

PATHFINDER INTERNATIONAL

Loop Electrosurgical Excision Procedure (LEEP)

Clinical Standards of Practice



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Acronyms and Abbreviations

ESU	Electrosurgical unit
HPV	Human Papilloma Virus
IUD	Intrauterine device
LEEP	Loop Electrosurgical Excision Procedure
LLETZ	Large Loop Excision of the Transformation Zone
PID	Pelvic Inflammatory Disease
SCJ	Squamocolumnar junction
SOP	Standard operating procedures
STI	Sexually transmitted infection
SVA	Single-visit approach
VIA	Visual Inspection with Acetic Acid

Electrosurgical Terms

Amperes	Current
Blended current	Current with complex wave form that allows cutting while coagulating
Cautery	Destruction of tissue by the application of heat or caustic substance
Circuit	Pathway that electricity takes
Coagulation	Process of homeostasis by contracting vessels and destruction of tissue
Current	Number of electrons flowing through a circuit
Cutting	Severing of tissue by a wave form that promotes tissue separating without coagulation
Desiccation	Drying of tissue resulting in tissue necrosis in absence of sparks
Electrosurgery	Cutting, desiccation, and coagulation of tissue by high frequency electrical waveforms
ESU	Abbreviation for electrosurgical unit
Fulguration	Destruction of tissue or production of homeostasis by means of sparks from a high frequency current
Ground	Conductor connected to earth
Patient electrode	Return electrode or grounding pad
Power	Energy produced or consumed over time
Voltage	Force that drives electricity through a circuit
Resistance	Difficulty that a substance presents to electric flow

Loop Electrosurgical Excision Procedure (LEEP)

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Introduction

The single-visit approach (SVA) to cervical cancer prevention (also referred to as “see and treat” approach) involves visual inspection of the cervix after an acetic acid wash (VIA) and treatment of identified precancerous lesions with cryotherapy. Not all identified acetowhite lesions are amenable to cryotherapy. The lesion may be too large or its location not well suited for cryotherapy (such as extensive endocervical involvement or the extension onto the vaginal wall) or the appearance of the lesion requires exclusion of microinvasive or invasive cervical cancer. So a number of VIA positive patients (around 10%) need to be referred for alternative treatments or further diagnosis (based on the experience of programs doing a single-visit screen after age 30 in an unscreened population).

A LEEP excisional biopsy and a LEEP conization (utilizing a loop or triangle electrode to excise a cervical cone) are procedures that can be performed in an outpatient setting under local anesthesia. These procedures can be both diagnostic and therapeutic, and replace traditional follow-up evaluations and treatments such as cold knife conization and hysterectomy. In some settings, LEEP is used as a “see and treat” method after a visual test such as VIA or colposcopy (if available) has identified a potential precancerous lesion, since the goal in most clients is to remove the lesion and the total transformation zone. The term Large Loop Excision of the Transformation Zone (LLETZ) is used interchangeably with LEEP in many textbooks.

In the context of a cervical cancer prevention program with a “see and treat” approach such as VIA and cryotherapy, LEEP is performed for clients who are not candidates for cryotherapy at the primary screening site and who are referred for further evaluation and treatment to a referral center.

This Standard Operating Procedures (SOP) manual describes the equipment, step-by-step procedure, safeguards in practice, and infection prevention guidelines surrounding LEEP and recommended follow-up schedules and procedures. This manual is intended for use by physicians or other trained health care providers.

I Principles of Electrosurgery

Electrosurgery is the use of radiofrequency electric current to cut, coagulate or fulgurate tissue. Coagulation and fulguration will cause tissue necrosis and achieve hemostasis.

- The heat and light energy by electrosurgical generators can be transmitted in a continuous waveform for cutting or a discontinuous wave form for coagulation or fulguration.
- Cutting occurs by vaporizing tissue at 100 C° and coagulation and fulguration by dehydrating tissue above 100 C°.
- Electrodes for cutting come in different sizes and forms (loops, triangles, and knife). For LEEP, loop electrodes and triangle electrodes are used.
- Coagulation occurs when the active electrode touches the tissue.
- Fulguration occurs when the active electrode does not touch the tissue but sparks are “sprayed” from close proximity onto the tissue.

Picture 1. Loop and ball electrodes¹



* Electrodes for coagulation and fulguration have different forms and sizes.

¹Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/Ethiopia Program.

Picture 2. Electrosurgical Unit (ESU)²



*An ESU generates the electric power for electrosurgery.

- At different power (wattage) settings, electricity flows to loop or ball electrodes through the tissue and returns in a circuit to a patient receptor electrode or grounding pad along the path of the least electrical assistance. The grounding pad is connected to the electrosurgical unit and to the patient.
- Cutting waveforms will do the least thermal damage to tissue but not result in hemostasis. Coagulation waveforms will do the most thermal damage to tissue and provide hemostasis.
- Since there is a need to minimize bleeding while excising a piece of cervical tissue electrosurgical settings are offered on the ESU that blend electrical currents with cutting and coagulation wave forms.
- This “blended” cutting waveform is used for electrosurgical conizations and excisions. To minimize bleeding while efficiently cutting with this “blended” waveform it is extremely important to use a technique where the electrode moves through the tissue SLOWLY BUT CONTINUOUSLY.
- The electrosurgical unit has a built in safety mechanism. It requires that a patient return electrode (also called dispersive plate or grounding pad) be used to allow an electrosurgical circuit to be completed close to the surgical site. At the surgical site there is a high density of current delivered (required for cutting and coagulation), while at the dispersive electrode the current is dispersed over a large area. This minimizes heat generation in the skin covered by the grounding pad and burns.

² Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/ Ethiopia Program.

- Modern electrosurgical units have a return electrode monitor system that evaluates the adequacy of the ground plate connection to the client. The monitor system will alert the operator and shut down activation of the active electrode when there is no safe circuit.

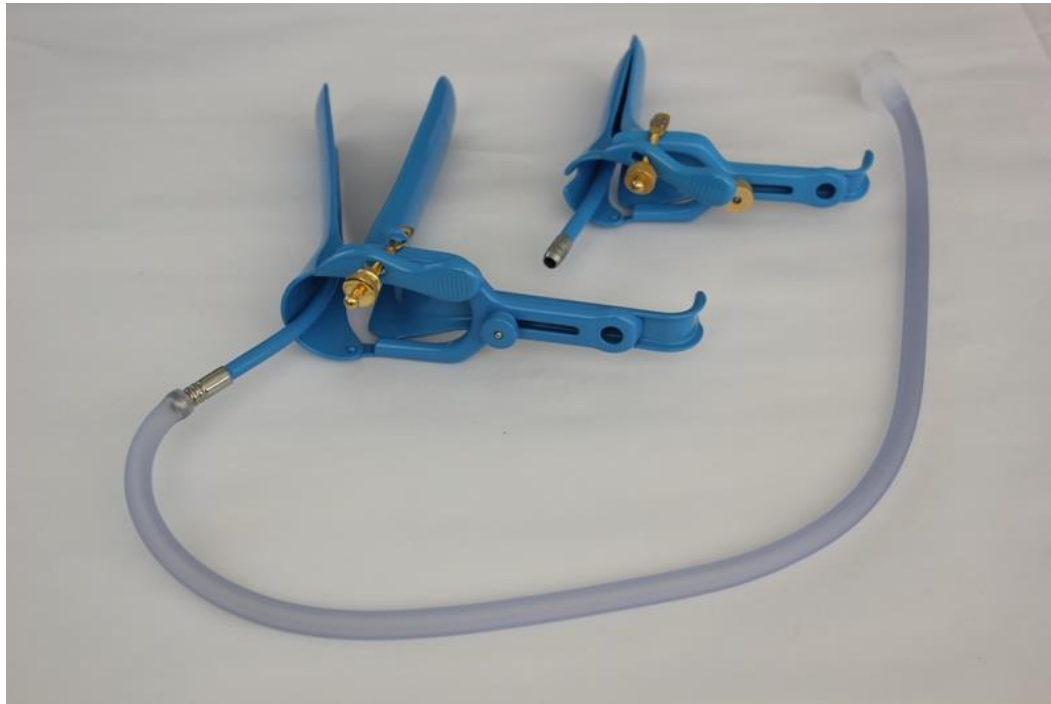
Picture 3. Smoke evacuator with attached hose³



*Since the active electrode (loop, triangle or ball) generates smoke and is used on the cervix at the top of the vagina, a smoke evacuator is needed to allow continuous visualization of the cervix being treated. In addition, the smoke evacuator prevents viral particles from entering the atmosphere and may reduce noxious fumes.

³ Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/Ethiopia Program.

Picture 4. Insulated speculum with smoke evacuator tube⁴



*Specula used for LEEP are designed with a channel for connection to a tube that is hooked up to the smoke evacuator, which generates negative pressure to remove the smoke. These specula are also specially coated with anticonductive material so as not to conduct current to the vagina if it is touched by the electrode.

Electrosurgery must not be performed in the close presence of flammable gases, anesthetics, or liquids (such as alcohol containing tinctures) or flammable objects and oxidizing agents. The heat generated can ignite a fire or explosion when these agents are close. Operators are at risk for burns when touching an active electrode or causing fire or burns when touching others or drapes with an activated electrode.

⁴Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/Ethiopia Program.

II. Equipment Used to Perform LEEP/LLETZ/LEEP Cone

LEEP begins like a regular pelvic examination, with a client being awake during the 20-30 minute procedure. The provider inspects the cervix that has been stained with acetic acid to identify abnormal cells followed by application of Lugol's Iodine to delineate the outer margin of the tissue to be removed.

Local anesthesia is then applied and an electrically charged loop made of thin wire is inserted through the speculum and up to the cervix. As the loop is passed across the cervix, it cuts away a thin layer of surface tissue, removing the abnormal cells.

To perform LEEP properly the following equipment, accessories, and consumable supplies are needed:

- A colposcope is used to rule out microinvasive or invasive cervical cancer among lesions requiring other therapy in a referral center where a "see and treat" approach to acetowhite lesions/potential precancerous lesions is used without utilization of histology.

Please note: In a referral center where histology will be performed on an excised specimen to determine further or additional treatment or follow-up, colposcopy may aid in delineating the lesion more precisely.

- ESU with "blended current" option and patient return plate monitoring system, preferably with a digital power read out
- A reusable patient return electrode (grounding plate) or an adhesive return plate
- A pencil for a loop or ball electrode with or without a finger switch and a cord to connect it to the ESU. If no finger switch is available, a foot switch connected to the ESU is needed.

Please note: A foot switch is preferable since it allows the operator more mobility while moving the electrode through the tissue during the excision.

- A foot switch cord to connect to the electrosurgical unit to activate the electrode (if a foot switch is being used)
- A smoke evacuator with tubing for attachment to speculum
- 10mm by 8mm and 10mm by 4mm loop electrodes
- 20mm by 8mm, 20mm by 15mm, and 10mm by 10mm triangle electrodes
- 3 mm ball electrodes and 5 mm ball electrodes

Please note: While there are many other sizes, this collection of electrodes should suffice in most settings for all cervical electrosurgical procedures.

- Needle electrodes (optional)
- Insulated/coated speculum with groove or tube for smoke evacuator tubing
- Insulated/coated vaginal wall retractor
- At a minimum, medium sized and large specula
- Two sizes of vaginal wall retractors to accommodate varying vaginal wall laxity
- Long pick-up forceps

- Ring forceps
- Syringe (dental or 5 cc syringe with needle extender) and spinal needles (25 or 27 gauge) for local anesthesia
- Local anesthetic (1 or 2 % xylocaine or lidocaine) with or without 1:100.000 epinephrine
- Cartridges for dental syringe or bottle with xylocaine or lidocaine
- Cotton swabs (large and small)
- Bottles of:
 - Normal saline b. 5 %
 - Acetic acid
 - Lugol's Solution
- Gauze
- Cotton balls
- Monsel's Solution for final hemostasis of the wound bed
- Kidney basin
- Light source (lamp, surgical light) adequate for visualization of the cervix
- Examination table with stirrups, preferably adjustable in height
- Large needle holder
- 00 chromic or vicryl suture

Picture 7. Foot pedal with connectors to ESU⁷



⁷ Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/Ethiopia Program.

III. Eligibility for LEEP

The cervical cancer screening program in place with its rules and treatment algorithm determines eligibility (see Appendix 1).

In settings where a traditional screening program utilizes cytology, colposcopy, and histology for diagnosis of a precancerous lesion, a diagnosis of CIN2 or CIN3 with exclusion of invasive cervical cancer is an indication, especially if the lesion is too big for cryotherapy or in a location where cryotherapy is less effective (such as in the endocervix).

In low- or mid-level countries where a “see and treat” approach, utilizing VIA followed by cryotherapy, is the approach that should be used.

- The eligibility is the same as the eligibility for cryotherapy but in addition larger lesions (not suitable for cryotherapy) or lesions with extension in the vagina or into the endocervix can be treated with LEEP depending on national protocols and practices.
- In “see and treat” VIA/cryotherapy programs, lesions will be identified at the primary screening levels which require referral to a center where LEEP is available and/or where other diagnostic procedures such as colposcopy, biopsy, and diagnostic/therapeutic conization can be performed.
- The most common reasons for referral would be: a lesion too large to fit under the probe, a lesion with endocervical extension, or lesions where there may be uncertainty of possible early invasive disease.
- A LEEP conization can be diagnostic and therapeutic at the same time and be an alternative to cold knife conization or hysterectomy.
- In case of failure of cryotherapy after VIA and the persistence of an acetowhite lesion, LEEP would be the preferred treatment option when available.

LEEP should not be performed in the presence of pelvic inflammatory disease (PID), acute cervicitis, or symptomatic vaginitis.

- Clients should have no medical condition for which a local anesthetic is contraindicated.

The client must be counseled about the details of the procedure, the expected cure rate, the short- and long-term effects, and alternative treatment options. After counseling, a written consent must be signed (see Appendix 3).

IV. Selecting the Electrodes and Power Settings for a LEEP Procedure

The size of the cervix and the size and location of the lesion determine the type and size of the electrode(s) used, and the power settings.

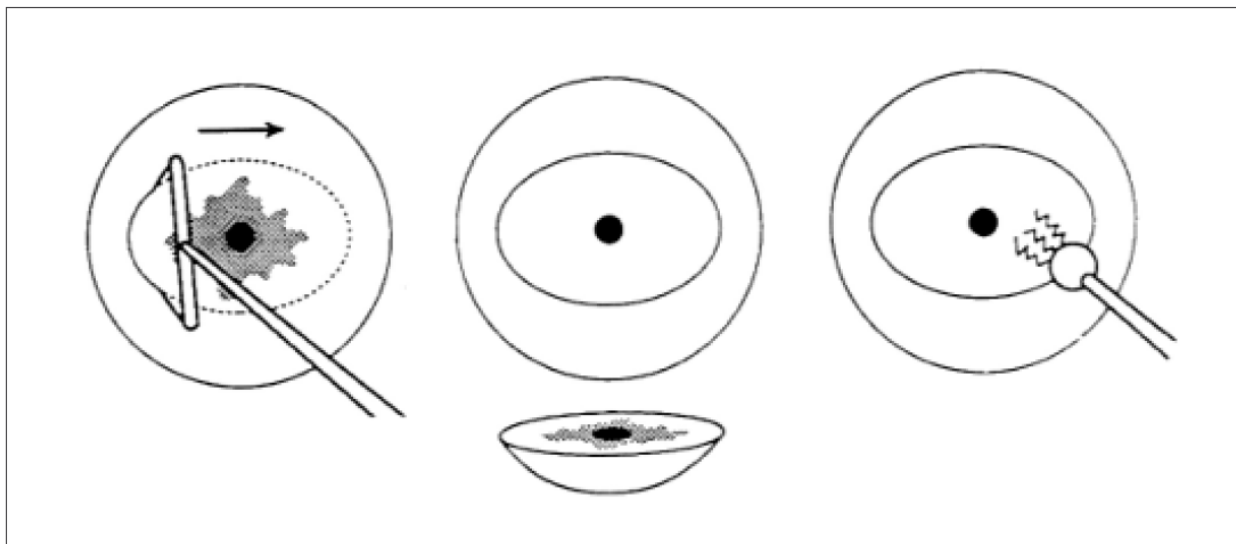
The goal of the procedure is to remove not only the lesion with a 3–4 mm margin, but also the total transformation zone. For larger lesions, the triangle electrodes have the advantage of removing a cone-shaped specimen with an extension into the endocervix. Whenever possible, remove the total transformation zone and the lesion itself in a single pass. As an alternative, use different sizes of loop electrodes to excise a similar specimen in 2 or 3 steps.

A set of triangle electrodes with different depths and sizes, and a variety of curvilinear loop electrodes and ball electrodes, are the tools needed to perform LEEP.

Table 1: Power settings for the different types of electrodes

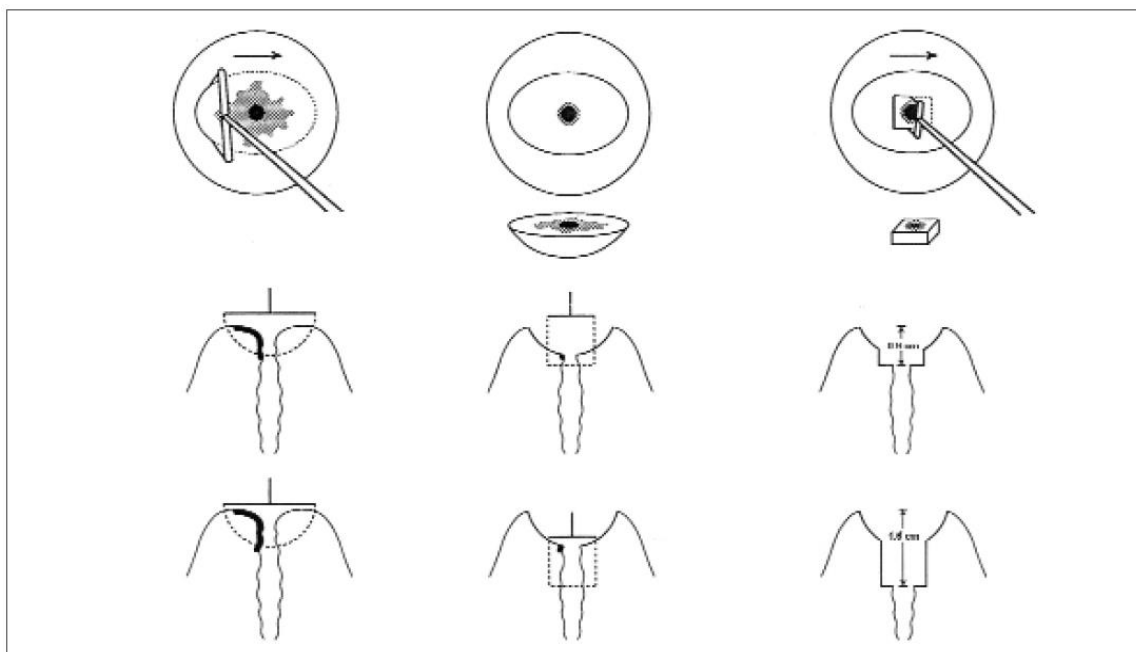
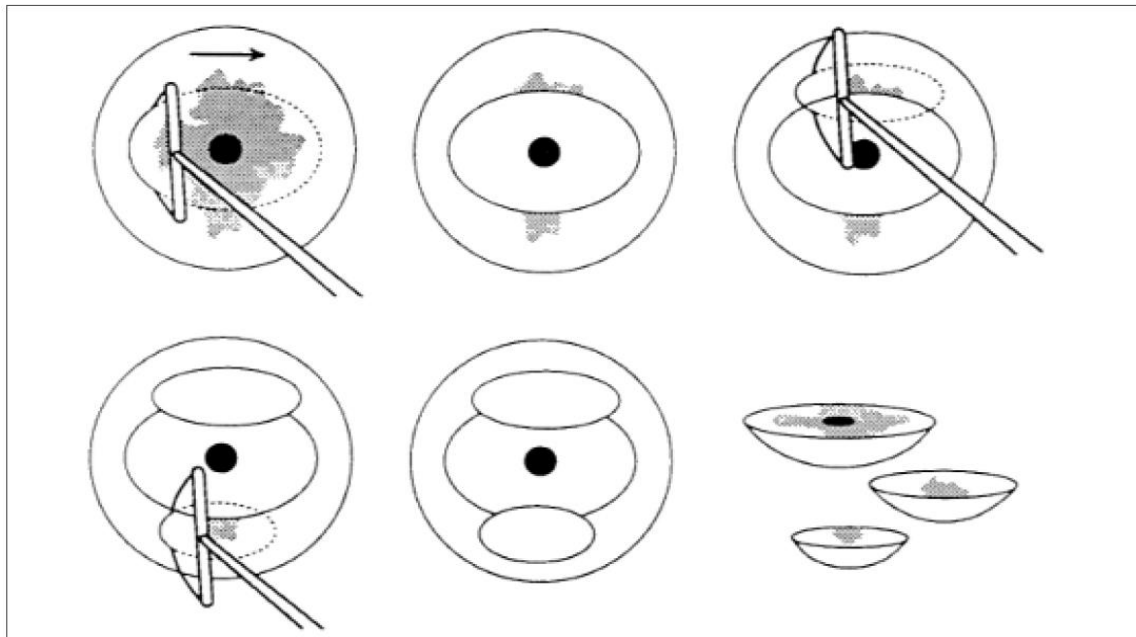
Types of Loops and Ball Electrode	Power settings
Triangle loops and 10 mm base loops	36 (range 32-38) watts blended
20 mm base loops	44 (range 40-48) watts blended
3 mm ball electrode	30 watts coagulation
5 mm ball electrode	35 watts coagulation

Figure 2: Excision of an ectocervical lesion with one pass⁸



⁸ International Agency for Research on Cancer: IARC Screening Group, "Colposcopy and Treatment of Cervical Intraepithelial Neoplasia: A Beginner's Manual." Available at: <http://screening.iarc.fr/colpo.php>.

Figure 3: Excision of an ectocervical lesion with multiple passes⁹



⁹ Ibid.

V. Training and Practice for LEEP

A series of theoretical classroom lectures and practice on inanimate materials such as chicken breast or sausage should precede supervised clinical training on clients. Depending on the number of participants and potential clients, training will require between 3 and 5 days.

When planning the training, keep in mind the following:

- Prior to performing LEEP on women, training in a classroom setting is mandatory.
- The trainee needs to be familiar with the ESU, the smoke evacuator, and all pieces of equipment and ancillaries required.
- The trainee needs to become familiar with all safety features and power settings. She/he needs to practice the excision technique in a classroom setting. Cervical lesions can be simulated on pieces of animal tissue (e.g., beef tongue, sausage, chicken breast).
- The trainee needs to experience the feel of the different loops and triangle at different power settings. She/he also needs to simulate the excisional moves/motions to become familiar with the techniques. The trainee can practice inserting the speculum on a pelvic model. She/he can also practice hooking up all equipment in a step-by-step fashion.
- Placing the animal tissue on a dispersive electrode (grounding pad) will allow the trainee to practice excision with a safe established electrical circuit.

VI. Step-by-Step LEEP

A. Prior to placing patient on table for procedure:

1. Determine the woman's eligibility for LEEP.
2. Take general medical history; determine if allergies are present and if there are any contraindications to the procedure.
3. If there is an evidence of infection indicated by client history, examine the client. If an infection is confirmed, delay LEEP and treat the infection.
4. Explain the procedure, counsel the woman, and obtain consent to perform LEEP.
5. Prepare the LEEP tray (contents shown in Picture 5).
6. Connect the ESU and smoke evacuator to the electrical outlet and verify functioning electricity.
7. Connect tubing to the smoke evacuator, and the loop electrode cord to the ESU.

B. Prior to activating electrode and conducting the excision:

1. Have the woman empty her bladder and undress.
2. Prepare the table with drapes and place the light source in proximity. Have a stool close by for the operator to sit on.
3. Place the woman on the table in a modified dorso-lithotomy position with her feet comfortable in stirrups, buttocks at edge of table, and a comfortable position for her the back and head.
4. Place a reusable patient return electrode under her buttock or on her thigh and connect to the electrosurgical unit.
5. Wash hands with soap and water and dry with clean dry towel or air dry.
6. Put high-level disinfected surgical gloves on both hands.
7. Connect the smoke evacuator tubing to the insulated speculum.
8. Insert the speculum and "centralize" the cervix. The cervix should be perpendicular to the path of the loop electrode.
9. Determine if a lateral vaginal wall retractor needs to be placed to avoid contact with the vaginal wall by the loop electrode. If so, place the retractor.
10. Remove excess secretions from the cervix with saline.
11. Apply 5% acetic acid first to delineate the lesion, followed by Lugol's Solution to outline the precancerous lesion and transformation zone.

12. Determine which triangle or loop electrode will be used to excise the lesion and transformation zone. If possible, one pass and one excision should be planned, but that is not always possible.

13. Inject 3–4 cc of a local anesthetic in a ring pattern intracervically.

14. Wait 1 minute.

C. To perform the electrosurgical excision:

1. Set the ESU to the appropriate “blended” power setting for the electrode chosen (see Table 1 for electrodes and power settings).

2. Plan the “cut” with the electrode (NOT activated), and simulate the entry point, the pathway, and the exit point. The goal is to remove the lesion and transformation zone with a 3–5 mm margin.

3. Turn on the smoke evacuator and check if electrode can be activated by turning on the switch. If both are functional, proceed with excision.

4. Do the excision under clear visualization.

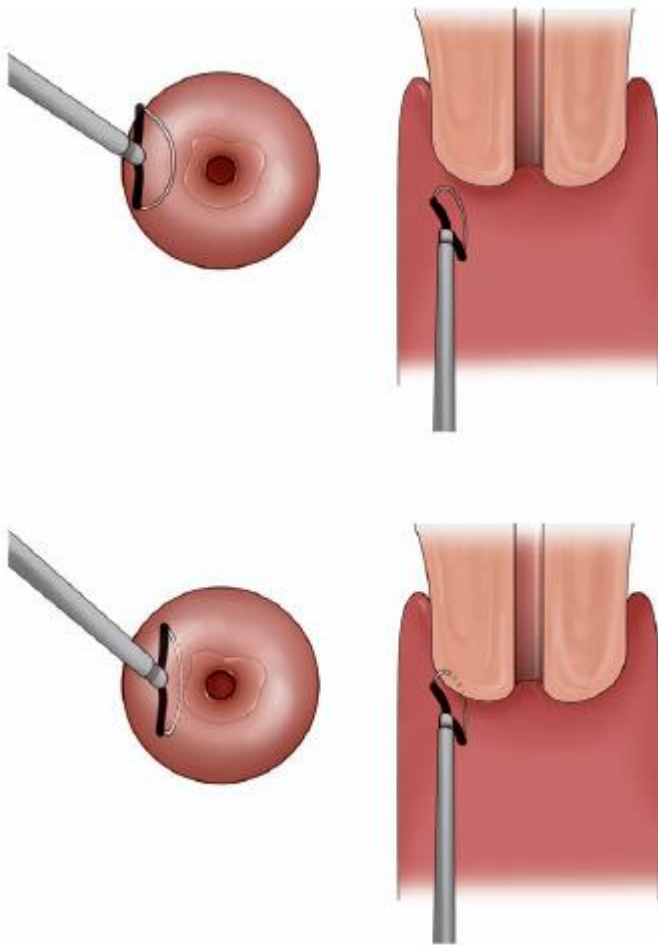
a. Triangle electrode: Place the tip of the triangle loop in the endocervix at 12 o’clock. Activate the electrode and advance the electrode to its base at 12 o’clock and then proceed in one slow but continuous movement with a rotation of 360 degrees until a cone-shaped specimen is excised. Do not “push” the electrode, “guide” the electrode. Once the specimen is excised, deactivate the electrode.

b. Curvilinear electrode (loop): Enter electrode at determined entry point and make a pass from south to north or west to east to excise lesion in one slow and continuous movement. Insert to a minimum of 5 mm or a maximum of 10 mm at beginning of the “pass.” Once the specimen is excised, deactivate electrode.

c. Sometimes there are lesions which require two or more passes to excise the whole lesion, or a lesion may require an additional “top hat” excision of the endocervix.

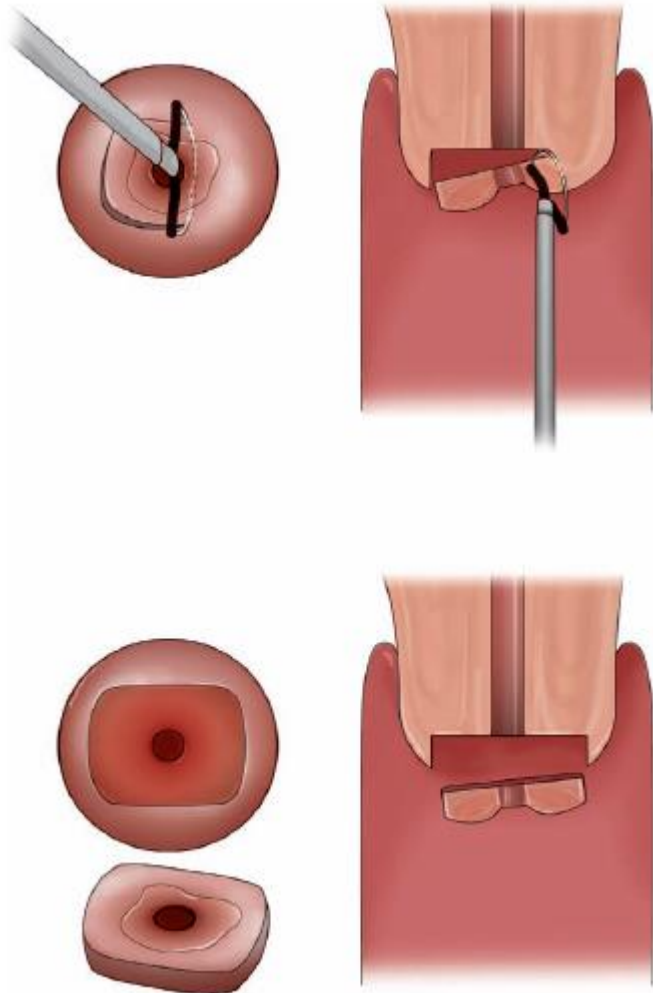
(Steps continued after illustrations.)

Figure 5: Loop electrode being positioned over area to be excised (top) and initial insertion of probe into cervical tissue (bottom)¹¹



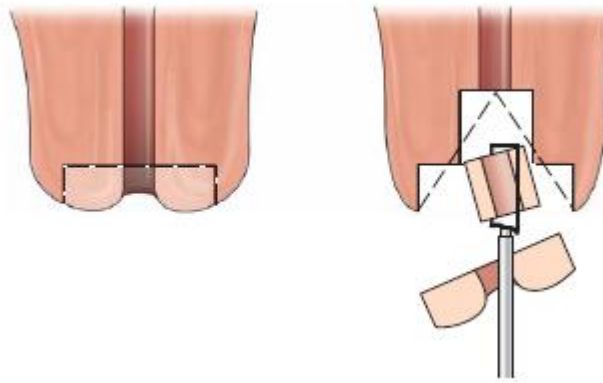
¹¹ Mayeaux EJ Jr., "Loop Electrosurgical Excisional Procedure," in *The Essential Guide to Primary Care Procedures*. Ed. Lippincott Williams & Wilkins (Philadelphia, PA, 2009), 609-617.

Figure 6: Loop electrode being passed through cervical stroma under the transformation zone (top) resulting in an excisional biopsy (bottom)¹²



¹² Ibid.

Figure 7: Rectangular probe being used to excise tissue from higher in the endocervical canal¹³



5. Pick up excised specimen(s) with ring forceps and place them in formaline solution, if the specimen needs to be sent for histology.
6. Change settings on the electrosurgical unit to coagulation and choose the ball electrode. For smaller lesions choose the 3 mm ball electrode and for larger lesions choose the 5 mm ball electrode (see Table 1 for power settings for electrodes).
7. Coagulate and fulgurate the wound bed until hemostasis is achieved. Fulgurate margins of the wound crater. Use swabs to remove blood clots. If carbonization of the ball electrode occurs, remove carbon from the ball.
8. Apply Monsel's Paste to the cervix with a swab. This solution can be applied generously to prevent later oozing. Pressure does not need to be applied. The swab should be removed immediately after application of the Monsel's Paste.
9. Remove the speculum with tubing and the patient return electrode. Place all reusable instruments in designated buckets. (Refer to infection prevention section.)
10. Help the woman to a sitting position, determine if she is stable enough to step off the table, provide her with a pad, and ask her to dress.
11. Counsel the woman on anticipated post-procedure effects (e.g., spotting, excessive discharge for one month, and mild cramping for 2–3 days). You should also counsel her on when to follow up, and on abstaining from sexual intercourse. Provide her with the prepared package of after-care products (including sanitary pads, post-LEEP information sheet, and a condom supply).
12. Place all reusable instruments in appropriate containers for cleaning, disinfection, and sterilization. (Refer to the infection prevention section for more information.)
13. Place contaminated non-reusable materials and accessories in identified biohazard trash containers.
14. Clean the table, lights, and any contaminated objects in accordance with approved infection prevention policies.

¹³ Ibid.

VII. Variations in LEEP

If the diameter of a lesion exceeds the width of the largest loop or triangle electrode, the lesion may be removed by multiple passes in separate pieces. The central part of the lesion is removed first, followed by the peripheral parts.

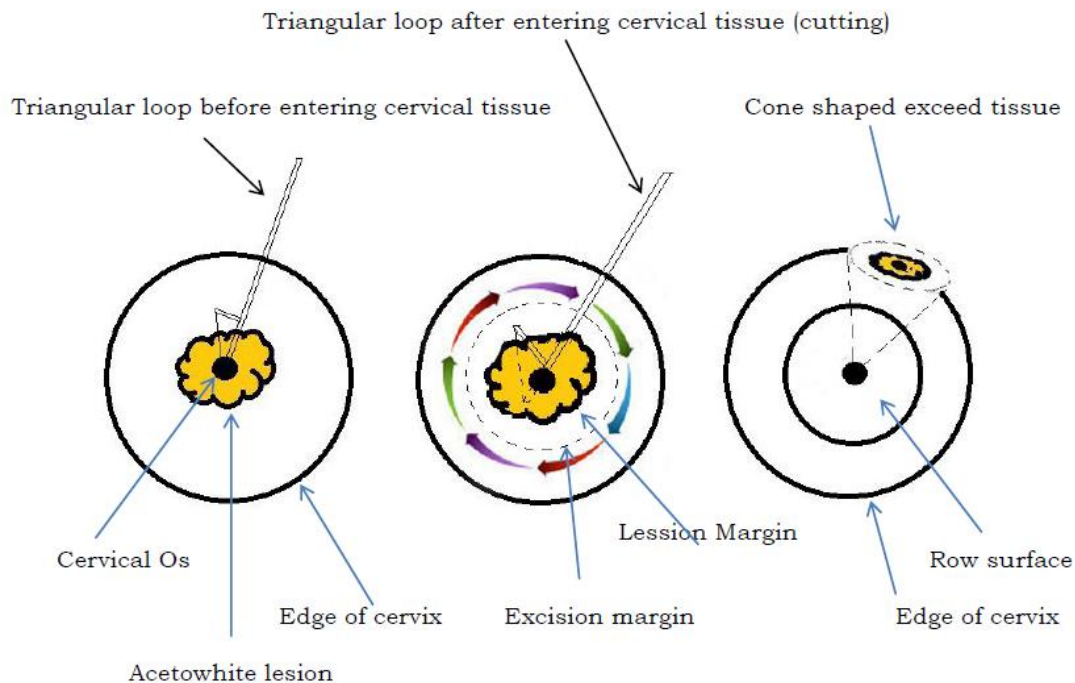
If the lesion has extensive endocervical involvement, triangle electrodes can remove a cone-shaped specimen with a depth of 1.5 cm. If an even deeper removal of the endocervix is warranted, a smaller curvilinear loop can excise the endocervix on top of the initial “cone.”

In most cases excision with a triangle loop guarantees endocervical lesion removal and usually guarantees excision of the lesion and the transformation zone. Using a triangle loop as the preferred initial loop is recommended in most cases.

Lesions with vaginal extensions require fulguration onto the vaginal portion in addition to LEEP. Do not use loop electrodes on the vagina unless with extreme caution and very superficially. Otherwise, excisions on the vaginal wall may extend to nearby tissue (such as bladder and rectum) and result in perforation, fistula formation, or damage to other nearby structures.

If intrauterine device (IUD) strings are present, push strings up with fine forceps into the endocervical canal prior to the procedure and bring them out after. An alternative method is to “push” the IUD strings to one side at 3 o’clock, then cut from 12 to 6 o’clock, move the strings to 9 o’clock, and finish the excision from 6 to 12 o’clock.

Figure 8: Cone loop excision with triangle electrode



Additional procedures for hemostasis in LEEP

If bleeding is difficult to stop with fulguration and coagulation with the ball electrodes and seems arterial in origin, hemostatic sutures can be placed laterally between 8 and 10 o'clock and 2 and 4 o'clock. Alternatively, a vaginal gauze pack saturated with Monsel's Paste can be left in place against the cervix for a few hours.

VIII. Instructions for Women after LEEP

Women should be advised that they will have a brown or black discharge with streaks of blood for up to 14 days. They should return after 2 weeks if they have persistent or malodorous, severe abdominal pain with fever or significant bleeding. Women must be instructed to have no intercourse for 4 weeks (it takes 3–4 weeks for the cervix to heal). A follow-up visit after 4 weeks to assess healing is recommended but not essential if the woman lives far away.

In low-resource settings, presumptive treatment with antibiotics is recommended. The regimen is Doxycycline 100 mgr po bid and Metronidazole 400 mgr po tid for 7 days. Local guidelines and protocols should be developed or followed.

The effect of LEEP on the transmissibility of HIV is unknown. It is recommended in areas where HIV is endemic to supply condoms to be used for 6–8 weeks after the procedure.

Follow-up is advised for VIA or colposcopy. Women are advised to have a Papanicolaou (Pap) smear in 12 months.

Picture 8. Post-LEEP package (sanitary pads, post-LEEP information sheet, and condom)¹⁴



¹⁴ Photograph courtesy of Netsanet Shiferaw and Konjit Kassahun, Addis Tesfa/Ethiopia Program.

A. Potential adverse effects of LEEP

1. The potential short-term adverse effects of LEEP are:
 - a. Abdominal cramps in about 5% of women after the procedure;
 - b. Severe bleeding during procedure in less than 1% of women;
 - c. Delayed bleeding in 4–6 days in less than 1% of women after the procedure which is usually controlled by fulguration, silver nitrate application or Monsel's Paste.
2. The potential long-term effects of LEEP are as follows:
 - a. Less than 1% of women experience cervical stenosis.
 - b. 2% of women experience inadequate visualization of the squamo columnar junction.
 - c. There is a small increase of risk for preterm birth.

Please note: Women should be informed that there is no known effect on fertility.

B. Effectiveness of LEEP and follow-up management

1. LEEP has been found to be extremely effective. 90–95 % of women will have no precancerous lesion at the 12 months follow-up.
 - a. If at 12 months lesions are seen that are new or persistent, treat with cryotherapy, redo LEEP or cold knife conization on an individualized basis.
 - b. If the lesion is still persistent at follow-up, repeat LEEP with cone-shaped excision.
 - c. In settings where colposcopy and histology is available, diagnostic procedure may be chosen to precede a cone procedure or on occasion a hysterectomy.
 - d. If no lesion is seen at the follow-up visit by VIA, recommend another screening in 3–5 years.

IX. LEEP Procedure Tips

In every procedure providers should:

- Always plan excisions using a simulated path with an electrode that has not been activated.
- Avoid touching the vagina with an activated electrode.
- Always finish cutting before stopping the excision or deactivating the electrode.
- Always remember to fulgurate edges of the wound crater.

X. Counseling Guidelines for LEEP

A. General counseling guidelines

1. All women have a right to make informed decisions about whether or not to receive treatment.
2. If a woman meets all of the criteria and is eligible for LEEP, it is essential that she is informed and counseled on the following:
 - a. What LEEP is
 - b. Benefits of the procedure
 - c. Potential risks
 - d. Post-treatment care and follow-up
 - e. Likelihood of success.

Please note: This information can alleviate anxiety, fear, and misunderstandings regarding LEEP and ensures the woman consents to the procedure according to her own free will and with full understanding.

3. Provide a safe and open environment for the woman by:
 - a. Explaining LEEP in detail, in a non-threatening manner, and in language the woman understands.
 - b. Ensuring confidentiality—share the woman’s information with her companion(s) and/or other clinic staff only if she provides consent.
 - c. Providing additional sexual and reproductive health information (e.g., other sexually transmitted infections [STIs], contraception, HIV and AIDS services) and available services.
 - d. Allowing time for discussion and encouraging the woman to ask questions and discuss her condition.
4. Once you have provided counseling and information on LEEP, ensure that the woman:
 - a. Does not have any more questions or concerns.
 - b. Believes she will be able to abstain from sexual intercourse.
 - c. Believes she can do self-care post-treatment.

Please note: If all of the above is true, ask the woman to sign a written consent for LEEP.

B. Suggested counseling language

1. Describe LEEP:

- a. Your VIA test showed abnormal cervical tissue that can be removed with a procedure called LEEP.
- b. LEEP is a procedure that is used to remove abnormal cervical tissue from the cervix with electricity.
- c. The procedure takes about 30 minutes.
- d. During LEEP you will hear beeping noises and vacuum cleaner noise, but it is nothing to be worried about.
- e. LEEP only involves removing abnormal cervical tissue. It will not be used for treatment or removal of any other internal or external female genitalia.
- f. Once the abnormal cells are removed, there is a wound that needs healing.

2. Explain the potential risks of LEEP:

- a. There are no serious risks associated with a LEEP.
- b. Bleeding can occur during the procedure, which can be controlled.
- c. A local anesthetic is placed in the cervix and the woman will feel mild pain from the injection.
- d. Many women will experience a warm feeling in their vaginas during the procedure and some women could experience mild cramping (like menstrual cramps) during the procedure. This is common and does not require hospitalization.
- e. Rarely, an infection may occur after the procedure.

3. Explain the benefits of LEEP:

- a. LEEP therapy removes precancerous tissue from the cervix.
- b. LEEP therapy does not require hospitalization, general anesthesia, or premedication. It can be completed in less than 30 minutes. A local anesthetic is required.
- c. LEEP therapy does not have a long-term impact on a woman's fertility.
- d. The removed tissue can be analyzed in the laboratory for diagnosis if pathologic service is available.

4. Explain what women should expect after being treated with LEEP:

- a. You will have brown, bloody discharge that lasts for up to 1 month.
- b. You may or may not have lower abdominal cramping and spotting/light bleeding.

- c. You are strongly advised to avoid sexual intercourse for about 1 month until the wound heals.
- 5. Explain the details of self-care at home:
 - a. Self-care at home involves avoiding: douching, use of vaginal tampons; and sexual intercourse.
 - b. If you experience mild pain, you can take any pain killer.
- 6. Explain the conditions that require coming to the clinic as soon as possible for care (outside of scheduled visits):
 - a. Malodorous discharge or persistent discharge for more than 2 weeks.
 - b. Severe lower abdominal pain accompanied by fever or discharge.
 - c. Moderate or severe post-procedure bleeding.
- 7. Explain why the woman must abstain from sexual intercourse.
 - a. To allow proper healing after LEEP and reduce increased transmission of HIV, it is essential that you abstain from sexual intercourse for 1 month following treatment.
- 8. Provide the woman with her next scheduled visit date (at 1 year after her last visit) and location.
- 9. Provide the woman with a post-procedure prepackaged set.
 - a. A post-procedure prepackaged set should contain a set of sanitary pads, condoms and a post-procedure information sheet on LEEP.

XI. Infection Prevention and Care of the LEEP Machine and Accessories

A. Hand washing

Hand washing is the single most important step in preventing infection. Hand washing removes many microorganisms from the skin, which helps to prevent transmission of infections from person to person.

1. Hand washing should be done **before**:
 - a. The day's work
 - b. Examining a client
 - c. Performing any medical procedure (e.g., VIA, Cryotherapy, LEEP, insertion of an IUD or pelvic exam)
 - d. Handling clean, disinfected, or sterilized supplies for storage
 - e. Putting on sterile gloves
 - f. Going home.
2. Hand washing should be done **after** any situation in which the hands may be contaminated such as:
 - a. Handling instruments
 - b. Touching bodily secretions or excretions
 - c. Removing gloves
 - d. Personal use of the toilet
 - e. Blowing nose, sneezing, or coughing.
3. Supplies needed for hand washing:
 - a. Clean water (water may be running or from a bucket, but it must be clean)
 - b. Soap
 - c. Soap dish that drains and keeps the soap dry
 - d. Clean, dry cloth/towel (avoid sharing cloths/towels to ensure proper infection prevention)
 - e. Bucket and dipper, or alcohol if no running water is available
 - f. Soft sticks or brushes for nail cleaning, if available.

B. Decontamination, cleaning, and high-level disinfection

1. The three basic steps of the infection prevention processes recommended to reduce disease transmission from soiled instruments (speculum, forceps, loop and ball electrodes, injecting needles, etc.) and other reusable items are:
 - a. Decontamination
 - b. Cleaning
 - c. Sterilization or high-level disinfection.

C. Equipment and instruments required for decontamination and cleaning

1. Prior preparation of the following equipment and instruments is essential for proper decontamination:
 - a. Liquid/powder soap
 - b. Clean water
 - c. Measuring jug/container
 - d. Buckets for three different solutions.

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

- e. 0.5% chlorine [bleach]
 - If the required chlorine concentration is not available, you need to dilute it with water.
 - To determine the total parts water needed for dilution, you can use the following formula. Finally, mix 1 part concentrated chlorine with the total parts water to be added.

$$\text{Total parts water to be added} = \left(\frac{\% \text{ Concentrate (written on container)}}{\% \text{ Dilute (required concentration for the decontamination)}} - 1 \right)$$

Example: For 5% concentrated chlorine, you will take 1 part concentrated solution and add to 9 parts water.

D. Decontamination and cleaning process after completing LEEP

There are various kinds of instruments used in LEEP. These include insulated instruments, plastics and cords, loops and needles, and metallic instruments. Each requires different cleaning and decontamination solutions depending on the material it is made of.

1. **Insulated instruments:** These include speculums, vaginal wall retractors, pick-up forceps, tenaculum, or any other insulated metallic instrument.
 - a. These instruments require cleaning thoroughly with a soft brush and soapy water, then rinsing at least three times with clean water and air drying. Do NOT use bleach (Chlorine solution) to decontaminate.
 - b. After cleaning, these instruments need to be sterilized using autoclave.
 - c. The Leeps/Lietz “NLT Blue” insulation instrument may be disinfected with a glutaraldehyde solution. You must follow the manufacturer’s instructions precisely because these solutions are very aggressive and failure to follow procedure will cause instruments to degenerate over time.

Please note: Do not leave the instruments in a disinfectant solution for more than 2 hours. Rinse off all traces of the disinfectant solution with sterile water.

Please note: Once the instrument has been disinfected with a glutaraldehyde solution, it may no longer be steam autoclaved. Using both methods on an instrument may cause damage to the insulation.
 - d. Inspect the instrument insulation frequently before and after each use for cracks, nicks, cuts, and depressions which may decrease the effectiveness of the insulation and may lead to electric burn or shock when in contact with charged electrode.
 - e. Avoid contact with sharp instruments.
 - f. Always verify that there is never metal visible underneath the insulation coating.
2. **Wires and needles:** These include loop and ball electrodes and injecting needles. In addition to the metal or wire they include rubbers and/or plastics.
 - a. These instruments require cleaning thoroughly with a soft brush and soapy water. Then rinse them at least three times with clean water and dry properly.
 - b. Do NOT use bleach to decontaminate.
 - c. After cleaning, they can be placed in high-level disinfection solution (glutaraldehyde) for 20–90 minutes.
 - d. Pack them in a clean, dry place for storage.
3. **Rubbers and plastics:** These include electrical cords, pencil holder and smoke evacuator tube. These instruments can be decontaminated with 0.5% chlorine.

- a. Fully submerge them in the plastic container filled with 0.5% chlorine solution for only 10 minutes.
- b. After 10 minutes, clean these instruments with a brush and soapy water, then rinse at least three times with clean water and dry properly (use examination glove during cleaning).
- c. After decontamination, they can be placed in high level disinfection solution (Glutaraldehyde) for 20–90 minutes.
- d. Pack them in a clean and dry place for storage.

4. Metallic instruments: These include sponge forceps, kidney dish, needle holder, and any other non-insulated metallic instruments.

- a. Fully submerge used instruments in the plastic container filled with 0.5% chlorine solution for only 10 minutes.
- b. After 10 minutes, clean instruments with a brush and soapy water, then rinse at least three times with clean water and dry properly (wear examination gloves during cleaning).
- c. After cleaning, these instruments can be autoclaved.

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

5. Contaminated surface(s):

- a. If there is any surface (procedure table or instrument stand) that could have been contaminated by blood or other bodily fluid, you should decontaminate it by wiping it down with chlorine solution before you remove the glove, or the surface should be cleaned after each procedure.
- b. Dispose of contaminated objects (swabs and other waste) in a leak-proof container with cover while still wearing your glove.
- c. Immerse both gloved hands in the bucket containing 0.5% chlorine solution and remove by turning them the inside out and dispose of them in a leak-proof container. Do not exceed 135 C (275 F).
- d. After sterilization and before transporting to the LEEP unit, make sure metal bands around all drums are closed.
- e. Make sure all packs with cotton cloth are dry. (Condensation might develop, which increases the probability of microorganism accumulation.)
- f. Allow 30 minutes after sterilization for instruments to dry and cool.
- g. Transfer forceps and their holding containers should be cleaned and dried daily and whenever visibly contaminated (need sterilization).

E. Steam sterilization

1. After decontamination and cleaning, and before sending to the central sterilization room, pack all instruments independently.
2. Forceps and all other jointed instruments should be in the open or unlocked position.
3. Instruments should not be held tightly together in a way that will prevent steam contact with all surfaces.
4. Protect instruments from contact with other instruments during sterilization to extend product life.
5. Do NOT autoclave instruments unwrapped. Instruments and other clean items should be wrapped in a double thickness of cotton cloth.
6. Make sure a metal band around the drum is open before sterilization to allow steam into the drum through the perforated wall.

F. Chemical sterilization

1. If an autoclave is not available for steam sterilization, chemical sterilization can be done by soaking instruments and tubing in 24% glutaraldehyde for 8–10 hours or in 8% formaldehyde for 24 hours.
2. After using these two chemical methods, instruments must be rinsed with sterile water before use and dried with a sterile cloth to remove chemical debris.
3. After sterilization, store the instruments in a clean and dry place for reuse (unknown after how many procedures the electrode will fail, so always have a new unused one available for next procedure).

G. How to prepare solutions used with LEEP

Please note: Solutions can be purchased or prepared.

1. Acetic Acid Solution for VIA
 - a. You will need 5% acetic acid, glacial acetic acid 5 ml, and distilled water 95 ml.
 - b. Carefully add 5 ml of glacial acetic acid into 95 ml of distilled water and mix.
 - c. Unused acetic acid should be discarded at the end of the day.
 - d. Label as “5% dilute acetic acid.”
 - e. It is important to dilute the glacial acetic acid since undiluted it will cause severe chemical burns.

2. Lugol's Iodine Solution

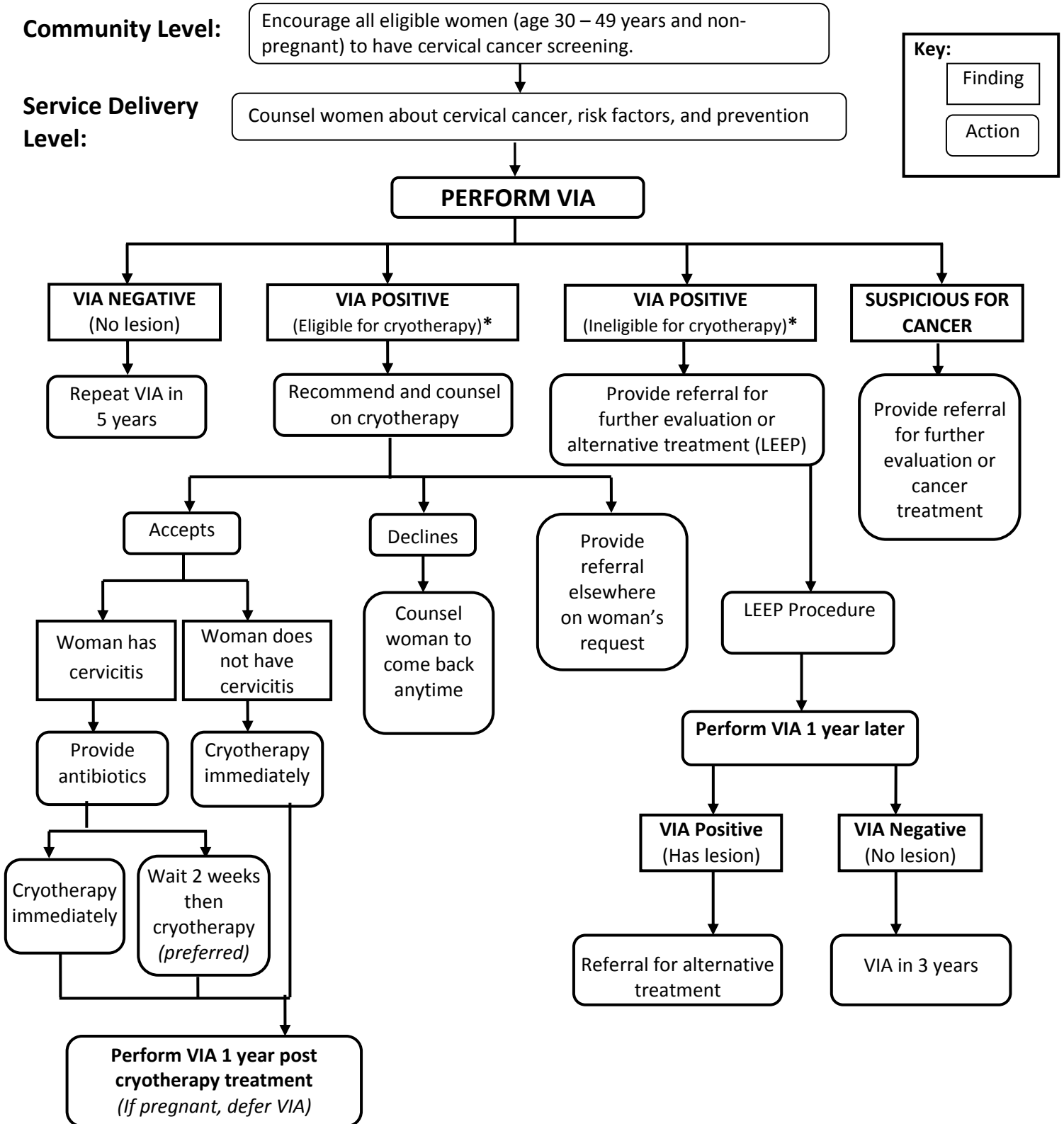
- a. You will need: 10 g potassium iodide, 100 ml distilled water, 5 g iodine crystals.
- b. Dissolve 10 g potassium iodide in 100 ml of distilled water.
- c. Slowly add 5 g iodine crystals while shaking.
- d. Filter and store in a tightly stoppered brown bottle.
- e. Label as "Lugol's Iodine Solution."
- f. Lugol's Iodine Solution can be stored for 1 month.

3. Monsel's Paste

- a. You will need: 15 g ferric sulfate, a few grains of ferrous sulfate powder, sterile water for mixing, 12 g glycerol starch.
- b. Make glycerol starch by mixing 30 g starch, 30 ml sterile water, and 390 g glycerine
- c. Dissolve the starch and add glycerine, and then shake and mix.
- d. Heat mixture over a Bunsen Burner.
- e. Mix with spatula until thick and swelling consistency (this solution is good for 1 year).
- f. Add a few grains of sulfate powder to 10 ml sterile water and shake.
- g. Dissolve the ferric sulfate base in the solution by stirring with glass stick (the solution should be clear).
- h. Put glycerol starch in a glass mortar and slowly add the ferric sulfate solution and mix to homogenous mixture.
- i. Place in 25 cc brown bottle. It may take 2–3 weeks to evaporate into paste-like consistency.

XII. Appendixes

Appendix 1: Cervical Cancer Prevention Flow Diagram for Service Provision



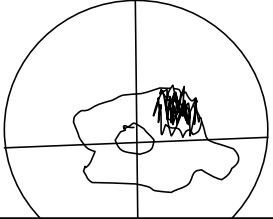
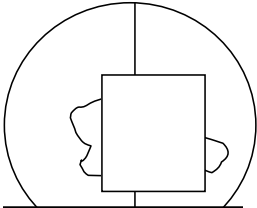
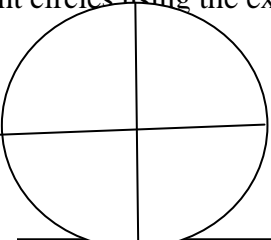
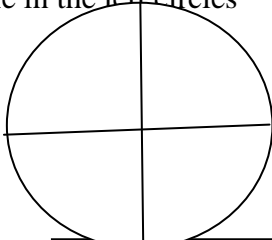
Appendix 2: LEEP Management Form

CLIENT IDENTIFICATION: MRN: _____ VIA Serial No. : _____
 Name of client: _____ Age: _____
 Address: _____ Tele: _____
 Date of visit _____ Time of examination: First examination Follow-up
 Educational Status (enter last grade completed): _____ Check box if illiterate

REPRODUCTIVE HISTORY:
 Marital status _____ Parity: _____ Current contraceptive(s): _____ Age at first intercourse: _____
 Pregnant: Yes (*If pregnant, do not screen*) No
Menstrual Bleeding Pattern: Regular (23-35 intervals) Irregular Menopause
 Postcoital spotting or bleeding
STI History: Number of sexual partner(s) of Client: _____ Of spouse: _____
 History of STI Client: Yes No Partner: Yes No
Risk Factors (check box with [Y] if yes and [N] if no):
 History of smoking Previous abnormal Pap smear Chronic corticosteroid use
HIV/AIDS testing: Unknown. Yes. If tested, enter chart status: Reactive Non-reactive

<p>FINDINGS FROM PREVIOUS VIA:</p> <ul style="list-style-type: none"> <input type="checkbox"/> VIA positive <input type="checkbox"/> Suspicious for cervical cancer <input type="checkbox"/> Uncertain diagnosis <p>DECISION: <input type="checkbox"/> Treated with LEEP onsite <input type="checkbox"/> Referred for LEEP excision</p>	<p>Reason for LEEP</p> <ul style="list-style-type: none"> <input type="checkbox"/> Lesion larger than cryoprobe <input type="checkbox"/> Lesion extending to vagina <input type="checkbox"/> Suspected early cancer <input type="checkbox"/> Uncertain about diagnosis <input type="checkbox"/> Other non gynecologic or gynecologic problem (state
---	---

Cervical map: Draw the lesion and excision on right circles using the example in the left circles

			
VIA positive lesion	LEEP Excision	VIA positive lesion	LEEP Excision

B: Description of LEEP procedures:.....
 Date of LEEP excision _____

C: Post-procedure note: Counseling given: Yes No
 Appointment given: Yes No Date of appointment: _____

Appendix 3: Client Consent Form for the Treatment of Cervical Precancerous Lesion

Name of hospital: _____

I, _____ have undergone voluntary screening for cervical cancer at _____ facility and was told by the health care provider that the screening result revealed acetowhite lesions (which could be cervical precancerous lesions) that can be removed/treated with a procedure called Loop Electro Surgical Excision Procedure.

The treatment procedure, the anesthetic technique, the intended benefit, follow-up schedule, post-treatment instructions, and possible side effects and complications have been described to me in language that I understand and I was given the opportunity to ask any questions about the procedure, effect of treatment, and any particular concerns I may have, including any available alternative treatments, and all have been answered. I am also well informed that the treatment is given voluntarily and I have full right to refuse from receiving the treatment without any penalty.

Thus, I understand all the necessary information given to me by the health care provider about the intended procedure and hereby would like to confirm by signing on this agreement form that I freely and voluntarily agree to receive the treatment.

Name of patient: _____ Name of health care provider: _____

Signature: _____ Signature: _____

Date: _____ Date: _____

Appendix 4: Post-LEEP Client Instructions/Advice

Expected symptoms after treatment (conditions you do *not* need to see health care provider about)

- You will have a brown or black vaginal discharge with streaks of blood for up to 2 weeks.
- If mild abdominal cramp (post-op pain) occurs you can take oral analgesics such as Acetaminophen or Ibuprofen.

Self-care at home (follow-up care after treatment)

- Do not use vaginal douche or tampons.
- No sexual intercourse for 1 month (it takes 3–4 weeks for the cervix to heal).
- You will receive a supply of condoms to be used for 6–8 weeks after the procedure (in areas where HIV is endemic).

Symptoms that require that you visit the health facilities and see a health provider:

- Malodorous discharge or persistent discharge for more than 2 weeks
- Severe abdominal pain with fever or with discharge
- Severe or moderate post-procedure bleeding

Follow-up:

- You are advised to come for VIA or colposcopy/Pap smear in 12 months.

XIII. References

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