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CHAPTER 4: SCREENING FOR CERVICAL CANCER

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Key points

- Screening is testing of all women at risk of cervical cancer, most of whom will be without symptoms.
- Screening aims to detect precancerous changes, which, if not treated, may lead to cancer.
- Screening is only effective if there is a well organized system for follow-up and treatment.
- Women who are found to have abnormalities on screening need follow-up, diagnosis and possibly treatment, in order to prevent the development of cancer or to treat cancer at an early stage.
- Several tests can be used in screening for cervical cancer. The Pap smear (cytology) is the only test that has been used in large populations and that has been shown to reduce cervical cancer incidence and mortality. Other tests (VIA, VILI, HPV) show promise but there is as yet no comparable evidence on their effectiveness. Large studies are still under way.
- Regardless of the test used, the key to an effective programme is to reach the largest proportion of women at risk with quality screening and treatment.
- Organized screening programmes designed and managed at the central level to reach most women at risk are preferable to opportunistic screening.

ABOUT THIS CHAPTER

This chapter provides detailed information on screening, and explains why organized screening is superior to opportunistic screening. It describes available screening tests and their comparative advantages and disadvantages.

ROLE OF THE HEALTH CARE PROVIDER

The health care provider is a central figure in any coordinated public health effort to screen women for cervical cancer. Such an effort may include the ministry of health, programme planners, managers, laboratory technicians, health professionals and community workers.

The role of health care providers is to ensure that:

- Women who come for screening receive appropriate information and counselling.
- National guidelines on cervical cancer screening and treatment are followed.
- Screening is well organized and no opportunity to screen targeted women attending services is missed.

- Each woman who comes for screening understands what is involved and gives informed consent for screening and follow-up.
- The screening test, treatment and referral are performed competently; patients are properly assessed and infection control measures are strictly adhered to.
- Women screened are informed of their test results, especially if they are inadequate or positive (abnormal).
- Any sexual and reproductive health problems identified by either the patient or the provider are managed appropriately.
- Appropriate and confidential records are kept in the facility; the records may be given to the woman herself.
- Women who need repeat screening, further testing, referral, or care after treatment are followed up appropriately.

These responsibilities are further explained in this chapter.

STORY ⁵

Pratibha is a 37-year-old woman living in Maharashtra, India. One day, when she returned home from fetching water, she found two women health workers talking with her husband. The health workers asked her many questions, such as how old she was, when she married, and how many children she had. Then they told her about cervical cancer and about an opportunity for her to be screened in the village. Pratibha asked why she was selected for this and she was relieved to learn that all women over 30 years old in the village were being visited and invited to attend the screening clinic. One of the advantages of attending this programme was that testing and treatment (if needed) were free. Almost all the women invited attended the clinic, including Pratibha. The test was fast and painless, as she had been told it would be. After the examination, the health worker emphasized that she should return in two weeks to get the test results. When Pratibha returned, she was told that her test was normal and that it would be important for her to repeat the test every 3 years.



⁵ Adapted from: Alliance for Cervical Cancer Prevention. *Women's stories, women's lives: experiences with cervical cancer screening and treatment*. Seattle, WA, ACCP, 2004.

SCREENING PROGRAMMES

What is screening?

Screening is a public health intervention used on a population at risk, or target population. Screening is not undertaken to diagnose a disease, but to identify individuals with a high probability of having or of developing a disease. Women targeted for screening for cervical cancer may actually feel perfectly healthy and may see no reason to visit a health facility.

Not all diseases can be screened for. The following criteria should be met by any disease that is the object of a screening programme:

- The disease must have serious public health consequences.
- The disease must have a detectable preclinical stage (without symptoms).
- The screening test must be simple, non-invasive, sensitive, specific, inexpensive and acceptable to the target audience.
- Treatment at the preclinical stage must favourably influence the long-term course and prognosis of the disease.
- Any further testing and treatment needed must be available, accessible and affordable for those who have a positive screening test.

Cervical cancer meets these criteria.

Screening programmes will only be successful if the following elements are present:

- high coverage ⁶ (80%) of the population at risk of the disease;
- appropriate follow-up and management for those who are positive on screening. Efforts to increase coverage will be wasted if those who test positive are not followed up correctly;
- effective links between programme components (e.g. from screening to diagnosis and treatment);
- high quality of coverage, screening tests, diagnosis, treatment, and follow-up;
- adequate resources.

Cervical cancer screening aims to test the largest possible proportion of women at risk and to ensure appropriate follow-up for those who have a positive or abnormal test result. Such women will need diagnostic testing and follow-up or treatment. Colposcopy and biopsy are often used to reach a specific diagnosis of the extent of the abnormality in women with a positive screening test (see Chapter 5).

⁶ “Coverage” is the proportion of women in the target age group who are screened at the recommended intervals during a given time period. The number of screening tests done is not coverage, since this number may include women outside the target age, and women screened more often than recommended.

Organized and opportunistic cervical cancer screening

Organized screening

Organized screening is designed to reach the highest possible number of women at greatest risk of cervical cancer with existing resources. It is usually planned at the national or regional level. An organized screening programme should specify:

- the target population;
- screening intervals;
- coverage goals;
- a mechanism for inviting women to attend screening services;
- the screening test or tests to be used;
- the strategies to ensure that all women found positive on screening are informed of their result;
- a mechanism for referring women for diagnosis and treatment;
- treatment recommendations;
- indicators for monitoring and evaluating the screening programme.

Opportunistic screening

Opportunistic screening is screening done independently of an organized or population-based programme, on women who are visiting health services for other reasons. Screening may be recommended by a provider during a consultation, or requested by a woman. Opportunistic screening tends to reach younger women at lower risk, who are attending antenatal, child health and family planning services.

It is generally accepted that organized screening is more cost-effective than opportunistic screening, making better use of available resources and ensuring that the greatest number of women will benefit. However, both organized and opportunistic screening can fail because of poor quality-control, low coverage of the population at risk, overscreening of low-risk populations, and high loss to follow-up.

Benefits and risks of screening

The benefits and risks of screening should be discussed with women as part of general health education and before obtaining informed consent. The benefits of screening have been described in previous chapters. However, as with all large efforts directed towards healthy populations, screening for cervical cancer has the potential to produce undesirable outcomes, such as:

- psychological consequences – anxiety and fear about being tested for cancer;
- a mistaken belief that a positive test is a cancer diagnosis;

- false positive test results (abnormalities reported in women whose cervix is normal), which may lead to unnecessary interventions and anxiety;
- false negative test results (a normal screening test in women with cervical abnormalities);
- identification of other illnesses, for which treatment may not be available.

Following the recommendations in this Guide will, in general, help to minimize these undesirable outcomes.

Target groups and frequency of screening

Decisions on the target age group and frequency of screening are usually made at the national level, on the basis of local prevalence and incidence of cervical cancer, related factors such as HIV prevalence, and availability of resources and infrastructure.

All existing data on recommended ages and frequency of screening are derived from experience in cytology programmes. To date, there are no comparable data from programmes using HPV-based and visual screening methods.

When deciding on target age group and screening frequency, planners should take into account the following:

- HPV infection is very common in young women, but most infections are transient.
- Only a small percentage of all HPV infections will lead to invasive cancer.
- Cervical cancer usually develops slowly, taking 10–20 years from early precancer to invasive cancer.
- Cervical cancer is rare before the age of 30 years. Screening younger women will detect many lesions that will never develop into cancer, will lead to considerable overtreatment, and is not cost-effective.
- Screening every three years is nearly as effective as yearly screening. If resources are limited, screening every 5–10 years – or even just once between the ages of 35 and 45 years – will significantly reduce deaths from cervical cancer.

RECOMMENDED TARGET AGES AND FREQUENCY OF CERVICAL CANCER SCREENING

- New programmes should start by screening women aged 30 years or more, and include younger women only when the higher-risk group has been covered. Existing organized programmes should not include women less than 25 years of age in their target populations.
- If a woman can be screened only once in her lifetime, the best age is between 35 and 45 years.
- For women over 50 years, a five-year screening interval is appropriate.
- In the age group 25–49 years, a three-year interval can be considered if resources are available.
- Annual screening is not recommended at any age.
- Screening is not necessary for women over 65 years, provided the last two previous smears were negative.

Special considerations

Before embarking on a widespread screening programme, national planners should ensure that the services needed to manage newly identified cancer cases are in place. To treat invasive cancer effectively, specialized facilities are needed; these must be in place before a screening programme is put into effect (see Chapter 6).

If a population has not previously been screened, many cases of pre-existing cancer in different stages will be detected in a new screening programme. Women whose disease is very advanced, or for whom treatment is impossible for any reason, should receive palliative care (see Chapter 7).

Screening in settings with high HIV prevalence

In settings with high HIV prevalence, screening for cervical cancer is particularly important. HIV-positive women have more persistent HPV infections, and a higher incidence of cervical precancer and, in some settings, invasive cervical cancer. Where HIV is endemic, screening results may be positive in up to 15–20% of the target population. Cytology screening is equally effective in HIV-positive and HIV-negative women. Although HIV-infected women are at greater risk of precancer and cancer, screening, follow-up and treatment may not be a priority for the women themselves, who have competing health or social needs. All women, regardless of their HIV status,

should be encouraged to be screened for cervical cancer, provided that they have access to affordable services. Care should be taken not to link a positive cervical cancer screening test to HIV testing. However, a woman with precancer may benefit from knowing her HIV status, especially if antiretroviral treatment (ART) is available. Screening criteria for women with known HIV infection should be developed at the national level with these issues in mind.

RECOMMENDATION

Women should be offered the same cervical cancer screening options irrespective of their HIV status.

Screening of pregnant women

Not screening for cervical cancer during pregnancy is sometimes seen as a missed opportunity. Visits for antenatal care may be a good occasion for screening. However, integrating screening into routine antenatal care is not the best option for the following reasons:

- Most pregnant women are younger than the target group.
- In some cultures, pregnant women may be reluctant to undergo a gynaecological examination.
- During pregnancy, interpretation of screening tests, such as cytological tests, is more difficult.
- Regression of CIN during pregnancy is minimal, but there is a significant rate of spontaneous regression postpartum.
- A biopsy for diagnosis should be taken from a pregnant woman only if invasive cancer cannot be ruled out.
- Treatment of preinvasive disease is contraindicated during pregnancy.

Women in the target age group who attend antenatal services should be advised to return for screening 12 weeks after giving birth. However, if a cervical abnormality is noted on speculum examination, or if the provider feels there is a risk that the woman will not return, she should be offered screening during the visit. In addition, the provider can suggest that the woman should encourage other women in the target age group in her extended family to be screened.

Screening family planning clients

Opportunistic cervical cancer screening is often integrated into family planning services. Family planning counselling provides a good opportunity to discuss the benefits of cervical cancer screening and a gynaecological examination is often more easily accepted during a reproductive health consultation. Screening should be encouraged and performed on clients of family planning services within the target age group. Contraceptive users do not need to be screened more often than other women, regardless of the method they use.

Screening women with a reproductive tract or sexually transmitted infection (RTI/STI)

Women in the target age group who present to health facilities with complaints suggestive of RTI/STI should be examined. They should be screened for cervical cancer only if there is no visible acute infection. If the speculum examination reveals evidence of acute infection, appropriate treatment should be given and cervical cancer screening should be deferred until after the infection has resolved.

Health education and counselling on RTI/STI should include information on HPV infection, its relation to cervical cancer, and the protection offered by safer sex behaviours, including condom use. Male partners too should be treated, and counselled on cervical cancer prevention. STI services aimed primarily at men should include information on HPV and cervical cancer prevention.

Other opportunities for cervical cancer screening

Women at the end of their reproductive years are at greatest risk of cervical cancer, particularly if they have never been screened. They tend to use reproductive health services less often than younger women, but may use other health services, e.g. for management of hypertension, heart disease, diabetes or infectious diseases. In addition, women in the target age group may come to a health facility with a child or relative who needs services. All women in the target age group who visit a facility for any reason should receive information and be encouraged to come for screening (see also Chapter 3). General medical services at primary, secondary and tertiary levels can provide cervical cancer screening for such women, using on-site, trained providers. If this is not possible, women should be given health education and referred to a convenient screening clinic.

No missed opportunities

Cervical cancer screening programmes should also try to reach all women in the target age group who have contact with the health system for any reason.

Choice of screening test to be used

The choice of screening test or tests to be used is usually made at the national or regional level. Nevertheless, providers should have some basic knowledge of all the available screening tests.

Decisions on the test or tests to be used may be based on:

- the organization of the health system;
- the funds available;
- the number and type of health workers;
- the availability of laboratory services and transport;
- the availability and cost of the various screening tests.

The test used may also be determined based on the physical proximity of services to women; for example, it might be decided to use the Pap smear (which requires women to return for their test results) in urban areas and visual inspection with acetic acid (VIA) (for which results are immediately available) in more inaccessible rural areas in the same country.

The most extensive and long-term experience in cervical cancer screening is with cytology, which has been used in numerous countries since the 1950s. Cytology-based screening and treatment programmes have reduced cervical cancer incidence and mortality by as much as 80% in Canada, the USA and some Nordic countries, and by 50–60% in other European countries.

It has been difficult to replicate this success in low-resource settings, because of the inherent requirements of a cytology-based programme. These include highly trained personnel, well equipped laboratories, transport of specimens, and an effective system for collecting information and following up patients. In addition, the demands of other competing health needs often result in a lack of resources or political will to make cervical cancer screening a priority.

Because of the problems of implementing quality cytology-based screening, alternative methods, such as visual inspection, have been developed. These methods have shown promise in controlled research settings but have not yet been widely implemented. Their ultimate impact on cervical cancer incidence and mortality will not be known until large ongoing population-based studies are completed. HPV-based tests are now also commercially available, but have disadvantages, including the need for sophisticated laboratory facilities and high cost.

Ethical issues

Decisions on how best to use scarce resources have to weigh the extent of disability and death caused by different diseases, and the efficacy, cost and impact of diagnosing and treating them. While decisions about priorities are usually made at national level, providers should understand the reasons for the decisions, so that they are motivated to implement them and can explain them to their patients (see Chapter 1). If well planned and integrated into other sexual and reproductive health activities, screening for cervical cancer has the potential to both strengthen the health care system and improve the health of women, particularly women over childbearing age, whose health is often relatively neglected.

Before a screening programme is implemented, the following elements should be considered to ensure an ethical and equitable approach:

- Screening should be accessible to all women in the target group, including the poorest, most vulnerable, and hardest to reach.
- Patients, providers and communities should receive health education to ensure informed decision-making on screening and treatment.
- Patient record systems should ensure confidentiality.
- Diagnostic tests, follow-up, and treatment should be available and accessible.
- Providers should have clear guidelines on follow-up and management of women with positive screening results.
- A referral system should be in place for other health problems, including gynaecological disorders, discovered during the screening process.

*Informed choice and Informed consent*⁷

Informed choice and informed consent are based on the ethical principles of autonomy and respect for the individual. In many cultures, the notion of consent may be a collective decision-making process involving others, such as partner, family, and village leaders. Accurate information provided through health education and counselling can ensure that women and their extended families understand the facts about cervical cancer, who is at risk, how screening can reduce risk, and any potential harm related to screening. Before consenting to screening, women should be given information on the specific test to be used, the meaning and consequences of a positive test, and the availability of treatment. In addition, when results are not available immediately (as they are with



Informed consent

⁷ *Note:* informed consent is not equivalent to informed choice. Consent refers to the explicit permission given by a person for a procedure or test, once she (or he) has received sufficient information to make a rational personal (informed) choice.

visual screening methods), informed consent should include explicit permission to be contacted at home or at work. Respect for autonomy requires that the choice to be screened is voluntary and free of coercion.

Client assessment

All clients attending for screening should have a basic assessment before proceeding to the screening test. This assessment should include information and counselling, informed consent, a social and clinical history, and a physical examination.



The history can provide useful information for guiding decisions about management or additional examinations or tests that might benefit the patient. Because of the stigma associated with genital problems, women are often reluctant to talk about their concerns or symptoms and signs. To establish and maintain trust and respect, confidentiality and privacy must be explicitly guaranteed to each woman who presents for screening before she is asked about her history.

For cervical cancer screening, the essential components of the pelvic examination are visual inspection of the external genitals and a speculum examination. Providers should explain what is being done at each step during the examination; if an abnormality is noted, the provider should inform the woman without alarming her. Having female providers perform the physical examination, if possible, can greatly reduce reluctance to be examined and can play a major role in making screening acceptable. When the provider is a man, the woman may request that a female companion or clinic attendant is in the room.



Sexual and reproductive health problems detected during history-taking and examination

An integrated approach to management of sexual and reproductive health problems during screening can help improve the health of women, especially older women. The provider should pay particular attention to signs and symptoms suggestive of cancer, STI, or other diseases detected during history-taking and pelvic examination. In addition, women should be offered an opportunity to raise personal concerns regarding sexual and reproductive health issues. Women with abnormal findings can be treated or referred for further investigation, as appropriate.

Infection prevention in cervical cancer screening

In screening, as in all clinical activities, scrupulous attention should be given to infection prevention. Pathogens, including HIV, can be transmitted if guidelines on handwashing, handling of instruments, and disposal of used supplies, including gloves, are neglected.

Universal precautions (see Annex 1) against spreading infection should be used with all patients, whether they appear sick or well, and whether their HIV or other infection status is known or not. In this way, providers protect both their patients and themselves. Providers should use only uncontaminated instruments, and should wear latex gloves on both hands when performing speculum or bimanual examinations and taking specimens, and when performing procedures such as cryotherapy.



Infection prevention

SCREENING TESTS

A good screening test should be:

- accurate;
- reproducible;
- inexpensive;
- easy to perform and easy to follow up;
- acceptable;
- safe.

The following tests meet the above criteria to a greater or lesser extent:

- cytology: conventional (Pap smear) and liquid-based;
- HPV DNA test;
- visual inspection: with acetic acid (VIA) or Lugol's iodine (VILI).

The performance of each test is described below. The strengths and limitations of the different tests are summarized in Table 4.1. Measurement and interpretation of performance characteristics are outlined in Annex 3.



Test's performance

Cytology

Conventional Pap smear

In the Pap smear test, a sample of cells is taken from the transformation zone of the cervix using an extended-tip wooden spatula or brush; using a cotton swab is no longer recommended. The entire transformation zone should be sampled since this is where almost all high-grade lesions develop. The sample is then smeared onto a glass slide and immediately fixed with a solution to preserve the cells. The slide is sent to a cytology laboratory where it is stained and examined using a microscope to determine whether the cells are normal (Figure 4.1) and to classify them appropriately, using the Bethesda classification (see Annex 2). The results of the Pap smear are then reported to the clinic where the



Pap smear

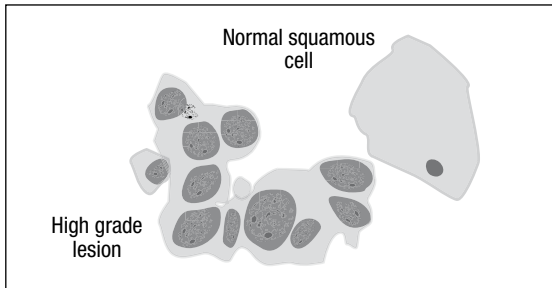


Bethesda system

specimen was taken. Health workers are responsible for ensuring that the woman is informed of her result and that she receives appropriate follow-up as outlined in Annex 4a. The Pap test takes less than 5 minutes to perform, is not painful, and can be done in an outpatient examination room. It is advisable to postpone taking a Pap smear if the woman is menstruating actively, has a clinically evident acute inflammation, or is pregnant. A satisfactory smear requires adequate numbers of well preserved squamous epithelial cells and an adequate endocervical/transformation zone component. Each smear should be legibly labelled.



Figure 4.1 Graphic representation of normal and abnormal epithelial cells



The accuracy of cytological testing depends on the quality of the services, including sampling practices (taking and fixing the smears), and preparation and interpretation of smears in the laboratory. Under the best conditions in developed countries or research settings, conventional cytology can detect up to 84% of precancer and cancer. However, under poor conditions its sensitivity can be as low as 38%. The specificity of the test is usually over 90%.

Liquid-based cytology (LBC)

This refinement of conventional cytology was introduced in the mid-1990s and is increasingly used in high-resource settings. Instead of smearing cervical cells on a slide, the provider transfers the specimen from a brush to a preservative solution. The specimen is sent to a laboratory where the slide is prepared. LBC is more expensive than conventional cytology and laboratory staff need to be specially trained. However, it appears to have a number of advantages over conventional methods.

- The specimens obtained are more representative of the areas sampled with fewer false negatives.
- There are fewer unsatisfactory specimens.
- Each specimen requires a shorter interpretation time, leading to increased efficiency and cost-effectiveness.
- The material collected can also be tested for HPV DNA.

Although, as yet, no randomized controlled trial comparing LBC with conventional Pap smear has been published, several studies have shown that LBC is more sensitive than Pap smear and has almost the same specificity.

Providers

After a short training course, any provider who knows how to do a speculum examination (nurse, auxiliary or assistant nurse, midwife, clinical officer, medical doctor) can take a Pap smear.

Indications

The following groups of women should be offered screening:

- Any woman between the ages of 25 and 65 years, who has never had a Pap smear before or who had one 3 or more years ago (or according to national guidelines).
- Women whose previous Pap smear was reported as inadequate or showed a mild abnormality.
- Women who have abnormal bleeding, bleeding after intercourse or after the menopause, or other abnormal symptoms.
- Women who have been found to have abnormalities on their cervix.

Interpretation of smears

Smears are read in a laboratory by trained cytotechnicians, under the supervision of a pathologist, who has final responsibility for the reported results. Correct interpretation of slides is crucial to a successful programme. To maintain proficiency and avoid fatigue, cytotechnicians should spend a maximum of 5 hours a day at the microscope and should review a minimum of 3000 slides per year. Quality assurance is crucial and should be established in all cytology laboratories. The two most commonly used methods are rapid review of all negative slides, and full rescreening of a 10% random sample of slides originally reported as negative. In both methods, the review is done by another cytotechnician, with confirmation of abnormal smears by the supervising pathologist. Current evidence shows that, of the two methods, rapid review of all negative smears is more effective and more cost-effective.⁸ Laboratories should be equipped to read a minimum of 15 000 smears annually.⁸ Therefore, cytology services should not be decentralized to primary health care clinics or to small laboratories. Reliable transport of slides and test results to and from the laboratory is essential.

⁸ Detailed information on cytology laboratories is beyond the scope of this Guide. Further information can be found in the references listed under “Additional resources” at the end of this chapter.

The speed with which results are sent to the health facility is an important element of the quality of the laboratory service and the quality of care, and greatly affects women's satisfaction with the service.

RECOMMENDATION

Cytology is recommended for large-scale cervical cancer screening programmes, if sufficient resources exist.

HPV DNA-based screening methods

New screening procedures are based on the detection of high-risk HPV DNA in vaginal or cervical smears. A sample of cells is collected from the cervix or vagina using a swab or small brush, and placed in a small container with a preservative solution. The specimen can be collected by a health care provider or by the woman herself, inserting a swab deep into the vagina. Studies comparing the two collection methods have shown that self-collection is less sensitive than provider-collection. In either case, the specimen containers are transported to a laboratory where they are processed. HPV DNA-based tests currently require sophisticated and expensive laboratory equipment, although work is under way to develop a more affordable and less complicated test that can be carried out in lower-level settings. Detection of high-risk HPV does not necessarily mean that precancer or cancer is present; it indicates simply that there is an HPV infection. As mentioned earlier, HPV infections are extremely common in women under 35 years, and most of them resolve spontaneously. When detection of HPV is used as a primary screening test, the sensitivity for detection of precancer and cancer varies from 50% to 95%, with most studies reporting high sensitivity of 85% or more. The specificity ranges from 50% to 95%, with an average of 84%. In women aged 35 years or older, HPV DNA tests perform better because in these women a positive test is more likely to be due to a persistent infection than in younger women. The average sensitivity and specificity in this group are 89% and 90%, respectively. The combination of cytology and HPV testing has very high sensitivity and negative predictive values approaching 100% (see Annex 3). It might therefore be possible to increase the interval between screenings for women who are negative on both tests. However, performing the two tests together is expensive. The high cost, and the need for both a molecular laboratory and reliable methods of transport, present major challenges, and the feasibility of HPV testing has not been demonstrated in low-resource settings. A new, faster, highly sensitive and less costly test for HPV is under development but is not yet available.



HPV test



Annex 3

Providers

HPV DNA testing can be done by trained providers at any level of the health care system, provided that there is an appropriate laboratory within a reasonable distance, and that reliable transport is available for specimens. Clinic needs for HPV testing are the same as for Pap smears and visual methods.

Indications

HPV is not generally used on its own as the primary screening test. It is mainly used in combination with cytology to improve the sensitivity of the screening or as a triage tool to assess which women with borderline Pap results need to be referred for colposcopy. The main indication is a Pap result of “atypical cells of undetermined significance” (ASC-US). Of the women with this lesion, only those who test positive for high-risk HPV will need to be referred for colposcopy and biopsy, significantly reducing the number of colposcopies.

Laboratory facilities

The HPV laboratory requires a special clean room to avoid contamination, and highly trained technicians. It also requires equipment and reagents as specified by the manufacturers of the test.

RECOMMENDATION

HPV DNA tests as primary screening methods, at this time, are recommended for use only in pilot projects or other closely monitored settings. They can be used in conjunction with cytological or other screening tests, where sufficient resources exist. HPV DNA-based screening should not begin before 30 years of age.

Visual methods

Two visual methods are available:

- visual inspection with acetic acid (VIA);
- visual inspection with Lugol's iodine (VILI).



VIA and VILI

Abnormalities are identified by inspection of the cervix without magnification, after application of dilute acetic acid (vinegar) (in VIA) or Lugol's iodine (in VILI). When vinegar is applied to abnormal cervical tissue, it temporarily turns white (acetowhite) allowing the provider to make an immediate assessment of a positive (abnormal) or negative

(normal) result. If iodine is applied to the cervix, precancerous and cancerous lesions appear well-defined, thick, and mustard or saffron-yellow in colour, while squamous epithelium stains brown or black, and columnar epithelium retains its normal pink colour.

Because they do not rely on laboratory services, VIA and VILI are promising alternatives to cytology where resources are limited. They are currently being tested in large, cross-sectional, randomized controlled trials in developing countries. Until data from these studies are available, VIA and VILI are recommended by WHO only for use in pilot settings, because the impact on cervical cancer incidence and mortality is still unproven. In research settings, VIA has been shown to have an average sensitivity for detection of precancer and cancer of almost 77%, and a range of 56% to 94%. The specificity ranges from 74% to 94% with an average of 86%. Low-level magnification does not improve the performance of VIA over and above that of naked eye visualization. One study has shown that VILI can detect 92% of women with precancer or cancer, a sensitivity considerably higher than that of either VIA or cytology. Its ability to identify women without disease is similar to that of VIA (85%), and lower than that of Pap smears. One study showed that VILI had a higher reproducibility than VIA. VIA and VILI can be performed in clinics and other outpatient facilities. They are both short procedures and cause no pain. Assessment is immediate, and no specimen is required.

Advantages

- VIA and VILI are relatively simple and can be taught to nurses, nurse-midwives and other health workers.
- Assessment is immediate and no transport, or laboratory equipment or personnel, is needed.
- The tests are likely to be less costly than other approaches in routine use.
- Results are available immediately, eliminating the need for multiple visits in most cases, and reducing loss to follow-up.
- They could potentially be used in an approach based on screening and treating women in a single visit (see Chapter 5).

Disadvantages

- Because of the low positive predictive value of the test (see Annex 3), a considerable number of women who test positive do not have disease, resulting in excessive diagnosis and treatment, and unnecessary anxiety.
- Visual tests cannot be relied on in postmenopausal women, because the transformation zone of these women is often inside the cervical canal.



Annex 3

- There is no permanent record of the test that can be reviewed later.
- VIA has mostly been evaluated as a once-in-a-lifetime screening test, and its performance in periodic screening has not been assessed.

Providers

Trained nurses, nurse-midwives, nurse assistants, physicians and other health workers with adequate and ongoing support and supervision can perform VIA. Training takes 5–10 days using a competency-based approach. To maintain quality services, it is important that an experienced provider conducts regular assessments. Studies show that immediately after training, providers have more false positive results. These decrease in a few months as the providers gain experience.

Indications

If adopted by a programme as a screening method, VIA and VILI are indicated for all women in the target age group specified in national guidelines, provided that:

- They are premenopausal. Visual methods are not recommended for postmenopausal women, because the transition zone in these women is most often inside the endocervical canal and not visible on speculum inspection.
- Both squamocolumnar junctions (i.e. the entire transformation zone) are visible.

If the patient does not meet the above indications and no alternative screening method is available in the particular clinical setting, she should be referred for a Pap smear.

RECOMMENDATION

Visual screening methods (VIA and VILI), at this time, are recommended for use only in pilot projects or other closely monitored settings. These methods should not be recommended for postmenopausal women.

Table 4.1 Summary of characteristics of screening methods for cervical cancer

Test	Procedure	Strengths	Limitations	Status
Conventional cytology (Pap smear)	Sample of cervical cells taken by provider and examined by trained cytotechnicians in a laboratory	• History of long use • Widely accepted • Permanent record of test • Training and mechanisms for quality control established • Modest investments in existing programmes can improve services • High specificity	• Results not immediately available • Systems needed to ensure timely communication of test results and follow-up of women • Transport required for specimen to laboratory and for results to clinic • Requires laboratory quality assurance • Moderate sensitivity	• Available in many countries since the 1950s • Cytology-based programmes have reduced cancer mortality in developed countries
Liquid-based cytology (LBC)	Sample of cervical cells is obtained with a small brush, immersed in special liquid and sent to laboratory for processing and screening	• Fewer inadequate or unsatisfactory samples requiring patient call-back and rescreening • Once cytotechnicians are proficient, LBC samples take less time to review • Samples can be used for molecular testing (such as for HPV)	• Results not immediately available • Supplies and laboratory facilities more expensive than for conventional cytology • No controlled studies, to date, comparing sensitivity and specificity with conventional cytology	Selected as screening method in some developed countries (e.g. United Kingdom)

continued next page

Continued from page 99

Table 4.1 Summary of characteristics of screening methods for cervical cancer

Test	Procedure	Strengths	Limitations	Status
HPV DNA testing	Molecular testing for HPV – swab taken by provider or woman herself and sent to laboratory	• Collection of specimen simple • Automated processing • Can be combined with Pap smear to increase the sensitivity, but this increases also the cost • A negative test means no HPV and related morbidity is present • The assay result is a permanent record • High specificity in women over age 35	• Results not immediately available • High unit cost • Complex laboratory requirements and specimen transport • Low specificity in young women leading to overtreatment • Storage of reagents problematic	• Commercially available and used in some developed countries in addition to cytology • Lower-cost tests in development
Visual methods (VIA and VILI)	Trained provider examines cervix after staining with vinegar (in VIA) and with Lugol's iodine (in VILI)	• Relatively simple and inexpensive • Results available immediately • Can be performed by wide range of personnel after short training • Low level of infrastructure required • Can be combined with offer of immediate treatment in single-visit approach	• High provider variability • Lower specificity resulting in high referral rate and overtreatment • No permanent record of test • Not appropriate for postmenopausal women • Lack of standardization • Frequent retraining needed	• Limited evidence available • Only recommended at this time for use in demonstration projects • Large randomized controlled trials under way to determine effect on cancer incidence and mortality

FOLLOW-UP

Follow-up and management of women with an abnormal (positive) test

Screening by itself will not prevent a single case of cervical cancer. An effective system for follow-up and treatment of women who test positive is perhaps the most important component of a successful cervical cancer prevention programme.

Ideally, all women should receive the results of their test, whether negative or positive. In practice, resources will sometimes be too limited to allow this.

At the very least, women whose test result is positive or abnormal must be informed of the result and of what follow-up is needed.

Follow-up should be in line with national protocols or based on the recommendations found in Annex 4.



Flowchart screening

Follow-up is essential for the woman's welfare and for the success of the programme and every effort should be made to contact women with positive test results.

The following actions will help ensure that women with an abnormal screening test can be reached for follow-up:

- The woman's address, or other information on how she can be reached, should be noted at the time of screening (with her consent).
- During counselling and after screening, providers need to emphasize the importance of coming back for results and follow-up care.
- Every clinic should have a directory of all women with abnormal test results, with an indication of whether they have received the results and been followed up. Clinics should designate someone to ensure that follow-up is done.

For women who do not return spontaneously as advised, providers can:

- send a letter by mail;
- telephone women at home or at work;
- ask community health workers to contact women directly at home.

Health care managers and providers can develop other locally appropriate approaches to reach women with abnormal screening tests.

Health facilities need to make every effort to find women with abnormal results if they do not return for scheduled appointments.

Record-keeping

Records should be compatible throughout a country, so that all the data collected by the cervical cancer control programme can be compared. The information system should include every woman's clinical record, appointments scheduled, and those kept or missed. This can be a simple paper record or can be computer-based. A logbook can be used to register women screened and record their test results. If women need to return later for their results, a system must be in place to ensure that those with abnormal results are notified and that women who are hard to locate are traced. Sample forms for follow-up can be found in Annex 7.



Documents

SCREENING ACTIVITIES AT DIFFERENT LEVELS OF THE HEALTH SYSTEM

In the community



- Educate and inform the community, promote the screening programme, and encourage women to attend.
- Refer appropriate women for screening.
- Assist women to attend screening clinics.
- Assist in follow-up of women with a positive screening to ensure that they return to the clinic for management.

At the health centre



- Screen, using methods specified by national guidelines and integrating screening into other services.
- Train, support and supervise CHWs.
- Work with CHWs to educate women, and recruit them for screening.
- Participate in campaigns to bring women at high risk for testing.
- Provide counselling and health education in the clinic and community.
- Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- Implement an accurate patient information system, to allow proper tracking and follow-up of women after treatment.

At the district hospital



- Carry out screening activities as per national programme.
- Inform and counsel women with positive screening test results, and advise them on needed follow-up, diagnosis and treatment.
- Train, support and supervise providers at health centre level.
- Manage referral systems with lower and higher levels of the health system.

At the central hospital



- Carry out screening in outpatient clinics where women are seen.
- Maintain central cytology, pathology, and molecular laboratories, as feasible.
- Interpret screening and histopathology results and ensure that results reach the screening site.
- Train medical personnel, and support and supervise providers in lower-level health facilities.
- Manage referral and links with lower levels of the health system.

Counselling messages

4

Chapter 4: Screening for Cervical Cancer

Women who have just had a screening test need to be told:

- if anything abnormal was noted;
- when the results will be available;
- the date of the next appointment.

Women returning for test results should be counselled on:

- the result of the test and what it means;
- if normal, when they need to return for repeat screening;
- if inadequate or not normal, what follow-up is needed;
- where and when to go for follow-up.

ADDITIONAL RESOURCES

- ACCP. *Planning and implementing cervical cancer prevention programs: a manual for managers*. Seattle WA, Alliance for Cervical Cancer Prevention, 2004.
- Arbyn M. *A technical guideline: collection of adequate Pap smears of the uterine cervix*. Brussels, Scientific Institute of Public Health, 2001.
- *Cervical cancer prevention: guidelines for low-resource settings*. Baltimore, MD, JHPIEGO Corporation, 2001.
- CHIP. *Implementing cervical screening in South Africa. Volume I. A guide for programme managers*. New York, Cervical Health Implementation Project, South Africa, University of Cape Town, University of the Witwatersrand, EngenderHealth, 2004.
- IARC. *A practical manual on visual screening for cervical neoplasia*. Lyon, IARC Press, 2003.
- IARC. *Cervix cancer screening*. Lyon, IARC Press, 2005 (IARC Handbooks of Cancer Prevention, Volume 10).
- *Infection prevention: a reference booklet for health care professionals*. New York, EngenderHealth, 2001.
- *Infection prevention curriculum: a training course for health care providers and other staff at hospitals and clinics*. New York, EngenderHealth, 1999.
- Miller AB. *Cervical cancer screening programmes, managerial guidelines*. Geneva, WHO, 1992.
- PATH. *Planning appropriate cervical cancer prevention programs*. Seattle, WA, Program for Appropriate Technology in Health, 2000.
- PATH VIA/VILI curriculum. Course in visual methods for cervical cancer screening. In: Tsu V et al., *Western Kenya Cervical Cancer Prevention Project Final Report*. Seattle, WA, Program for Appropriate Technology in Health, 2004 (Annex 10).
- Salas Diehl I, Prado Buzeta R, Muñoz Magna R. *Manual de Procedimientos de Laboratorio de Citología*. Washington, DC, Organización Panamericana de la Salud, 2002.
- WHO. *Cervical cancer screening in developing countries. Report of a WHO Consultation*. Geneva, 2002.

PRACTICE SHEET 6: OBTAINING INFORMED CONSENT

PS 6

Practice Sheet 6: Obtaining Informed Consent

WHAT IS INFORMED CONSENT?

Women must give informed consent before being screened for cervical cancer. This means that she should understand what is to take place, including the potential risks and complications of both proceeding and not proceeding, and has given permission for the procedure. It should be made clear to the woman that there will be no punitive action if she refuses the procedure.

When asking for informed consent:

- Give the woman all essential information on what you are about to do and request her consent before starting any examination or procedure. It is unethical to ask for informed consent retroactively.
- If there is a possibility that she might need to be contacted at home or at work (e.g. to give test results or remind her to return for an appointment), obtain consent for doing so.
- Family members should be included in the discussion only if the woman has given explicit permission.
- Keep medical terminology to a minimum. Explain any technical words that have no local equivalent.
- You may find it helpful to draw or use pictures to illustrate your explanations.
- Be clear and direct; do not use words the patient will not understand, or which are vague, such as “growth” or “neoplasm”.
- Do not confuse the woman by saying too much, but cover all the important issues.
- Allow some time for the woman to take in what you have said. Then let her ask questions. When all the questions have been addressed, ask the woman for her formal consent.
- It might be culturally important to include others, such as the woman’s partner, in the decision-making process; however, you should ensure that the woman’s wishes are respected.

EXPLAINING PRACTICES AND PROCEDURES

You will find explanations for patients included in each chapter of this Guide and in the practice sheets. You may adapt these to individual situations to help explain procedures in terms the patient and her family understand.

PS6

STEPS FOR OBTAINING INFORMED CONSENT**Preparation**

1. Ensure privacy and explain that confidentiality is always respected in your facility.
2. Follow your facility's regulations on obtaining informed consent.
3. Apply general rules on counselling and good communication. Listen carefully and address the woman's concerns; give her the time she needs to understand and to make a decision.
4. Ask her if she would like to have family members present or if she would like to discuss the decision with family members at home. Do not pressure her to make a decision before she is ready.

**Process**

5. Give all the necessary information on the test, procedure or treatment you are recommending and any available alternatives. Use the explanations for patients included in this Guide, adapted to your facility and the individual situation, to help explain procedures such as cryotherapy, surgery, and radiotherapy. Include the following information:
 - purpose of the procedure;
 - possible benefits;
 - risks of doing what you suggest and of not doing it;
 - need for anaesthesia or hospitalization;
 - potential side-effects and complications and what to do if any of them occur;
 - recovery time;
 - cost;
 - chance of success or failure.
6. Ask the woman if she has any questions, and answer them.
7. Check that the patient has understood. You can do this by asking her to repeat points that may be difficult or important, or by using other words to reiterate the most important issues, such as: "Did you understand that you should not have intercourse for 4 weeks after this procedure? How do you think your husband will feel about that?"
8. Correct any misunderstanding.
9. Keep a written record, either on a consent form or in the medical record (according to your facility's guidelines), that:
 - you confirmed her understanding of the information;
 - her decision to undergo a test or treatment (or to refuse it) was voluntary.

PRACTICE SHEET 7: TAKING A HISTORY AND PERFORMING A PELVIC EXAMINATION⁹

PS7

Cervical cancer screening includes taking a history, to assess if the woman has specific risk factors or suggestive symptoms. Most screening tests involve a speculum examination.

The following equipment and supplies should be available:

- clinical chart and pencil;
- drawings of pelvic organs, if possible;
- soap and water for washing hands;
- light source to examine the cervix;
- examination table covered by clean paper or cloth;
- disposable or high-level disinfected examination gloves;
- specula of different sizes, high-level disinfected (need not to be sterile);
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

HISTORY

Ask the patient about:

- her age, education, number of pregnancies, births and living children, last menstrual period, menstrual pattern, previous and present contraception;
- previous cervical cancer screening tests, their dates and results;
- medical history including any medications or drug allergies;
- social history, including factors that may increase her risk of cervical cancer;
- sexual history including age of sexual initiation and of first pregnancy, number of partners, previous STIs, and any behaviours that may suggest an increased risk of cervical cancer;
- any symptoms and signs of cervical cancer and other illnesses.

⁹ Adapted from: Burns A et al. Where women have no doctor. Berkeley, CA, Hesperian Foundation, 1997; and WHO. *Sexually transmitted and other reproductive tract infections: a guide to essential practice*. Geneva, 2005.

PS7

PERFORMING A PELVIC EXAMINATION

After taking a history, perform a pelvic examination. There are three components to the female genital examination:

- an external genital examination;
- a speculum examination;
- a bimanual examination.

Before the examination

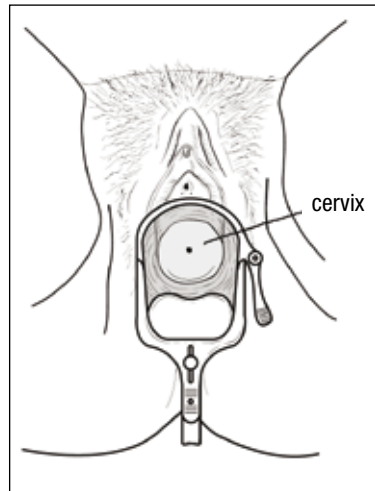
1. Have all necessary equipment and supplies ready. Ensure the speculum used is at a comfortable temperature.
2. If tests or interventions are planned (e.g. a Pap smear), tell the woman what they are, what they are for, and when you expect to have the results.
3. Ask the woman if she has any questions, and answer them truthfully.
4. Explain what the pelvic examination consists of and show the woman a speculum.
5. Ask the woman to empty her bladder (urinate) and have her undress from the waist down. Be particularly sensitive to her sense of modesty about uncovering normally clothed areas, or if the examination is perceived to be invasive.
6. Position the woman on the examination table.

Examination of the external genital area

7. Using a gloved hand to gently touch the woman, look for redness, lumps, swelling, unusual discharge, sores, tears and scars around the genitals and in between the skin folds of the vulva. These can be signs of a sexually transmitted infection.

The speculum examination

8. Hold the speculum blades together sideways and slip them into the vagina. Be careful not to press on the urethra or clitoris because these areas are very sensitive. When the speculum is halfway in, turn it so the handle is down. Gently open the blades and look for the cervix. Move the speculum slowly and gently until you can see the entire cervix. Tighten the screw (or otherwise lock the speculum in the open position) so it will stay in place.

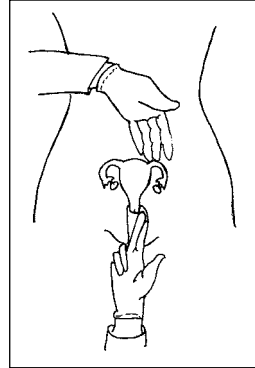
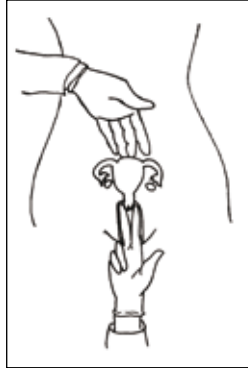
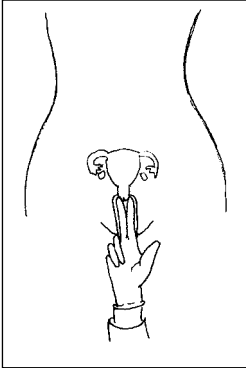


9. Check the cervix, which should look pink, round and smooth. There may be small yellowish cysts, areas of redness around the opening (cervical os) or a clear mucoid discharge; these are normal findings.
10. Look for any abnormalities, such as:
 - a. Vaginal discharge and redness of the vaginal walls, which are common signs of vaginitis. If the discharge is white and curd-like, there is probably a yeast infection.
 - b. Ulcers, sores or blisters. Genital ulcers may be caused by syphilis, chancroid, herpes virus or, in some cases, cancer. Sores and blisters are usually caused by herpes virus.
 - c. Easy bleeding when the cervix is touched with a swab, or a mucopurulent discharge, which are signs of a cervical infection.
 - d. An abnormal growth or tumour, which might be cervical cancer.
11. Gently pull the speculum towards you until the blades are clear of the cervix, close the blades and remove the speculum.

PS7

The bimanual examination

The bimanual examination allows you to feel the reproductive organs inside the abdomen.



12. Test for cervical motion tenderness. Put the pointing and the middle finger of your gloved hand in the woman's vagina. Turn the palm of your hand up. Feel the cervix to see if it is firm and round. Then put one finger on either side of the cervix and move the cervix gently while watching the woman's facial expression. If this causes pain (you may see the woman grimace), this indicates cervical motion tenderness, and she may have an infection of the womb, tubes or ovaries (pelvic inflammatory disease or PID). If her cervix feels soft, she may be pregnant.
13. Feel the womb by gently pushing on her lower abdomen with your other hand. This moves the womb, tubes and ovaries closer to the fingers inside her vagina. The womb may be tipped forwards or backwards. When you find the womb, feel for its size and shape. It should feel firm, smooth and smaller than a lemon.
 - If the womb feels soft and large, the woman is probably pregnant.
 - If it feels lumpy and hard, she may have a fibroid or other growth.
 - If it hurts her when you touch it, she may have an infection.
 - If it does not move freely, she may have scars from an old infection.

14. Feel the tubes and ovaries. If these are normal, they will be hard to feel. If you feel any lumps that are bigger than an almond or that cause severe pain, she may have an infection or other condition needing urgent treatment. If she has a painful lump, and her period is late, she may have an ectopic pregnancy; in this case, she *needs medical help* right away.
15. Move your finger to feel the inside of the vagina. Make sure there are no unusual lumps, tears or sores.
16. Ask the woman to cough or push down as if she were passing stool. Look to see if something bulges out of the vagina. If it does, she may have a fallen womb or fallen bladder (prolapse).

After the examination

17. Place used equipment and gloves in decontamination solution.
18. Wash your hands with soap and water.
19. Record all findings on the woman's chart.
20. Tell the woman if her examination was normal or if you noted anything unusual or abnormal, and explain what any abnormality you noted might mean.
21. If you noted any signs that might indicate a sexually transmitted infection, treat the woman and her partner immediately, according to national or WHO guidelines.¹⁰ Provide condoms and teach them how to use them. If you found an acute cervical infection or PID, provide treatment as outlined in Annex 8.
22. If you found something that needs urgent treatment or that cannot be handled at your centre (e.g. ectopic pregnancy, prolapse, cervical tumour), refer the woman to a higher level of care.
23. Give her a date to return for follow-up if necessary.



Annex 8

¹⁰ WHO. *Sexually transmitted and other reproductive tract infections: a guide to essential practice*. Geneva, 2005.

PS7

PRACTICE SHEET 8: TAKING A PAP SMEAR

PS 8

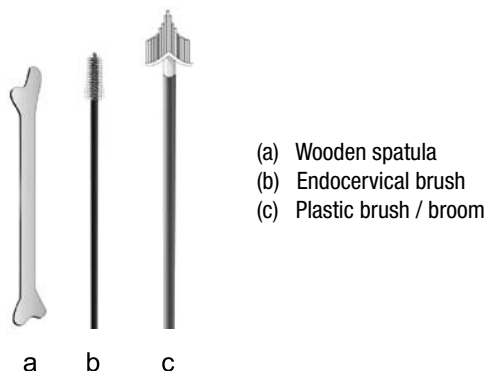
PS 8: Taking a Pap Smear

In a Pap smear test, a sample of cells is taken from the uterine cervix using a spatula or brush (see figure PS8.1), smeared onto a slide, and examined under a microscope for abnormal cells (precancer or cancer). When a Pap smear shows abnormal epithelial cells, it is reported as positive. Most women with a positive Pap smear need more tests to confirm the diagnosis and to determine whether treatment is needed.¹¹

The following materials and equipment are needed for taking a conventional Pap smear:

- soap and water for washing hands;
- a light source to examine the cervix;
- an examination table covered by clean paper or cloth;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves;
- an extended-tip wooden or plastic spatula (or another device for sampling);
- a glass slide with frosted edge and pencil for labelling;
- fixative solution;
- recording form;
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

Figure PS8.1 Devices for Pap smear sampling



¹¹ When the Pap smear reports ASC-US or LSIL, only persistent lesions (reported on two Pap smears within 6 months to 1 year) should be investigated further.

PS8

TAKING A PAP SMEAR

Note the following:

- It is best not to take a smear from women who are actively menstruating or have symptoms of an acute infection. Slight bleeding is acceptable.
- Pregnancy is not an ideal time for a Pap smear, because it can give misleading results. However, if the woman is in the target age group and it is likely that she will not return after giving birth, proceed with the smear.

Use Practice Sheet 4 to give counselling before doing any examination, test or procedure. Counselling steps specific to taking smears are included in the steps below.



Counselling

Preparation

1. Explain the procedure, what the test results mean, and why it is important to return for the test results and act on them appropriately. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



Informed consent

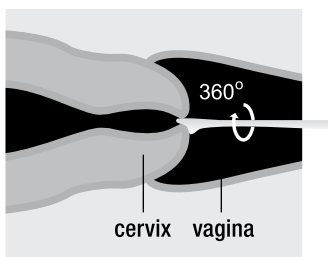


PS7 Pelvic exam

Taking the smear with a wooden spatula

3. Insert the long tip of the spatula into the os, and rotate it through a full circle (360 degrees).

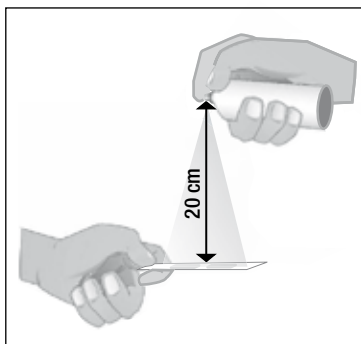
Figure PS8.2 Taking a sample of cervical cells with a wooden spatula



4. Smear both sides of the spatula onto the glass slide with one or two careful swipes. If you see any abnormalities outside the area sampled, take a separate specimen and smear it on another slide.

5. Immediately fix each slide. Either use spray fixative, at a right angle to, and a distance of 20 cm from, the slide, or immerse the slide in a container of 95% ethanol for at least 5 minutes.

Figure PS8.3 Fixing a conventional Pap smear



If the slide is not fixed immediately, the cells will dry and become misshapen; it will then not be possible to read the slide accurately in the laboratory.

6. Gently close and remove the speculum.
7. Place all used instruments in decontamination solution.

After taking the smear

8. Label the frosted edge of each slide carefully with the woman's name and clinic record number, and the date.
9. On the patient record, note and illustrate any features you have noted: visibility of the transformation zone, inflammation, ulcers or other lesions, abnormal discharge. Note whether other samples were taken, for example Pap smear of other areas, any STI tests and, if the woman has been referred elsewhere, to whom and when.
10. Ask the woman if she has any questions.
11. Tell her when and how she will receive the test results and stress the importance of returning for her results. Ideally, results should be sent to the clinic within 2 or 3 weeks. It is not acceptable for the laboratory to take more than 1 month before reporting back.

PS8

12. If you saw something for which you wish to refer the woman to a higher level, explain why, where and when she must go, and whom to see; stress the importance of keeping this appointment.
13. Suggest to the woman that she encourage family members and friends in the target age group to come in for a Pap smear.

Follow-up

14. When the woman returns, give her the test results, explain what they mean, and advise what needs to be done.
 - If the test is negative (normal), tell her to have another test within 3 years (or as per national guidelines).
 - In the other cases, use the flowchart in Annex 4a to advise the woman on how she should be followed up.



Flowchart PAP

15. If the woman does not return, and her smear was abnormal or inadequate, try to contact her. A sample letter to send to such patients is given in Annex 7. Other strategies to ensure return are described in Chapter 4.



Documents

Your task is not completed until each woman has been told her test results, or at least those women with abnormal test results.

PRACTICE SHEET 9: COLLECTING SAMPLES FOR HPV DNA TESTING

PS9

Practice Sheet 9: Collecting Samples for HPV DNA Testing

For HPV DNA testing, secretions are collected from the cervix or vagina using a swab or small brush, and placed in a special liquid to be sent to the laboratory. There they can be tested for HPV infection, which can stimulate changes in the cells covering the cervix. The test does not diagnose cervical precancer or cancer.

The following materials and supplies are needed to collect samples for HPV testing:

- soap and water for washing hands;
- a light source to examine the cervix;
- an examination table covered by clean paper or cloth;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves;
- small brush or soft swab;
- small container with preservative solution;
- recording form;
- small container of warm water to lubricate and warm the speculum;
- 0.5% chlorine solution for decontaminating instruments and gloves.

TAKING A SAMPLE FOR HPV TESTING

Note the following:

- It is best not to take a sample from women who are actively menstruating. Slight bleeding is acceptable.
- HPV testing, if available, is most useful when done in conjunction with a cytological test, in women aged 35 years or older.

Use Practice Sheet 4 to give counselling before doing any examination, test or procedure. Counselling steps specific to the HPV test are included in the steps below.



PS9

Preparation

1. Explain what an HPV test is and what a positive test means. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



PS7 Pelvic exam

Taking the sample

3. Take a smear from the top of the vagina and the cervical os using a brush or swab.
4. Place the brush or swab in a special container with preservative solution.
5. Gently close and remove the speculum.
6. Place all used instruments in decontamination solution.
7. Label the container with the woman's name and clinic record number, and the date.

After taking the specimen

8. Tell the patient about anything unusual you noted.
9. Record your observations and the taking of the sample on the patient chart.
10. Tell the woman when she should return for the test results.
11. If you saw something for which you wish to refer the woman to a higher level, explain why, where and when she must go, and whom to see; stress the importance of keeping this appointment.

Alternative method: self-collection

1. Explain to the woman how to collect her own specimen, as per instructions of the manufacturer of the test kit.
2. Provide her with swabs and a vessel with preservative solution.
3. She can collect the specimen in the clinic, if there is a private area, or at home.
4. If she collects the specimen at home, she should bring it to the clinic as soon as possible, and in any case within the time specified by the manufacturer of the test kit.
5. Send the specimen to the special laboratory for examination.

Follow-up

12. When the woman returns, whether the specimen was collected by herself or by the provider, give her the test result, explain what it means, and if necessary advise her on any additional tests or treatment needed.
13. If the test was used as a primary screening tool, women with a positive test should be referred for colposcopy. If the test was done in conjunction with a Pap smear, whose result was ASC-US, only women positive for high-risk HPV need to be referred for colposcopy and biopsy.
14. Be prepared to respond to questions concerning the implications of a positive HPV test.



FAQs

PS9

Practice Sheet 9: Collecting Samples for HPV DNA Testing

PRACTICE SHEET 10: VISUAL SCREENING METHODS

PS10

Practice Sheet 10: Visual Screening Methods

In a visual test, the provider applies acetic acid (in VIA) or Lugol's iodine solution (in VILI) to the cervix, and then looks to see if there is any staining. A VIA test is positive if there are raised and thickened white plaques or acetowhite epithelium; a VILI test is positive if there are mustard or saffron-yellow coloured areas, usually near the SCJ. Either test is suspicious for cancer if a cauliflower-like fungating mass or ulcer is noted on the cervix. Visual screening results are negative if the cervical lining is smooth, uniform and featureless; it should be pink with acetic acid and dark brown or black with Lugol's iodine.

The following materials and equipment are needed for visual methods:

- soap and water for washing hands;
- a bright light source to examine the cervix;
- a speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves (need not be sterile);
- examination table covered by clean paper or cloth;
- cotton-tipped swabs;
- dilute acetic acid solution (3–5%) or white vinegar;
- Lugol's iodine solution;
- 0.5% chlorine solution for decontaminating instruments and gloves;
- recording form.

PERFORMING VISUAL SCREENING TESTS

Note the following:

- Visual methods are not recommended for use in postmenopausal women, because their transition zone is most often inside the endocervical canal and not visible on speculum inspection.

Preparation

1. Explain the procedure, how it is done, and what a positive test means. Ensure that the woman has understood and obtain informed consent.
2. Do a speculum examination as described in Practice Sheet 7.



Informed consent



PS7 Pelvic exam

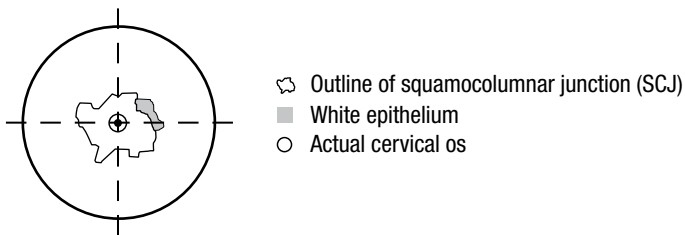
PS10

Performing the test

3. Adjust the light source in order to get the best view of the cervix.
4. Use a cotton swab to remove any discharge, blood or mucus from the cervix.
5. Identify the SCJ, and the area around it.
6. Apply acetic acid or Lugol's iodine to the cervix; wait a minute or two to allow colour changes to develop. Observe any changes in the appearance of the cervix. Give special attention to abnormalities close to the transformation zone.
7. Inspect the SCJ carefully and be sure you can see all of it. Report if the cervix bleeds easily. Look for any raised and thickened white plaques or acetowhite epithelium if you used acetic acid or saffron-yellow coloured areas after application of Lugol's iodine. Remove any blood or debris appearing during the inspection.
8. Use a fresh swab to remove any remaining acetic acid or iodine solution from the cervix and vagina.
9. Gently remove the speculum.

After screening

10. Record your observations and test result. Draw a map of any abnormal findings on the record form.

Figure PS10.1 VIA results recorded on labelled drawing

11. Discuss the results of the screening test with the patient. If the test is negative, tell her that she should have another test in three years. If the test is positive or cancer is suspected, tell her what the recommended next steps are (see Annex 4a for standard approach and Annex 4b for the screen-and-treat approach). If she needs to be referred for further testing or treatment, make arrangements and provide her with all necessary forms and instructions before she leaves. If you can make the appointment immediately, do so.



5

CHAPTER 5: DIAGNOSIS AND MANAGEMENT OF PRECANCER

CHAPTER 5: DIAGNOSIS AND MANAGEMENT OF PRECANCER

Key points

- Further investigations are needed in all women with a positive or abnormal screening test, in order to make a definitive diagnosis.
- The standard method for diagnosis of cervical precancerous lesions is histopathological examination of tissue obtained through biopsy guided by colposcopy.
- The “screen-and-treat” approach involves providing treatment on the basis of a positive screen test, without further diagnostic testing. This is a new approach and the long-term impact on cancer incidence has yet to be evaluated.
- It is essential that precancerous lesions graded CIN 2 or 3 are treated. CIN 1 lesions are more likely to resolve spontaneously, but should be treated if it is likely that the woman will not return for follow-up, and in other special circumstances.
- Outpatient treatments, such as cryotherapy and loop electrosurgical excision procedure (LEEP), are preferable to more invasive treatments (such as cold knife conization), which require anaesthesia and often hospitalization, and have more complications.
- Cold knife conization is appropriate when the eligibility criteria for cryotherapy and LEEP are not met.
- Hysterectomy should not be used to treat precancer, unless there are other compelling reasons to remove the uterus. A desire for surgical sterilization is not an acceptable reason.

ABOUT THIS CHAPTER

This chapter describes diagnostic and treatment procedures for precancer – colposcopy and biopsy, cryotherapy, loop electrosurgical excision procedure and cold knife conization – and discusses their indications, advantages and disadvantages. It also outlines the “screen-and-treat” approach.

ROLE OF THE PROVIDER

The health care provider is responsible for ensuring that all women with abnormal screening tests receive the follow-up and treatment they need. They should explain to women with a positive screening test what follow-up is indicated, managing cases

locally where possible, or referring them to a higher-level facility. They also need to counsel women who undergo diagnostic and treatment procedures on the importance of abstaining from sexual intercourse, or using condoms correctly and consistently, for some time afterwards.

STORY

Maria is a 60-year-old Nicaraguan mother with 12 children, who has been married to the same man for 45 years. The teacher at her literacy class told her about a clinic to be held in her village to test women for cervical cancer, and advised her to attend. At the clinic, she had a Pap smear. When she returned for her test results, she was told she had a HSIL, a condition that needed to be treated because otherwise it could get worse and become cancer. She was referred to the district hospital, where a doctor looked inside her vagina with a colposcope and took a biopsy from the abnormal area. The biopsy confirmed that she had a precancerous lesion and she was treated with cryotherapy. The doctor explained the importance of regular examinations after treatment, as sometimes a few abnormal cells remain and continue to progress towards cancer. But Maria was leaving the country and did not return for many months. When she came back, she was told that the health worker had come to visit her and had left a message that it was very important for her to attend the follow-up visit. She finally attended the clinic 18 months after treatment. The doctor in the hospital repeated the colposcopy, which revealed that there was again a suspicious lesion. The biopsy confirmed a CIN 3 lesion, needing further treatment. Maria was admitted to the hospital for a cold knife conization under anaesthesia; she was operated on early in the morning and discharged the same day. The entire abnormal area was removed, and she has had normal follow-up tests since then.



MANAGEMENT OPTIONS FOR PRECANCER

Standard practice for diagnosis: colposcopy and biopsy

Biopsy performed with the aid of a colposcope is the standard method for diagnosis of cervical precancer and preclinical invasive cancer. For satisfactory biopsy, the entire transformation zone must be visible to allow the degree of abnormality to be assessed and to identify areas for biopsy. If the SCJ or the transformation zone is partially or entirely inside the cervical canal, an endocervical speculum examination should be done to visualize any lesions in their entirety, and an endocervical curettage (ECC) done to obtain a sample for histopathological examination. If precancer is diagnosed, it should be treated using cryotherapy, LEEP or cold knife conization.

Barriers to colposcopy and biopsy services

Ideally, colposcopy and biopsy should be used to manage women with a positive screening test, but there are frequently barriers to the establishment of these services:

- Colposcopes are sophisticated, relatively expensive instruments.
- Specialized training and experience are required to maintain proficiency.
- Biopsy samples need to be transported to a histopathology service, which may be difficult in low-resource settings.

Alternative approaches to diagnosis and treatment

“Screen-and-treat” approach

In this approach, treatment decisions are based on the results of the screening test, without a prior diagnostic test. Most screen-positive women can be treated with cryotherapy at primary health care level at the time of screening; this could reduce loss to follow-up and have an impact on cervical cancer control. However, tissue will not be available for later examination. This approach is discussed in more detail in Annex 4b.



Screen and treat

Colposcopy-based “see-and-treat” approach

To address the issue of potential overtreatment with the screen-and-treat approach, an intermediate approach can be used. Patients with a positive screen (on Pap smear, VIA, VILI, or HPV) can be examined with a colposcope. If a precancerous lesion is detected, it can be treated immediately. If cryotherapy is the chosen treatment, colposcopically-directed biopsies can be taken before treatment to confirm the diagnosis following the procedure. If LEEP is used, tissue will be available as a result of the procedure. This approach is contingent on the availability of equipment and trained and experienced providers.

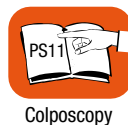
DIAGNOSIS

5

Colposcopy, biopsy and endocervical curettage

Colposcopy

Colposcopy is the examination of the cervix, vagina and vulva with a colposcope, which provides illumination and magnification, allowing the cellular patterns in the epithelial layer and surrounding blood vessels to be examined. Application of dilute acetic acid¹² will highlight abnormal areas, which can then be biopsied. Used as a diagnostic tool on patients with a positive screen test, colposcopy has a high sensitivity (around 85%) and a specificity of about 70% for the detection of precancer and cancer.



Colposcopy is used to:

- visually evaluate precancerous and cancerous lesions;
- help define the extent of lesions;
- guide biopsies of areas that appear abnormal;
- assist treatment with cryotherapy or LEEP.

Colposcopy should not be used as a screening tool.

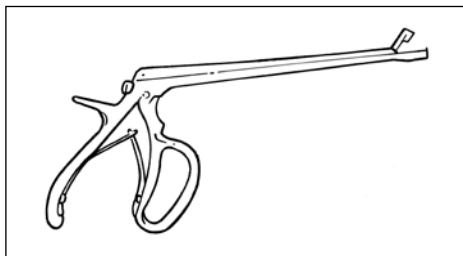
RECOMMENDATION

Colposcopy is recommended only as a diagnostic tool and should be performed by properly trained and skilled providers.

Biopsy

Biopsy is the removal of small areas of the cervix for histopathological diagnosis. It should be done only with colposcopic assistance. With a punch biopsy forceps (Figure 5.1), one or more small pieces of tissue (1–3 mm across) are removed from the abnormal areas of the cervix identified by colposcopy. Bleeding is usually minimal. The samples are placed in a preservative, such as formalin, and the container labelled. This is then sent to a laboratory for precise histopathological diagnosis of the abnormalities, whether they are precancer or cancer, and their severity and extent, so that treatment can be tailored to each case.

¹² Staining with Lugol's iodine, although still used, is not recommended for routine use because it can potentially produce artefacts in the biopsy specimen.

Figure 5.1 Cervical punch biopsy forceps***Endocervical curettage***

If a woman has a positive Pap test, but no abnormal areas are observed with colposcopy, there may be a lesion in the cervical canal. In this case, the endocervix can be examined with a special speculum and a sample of cells can be obtained with an endocervical curette for microscopic diagnosis. Endocervical curettage is a simple procedure, in which some of the surface cells are gently scraped from the cervical canal. The cells are then sent to a laboratory for examination. The procedure takes only a few minutes.

Colposcopy, biopsy and endocervical curettage are almost painless (although they may cause brief cramping) and do not require anaesthesia. After a biopsy or endocervical curettage, the woman should abstain from sexual intercourse until she has no more discharge or bleeding; this usually means a couple of days. If this is not possible, she should use condoms.

Providers

If a colposcope, biopsy forceps and an endocervical curette are available, colposcopy, biopsy and endocervical curettage can be performed at primary care level by trained and skilled physicians, nurses and other health care providers. More commonly, they are performed as outpatient procedures at secondary level (district hospital).

Indications for colposcopy and biopsy

Colposcopy and biopsy should be performed:

- on women with an abnormal screening test;
- if suspicious lesions are seen on the cervix on speculum examination;
- to map abnormalities before cryotherapy or LEEP.

Indications for endocervical curettage

Endocervical curettage should be performed in the following circumstances:

- The patient has a positive Pap smear, but no abnormality is seen with colposcopy. There may be a precancer or cancer hidden inside the cervical canal, which can be detected by examining tissue obtained by curettage.
- The Pap smear revealed a glandular lesion. These usually arise from the columnar epithelium inside the canal. In this case, endocervical curettage must be performed regardless of the colposcopy findings.
- Colposcopy was unsatisfactory because the transformation zone was not seen in its entirety.

Special considerations

- **The entire transformation zone is not visible.** In this case, the colposcopy is unsatisfactory and an endocervical curettage should be done. If this is not possible, women should be referred for LEEP or cold knife conization. This is especially important if the screening test revealed a high-grade lesion.
- **The woman is pregnant.** As discussed in Chapter 4, pregnancy is not the ideal time to perform a screening test. However, if a test is done and is abnormal, or if a lesion is noted on speculum examination, the patient should be referred for colposcopy. Taking biopsies during pregnancy can be associated with significant bleeding. Therefore, if there is no colposcopic indication of invasive cancer, the patient can be given an appointment to return at 12 weeks postpartum for colposcopic re-evaluation and possible biopsy. If cancer is suspected, she should be referred immediately to a specialist.
- **The woman is postmenopausal.** In many postmenopausal women, the entire transformation zone is not visible. If an adequate endocervical curettage is not possible, a cold knife conization should be done.
- **The woman is HIV-positive.** Management of abnormalities, including colposcopy and biopsy, should not be modified on the basis of a woman's HIV status. During the healing process after any procedure, seropositive women might have increased virus shedding and, if re-exposed, might be more likely to acquire an additional virus load. Abstinence from intercourse until healing has occurred is most important.

Follow-up

The patient should be asked to return in 2–3 weeks for the results of the biopsy. Treatment options, according to the severity and extent of the abnormality, should then be discussed with her. Women who do not return as requested should be contacted, given their results and advised about what treatment they need (see Chapter 4 for strategies to ensure that women receive the information they need).

TREATMENT OF PRECANCER

Patient management depends on the results of the colposcopy, biopsy and endocervical curettage, and should be in line with national guidelines. The flowchart in Annex 5 indicates management options.



Flowchart precancer

Principles of treatment

In most cases, precancerous lesions can be treated on an outpatient basis using relatively non-invasive procedures, such as cryotherapy or LEEP. For lesions that cannot be treated in this way, inpatient methods such as cold knife conization can be used. Hysterectomy, a highly invasive procedure with a risk of complications, such as infection, haemorrhage and injury to adjacent organs, should not be used to treat precancer, unless there are other reasons to remove the uterus. Desire for permanent contraception on the part of the patient is *not* an acceptable concurrent reason for hysterectomy.

RECOMMENDATION

Precancer should be treated on an outpatient basis whenever possible. Both cryotherapy and LEEP may be suitable for this purpose, depending on eligibility criteria and available resources.

Indications for treatment

All biopsy-confirmed CIN 2 and 3 lesions should be treated, because the majority of them persist and may eventually progress to invasive cancer. CIN 1 is more likely to resolve spontaneously; these patients can be followed up with colposcopy and cytology every 6 months until the lesion regresses to normal, or there is evidence of progression of the abnormality. If progression is noted, or in cases where follow-up is problematic, as well as in older women in whom spontaneous regression is less likely, immediate treatment should be considered.

Special considerations

- **Pregnancy.** Women known or suspected to be pregnant should not be treated for precancer; they should be advised to return at 12 weeks postpartum for further evaluation. If invasive cancer is suspected, the patient should be referred immediately to a specialist (see Chapter 6).
- **The woman is menstruating.** Women who present for treatment during menstruation can be treated if the bleeding is slight. It is advisable to delay the procedure if menstruation is heavy and interferes with visualization of the extent of the lesion.
- **The woman has a cervical infection or pelvic inflammatory disease (PID).**
 - A cervical infection with no evidence of PID (diagnosed clinically during speculum examination or with laboratory tests) can be treated with antibiotics concurrently with cryotherapy. If LEEP or cold knife conization is to be used, the infection must be treated before the procedure.
 - If PID is suspected, a full course of appropriate antibiotic treatment should be completed prior to any treatment.
 - Whenever a woman is treated for a cervical infection, with or without PID, her partner also needs to be fully treated to prevent reinfection. Until both have been fully treated, they should be advised to abstain from sexual intercourse or use condoms. Condoms and instructions on their use need to be provided to all such patients.
- **The woman is HIV-infected.** HIV-positive women should be managed in the same manner as uninfected women. However, HIV-positive women are known to have higher rates of persistence, progression and recurrence of disease after treatment. Women with HIV infection should therefore be monitored every 6 months after treatment, and promptly re-treated if persistent, progressive or recurrent high-grade lesions are detected.

At present there is no clear evidence on whether treatment with highly active antiretroviral drugs modifies regression or progression of cervical precancer and cancer. Before any treatment, HIV-positive women should receive counselling to ensure that they understand the need for close follow-up, and the possibility of need for repeat treatments, as well as the potential for increased transmission and acquisition of STIs and HIV during healing. Abstinence from sexual intercourse is the best protection following treatment; if this is not feasible, condoms should be used consistently and correctly.

RECOMMENDATION

Women should be offered the same treatment options irrespective of their HIV status.

Treatment methods

Treatment methods may be ablative (destroying abnormal tissues by heating or freezing) or excisional (surgically removing abnormal tissues). The main disadvantage of ablative methods is that, unless a biopsy is taken before treatment, there is no tissue specimen for histological examination and confirmation of the lesion.

The choice of treatment will depend on:

- the training and experience of the provider;
- the cost;
- the advantages and disadvantages of each method;
- the location and extent of the lesion.

Cryotherapy and LEEP are the recommended outpatient treatment options. Cryotherapy is the easiest and least costly treatment method for precancer. However, LEEP is the treatment of choice when the lesion is too large for the cryoprobe or involves the endocervical canal, or when a histological specimen is needed. The two methods have comparable effectiveness (see Table 5.1). Cold knife conization should be done when the eligibility criteria for outpatient methods are not fulfilled, or when such methods are not available.

Regardless of the treatment method to be used, the patient must receive full information on what will be done. Informed consent must be obtained before the procedure is undertaken.



Informed consent

Cryotherapy

Cryotherapy eliminates precancerous areas on the cervix by freezing them. This relatively simple procedure takes about 15 minutes and can be performed on an outpatient basis. It involves applying a highly cooled metal disc (cryoprobe) to the cervix, and freezing its surface using carbon dioxide (CO2) or nitrous oxide (N2O) gas. The cryoprobe is applied to the cervix twice, for three minutes each time, with a 5-minute thaw in between (double-freeze technique). A continuous supply of carbon dioxide or nitrous oxide is required. The more expensive, bone-dry medical grade of gas is preferred, but industrial-grade gas can be used if that is what is locally available and affordable. Cryotherapy is highly effective for the treatment of small lesions, but for larger lesions the cure rate is below 80%. Because the area of the cervix that is frozen has very few nerve endings, cryosurgery is generally associated only with some cramping or mild pain. It can, therefore, be done without anaesthesia.



Providers

Cryotherapy can be performed at all levels of the health care system by a variety of trained providers (doctors, nurses, midwives) skilled in pelvic examination, and trained in cryotherapy as an outpatient procedure.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• Positive screening test for cervical precancer • Lesion small enough to be covered by the cryoprobe with no more than 2 mm beyond its edges • The lesion and all edges fully visible with no extension into the endocervix or onto the vaginal wall	• Evidence or suspicion of invasive disease or glandular dysplasia • The lesion extends more than 2 mm beyond the cryoprobe edge • Pregnancy • PID (until treated) • Active menstruation

Loop electrosurgical excision procedure (LEEP)

LEEP, also called large loop excision of the transformation zone (LLETZ), is the removal of abnormal areas from the cervix using a thin heated wire. It requires an electrosurgical unit that produces a constant low voltage and transmits it to a wire loop device, which is used to remove the abnormal tissue. The loops are of very fine stainless steel or tungsten wire and come in different sizes and shapes. The loop cuts and coagulates at the same time. LEEP aims to remove both the lesion and the entire transformation zone. The tissue removed can be sent for examination to the histopathology laboratory, allowing the extent of the lesion to be assessed. Thus, LEEP serves a double purpose: it treats the lesion, and at the same time, produces a specimen for pathological examination. The procedure also has the advantage that it can be performed under local anaesthesia on an outpatient basis. It is successful in eradicating precancer in more than 90% of cases. Treatment failure (i.e. persistent lesions at 6 or 12 months follow-up) is seen in less than 10% of women.



Providers

LEEP is a relatively simple surgical procedure, but it should be performed only by a well trained provider with demonstrated competence in the procedure and in recognizing and managing intraoperative and postoperative complications, such as haemorrhage. LEEP is best carried out in facilities where back-up is available for management of potential problems. In most resource-poor countries, this will limit LEEP to second-level (district hospital) facilities.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• A positive diagnostic test for precancer • Lesion extending less than 1 cm into the endocervical canal	• Suspicion of invasive cancer or glandular dysplasia • Lesion extending more than 1 cm into the endocervical canal, or whose distal or upper extent is not visible (these lesions are treated by cold knife conization) • Cervical infection or PID (until treated or resolved) • Pregnancy or delivery within the last 12 weeks • Bleeding disorders

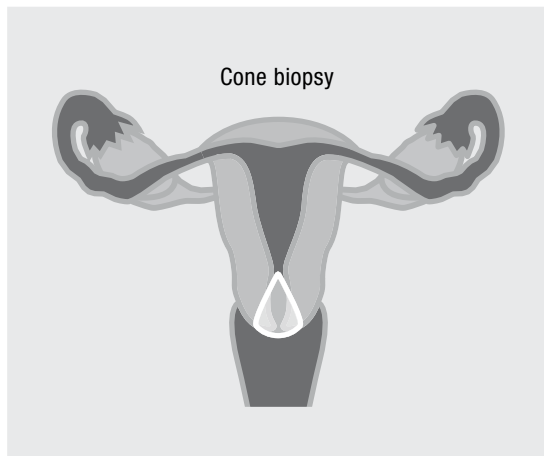
Cold knife conization

Cold knife conization is the removal of a cone-shaped area from the cervix, including portions of the outer (ectocervix) and inner cervix (endocervix) (Figure 5.2). Conization is recommended for the treatment of dysplasia when outpatient treatment is not feasible or not accessible, and to rule out invasive cervical cancer. It is a rather extensive operation, involving removal of a large area of the cervix with a scalpel, and is usually done under general or regional (spinal or epidural) anaesthesia. It takes less than one hour. The patient may be discharged from hospital the same or the next day. Because of possible side-effects, cold knife conization should be reserved for cases that cannot be resolved with cryotherapy or LEEP excision. The extent of the conization will depend on the size of the lesion and the likelihood of finding invasive cancer. The woman's desire to have more children also has to be taken into account, as conization may result in cervical stenosis or incompetence in a few women. The tissue removed is sent to the pathology laboratory for histological diagnosis and to ensure that the abnormal tissue has been completely removed.



Conization

Fig 5.2 Area of the cervix removed in conization



Providers

Cold knife conization should be performed only by providers with surgical skills, in an equipped surgical facility. Providers are usually gynaecologists or surgeons trained to perform the procedure and to recognize and manage complications.

Indications and exclusion criteria

Eligibility criteria	Exclusion criteria
• Screen or diagnostic test suspicious for microinvasive cancer • Endocervical glandular neoplasia • Abnormal endocervical curettage • Positive screen showing need for excisional procedure and outpatient procedures, such as LEEP, are not feasible • No contraindications to anaesthesia	• Untreated cervicitis or PID • Pregnancy or childbirth within the past 12 weeks • Obvious invasive cancer

Management of complications

After cold knife conization, bleeding is the most common complication; it can occur immediately (primary bleeding) or up to 14 days after the procedure (secondary bleeding). In either case, the patient needs to return to the surgical facility. Secondary haemorrhage is usually related to local infection and, along with measures to stop the bleeding, treatment with antibiotics should be prescribed.



Table: 5.1 Comparison of cryotherapy, LEEP and cold knife conization

	Cryotherapy	LEEP	Cold Knife Conization
Advantages	• High cure rate (86–95%) for small lesions • Equipment simple and relatively inexpensive • Can be performed by trained and competent physicians and non-physicians. Training takes a few days • Can be performed as an outpatient procedure in a primary care setting • Fast (about 15 minutes for double-freeze method) • Anaesthesia not required • Electricity not required • Complications and side-effects rare	• High cure rate (91–98%) • Reliable histology specimen obtained, which allows invasive disease to be ruled out • Few complications • Can be performed on an outpatient basis at a secondary level • Fast (5–10 min) and technically simple to perform • In a see-and-treat approach, diagnosis and treatment can be offered at the same time, maximizing treatment coverage	• Highly effective (cure rate 90–94%) • A single surgical specimen, without “burnt” edges, is removed, which facilitates the evaluation of the margins for complete excision of the diseased area
Disadvantages	• Less effective for larger lesions (cure rates < 80% at one year) • No tissue sample available for histological examination • Needs continuous supply of carbon dioxide or nitrous oxide • Causes prolonged and profuse watery discharge	• Requires intensive training • Postoperative bleeding in less than 2% of treated women • More sophisticated equipment needed • Requires electricity • Requires local anaesthesia	• Requires hospitalization and an operating theatre • Requires spinal or general anaesthesia • Requires highly skilled personnel • Complications may occur, including bleeding, infection, stenosis and cervical incompetence with possible decreased fertility

The “screen-and-treat” approach

If there is no capacity for tissue diagnosis with colposcopy and histology, treatment based on screening alone may be appropriate, especially in limited-resource settings. Screening tests for the screen-and-treat approach can include visual tests, HPV or

cytological tests. With screening tests that provide immediate results, such as VIA and VILI, screening and treatment can be provided during a single hospital visit. However, a second visit might be needed in the following circumstances:

- The patient is menstruating heavily, is pregnant or needs treatment for PID.
- The therapy available is not appropriate for the lesion.
- Treatment is not available at the same site and the patient needs to be referred to another facility.
- The client prefers to discuss the treatment with her partner before proceeding.
- The client needs further evaluation.

Studies and pilot projects using the screen-and-treat approach have mainly focused on the use of visual tests for screening and cryotherapy for treatment, because of the advantages of a single-visit approach that can be decentralized to primary care level. A flowchart for this approach is given in Annex 4b. It is important to note that the impact of the screen-and-treat approach on the incidence and mortality of invasive cervical cancer is not yet known. Therefore, if this approach is implemented in countries, careful monitoring and evaluation must be carried out.



Advantages and limitations of the screen-and-treat approach

Advantages	Limitations
• Infrastructure and equipment are simpler and less costly, and provider level lower • Single-visit approach reduces loss to follow-up and treatment, resulting in a reduced burden of tracking and contacting women • Lowers burden for women by reducing the number of visits • Highly acceptable to women and providers	• Impact on cervical cancer incidence and mortality not yet known • Important ethical and resource use concerns, including overtreatment and undertreatment ¹³ • No specimen available for later evaluation, unless biopsy taken before treatment

¹³ Overtreatment is treatment of women who do not have disease. If specificity of VIA is 85%, about 15% of women screened would be treated on the basis of false positive results, wasting resources and increasing exposure to potential risks and side-effects. Undertreatment occurs if women with invasive disease or disease within the endocervical canal are treated with cryotherapy.

FOLLOW-UP AFTER TREATMENT

Women should return for a follow-up visit 2–6 weeks after treatment. The visit should include the following:

- gynaecological examination to ensure the cervix is healing well;
- counselling to emphasize the need for regular follow-up;
- discussion of results of histopathology (in the case of LEEP and conization).

If the entire lesion was removed, the patient should return for further follow-up visits at 6 and 12 months. In cases of positive margins (for precancer) after LEEP or cold knife conization, the patient should be advised that she will need close follow-up and might need further treatment.

Follow-up visits after 6 and 12 months should include the following:

- A screening test and, if possible, colposcopy and directed biopsy of any persistent lesions.
- If no abnormalities are seen on the first two follow-up visits, patients treated for CIN 1 or CIN 2 can be referred back to the screening programme. Patients treated for CIN 3 should be rescreened every year for 5 years, and then referred back to the screening programme (see Annex 5).



Flowchart precancer

- If the lesion progresses or persists, re-treatment is needed.

DIAGNOSIS AND TREATMENT ACTIVITIES AT DIFFERENT LEVELS

In the community



- Support women who have been treated, by encouraging abstinence from intercourse or condom use, helping with removal of vaginal packing, enquiring about and acting on symptoms of complications.
- Provide condoms to all women. Train them in consistent and correct use.
- Contact the health centre if the patient has questions that you cannot answer, or if you are concerned about her status.
- Keep records and visit women to remind them when they have to return to the health centre for follow-up.
- Track women who do not return for follow-up, on request of providers at the health centre.

At the health centre



- Perform colposcopy, biopsy and cryotherapy (if providers have necessary training and equipment).
- Refer women who need further care to the district hospital.
- Provide routine and emergency follow-up care for women treated in the health centre and district hospital.
- Maintain communication with the district hospital and with CHWs.
- Train, supervise, and support CHWs doing home visits, and provide supplies.
- With CHWs, track women who do not return to the centre in a timely manner.

At the district hospital



- Manage women referred by the health centre (for diagnosis and treatment) and advise women on follow-up.
- Refer women with invasive disease and complications requiring higher expertise to the central hospital.
- Assist in the training and supervision of CHWs and health centre staff.
- Maintain two-way communication with health centre staff.

At the central hospital



- Maintain quality services in the histopathology laboratory.
- Manage women who are referred by the lower levels.
- Train and supervise workers at lower levels.
- Maintain communication with lower levels about referred women, their management and follow-up.

Counselling messages

5

For women who will be managed at your level:

- Explain management options.
- Explain procedures that they are likely to need and where they take place.
- Obtain informed consent.
- Explain what follow-up is needed.

For women who are referred to a different level for diagnosis, treatment or complications:

- Explain why you are referring her, and when and where she must go.
- Tell her that she can come to see you if she has questions and concerns.
- Educate her about self-care, and symptoms of complications, and advise her what to do if she experiences any symptoms.

Advise all women to use condoms, train women (and their partners) in how to use them, and provide them with condoms.

ADDITIONAL RESOURCES

- ACCP. *Effectiveness, safety, and acceptability of cryotherapy. A systematic literature review*. Seattle, WA, Alliance for Cervical Cancer Prevention, 2003 (Cervical Cancer Prevention Issues in Depth, No.1).
- McIntosh N, Blumenthal P, Blouse A, eds. *Cervical cancer prevention: guidelines for low-resource settings*. Baltimore, MD, JHPIEGO, 2001.
- Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, IARCPress, 2003.
- WHO. *Sexually transmitted and other reproductive tract infections. A guide to essential practice*. Geneva, 2005.
- Wright TC, Richart RM, Ferenczy, A. *Electrosurgery for HPV-related diseases of the lower genital tract. A practical handbook for diagnosis and treatment by loop electrosurgical excision and fulguration procedures*. Quebec, Arthur Vision Inc., 1992.

PRACTICE SHEET 11: COLPOSCOPY, PUNCH BIOPSY AND ENDOCERVICAL CURETTAGE

PS11

Practice Sheet 11: Colposcopy, Punch Biopsy and Endocervical Curettage

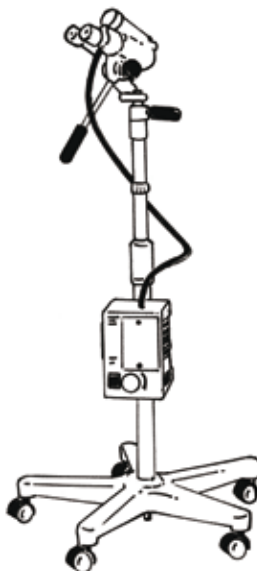
WHAT ARE COLPOSCOPY AND BIOPSY?

Colposcopy is the use of a colposcope (Figure PS11.1) – an instrument that provides magnification and a strong light – to look at the cervix. Biopsy involves taking a small tissue sample from the abnormal areas of the cervix using a biopsy forceps. Biopsy may cause mild discomfort or cramping. An endocervical curettage (ECC) can also be performed to obtain a sample of cells from inside the cervical canal. This can cause cramping, but not severe pain, and occasionally may trigger a vasovagal reaction.¹⁴

The following equipment and supplies are needed for colposcopy, biopsy and ECC:

- vaginal speculum, high-level disinfected, and sterile endocervical speculum;
- normal saline solution;
- 3–5% acetic acid;
- colposcope;
- Monsel's paste;
- punch biopsy forceps;
- endocervical curette;
- ring forceps;
- cotton swabs;
- specimen bottles with 10% formalin;
- pencil and labels.

Figure PS11.1 Colposcope



For basic equipment to perform a pelvic examination refer to PS7.

¹⁴ Occasionally, when an ECC is being performed, the patient may experience a vasovagal reaction, which is usually self-limiting. If it persists, elevate the patient's legs and lower her head.

PS 11

PERFORMING COLPOSCOPY, BIOPSY AND ECC**Preparation**

1. Explain the procedure, what the tests may show, and why it is important to return for further management as requested. Ensure that the patient has understood and obtain informed consent.
2. Show the patient the colposcope and explain how you will use it to examine her.
3. Prepare the patient for a gynaecological examination, and do a speculum examination (see Practice Sheet 7).
4. Make sure the posterior fornix (vaginal space surrounding the ectocervix) is dry.

Procedure

5. Tell the patient what you will do at every step, and warn her before you do anything that might cause cramps or pain.
6. Inspect the cervix at low-power magnification (5x to 10x), looking for any obvious areas of abnormality (e.g. leukoplakia, condylomata). Identify the transformation zone and the original and new squamocolumnar junctions. If advisable, or if the entire SCJ is not visible, you can inspect the cervical canal using an endocervical speculum. If the entire SCJ is still not visible, the colposcopic procedure is termed inadequate or unsatisfactory and an endocervical curettage should be done (see Step 12).
7. Apply saline to the cervix. Inspect the cervix with a green filter and 15x magnification, noting any abnormal vascular patterns.
8. After telling the patient that she might feel a mild stinging sensation, apply acetic acid.¹⁵ Wait one or two minutes to allow colour changes to develop. Observe any changes in the appearance of the cervix. Give special attention to abnormalities close to the SCJ.
9. Integrate the findings of the saline test and the acetic acid test to make a colposcopic assessment.
10. Tell the woman that you will take a biopsy of her cervix, which may cause some cramping.

¹⁵ Sometimes Lugol's iodine is applied after the acetic acid, to help in identifying the lesion. However, it is not always possible in resource-poor settings. Moreover, the routine use of Lugol's iodine is not recommended because high concentrations can cause histological artefacts in the biopsy specimen.

11. Take cervical biopsies of the most abnormal areas, and place tissues in separate labelled bottles containing formalin.
12. If necessary, perform an endocervical curettage. Hold the curette like a pen and scrape the endocervical canal in short firm strokes until it is completely sampled. Keep the curette inside the canal during the entire procedure. At the end, remove the curette, place the curettings on gauze or brown paper, and immediately immerse in 10% formalin.
13. If active bleeding is noted, apply Monsel's paste to the bleeding areas.
14. Withdraw the colposcope and gently remove the speculum.



After the procedure

15. Explain what you saw and, if you took biopsies and endocervical curettings, what these may reveal.
16. Advise the woman how to take care of herself when she goes home:
 - a. She should abstain from sexual intercourse until she has no more discharge or bleeding. If this is not possible, she should use condoms.
 - b. She should not insert anything in the vagina for 3 or 4 days.
 - c. Tell her the signs and symptoms of complications: active bleeding, serious cramping or lower abdominal pain, pus-like discharge, fever. If she experiences any of these, she needs to return to the centre or go to hospital.
17. Provide condoms and teach her how to use them.
18. Give a specific date for the return visit. Laboratory reports should be available within 2–3 weeks, so a follow-up visit should be planned 2–3 weeks after the colposcopy.
19. Explain when the results will be available, and the importance of returning to the clinic for them.
20. Document the findings. Use appropriate forms to record the colposcopic assessment.
21. Send labelled biopsies and curetted tissue to the laboratory.
22. If you noted something you cannot handle, refer the woman immediately to a higher level for further examinations or tests.



Follow-up (2-3 weeks after the colposcopy)

23. Explain what is in the laboratory report.
24. Advise the patient what follow-up she needs, on the basis of the results. Use national guidelines or, if not available, the flowchart in Annex 5, to advise the woman of her diagnosis and recommended treatment plan.
25. Do a pelvic examination and check for healing.
26. Refer her for needed therapy or make an appointment for the next visit.



Flowchart precancer

Your job is not done until you have reviewed the histopathological report with the patient and have a treatment plan in place.

PRACTICE SHEET 12: CRYOTHERAPY

PS12

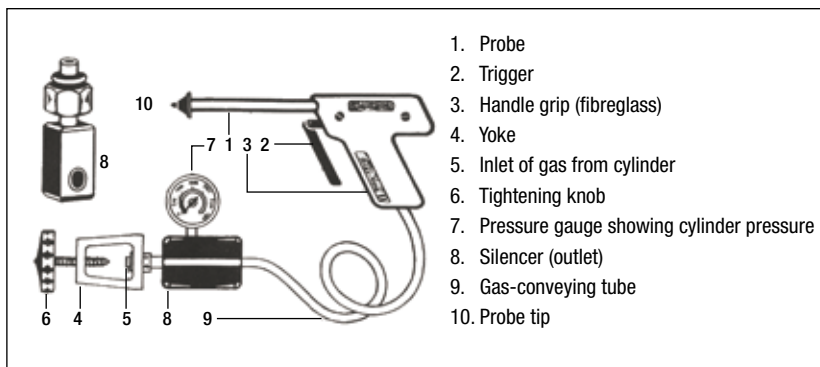
Cryotherapy is the freezing of the abnormal areas of the cervix by the application of a very cold disc to them. It takes only a few minutes and usually only causes some cramping.

The following materials and equipment are needed for cryotherapy:

- speculum, high-level disinfected (it need not be sterile);
- disposable or high-level disinfected examination gloves (need not be sterile);
- cotton swabs for wiping the cervix;
- normal saline solution;
- colposcope, if used in the particular venue;
- cryosurgery unit with adequate gas supply (Figure PS12.1).

For basic equipment to perform a pelvic examination refer to PS7.

Figure PS12.1 Cryotherapy equipment components



Source: Sellors JW, Sankaranarayanan R. *Colposcopy and treatment of cervical intraepithelial neoplasia: a beginners' manual*. Lyon, IARCPress, 2002.

PERFORMING CRYOTHERAPY

Before the procedure

1. Explain the procedure, and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.
2. Show her the cryotherapy equipment and explain how you will use it to freeze the abnormal areas on the cervix.
3. Prepare the patient for a gynaecological examination, and perform a speculum examination (see Practice Sheet 7).
4. If there is no evidence of infection, proceed with cryotherapy.
5. If there is a cervical infection, provide treatment as described in Annex 8. You may proceed with the cryotherapy, or you may give the patient an appointment to return once the infection is cured.



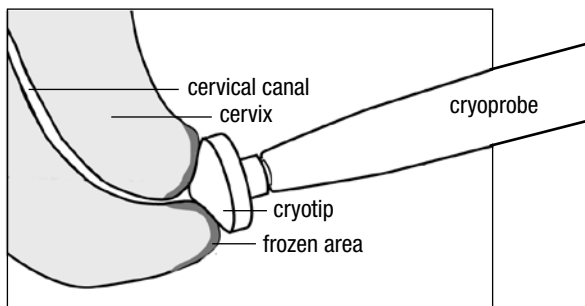
PS6 Informed consent
PS7 Pelvic exam

Procedure

6. Wipe the cervix with a saline-soaked cotton swab and wait a few minutes.
7. Apply acetic acid to outline the abnormality and wait a further few minutes.
8. Tell the woman she might feel some discomfort or cramping while you are freezing the cervix.¹⁶
9. Wipe the cryoprobe surface with saline to ensure optimum effectiveness.
10. Apply the cryoprobe tip in the centre of the os and make sure the probe adequately covers the lesion (Figure PS12.2). If the lesion extends more than 2 mm beyond the probe, discontinue the procedure. Explain to the woman why you are doing this and what needs to be done for her as an alternative.
11. Ensure that the vaginal wall is not in contact with the cryoprobe or you may cause a freezing injury to the vagina.
12. Set the timer and release the gas trigger to cool the probe.
13. You will observe the ice forming on the tip of the cryoprobe and on the cervix (Figure PS12.2). When the frozen area extends 4–5 mm beyond the edge of the cryoprobe, freezing is adequate.

¹⁶ In some cases, the patient may have a vasovagal reaction, with fainting and plummeting blood pressure. If this happens, stop the treatment immediately and raise the patient's legs as much as possible.

Figure PS12.2 Position of cryoprobe on the cervix and ice forming



14. Allow two cycles of freezing and thawing: 3 minutes freezing, followed by 5 minutes thawing, followed by a further 3 minutes freezing.
15. Once the second freezing is complete, allow time for thawing before attempting to remove the probe from the cervix. Removing it before it is fully thawed will pull tissue off the cervix.
16. Gently rotate the probe on the cervix to remove it. The area you have frozen will appear white.
17. Examine the cervix for bleeding. If bleeding is noted, apply Monsel's paste.
18. Do not pack the vagina.
19. Remove the speculum.



Monsel's paste

After the procedure

20. Provide a sanitary pad.
21. Instruct the woman to abstain from intercourse and not to use vaginal tampons for 4 weeks, until the discharge stops completely. This to avoid infection.
22. Provide condoms for use if she cannot abstain from intercourse as instructed. Teach her how to use them.
23. Invite her to return in 2–6 weeks to be checked for healing, and again in 6 months for a repeat Pap smear and possible colposcopy.



Condom use

PS12

24. Inform her of possible complications and ask her to return immediately if she notes:
 - a. fever with temperature higher than 38 °C or shaking chills;
 - b. severe lower abdominal pain;
 - c. foul-smelling or pus-like discharge;
 - d. bleeding for more than two days or bleeding with clots.
25. Clean and disinfect the cryoprobe and decontaminate the cryogun, tubing, pressure gauge and gas tank:¹⁷
 - a. Decontaminate the cryotherapy unit, hose and regulator by wiping them with alcohol.
 - b. Wash the cryotip and the plastic sleeve with soap and water until visibly clean.
 - c. Rinse the cryotip and plastic sleeve thoroughly with clean water.
 - d. High-level disinfect (HLD) the cryotip and plastic sleeve by one of the following methods:
 - boil in water for 20 minutes; or
 - steam for 20 minutes; or
 - soak in chemical disinfectant (0.1% chlorine solution or 2–4% glutaral) for 20 minutes and then rinse with boiled water.
 - e. It is critical that the hollow part of the cryotip is completely dry when next used, otherwise the water will freeze and the probe could crack or the treatment not work.
 - f. Either use a rubber cap to seal off the hollow part of the cryoprobe during processing, or thoroughly dry the cryoprobe before it is reused.
 - g. If none of the high-level disinfection options are available, the cryotip and sleeve may be disinfected by soaking in 70–90% ethanol or isopropanol for 20 minutes. Allow to air-dry and then reassemble.

Follow-up

26. Perform a pelvic examination to check for healing 2–6 weeks after the cryotherapy.
27. At 6 and 12 months, do a Pap test and a colposcopy and take a biopsy if necessary. Follow up as described in Annex 5.



Flowchart precancer

¹⁷ Some cryoguns get blocked by ice. This can be avoided by pushing the defrost button every 20 seconds to clean the tube. Alternatively, use the cryotherapy gas conditioner developed by PATH.

PRACTICE SHEET 13: LOOP ELECTROSURGICAL EXCISION PROCEDURE (LEEP)

PS13

Practice Sheet 13: Loop Electrosurgical Excision Procedure (LEEP)

LEEP is the removal of abnormal areas from the cervix, using a thin wire heated with electricity. It is successful in curing precancer in 9 out of 10 women.

The following equipment and supplies are needed for LEEP:

- reliable power supply;
- electrosurgical generator and electrode handle;
- colposcope;
- non-conducting speculum, preferably with side retractors;
- return electrode;
- wire electrodes of several sizes (Figure PS13.1);
- coagulating/ball electrode;
- smoke evacuator;
- forceps;
- local anaesthetic: 1% or 2% lidocaine, with or without 1:100 000 epinephrine;
- 5-ml syringes with long 27-gauge needle;
- bottles with normal saline and with 5% acetic acid;
- Monsel's paste;
- large swabs;
- needles and suture material;
- specimen containers with 10% formalin.

For basic equipment to perform a pelvic examination refer to PS7.

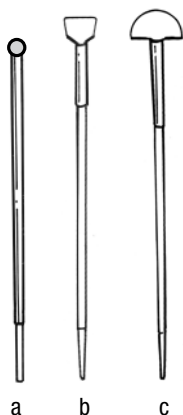


Figure PS13.1 Different types and sizes of electrodes

- (a) Ball electrode
- (b) Square loop electrode
- (c) Semicircular loop electrode

PERFORMING LEEP

Before the procedure

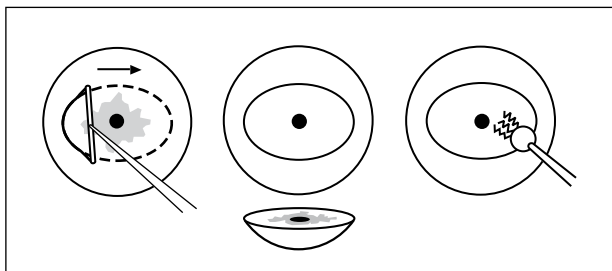
1. Explain the procedure and why it is important to return for further management as requested. Ensure that the woman has understood and obtain informed consent.
2. Prepare the patient for a gynaecological examination.
3. Attach a return electrode to the inner thigh.
4. Insert a non-conducting speculum with an electrically insulating coating, or a speculum covered with a latex condom.
5. Look at the cervix, and note any abnormalities, such as discharge from the os, inflammation, bleeding or lesions. Record the findings.
6. If there is no evidence of infection, proceed. If you note signs of infection, suspend the procedure and treat the patient and her partner completely before making a second attempt.

During LEEP¹⁸

7. Before each step, tell the woman what you will do and what she may feel.
8. Wipe the cervix with a saline-soaked cotton swab.
9. Apply 5% acetic acid and examine with the colposcope to determine the location and extent of the lesion.
10. Inject 3–5 ml of local anaesthetic (1% or 2% lidocaine with 1:100 000 epinephrine (to control bleeding)), using a long 27-gauge needle, just beneath the cervical epithelium at the 12 o'clock, 3 o'clock, 6 o'clock and 9 o'clock positions (in patients with cardiac problems, use lidocaine without epinephrine).
11. Select the appropriate electrode to remove the entire abnormal area in a single pass: for small low-grade lesions in nulliparous women, use an electrode 1.5 cm wide by 0.5 cm deep; for larger lesions and multiparous women, use one 2.0 cm wide by 0.8 cm deep.
12. Turn the vacuum suction on and activate the generator.
13. Excise the lesion: push the electrode perpendicularly into the tissue to a depth of 4–5 mm and draw it laterally across the cervix to the other side, producing a dome-shaped circle of tissue with the canal in the centre. *Do not* insert the electrode deeper than 5 mm at the 3 o'clock and 9 o'clock positions, because this can damage the uterine arteries.

¹⁸ In some cases, the patient may have a vasovagal reaction, with fainting and plummeting blood pressure. If this happens, stop the treatment immediately and raise the patient's legs as much as possible.

Figure PS13.2 LEEP of an ectocervical lesion with one pass: excision of the lesion with wire electrode and fulguration with ball electrode



14. Additional passes with the loop can be made to excise residual tissue.
15. Pick up all excised tissues with the forceps, and place in a labelled bottle with formalin to send to the histopathology laboratory.
16. Perform an endocervical curettage and place the tissue in a separate bottle with formalin.
17. Fulgurate any bleeding tissue in the crater base using a ball electrode and coagulation current.
18. Apply Monsel's paste to the crater base to prevent further bleeding and remove the speculum.



Monsel's paste

After the procedure

19. Provide a sanitary pad.
20. Instruct the patient to abstain from sexual intercourse for a minimum of 4 weeks, and until the bleeding stops completely. This to avoid infection and heavy bleeding.
21. Provide condoms for use if she cannot abstain as instructed. Teach her how to use them.



Condom use

PS13

Practice Sheet 13: Loop Electrosurgical Excision Procedure (LEEP)

22. Tell her she may have some mild to moderate pain for a couple of days; she can take ibuprofen or paracetamol.
23. Explain that she may have very light bleeding and that she will notice blood-tinged discharge for one month or more. She can use sanitary pads but not tampons for this.
24. Advise her how to take care of herself when she goes home:
 - a. She should rest and avoid heavy work for several days.
 - b. She should not put anything in the vagina.
25. Inform her of possible complications and ask her to return immediately if she notes:
 - a. fever with temperature higher than 38 °C or shaking chills;
 - b. severe lower abdominal pain;
 - c. foul-smelling or pus-like discharge;
 - d. heavy bleeding or bleeding with clots.
26. Answer her questions.
27. Recommend that she should return to the health centre in 2–6 weeks to be checked for healing and to receive the laboratory report.
28. Agree a follow-up date with her.

Management of complications of LEEP

Problem	Treatment
Bleeding during the procedure: can be diffuse or arterial	For diffuse bleeding: use a combination of pressure and coagulation with ball electrode. For arterial bleeding: place ball electrode in firm contact with the source and use coagulation current.
Bleeding after the procedure (happens in less than 2% of cases)	Remove blood clot, clean with 5% acetic acid, identify bleeding area, anaesthetize with lidocaine and epinephrine. If bleeding is not heavy, apply Monsel's paste. If bleeding is heavy, fulgurate using either a 5-mm ball electrode or a macroneedle electrode and the coagulation current.
Infection after the procedure: pus-like discharge, pain, fever	Treat with antibiotics: for example, • cefixime 400 mg, orally, single dose, plus • doxycyclin 100 mg orally twice a day for 14 days, plus • metronidazole 400–500 mg, orally, twice daily for 14 days

At the first follow-up visit (2–6 weeks)

- 29. Ask how she is feeling and if she has had any unexpected problems since the LEEP.
- 30. Review the pathology report and advise next steps based on it.
- 31. Examine her to check healing.
- 32. Make an appointment for the next visit.

At 6 months and 12 months

- 33. Do a Pap test and a colposcopy, and take a biopsy if necessary. Follow up as described in Annex 5.



PS13

Practice Sheet 13: Loop Electrosurgical Excision Procedure (LEEP)

PRACTICE SHEET 14: COLD KNIFE CONIZATION

PS 14

Practice Sheet 14: Cold Knife Conization

Cold knife conization is the surgical removal of a cone-shaped area of the cervix. It should be done by a specialist, and the patient should be given anaesthesia or sedation. This Practice Sheet is included to allow a first- or second-level health care provider to explain to a patient, before she goes to hospital, how the procedure will be performed, and to help her recover once she returns home.

EXPLAINING THE PROCEDURE

Give the woman as much information as you can on the procedure, the anaesthesia, and the possible side-effects and complications of surgery. The description below will help you answer any questions she may have.

Before the woman goes to hospital

1. The hospital staff will give her instructions for preparation: what clothing to take with her and any medicines she needs to take beforehand. She will be told not to eat or drink anything in the 8 hours before surgery, and to bathe before going to hospital.

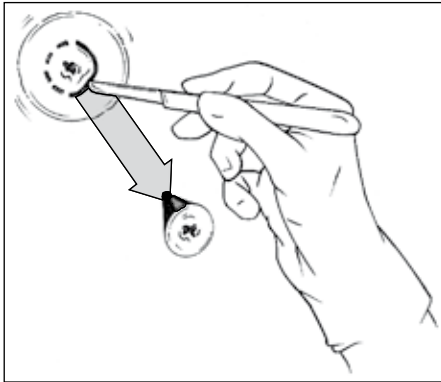
The operation

2. General or regional anaesthesia will be used for the operation.
3. The surgeon will insert a speculum to visualize the cervix.
4. An iodine solution will be applied to highlight the abnormal areas, and the cervix will be examined with a colposcope.
5. A substance to reduce risk of heavy bleeding will be injected into the cervix. Or the surgeon may suture the small arteries supplying the area to be removed.

PS14

6. A cone-shaped area of the cervix, including the endocervical canal, will be removed using a special knife (Figure PS14.1). The removed tissue will be placed in a jar with formalin and sent to the laboratory, with the findings recorded on the appropriate histology form.

Figure PS14.1 Removal of a cone-shaped area of the cervix



7. After the cone is removed, the base of the crater (the area of the cervix after excision) will be cauterized using ball cautery.
8. Any active bleeding will be stemmed by applying pressure using cotton balls, and by applying Monsel's paste or by cauterizing using ball cautery.
9. A gauze pack may be placed in the vagina to apply pressure and control the bleeding, but this will not be done if Monsel's paste has been used.



Monsel's paste

Just after the operation

10. After the operation, the patient will be monitored by the hospital staff in the recovery room. Once she wakes up, she will be moved to a regular bed to recover fully.
11. If she feels well, has no significant bleeding, and lives near the hospital, she will be discharged after a few hours. If she is not able to go home the same day, she will be discharged the next day, provided there are no complications.
12. The woman and her partner will be instructed to abstain from sexual intercourse for 6 weeks after the operation, so that the raw area of the cervix has a chance to heal.

At the first follow-up visit (2–6 weeks)

13. A speculum examination will be done to determine if the wound has fully healed.
14. The laboratory results will be discussed and the next steps planned.
15. The patient will be advised to return in 6 months and 12 months for assessment.

At 6 months and 12 months

16. A Pap test and colposcopy will be done, and a biopsy if necessary. The patient will then be followed up as described in Annex 5.



Flowchart precancer

FOLLOW-UP AT HOME

Before she leaves hospital, the woman will be given counselling on how to take care of herself, and what symptoms of complications to look for. You can help her by reinforcing this advice.

1. If gauze packing was left in the vagina, it must be removed within 6–12 hours to avoid infection. If there is a local health care provider who knows how to do this, he or she can assist the woman.
2. Relative rest for a few days is recommended. The patient should avoid heavy work for the first three weeks. Normal daily activities can be performed, such as light housework, bathing, showering, and eating.
3. If the patient has discomfort (not severe pain), she may take paracetamol.
4. She will have a hidden wound in the vagina, which needs at least 4–6 weeks to heal. To prevent infection and allow proper healing, she should not put anything into the vagina for that time, including fingers or tampons, and she should not douche or have sexual intercourse (although she can be intimate in other ways). If she is unable to abstain from intercourse, provide condoms and teach her (and her partner) how to use them.
5. Make sure she knows the symptoms of complications (see next page) and instruct her to go to the health centre or hospital immediately if any of them occur.
6. She should have been given an appointment for a check-up in 2–6 weeks to discuss the results of the tissue examination and to be examined by the surgeon. Encourage her to keep this appointment.

PS 14

Complication	Symptoms	Treatment
Infection	Pain in the lower abdomen Foul-smelling yellow discharge from vagina	• Provide treatment for PID
Haemorrhage	Heavy vaginal bleeding	• Speculum examination, remove blood clot, identify bleeding areas • Fulgurate/cauterize bleeding area using ball electrode • Apply Monsel's paste or pack with ribbon gauze



Infection treatment