due to potential breakdown of the insulation material if both methods are used.

Item	Surface Disinfection	Decontamination	Cleaning	HLD	Sterilization
Storage containers for instruments		Soak in 0.5% chlorine solution for 10 minutes before cleaning. Rinse or wash immediately.	Wash with soap and water. Rinse with clean water, air or towel dry.	Boil container and lid for 20 minutes. If container is too large: • Fill container with 0.5% chlorine solution and soak for 20 minutes. • Rinse with water that has been boiled for 20 minutes and air dry before use.	• Dry heat for 1 hour after reaching 170°C (340°F), or • Autoclave at 121°C (250°F) and 106 kPa (15 lb/in2) for 20 minutes (30 minutes, if wrapped).

Avoid prolonged/excessive exposure to chlorine solution (more than 20 minutes, more than 0.5%) to minimize corrosion of instruments and deterioration of rubber or cloth products.

REFERENCES

Abha S, Arthur B, Agarwal V. 2011. LEEP verses cryotherapy in CIN. *The Journal of Obstetrics and Gynecology of India* 61(4): 431–435.

Adjorlolo-Johnson G, Unger ER, Boni-Ouattara E, et al. 2010. Assessing the relationship between HIV infection and cervical cancer in Côte d'Ivoire: A case-control study. *BMC Infect Dis* 10: 242.

Ahdieh L, Munoz A, Vlahov D, Trimble C, Timpson L, Shah K. 2000. Cervical neoplasia and repeated positivity of human papillomavirus infection in human immunodeficiency virus-seropositive and -seronegative women. *Am J Epidemiol* 151(12): 1148–1157.

Alliance for Cervical Cancer Prevention (ACCP). 2011. Cervical Cancer Prevention Fact Sheet: Recent Evidence on Cervical Cancer Screening in Low-Resource Settings. Available at: http://screening.iarc.fr/doc/ACCP_cxca_screening_2011.pdf

Alliance for Cervical Cancer Prevention (ACCP). 2009. *Cervical Cancer Prevention FACT SHEET*: New evidence on the impact of cervical cancer screening and treatment using HPV DNA tests, visual inspection, or cytology, ACCP: Seattle, WA. Available at: http://screening.iarc.fr/doc/ACCP_screening_factsheet_July09.pdf

Alliance for Cervical Cancer Prevention (ACCP). 2007. *Cervical Cancer Prevention FACT SHEET*: 10 Key Findings and Recommendations for Effective Cervical Cancer Screening and Treatment Programmes, ACCP: Seattle, WA. Available at: http://www.rho.org/files/ACCP_recs_2007.pdf.

Alliance for Cervical Cancer Prevention (ACCP). 2004. *The Case for Investing in Cervical Cancer Prevention*: *Cervical Cancer Prevention Issues in Depth, No. 3.* ACCP: Seattle, WA.

Alliance for Cervical Cancer Prevention (ACCP). 2003. *Effectiveness, Safety, and Acceptability of Cryotherapy: A Systematic Literature Review Cervical Cancer Prevention Issues in Depth, No. 1.* ACCP: Seattle, WA.

American College of Obstetricians and Gynecologists (ACOG). 2013. Management of abnormal cervical cancer screening test results and cervical cancer precursors. Practice Bulletin 140. *Obstetrics and Gynecology* 122: 1238–1267.

American College of Obstetricians and Gynecologists (ACOG). 2012. Screening for cervical cancer. Practice Bulletin 131. *Obstetrics and Gynecology* 120: 1222–1238.

American College of Obstetricians and Gynecologists (ACOG). 2010. Human papillomavirus vaccination. Committee Opinion No. 467. *Obstetrics and Gynecology* 116: 800–803.

American Society for Colposcopy and Cervical Pathology (ASCCP). 2013. 2012 Updated Consensus Guidelines Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. *Journal of Lower Genital Tract Disease* 17(5): S1–27.

Anorlu RI. 2008. Cervical cancer: The sub-Saharan African perspective. 2008. *Reprod Health Matters* 16(32): 41–49.

Bingham A, Bishop A, Coffey P, et al. 2003. Factor affecting utilization of cervical cancer prevention services in low-resource settings. *Salud de Publica de México* 45(2): S283–291.

Bradley J, Barone M, et al. 2005. Delivering cervical cancer prevention services in low resource settings. *International Journal of Gynecology & Obstetrics* 89: 30–37.

Branca M, Gabruglia AR, Benedetto A, et al. 2003. Factors predicting the persistence of genital human papillomavirus infections and Pap smear abnormality in HIV-positive and HIV-negative women during prospective follow up. *International Journal on STD AIDS* 14: 417–425.

Castilaw D, Wittet S, 2007. Preventing cervical cancer: Unprecedented opportunities for improving women's health. *Outlook* 23(1). PATH: Seattle, WA. Available at: http://www.rho.org/files/PATH_outlook23_1_web.pdf.

Centers for Disease Control and Prevention (CDC). 2012. *Human Papillomavirus: Epidemiology and Prevention of Vaccine-Preventable Diseases*. Available at: http://www.cdc.gov/vaccines/pubs/pinkbook/hpv.html (Accessed November 26, 2013)

Cervical Cancer Action (CCA). 2012. *Progress in Cervical Cancer Prevention: The CCA Report Card* (December 2012). Available at: http://www.cervicalcanceraction.org/pubs/CCA_reportcard_low-res.pdf.

Charmot E, Kristensen S, Stringer J, Mwanahamuntu M. 2010. Are treatments for cervical precancerous lesions in less-developed countries safe enough to promote scaling-up of cervical screening programs? A systematic review. *BMC Women's Health* 10: 11.

Chaturvedi AK, Madeleine MM, Biggar RJ, Engels EA. 2009. Risk of human papillomavirus-associated cancers among persons with AIDS. *J Natl Cancer Inst* 101(16): 1120–1130.

Chirenje ZM, Rusakaniko S, Akino V and Mlingo M. 2001. A randomised clinical trial of loop electrosurgical excision procedure (LEEP) versus cryotherapy in the treatment of cervical intraepithelial neoplasia. *Journal of Obstetrics and Gynaecology* 21(6): 617–621.

Chung MH, McKenzie KP, Richardson BA, John-Stewart GC, Coombs RW, De Vuyst H, Njoroge JW, Nyongesa-Malava E, Sakr SR, Mugo NR. 2011. Cervical HIV-1 RNA shedding after cryotherapy among HIV-positive women with cervical intraepithelial neoplasia stage 2 or 3. *AIDS* 25(15): 1915–1919. doi: 10.1097/QAD.0b013e32834a3654.

Cronje HS. 2004. Screening for cervical cancer in developing countries. *International J Gynaecol Obstet* 84(2): 101–108.

de Sanjose S, Quint WG, Alemany L, Geraets DT, et al. 2010. Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study. *Lancet Oncol* 11(11): 1048–1056.

De Vuyst H, Lillo F, Broutet N, Smith JS 2008. HIV, human papillomavirus, and cervical neoplasia and cancer in the era of highly active antiretroviral therapy. *Eur J Cancer Prev* 17(6): 545–554.

Denny L, Boa R, Williamson AL, Allan B, Hardie D, Stan R, Myer L. 2008. Human papillomavirus infection and cervical disease in human immunodeficiency virus-1-infected women. *Obstet Gynecol* 111(6): 1380–1387.

Denslow SA, Rositch AF, Firnhaber C, Ting J, Smith JS. 2013. Incidence and progression of cervical lesions in women with HIV: A systematic global review. *Int J STD AIDS*. [Epub ahead of print]

Ferlay J, Shin H, Bray F, Forman D, Mathers C, Parkin D. *GLOBOCAN 2008 v2.0, Cancer Incidence and Mortality Worldwide.*: IARC CancerBase No. 10. Available at: http://globocan.iarc.fr.

Firnhaber C, Zungu K, Levin S, Michelow P, Montaner LJ, McPhail P, Williamson AL, Allan BR, Van der Horst C, Rinas A, Sanne I. 2009. Diverse and high prevalence of human papillomavirus associated with a significant high rate of cervical dysplasia in human immunodeficiency virus-infected women in Johannesburg, South Africa. *Acta Cytol* 53(1): 10–17.

Gadducci A, Barsotti C, Cosio S, Domenici L, and Riccardo Genazzani A. 2011. Smoking habit, immune suppression, oral contraceptive use, and hormone replacement therapy use and cervical carcinogenesis: A review of the literature. [Review]. *Gynecol Endocrinol* 27(8): 597–604.

Gaffikin L, Lauterbach L, Emerson M. 2003. Safety, acceptability, and feasibility of a single visit approach to cervical cancer prevention: Results from a demonstration project in Rural Thailand. *Lancet* 361: 814–820.

Gichangi PB, Bwayo J, Estambale B, De Vuyst H, Ojwang S, Rogo K, Abwao H, Temmerman M. 2003. Impact of HIV infection on invasive cervical cancer in Kenyan women. *AIDS* 17(13): 1963–1968.

GLOBOCAN. 2012a. Cervical Cancer Factsheet. Available at: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. (Accessed March 20, 2014)

GLOBOCAN. 2012b. Population Factsheet. Available at: http://globocan.iarc.fr/Pages/fact_sheets_population.aspx. (Accessed March 20, 2014)

Goldie SJ, Gaffikin L, Goldhaber-Fiebert JD, Gordillo-Tob A; Alliance for Cervical Cancer Prevention Cost Working Group. 2005. Cost-effectiveness of cervical-cancer screening in five developing countries. *New England Journal of Medicine* 353(20): 2158–2168.

Gray RH, Serwadda D, Kong X, et al. 2010. Male circumcision decreases acquisition and increases clearance of high-risk human papillomavirus in HIV-negative men: A randomized trial in Rakai, Uganda. *J Infect Dis* 201(10): 1455–1462.

Hawes SE, Critchlow CW, Faye-Niang MA, et al. 2003. Increased risk of high-grade cervical squamous intraepithelial lesions and invasive cervical cancer among African women with human immunodeficiency virus type 1 and 2 infections. *J Infect Dis* 188 (4): 555–563.

Holowaty P, Miller A, Rohan T, To T. 1999. Natural history of dysplasia of the uterine cervix. *Journal National Cancer Institute* 91: 252–258.

International Federation of Gynecology and Obstetrics. 2009. *Global Guidance for Cervical Cancer Prevention and Control.* Available at:
http://www.figo.org/publications/miscellaneous_publications/global_guidance

Jacob M, Broekhuizen FF, Castro W, Sellors J. 2005. Experience using cryotherapy for treatment of cervical precancerous lesions in low-resource settings. *International Journal of Gynecology & Obstetrics* 89: S13–20.

Jakobsson M, Gissler M, Paavonen J, Tapper AM. 2009. Loop electrosurgical excision procedure and the risk for preterm birth. *Obstetrics and Gynecology* 114: 504–510.

Jamieson DJ, Duerr A, Burk R, et al. 2002. HIV Epidemiology Research Study (HERS).

Characterization of genital human papillomavirus infection in women who have or who are at risk of having HIV infection. *Am J Obstet Gynecol* 186(1): 21–27.

Kahesa C, Mwaiselage J, Wabinga HR, Ngoma T, Kalyango JN, Karamagi CA. 2008. Association between invasive cancer of the cervix and HIV-1 infection in Tanzania: The need for dual screening. *BMC Public Health* 8: 262. doi: 10.1186/1471-2458-8-262.

Kahn JA, Rosenthal SL, Succop PA, Ho GY, and Burk RD. 2002. The interval between menarche and age of first sexual intercourse as a risk factor for subsequent HPV infection in adolescent and young adult women. *J Pediatr* 141(5): 718–723.

Luque A, Demeter L, Reichman R. 1999. Association of human papillomavirus infection and disease with magnitude of human immunodeficiency virus type 1 (HIV-1) RNA plasma level among women with HIV-1 infection. *J Infect Dis* 179(6): 1405–1409.

Mandelblatt JS, WF Lawrence, L Gaffikin, et al. 2002. "Costs and benefits of different strategies to screen for cervical cancer in less-developed countries" *Journal of the National Cancer Institute* 94: 1–15.

Minkoff H, Feldman J, DeHovitz J, Landesman S, Burk R. 1998. A longitudinal study of human papillomavirus carriage in human immunodeficiency virus-infected and human immunodeficiency virus-uninfected women. *Am J Obstet Gynecol* 178(5): 982–986.

Noehr B, Jensen A, Frederiksen K, Tabor A, Kjaer SK. 2009. Depth of cervical cone removed by loop electrosurgical excision procedure and subsequent risk of spontaneous preterm delivery. *Obstet Gynecol* 114(6): 1232–1238. doi: 10.1097/AOG.0b013e3181bf1ef2.

Palefsky JM, Minkoff H, Kalish LA, et al. 1999. Cervicovaginal human papillomavirus infection in human immunodeficiency virus-1 (HIV)-positive and high risk HIV-negative women. *J Natl Cancer Inst* 91(3): 226–236.

Parham GP, Sahasrabuddhe, VV, Mwanahamuntu MH, et al. 2006. Prevalence and predictors of squamous intraepithelial lesions of the cervix in HIV-infected women in Lusaka, Zambia. *Gynecologic Oncology* 103:1017–1022

Pfaendler KS, Mwanahamuntu MH, Sahasrabuddhe VV, Mudenda V, Stringer JS, Parham GP. 2008. Management of cryotherapy-ineligible women in a "screen-and-treat" cervical cancer prevention program targeting HIV-infected women in Zambia: Lessons from the field. *Gynecol Oncol* 110(3): 402-407.

Rema P, Suchetha S, Thara S, Fayette JM, Wesley R, Sankaranarayanan R. 2008. Effectiveness and safety of loop electrosurgical excision procedure in a low-resource setting. *Int J Gynaecol Obstet* 103(2): 105–110.

Sahasrabuddhe V, Mwanahamuntu M, Vermund S, Huh W, Lyon M, Stringer J, Parham G. 2007. Prevalence and distribution of HPV genotypes among HIV-infected women in Zambia. *Br J Cancer* 96(9): 1480–1483.

Sankaranarayanan R, Gaffikin L, Jacob M, et al. 2005. A critical assessment of screening methods for cervical neoplasia. *International Journal of Gynecology & Obstetrics* 89: S4–12.

Sankaranarayanan R, Rajkumar R, Esmy PO, Fayette JM, Shanthakumary S, Frappart L, et al. 2007. Effectiveness, safety and acceptability of 'see and treat' with cryotherapy by nurses in a cervical screening study in India. *Br J Cancer* 96(5): 738–743.

Sauvaget C, Fayette JM, Muwonge R, Wesley R, Sankaranarayanan R. 2011. Accuracy of visual inspection with acetic acid for cervical cancer screening. *Int J Gynaecol Obstet* 113(1): 14–24.

Sellors JW and Sankaranarayanan R. 2003. *Colposcopy and Treatment of Cervical Intraepithelial Neoplasia: A Beginners' Manual.* International Agency for Research on Cancer (IARC), World Health Organization: Lyons, France. Available at: http://screening.iarc.fr/doc/Colposcopymanual.pdf.

Stein L, Urban MI, O'Connell D, et al. 2008. The spectrum of human immunodeficiency virus-associated cancers in a South African black population: results from a case-control study, 1995–2004. *Int J Cancer* 122(10): 2260–2265.

Tebeu PM, Major AL, Mhawech P, Rapiti E. 2006. The recurrence of cervical intraepithelial neoplasia in HIV-positive women: a review of the literature. *Int J STD AIDS* 17(8): 507–511.

Tobian AA, Kong X, Wawer MJ, Kigozi G, Gravitt PE, Serwadda D, et al. 2011. Circumcision of HIV-infected men and transmission of human papillomavirus to female partners: analyses of data from a randomized trial in Rakai, Uganda. *Lancet Infect Dis* 11(8): 604–612.

Uberti-Foppa C, Origoni M, Maillard M, et al. 1998. Evaluation of the detection of human papillomavirus genotypes in cervical specimens by hybrid capture as screening for precancerous lesions in HIV-positive women. *J Med Virol* 56(2): 133–137.

UNAIDS (Joint United Nations Programme on HIV/AIDS). 2012. Women Out Loud: How Women Living with HIV Will Help the World End AIDS. Available at: http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2012/20121211_Women_Out_Loud_en.pdf

UNAIDS (Joint United Nations Programme on HIV/AIDS). Data: Know your epidemic 2010. Available at: http://www.unaids.org/en/dataanalysis/knowyourepidemic/ (Accessed November 22, 2013)

UNAIDS. (Joint United Nations Programme on HIV/AIDS). Data: AIDSinfor. Available at: http://www.unaids.org/en/dataanalysis/datatools/aidsinfo. (Accessed November 5, 2014)

Vaccarella S, Franceschi S, Hererro R, et al. 2006. Sexual behavior, condom use, and human papillomavirus: Pooled analysis of the IARC Human Papillomavirus Prevalence Surveys. *Cancer Epidemiol Biomarkers Prev* 15: 326–333.

Werner CL, Lo JY, Heffernan T, Griffith WF, McIntire DD, Leveno KJ. 2010. Loop electrosurgical excision procedure and risk of preterm birth. *Obstet Gynecol* 115(3): 605–608. doi: 10.1097/AOG.0b013e3181d068a3.

World Health Organization (WHO). 2013a. *WHO Guidance Note: Comprehensive Cervical Cancer Prevention and Control: A Healthier Future for Girls and Women*. Available at: http://www.who.int/reproductivehealth/publications/cancers/9789241505147/en/

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

World Health Organization (WHO). 2012. *Prevention of Cervical Cancer through Screening Using Visual Inspection with Acetic Acid (VIA) and Treatment with Cryotherapy. A Demonstration Project in Six African Countries: Malawi, Madagascar, Nigeria, Uganda, the United Republic of Tanzania, and Zambia*. Available at: http://apps.who.int/iris/bitstream/10665/75250/1/9789241503860_eng.pdf.

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

World Health Organization (WHO). 2009. Human papillomavirus vaccines: WHO position paper. Available at: http://www.who.int/wer/2009/wer8415/en/index.html.

World Health Organization (WHO). 2007. Standard Precautions in Health Care. Available at: http://www.who.int/csr/resources/publications/EPR_AM2_E7.pdf?ua=1

World Health Organization (WHO). 2006. *Comprehensive Cervical Cancer Control: A Guide to Essential Practise.* Available at: http://www.who.int/reproductivehealth/publications/cancers/9241547006/en/.

World Health Organization (WHO) and Pan American Health Organization. 2013. *WHO Guidelines: Monitoring National Cervical Cancer Prevention and Control Programmes: Quality Control and Quality Assurance for Visual Inspection (VIA)-Based Programmes*. Available at: http://apps.who.int/iris/bitstream/10665/79316/1/9789241505260_eng.pdf?ua=1.

Wright T, Subbarao S, Ellerbrock T, et al. 2001. Human immunodeficiency virus 1 expression in the female genital tract in association with cervical inflammation and ulceration. *Am J Obstet Gynecol* 184: 279–285.