Cervical cancer screening and management of cervical pre-cancers

Training of health staff in VIA, HPV detection test and cryotherapy

Trainees’ handbook
Cervical cancer screening and management of cervical pre-cancers

Training of health staff in
VIA, HPV detection test and cryotherapy

Trainees’ handbook
Cervical cancer screening and management of cervical pre-cancers

Package contents

- Training of health staff in VIA, HPV detection test and cryotherapy
  - Trainees’ handbook
  - Facilitators’ guide
- Training of health staff in colposcopy, LEEP and CKC
  - Trainees’ handbook
  - Facilitators’ guide
- Trainees’ handbook and facilitators’ guide
  - Programme managers’ manual
- Trainees’ manual for community health workers
- Counselling cards
- Flip chart
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Foreword

Cervical cancer is the second most common cancer among women worldwide and causes a significant number of deaths in the South-East Asia Region. Nearly 200,000 new cases of cervical cancer occurred in SEA Region Member States in 2008, giving an incidence of almost 25 per 100,000 and a mortality rate of almost 14 per 100,000. Cervical cancer can be prevented by early screening and vaccination. However, due to poor access to screening and treatment services, the vast majority of these deaths occur in women from nine Member States of the South-East Asia Region which account for more than one third of the global burden of cervical cancer.

In 2015, the WHO Regional Office for South-East Asia, in consultation with Member States, launched a Strategic Framework for the Comprehensive Control of Cervical Cancer in the South-East Asia Region. To strengthen the capacity of health-care providers, a training package has been developed based on the emerging scientific evidence related to new technologies and novel paradigms in cervical cancer screening and to the safety and efficacy of the vaccines.

A paradigm shift has taken place over the recent years in the understanding of the natural history of the disease, the preventive strategies, and the technologies associated with its early detection and treatment. The availability of effective and safe human papillomavirus (HPV) vaccine has introduced an entire new dimension to the prevention of the disease.

The South-East Asia Region is the first region of WHO to publish a training package on a comprehensive approach to cervical cancer screening and management of cervical pre-cancers. The training package provides strategies for a screen-and-treat programme building upon the existing evidence-based WHO global guidelines.

The training package is intended for programme managers, health-care providers and other professionals who have a responsibility for cervical cancer prevention, detection and treatment at the national and sub-national levels. There are eight separate modules for different target audiences including the facilitator’s guides.

I am convinced that the success of the Sustainable Development Goals and implementation of the Global Strategy on Women’s, Children’s and Adolescents’ Health will depend on strong commitment towards the 'Survive, Thrive and Transform' objectives for building healthy societies. This is our vision as we work together for stronger health systems, universal health coverage and scaling-up of life-saving interventions for comprehensive cervical cancer prevention and control. I would urge Member States to strengthen the capacity of health-care providers in the prevention and control of cervical cancer.

Dr. Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region
Acknowledgements

The World Health Organization (WHO) would like to thank all experts, partners and reviewers involved in developing this training package on cervical cancer screening and management of pre-cancers. The enormous task of preparing the comprehensive package to train the complete spectrum of providers in a cervical cancer screening program could be completed successfully due to the contributions of several experts from Member States of the WHO South-East Asia Region.

The development of the training package was coordinated by the WHO Collaborating Centre for Human Reproduction at the Department of Obstetrics and Gynaecology, Post-Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, India, under the leadership of Professor Lakhbir Dhaliwal and Professor Vanita Suri, along with team members Professor Reshmi Bagga, Dr Rakhi and Dr Parul. Inputs from consultants who worked on the project, Dr Partha Basu, Screening Group, International Agency for Research on Cancer (WHO), France, and Dr Srabani Mittal, Child in Need Institute, India, were critical.

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The pictures have been taken from IARC and reproduced with permission from IARC.
# Abbreviations

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIS</td>
<td>adenocarcinoma in situ</td>
</tr>
<tr>
<td>CA</td>
<td>cancer</td>
</tr>
<tr>
<td>C4GEP</td>
<td>Comprehensive Cervical Cancer Control: A Guide to Essential Practice</td>
</tr>
<tr>
<td>CIN</td>
<td>cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>CKC</td>
<td>cold knife conization</td>
</tr>
<tr>
<td>CTZ</td>
<td>congenital transformation zone</td>
</tr>
<tr>
<td>DNA</td>
<td>deoxyribonucleic acid</td>
</tr>
<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
</tr>
<tr>
<td>HC2</td>
<td>hybrid capture 2</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
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<tr>
<td>HLD</td>
<td>high-level disinfection</td>
</tr>
<tr>
<td>HPV</td>
<td>human papillomavirus</td>
</tr>
<tr>
<td>HSIL</td>
<td>high-grade squamous intraepithelial lesion</td>
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<tr>
<td>HSV</td>
<td>herpes simplex virus</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>IUCD</td>
<td>intrauterine contraceptive device</td>
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<tr>
<td>LBC</td>
<td>liquid based cytology</td>
</tr>
<tr>
<td>LEEP</td>
<td>loop electrosurgical excision procedure</td>
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<tr>
<td>LMIC</td>
<td>low and middle-income countries</td>
</tr>
<tr>
<td>LMP</td>
<td>last menstrual period</td>
</tr>
<tr>
<td>LSIL</td>
<td>low grade squamous intraepithelial lesion</td>
</tr>
<tr>
<td>N₂O</td>
<td>nitrous oxide</td>
</tr>
<tr>
<td>PID</td>
<td>pelvic inflammatory disease</td>
</tr>
<tr>
<td>QA</td>
<td>quality assurance</td>
</tr>
<tr>
<td>QC</td>
<td>quality control</td>
</tr>
<tr>
<td>RNA</td>
<td>ribonucleic acid</td>
</tr>
<tr>
<td>SCJ</td>
<td>squamocolumnar junction</td>
</tr>
<tr>
<td>SEAR</td>
<td>South-East Asia Region</td>
</tr>
<tr>
<td>SVA</td>
<td>single visit approach</td>
</tr>
<tr>
<td>TZ</td>
<td>transformation zone</td>
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<tr>
<td>VIA</td>
<td>visual inspection with acetic acid</td>
</tr>
<tr>
<td>VILI</td>
<td>visual inspection with Lugol’s iodine</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
Section 1: General guidelines for training
1.1 How to use the handbook

The Trainees’ handbook is designed for paramedical workers, midwives, nurses and clinicians involved in cervical cancer screening to help them acquire the necessary skills to perform VIA, collect samples for HPV test and treat cervical pre-cancers by ablative methods. The publication of the World Health Organization guidance document Comprehensive cervical cancer control: A guide to essential practice, 2nd edition, 2014 has necessitated modifications in the existing training resources for cervical cancer screening and treatment. The new screening recommendations and management algorithms have been incorporated in the present Trainees’ handbook.

The Trainees’ handbook contains guidelines and information intended to be used both by trainees and facilitators while participating in the structured training on cervical cancer screening and treatment. The handbook contains different modules to assist trainees to learn various screening and treatment procedures step-by-step and to comprehend their underlying principles. The modules contain checklists that serve as ready reckoners to develop skills in various procedures during clinical sessions. These checklists are also intended to be used by trainees during their post-training practice.

The structure and methodology of the training have been designed to impart knowledge in the most effective manner and have taken into consideration the overall training objectives, profiles of trainees and the expected learning outcomes. For further information on individual modules, trainees should refer to the corresponding chapter and the practice sheets in the Comprehensive cervical cancer control: A guide to essential practice (C4GEP), 2nd edition, available online from http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf. Henceforth, the book will be referred to as the WHO Guidance book.

1.2 Training objectives

The training on Cervical Cancer Screening and Management of Cervical Pre-cancers aims to enhance the knowledge and skills of paramedical workers, midwives, nurses and clinicians involved in various activities related to cervical cancer screening, early detection and treatment at different tiers of the health system.

After completion of the training, trainees will be able to:

• counsel women before and after cervical cancer screening;
• screen women using VIA and HPV detection test;
• make decisions related to treatment and/or referral of women with pre-cancers of cervix;
• treat pre-cancers of the cervix by ablative methods.

The objectives include both knowledge enhancement and skill development.

Knowledge-based objectives

By the end of the training, trainees will be able to:

• describe the concept of screening for cervical cancer, the necessity, basic principles and different components of the programme;
• describe the anatomy and physiology of female genital organs in relation to cervical cancer screening;
• explain the natural history of cervical neoplasia and causal role of HPV infection;
• describe VIA principles, techniques, interpretation of test results;
• explain the management algorithms of VIA positive women;
• describe the HPV test—sample collection and interpretation of results;
• explain the management algorithms for women positive on HPV test results;
• explain principles and techniques of cryotherapy and cold coagulation;
• describe infection prevention practices;
• describe how to ensure quality parameters at each level of services;
• discuss how to maintain a referral system;
• describe record keeping and data management.

**Skill-based objectives**

By the end of the training, trainees will be able to:

• demonstrate counselling of women for VIA/HPV test;
• perform VIA step-by-step;
• collect cervical samples for HPV testing;
• perform cryotherapy or cold coagulation as appropriate;
• manage women with procedure-related complications;
• conduct follow-up of the women after treatment;
• follow appropriate infection prevention practices;
• provide quality services as per the standard operating procedures.

### 1.3 Trainees’ profile

The paramedical workers, midwives, nurses and clinicians designated by the health authorities at the national or the sub-national levels to provide cervical cancer screening services need to be trained. It is preferable that trainees should have the basic knowledge and skills of performing female pelvic examinations.

Each trainee has to fill in the experience record (Box 1.1) prior to initiation of the training to help facilitators understand their background and job experience.
Box 1.1: Experience record of trainees

**Fill in details wherever specified or circle appropriate response**

1. Name: _______________________________________________________
2. Designation: ___________________________________________________
3. Age: ___________________________________________________________
4. Sex: ___________________________________________________________
5. Contact no.: ___________________________________________________
6. Place of posting: _______________________________________________
   Govt./Non-govt./Private_________________________________________
7. Highest educational qualification: ___________ Year of passing:_________
8. Duration of work experience:_____________________________________
9. Have you ever been trained to do screening for cervical cancer?
   YES NO
10. If yes, in which of the following procedures?
    VIA/Taking Pap smear/Taking sample for HPV test/Other-specify________
11. Have you been trained to do cryotherapy or cold coagulation?
    YES NO
12. Current job responsibilities:
    Clinical/Training/Supervision/Others
13. Do you practise the following in your work?
   a) Vaginal delivery: YES NO
   b) IUCD insertion: YES NO
   c) Medical termination of pregnancy: YES NO
   d) Other procedures requiring female pelvic examination: YES NO
   e) If yes, please specify _________________________________________
1.4 Training materials

The following training materials will be provided:

- Trainees’ Handbook for *Training of health staff in VIA, HPV test and Cryotherapy*
- CD-ROMs/flash drives containing the PowerPoint presentations, digital images, videos of various procedures and electronic copies of *Comprehensive cervical cancer control: A guide to essential practice, 2nd edition, WHO, 2014* and *Strategic framework for the comprehensive control of cancer cervix in South-East Asia region, WHO SEARO, 2015*
- Counselling cards and flip chart

1.5 Duration of training

The total duration of training is 10 days. For details of the session plan, please refer to Section 2.

1.6 Ground rules for trainees

- Adhere to the training schedule according to the session plan.
- Maintain attendance record for certification by the facilitator.
- Go through the subjects discussed at various sessions in the *WHO Guidance book* at the end of the day for better understanding and discussion with the facilitator.
- Attend all clinical sessions as per the schedule
- Participate in the group activities as per the session plan.
- Complete the specified number of worksheets during each clinical session and get them certified by the facilitator.
- Ensure and respect privacy and rights of the clients in the examination rooms.
1.7 Dos and don’ts for trainees

<table>
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<tr>
<th>Do</th>
<th>Don’t</th>
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<tbody>
<tr>
<td>• Reach training venue at least 15 minutes ahead of beginning of the session each day</td>
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<tr>
<td>• Familiarize with training sessions and training materials provided to you</td>
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<tr>
<td>• Interact with facilitators as and when required and get your doubts cleared</td>
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<tr>
<td>• Know your group members and stick to your allocated group during group activities</td>
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<tr>
<td>• Listen carefully to the instructions given by facilitators for the clinical sessions</td>
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<tr>
<td>• Be respectful and considerate to the clients</td>
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<tr>
<td>• Be respectful to each other and to the facilitator</td>
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<tr>
<td>• During clinical sessions, know and follow the safety precautions</td>
<td>• Cross-talk among yourselves during teaching sessions</td>
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<tr>
<td></td>
<td>• Use mobile phones or do anything to distract your colleagues</td>
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<tr>
<td></td>
<td>• Hesitate to ask questions</td>
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<td></td>
<td>• Examine a client without consultation or supervision of your facilitators</td>
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</table>

1.8 Minimum client practice by trainees

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Activity</th>
<th>Number to be observed</th>
<th>Number to be performed under supervision</th>
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<td>2.</td>
<td>VIA</td>
<td>10</td>
<td>10</td>
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<td>3.</td>
<td>Sample collection for HPV Test</td>
<td>2</td>
<td>3</td>
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<td>4.</td>
<td>Cryotherapy</td>
<td>2</td>
<td>2</td>
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<tr>
<td>5.</td>
<td>Cold coagulation (optional)</td>
<td>2</td>
<td>2</td>
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</table>
Section 2: Session plan
<table>
<thead>
<tr>
<th>Day</th>
<th>Session</th>
<th>Time</th>
<th>Contents</th>
</tr>
</thead>
</table>
| Day 1     | Registration                                 | 8:30 a.m.–9:00 a.m. | Registration of name and contact details and filling in of experience records of trainees  
Signature of trainee on attendance sheet  
Handing over of the training folder                                                                 |
|           | Opening session                              | 9:00 a.m.–10:00 a.m. | Welcome of participants  
Introduction of facilitators and trainees  
Assessment of trainees’ expectations and concerns  
Presentation of training objectives  
Ground rules and other logistics of training  
Agenda of training  
Pre-training knowledge assessment                                                                 |
|           | Session 1: Introduction to cervical cancer screening | 10:00 a.m.–11:00 a.m. | Need for cervical cancer screening                                                                                                      |
|           | Interactive presentation                     |                  | Magnitude of the problem of cervical cancer  
Principles of cervical cancer screening  
Concept of an organized screening programme  
Concept of an opportunistic screening programme  
Protocol for cervical cancer screening  
Screening tests for cervical cancer  
Target population for cervical cancer screening  
Frequency of cervical cancer screening  
Informed consent for cervical cancer screening  
National Cervical Cancer Screening Protocol                                                                 |
<p>|           | Session 2: Anatomy and physiology of female genital tract | 11:00 a.m.–12:00 p.m. |                                                                                                                                         |
|           | 2 a: Interactive presentation                |                  | Gross anatomy of female external and internal genitalia                                                                                   |</p>
<table>
<thead>
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<th>Day</th>
<th>Session</th>
<th>Time</th>
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<td>Microscopic features of cervical epithelium and concept of squamocolumnar junction (SCJ)</td>
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<td></td>
<td>Metaplasia and concept of transformation zone (TZ)</td>
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<td></td>
<td>Features of normal TZ</td>
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<td></td>
<td>Changes in TZ during pregnancy and menopause</td>
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<tr>
<td>2 b: Facilitated group learning activity</td>
<td>Recognition of parts of uterus and cervix on models</td>
<td></td>
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<tr>
<td></td>
<td>Recognition of the microscopic anatomy on digital images</td>
<td></td>
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<td></td>
<td>Speculum examination on ZOE Model</td>
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<td>Session 3: Pathogenesis of cervical cancer with special reference to HPV infection</td>
<td>12:00 p.m.–1:00 p.m.</td>
<td>Risk factors of cervical cancer</td>
<td></td>
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<td></td>
<td>Interactive presentation</td>
<td></td>
<td>Epidemiology of HPV infection</td>
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<td></td>
<td></td>
<td></td>
<td>Mechanism of carcinogenesis by HPV infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Natural history of cervical intra-epithelial neoplasia</td>
</tr>
<tr>
<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<tr>
<td>Session 4: Counselling</td>
<td>2:00 p.m.–4:00 p.m.</td>
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<tr>
<td>4 a: Interactive presentation</td>
<td>Necessity of counselling</td>
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<tr>
<td></td>
<td>Being a good counsellor</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Steps of counselling</td>
<td></td>
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<tr>
<td></td>
<td>Using checklists, flip chart and counselling cards</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Counselling messages</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 b: Facilitated group learning activity</td>
<td>Role play</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of the day's activities</td>
<td>4:00 p.m.–4:30 p.m.</td>
<td>Key points to be presented by trainees</td>
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<td>Discussion of the next day's agenda</td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Discussion to be led by the facilitator</td>
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<tr>
<td>Day 2</td>
<td>Review of the previous day's activities and doubt clearance</td>
<td>9:00 a.m.–9:30 a.m.</td>
<td>Presentation of key-points by trainees</td>
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<td>Session 5: Screening by visual inspection using acetic acid (VIA)</td>
<td>9:30 a.m.–11:00 a.m.</td>
<td>Discussion to be led by facilitators for doubt clearance</td>
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<td>5 a: Interactive presentation</td>
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<td>Principles of VIA</td>
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<td>Equipment/Instruments required</td>
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<td>Steps of VIA</td>
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<td>VIA test outcome categories</td>
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<td>Documentation of VIA findings</td>
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<td>Common benign conditions of cervix detected at VIA</td>
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<td>Common lower genital tract infections detected before VIA</td>
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<td>Post-VIA tasks and follow-up</td>
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<td>5 b: Facilitated group learning activity</td>
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<td>Image recognition skill (flash cards/digital images)</td>
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<td>Session 6: HPV detection test and cervical sample collection technique for HPV test</td>
<td>11:00 a.m.–12:00 p.m.</td>
<td>Types of HPV detection tests</td>
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<td>6 a: Interactive presentation</td>
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<td>Equipment/Instruments required</td>
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<td>Steps of cervical sample collection</td>
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<td>Interpretation of test results</td>
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<td>6 b</td>
<td>Practise on ZOE model</td>
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<td>Session 7: Management of women with positive VIA or HPV test</td>
<td>12:00 p.m.–1:00 p.m.</td>
<td>Management of VIA positive women</td>
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<td>Management of HPV positive women</td>
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<td>Importance of reducing the number of visits for screening</td>
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<td>Treatment options for cervical pre-cancers</td>
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<td>Follow-up of women after treatment</td>
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<td>7 a: Interactive presentation</td>
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<td>Case studies</td>
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<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<td>7 b</td>
<td>Facilitated group learning activity</td>
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<td>Session 8: Treatment of cervical pre-cancers by cryotherapy and follow-up</td>
<td>2:00 p.m.–3:00 p.m.</td>
<td>Principles of cryotherapy</td>
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<td>Instruments and consumables required</td>
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<td>Eligibility criteria for cryotherapy</td>
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<td>Steps of cryotherapy</td>
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<td>Post treatment advice</td>
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<td>Advantages and limitations</td>
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<td>Management of treatment complications</td>
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<td>Troubleshooting</td>
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<td>Sterilization of equipment</td>
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<td>8 a: Interactive presentation</td>
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<td>Role play</td>
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<td>8 b: Facilitated group learning activity</td>
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<td>Day 3</td>
<td>Review of the previous day’s activities and doubt clearance</td>
<td>9:00 a.m.–9:30 p.m.</td>
<td>Presentation of key-points by trainees. Discussion to be led by facilitators for doubt clearance</td>
</tr>
<tr>
<td>Session 9: Treatment of cervical pre-cancers by cold coagulation and follow-up</td>
<td>3:00 p.m.–3:45 p.m.</td>
<td>Principles of cold coagulation Instruments and consumables required Eligibility criteria for cold coagulation Steps of cold coagulation Post treatment advice Advantages and disadvantages Management of treatment complications Troubleshooting Sterilization of equipment</td>
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<td>9 a: Interactive presentation</td>
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<td>9 b: Facilitated group learning activity</td>
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<td>Role play</td>
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<tr>
<td>Session 10: Infection prevention practices</td>
<td>3:45 p.m.–4:15 p.m.</td>
<td>Importance of infection prevention practices</td>
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<td>10 a: Interactive presentation</td>
<td></td>
<td>Prevention of spread of infection Processing of instruments Waste disposal</td>
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<td>10 b: Facilitated group learning activity</td>
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<td>Role play</td>
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<td>Summary of the day’s activities</td>
<td>4:15 p.m.–4:45 p.m.</td>
<td>Key points to be presented by trainees</td>
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<tr>
<td>Discussion of the next day’s agenda</td>
<td>4:45 p.m.–5:00 p.m.</td>
<td>Discussion to be led by the facilitator</td>
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<td>Session 11: Ensuring quality of services and programme monitoring in cervical cancer screening</td>
<td>9:30 a.m.–10:30 a.m.</td>
<td>Ensuring quality of services by healthcare providers</td>
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<td></td>
<td>Organization of groups for clinical sessions</td>
<td>10:30 a.m.–11:00 a.m.</td>
<td>Programme monitoring and its necessity</td>
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<td></td>
<td>Clinic-based training</td>
<td>11:00 a.m.–4:00 p.m.</td>
<td>Indicators to monitor cervical cancer screening programme</td>
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<td></td>
<td>Demonstration session</td>
<td>11:00 a.m.–11:30 a.m.</td>
<td>Quality assurance and quality control</td>
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<tr>
<td></td>
<td>i) Preparation of dilute acetic acid</td>
<td></td>
<td>Framework for effective quality assurance</td>
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<td>ii) Preparation of Lugol’s Iodine</td>
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<td>Supportive supervision</td>
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<td>iii) Preparation of 0.5% chlorine solution</td>
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<td>Supportive supervision guidelines and tool</td>
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<td>iv) Arrangement of instrument tray for HPV sample collection</td>
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<td>Evaluation of programme performance</td>
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<td>v) Arrangement of instrument tray for VIA</td>
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<td>Using evaluation results for quality improvement</td>
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<td><strong>Clinical skills training</strong></td>
<td>11:30 a.m.–1:00 p.m.</td>
<td>i) Counselling</td>
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<td>Individual counselling /group counselling/couple counselling using skills</td>
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<td>checklist, counselling cards and flip charts</td>
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<td>ii) Sample collection</td>
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<td>Observation of procedure on client</td>
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<td>Procedure to be performed under</td>
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<td>Procedure to be performed independently under supervision</td>
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<td>iii) VIA</td>
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<td>Observation of procedure on client</td>
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<td>Procedure to be performed independently on client</td>
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<td><strong>Lunch break</strong></td>
<td>1:00 p.m.–2:00 p.m.</td>
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<tr>
<td></td>
<td><strong>Demonstration session</strong></td>
<td>2:00 p.m.–2:30 p.m.</td>
<td>i) Getting to know cryotherapy/ cold coagulator equipment</td>
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<td>Introduction to different parts of cryotherapy/ cold coagulator unit</td>
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<td>Functions of each part of the unit</td>
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<td>Connections and adjustments</td>
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<td>Equipment maintenance</td>
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<td>Troubleshooting</td>
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<td>ii) Arrangement of instrument tray for cryotherapy/ cold coagulation</td>
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<td>Introduction to instruments and consumables</td>
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<td>Working with the instruments</td>
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<td>Decontamination and sterilization of instruments</td>
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<td><strong>Clinical skills training</strong></td>
<td>2:30 p.m.–4:00 p.m.</td>
<td>i) Treatment with cryotherapy/ cold coagulation</td>
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<td>Observation of procedure on client</td>
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<td>Simulated learning</td>
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<td>Procedure to be performed under supervision</td>
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<td><strong>Summary of the day’s activities</strong></td>
<td>4:00 p.m.–4:30 p.m.</td>
<td>Key points to be presented by trainees</td>
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<td><strong>Discussion of the next day’s agenda</strong></td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Discussion to be led by the facilitator</td>
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<td>Day 4 –</td>
<td>Review of the previous day’s activities and doubt clearance</td>
<td>9:00 p.m.–9:30 p.m.</td>
<td>Presentation of key-points by trainees. Discussion to be led by facilitators for doubt clearance</td>
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<td>Day 5</td>
<td>Classroom training</td>
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<td></td>
<td>Image recognition session (digital or flash cards) / Video presentation</td>
<td>9:30 a.m.–10:30 a.m.</td>
<td>Presentation of videos of procedures being performed</td>
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<td>Clinic-based training</td>
<td>10:30 a.m.–4:00 p.m.</td>
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<td></td>
<td>Practice session on preparation of dilute acetic acid, Lugol’s iodine, 0.5% chlorine solution</td>
<td>10:30 a.m.–11:00 a.m.</td>
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<td>Clinical skills training</td>
<td>11:00 a.m.–1:00 p.m.</td>
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<td></td>
<td>i) Counselling</td>
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<td>Individual counselling/group counselling/couple counselling using skills checklists, counselling cards and flip charts</td>
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<td></td>
<td>ii) Sample collection technique for HPV testing</td>
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<td>Observation of procedure on client, Procedure to be performed under supervision, Procedure to be performed independently on client</td>
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<td>iii) VIA</td>
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<td>Observation of procedure on client, Procedure to be performed under supervision, Procedure to be performed independently on client</td>
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<td></td>
<td>iv) Treatment with cryotherapy/cold coagulation</td>
<td></td>
<td>Observation of procedure on client, Simulated learning, Procedure to be performed under supervision, Procedure to be performed independently on client</td>
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<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<td>Clinical skills training</td>
<td>2:00 p.m.–4:00 p.m.</td>
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<td>ii) Sample collection technique for HPV testing</td>
<td>Observation of procedure on client</td>
<td>Procedure to be performed under supervision</td>
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<td>iii) VIA</td>
<td>Observation of procedure on client</td>
<td>Procedure to be performed under supervision</td>
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<td>iv) Treatment with cryotherapy/cold coagulation</td>
<td>Observation of procedure on client</td>
<td>Simulated learning</td>
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<td>Procedure to be performed under supervision</td>
<td>Procedure to be performed independently on client</td>
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<td><strong>Summary of the day’s activities</strong></td>
<td>4:00 p.m.–4:15 p.m.</td>
<td>Key points to be presented by trainees</td>
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<td><strong>Discussion of the next day’s agenda</strong></td>
<td>4:15 p.m.–4:30 p.m.</td>
<td>Discussion to be led by the facilitator</td>
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<td></td>
<td><strong>Preparation for mid-course assessment</strong></td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Orientation to mid-course assessment, explanation of assessment process (knowledge assessment and skills assessment)</td>
</tr>
<tr>
<td>Day 6</td>
<td><strong>Review of the previous day’s activities and doubt clearance</strong></td>
<td>9:00 a.m.–9:30 a.m.</td>
<td>Presentation of key-points by trainees</td>
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<td><strong>Mid-course assessment</strong></td>
<td>9:30 a.m.–3:30 p.m.</td>
<td>Discussion to be led by facilitator for doubt clearance</td>
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<td></td>
<td><strong>Knowledge assessment</strong></td>
<td>9:30 a.m.–11:00 a.m.</td>
<td>Aims and objectives</td>
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<td><strong>Preparation</strong></td>
<td>9:30 a.m.–10:00 a.m.</td>
<td>Assessment process (Knowledge assessment and clinical skills assessment)</td>
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<td>Day 7 – Day 8</td>
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<td>9:00 a.m.–9:30 a.m.</td>
<td>Presentation of key points by trainees</td>
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<td>Discussion to be led by facilitator for doubt clearance</td>
<td>4:30 p.m.–5:00 p.m.</td>
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<td>Image recognition session (digital or flash cards)/Video presentation</td>
<td>9:30 a.m.–10:30 a.m.</td>
<td>Presentation of videos of procedures being performed</td>
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<td>Clinic-based training</td>
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<td></td>
<td>Practice session on preparation of dilute acetic acid, Lugol’s Iodine, 0.5% chlorine solution</td>
<td>10:30 a.m.–11:00 a.m.</td>
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<td>1:00 a.m.–1:00 p.m.</td>
<td><strong>Clinical skills training</strong></td>
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<td>Clinical skills training</td>
<td>11:00 a.m.–1:00 p.m.</td>
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<td>i)</td>
<td>Counselling</td>
<td>Observation of procedure on client</td>
<td>Individual counselling/group counselling/couple counselling using skills checklists, counselling cards and flip charts</td>
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<td>Sample collection technique for HPV testing</td>
<td>Procedure to be performed independently on client</td>
<td>Procedure to be performed under supervision</td>
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<td>Observation of procedure on client</td>
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<td>Laboratory practice on preparation of dilute acetic acid, Lugol’s Iodine, 0.5% chlorine solution</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<td><strong>Clinical skills training</strong></td>
<td>2:00 p.m.–4:00 p.m.</td>
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<tr>
<td>i)</td>
<td>Counselling</td>
<td>Observation of procedure on client</td>
<td>Individual counselling/group counselling/couple counselling using skills checklists, counselling cards and flip charts</td>
</tr>
<tr>
<td>ii)</td>
<td>Sample collection technique for HPV testing</td>
<td>Procedure performed independently on client</td>
<td>Procedure performed under supervision</td>
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<tr>
<td></td>
<td>Observation of procedure on client</td>
<td>Procedure performed independently on client</td>
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<td>Observation of procedure on client</td>
<td>Procedure to be performed independently on client</td>
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<td></td>
<td>Observation of procedure on client</td>
<td>Procedure to be performed independently on client</td>
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**Lunch break**
<table>
<thead>
<tr>
<th>Day</th>
<th>Session</th>
<th>Time</th>
<th>Contents</th>
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<tr>
<td></td>
<td>iv) Treatment with cryotherapy/cold coagulation</td>
<td>4:00 p.m.–4:15 p.m.</td>
<td>Procedure to be performed independently on client</td>
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<td></td>
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<td></td>
<td>Observation of procedure on client</td>
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<td></td>
<td>Procedure to be performed under supervision</td>
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<td>Procedure to be performed independently on client</td>
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<tr>
<td></td>
<td>Summary of the day's activities</td>
<td>4:00 p.m.–4:15 p.m.</td>
<td>Key points to be presented by trainees</td>
</tr>
<tr>
<td></td>
<td>Discussion of the next day's agenda</td>
<td>4:15 p.m.–4:30 p.m.</td>
<td>Discussion to be led by the facilitator</td>
</tr>
<tr>
<td></td>
<td>Preparation for final assessment (Day 8)</td>
<td>4:30 p.m.–5:00 p.m.</td>
<td>Orientation to final assessment, explanation of final assessment process</td>
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<td>(knowledge assessment and skills assessment)</td>
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<tr>
<td>Day 9</td>
<td>Review of the previous day's activities and doubt clearance</td>
<td>9:00 a.m.–9:30 a.m.</td>
<td>Presentation of key points by trainees</td>
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<td></td>
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<td></td>
<td>Discussion to be led by facilitator for doubt clearance</td>
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<tr>
<td></td>
<td>Final assessment</td>
<td>9:30 a.m.–4:00 p.m.</td>
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<tr>
<td></td>
<td>Knowledge assessment</td>
<td>9:30 a.m.–11:00 a.m.</td>
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<tr>
<td></td>
<td>Preparation</td>
<td>9:30 a.m.–10:00 a.m.</td>
<td>Aims and objectives</td>
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<tr>
<td></td>
<td>Conducting knowledge assessment</td>
<td>10:00 a.m.–11:00 a.m.</td>
<td>Administration of knowledge assessment questionnaire and image</td>
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<td></td>
<td></td>
<td></td>
<td>recognition skill assessment form</td>
</tr>
<tr>
<td></td>
<td>Clinical skills assessment</td>
<td>11:00 a.m.–4:00 p.m.</td>
<td>Counselling, sample collection technique for HPV testing</td>
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<td></td>
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<td></td>
<td>VIA, treatment with cryotherapy/cold coagulation</td>
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<td>Lunch break</td>
<td>1:00 a.m.–2:00 p.m.</td>
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<tr>
<td></td>
<td>Review of filled in knowledge assessment questionnaires, image</td>
<td>4:00 p.m.–4:30 p.m.</td>
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<td></td>
<td></td>
<td></td>
<td>recognition forms and assessment matrix sheets</td>
</tr>
<tr>
<td></td>
<td>Discussion of next steps forward and action plan</td>
<td>4:30 p.m.–5:00 p.m.</td>
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<tr>
<td>Day</td>
<td>Session</td>
<td>Time</td>
<td>Contents</td>
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<tr>
<td>Day 10</td>
<td><strong>Clinical skills assessment</strong></td>
<td>9:30 a.m.–12:30 p.m.</td>
<td>Counselling, sample collection technique for HPV testing</td>
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<td></td>
<td></td>
<td></td>
<td>VIA, treatment with cryotherapy/cold coagulation</td>
</tr>
<tr>
<td></td>
<td>Filling in of feedback forms</td>
<td>12:30 p.m.–1:00 p.m.</td>
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<tr>
<td></td>
<td>Lunch break</td>
<td>1:00 p.m.–2:00 p.m.</td>
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<tr>
<td></td>
<td>Discussion of clinical skills assessment</td>
<td>2:00 p.m.–3:00 p.m.</td>
<td>Discussion of summary performance sheets</td>
</tr>
<tr>
<td></td>
<td>Certificate distribution and comments from trainees</td>
<td>3:00 p.m.–4:00 p.m.</td>
<td>Feedback forms</td>
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<tr>
<td></td>
<td>Closing</td>
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Section 3: Modules

Module 1: Introduction to cervical cancer screening
Module 2: Anatomy and physiology of the female genital tract
Module 3: Pathogenesis of cervical cancer with special reference to HPV infection
Module 4: Counselling
Module 5: Screening by visual inspection with acetic acid (VIA)
Module 6: HPV detection test and cervical sample collection technique for HPV test
Module 7: Management of women with positive VIA or HPV test
Module 8: Treatment of cervical pre-cancers by cryotherapy and follow-up
Module 9: Treatment of cervical pre-cancers by cold coagulation and follow-up
Module 10: Infection prevention practices
Module 11: Ensuring quality of services and programme monitoring in cervical cancer screening
Module 1: Introduction to cervical cancer screening

1.1 Module overview
This module is designed to help paramedical workers, midwives, nurses and clinicians understand the concept of screening for cervical cancer. The module will also give them an overview of the different techniques of cervical cancer screening and the components of an organized screening programme. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading, refer Chapter 5 – Screening and treatment of cervical pre-cancer; Section 5.2 – Cervical cancer screening)

1.2 Module contents
• Need for cervical cancer screening
• Magnitude of the problem of cervical cancer
• Principles of cervical cancer screening
• Concept of an organized screening programme
• Concept of an opportunistic screening programme
• Protocol for cervical cancer screening
• Screening tests for cervical cancer
• Target population for cervical cancer screening
• Frequency of cervical cancer screening
• Informed consent for cervical cancer screening
• National Cervical Cancer Screening Protocol

1.3 Learning objectives
By the end of this module, trainees will be able to:
• describe the concept of cervical cancer screening;
• state the burden of cervical cancer in the population;
• explain how screening for cervical cancer helps to reduce the burden of the disease
• list out the various components of an organized screening programme;
• describe the advantages and disadvantages of different screening tests for cervical cancer ;
• define the target age group and the frequency of screening;
• describe the protocol for cervical cancer screening of the country.
1.4 Key points for discussion

1.4.1 What is screening for cervical cancer?

Screening in general is defined as the application of a test on an apparently asymptomatic healthy population to identify those with high-risk of having or developing a particular disease. Screening test positive women need to have further investigations to confirm the diagnosis. To screen for cervical cancer, apparently healthy women belonging to a specified age group are tested routinely, irrespective of whether they have any symptom or not. The tests applied are called the screening tests.

1.4.2 Why is it necessary to screen women for cervical cancer?

Cancer of the uterine cervix is the fourth most common cancer among women globally. In Asian women, cervical cancer ranks second after breast cancer. The cancer causes a large number of deaths amongst women in the South-East Asia regional countries (Table 1.1). Cervical cancer affects women at a relatively younger age causing great personal, social and economic loss. Screening helps to detect the cancer at a potentially curable precancerous stage. Detection of the precancerous conditions by screening tests and their appropriate treatment help prevent the cancer and avoid untimely deaths of from the disease.

Table 1.1: The burden of cervical cancer in South-East Asian countries\(^{(1, 2)}\)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of cases</th>
<th>Age standardized rates (/100 000)</th>
<th>Rank among all cancers in women</th>
<th>Number of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>527 624</td>
<td>14.0</td>
<td>4(^{th})</td>
<td>265 672</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>11 956</td>
<td>19.2</td>
<td>2(^{nd})</td>
<td>6 582</td>
</tr>
<tr>
<td>Bhutan</td>
<td>37</td>
<td>12.8</td>
<td>1(^{st})</td>
<td>19</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>1881</td>
<td>12.4</td>
<td>4(^{th})</td>
<td>1119</td>
</tr>
<tr>
<td>India</td>
<td>122 844</td>
<td>22.0</td>
<td>2(^{nd})</td>
<td>67 477</td>
</tr>
<tr>
<td>Indonesia</td>
<td>20 928</td>
<td>17.3</td>
<td>2(^{nd})</td>
<td>9 498</td>
</tr>
<tr>
<td>Maldives</td>
<td>14</td>
<td>11.0</td>
<td>2(^{nd})</td>
<td>7</td>
</tr>
<tr>
<td>Myanmar</td>
<td>5286</td>
<td>20.6</td>
<td>2(^{nd})</td>
<td>2 998</td>
</tr>
<tr>
<td>Nepal</td>
<td>2332</td>
<td>19.0</td>
<td>1(^{st})</td>
<td>1 367</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>1721</td>
<td>13.1</td>
<td>2(^{nd})</td>
<td>690</td>
</tr>
<tr>
<td>Thailand</td>
<td>8184</td>
<td>17.8</td>
<td>2(^{nd})</td>
<td>4 513</td>
</tr>
<tr>
<td>Timor-Leste</td>
<td>46</td>
<td>13.3</td>
<td>3(^{rd})</td>
<td>24</td>
</tr>
</tbody>
</table>


1.4.3 How does screening for cervical cancer reduce the disease burden?

Cervical cancer has a unique natural history that allows its prevention through screening. The cancer is caused by infection from high-risk types of human papillomavirus (HPV). About 10% of Asian women are estimated to harbour cervical HPV infection at any given time, and 65–85% of invasive cancers of cervix detected in Asian women are attributed to HPV types 16 or 18. The details of the virus infection and how it causes cancer are discussed in Module 3. The virus infection induces a precancerous change known as cervical intraepithelial neoplasia (CIN). CIN can be detected by various screening tests and can be treated by simple techniques. Detection and treatment of the disease at the CIN stage prevents development of cervical cancer in the future. Countries that introduced national programmes to systematically screen women for cervical cancer and treat precancerous conditions, observed significant reduction in deaths from cervical cancer over a few years. Fig. 1.1 shows the decline of cervical cancer deaths over time in Australia with the introduction of the National Cervical Screening Programme in 1991. The mortality rates more than halved from 1991 to 2007, from 4.0 to 1.9 deaths per 100 000 women due to systematic screening of the population.

Reasons for high incidence of and mortality from cervical cancer in developing countries

- The disease is detected late as it remains asymptomatic for a long time.
- Lack of awareness of cervical cancer among the population, healthcare providers and policy-makers.
- Cervical cancer prevention is not yet a priority among national public health programmes resulting in inadequate resource allocation.
- Absence or poor quality of cervical cancer screening programmes.
- Limited access to quality healthcare services for early detection and treatment of cervical cancer.
- Lack of a functional referral systems
1.4.4 What is an organized cervical cancer screening programme?

A screening programme may be organized or opportunistic. An organized screening programme is essential for effective reduction of the incidence of cervical cancer and deaths from this disease. The screening programme is considered to be organized when it includes the following:

- a commitment and policy at the national level to make the services accessible to all in the target population;
- a programme protocol that clearly defines—
  - screening and treatment methodologies
  - frequency of screening and the target age for screening
  - operational aspects of the programme
- a mechanism for systematically inviting target women to ensure high participation rates;
- linkage between screening, diagnosis and treatment;
- a programme monitoring, supervision and quality assurance plan.

1.4.5 What is an opportunistic cervical cancer screening programme?

An opportunistic cervical cancer screening programme is one in which screening tests are offered to eligible women when they visit health facilities for any reason. Unlike an organized screening programme, opportunistic screening may not have a high participation rate and appropriate quality control.
1.4.6 What is a screening protocol?

A screening protocol is a set of guidelines that all healthcare providers involved in a screening programme must follow. The protocol specifies the eligible population for screening, the screening test to be used, the frequency of screening and management of screen positive women. The contents of the protocol vary from programme to programme.

1.4.7 What are the different screening tests for cervical cancer?

A screening test is a simple test performed on a large number of people to identify those who already have or are likely to develop a specified disease. An ideal screening test for cervical cancer should be accurate, easy to use on a large number of women, feasible to perform in the particular setting, be able to provide results immediately (point of care), acceptable to the women and inexpensive. There are a number of tests available for cervical cancer screening. (Fig. 1.2). The different screening tests and their advantages and disadvantages are given in Table 1.2.

Fig. 1.2: Screening tests for cervical cancer

**A screening programme will be effective if there is:**

- high coverage (nearly 80%) of the target population;
- appropriate follow-up and management of those who are positive on screening;
- effective linkage between programme components (from screening to diagnosis and treatment);
- high quality of screening tests, diagnostic evaluation, treatment and follow-up;
- Adequate infrastructure with trained and dedicated manpower and financial resources.
<table>
<thead>
<tr>
<th>Method</th>
<th>Procedure</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
</table>
| HPV DNA test            | Cervical cells are collected using a brush or a swab by a provider or by the woman herself. Samples are stored in a container with appropriate preservative solution and sent to the laboratory. | • Collection of the specimen is simple  
• Self-collection is possible  
• Highly sensitive  
• Allows screening interval to be extended up to 10 years for screen negative women  
• Test is objective and reproducible  
• Can be performed by a trained technician  
• Training is simple  
• Possible to obtain results in a few hours | • Requires specialized equipment and consumables  
• Expensive  
• Requires functioning laboratory, storage facilities for samples and consumables  
• Arrangement for specimen transport may be complex.  
• Results may not be immediately available |
| Visual inspection with acetic acid (VIA) | Cervix is visualized with the naked eye under a good light source at least 1 minute after applying 3–5% acetic acid. | • Relatively simple and can be performed by trained paramedical workers  
• Inexpensive  
• Results are available immediately  
• A positive result can be followed by immediate treatment (single-visit approach)  
• Infrastructure requirements are minimal  
• Consumables are easily available | • Subjective test, requires rigorous training and supervision of the providers to ensure good performance  
• Sensitivity lower than HPV test  
• Sensitivity lower in post-menopausal women |
| Conventional cytology (Pap smear) | A provider collects cervical cells using a brush and a spatula. The cells are spread and stained on slides to be examined by | • Widely used in high-resource countries | • Sensitivity low to moderate  
• Expensive |
A provider collects cervical cells using a brush in a liquid preservative. The cells are spread and stained on slides to be examined by a trained cytotechnician or a pathologist.

Liquid-based cytology (LBC)

• Slides are easier to read and take less time
• Samples can also be used for molecular testing (such as for HPV DNA test)
• Training and mechanisms for quality control and quality assurance are well-established

• Supplies and laboratory facilities are more expensive than for conventional cytology
• Other limitations are the same as for conventional cytology

1.4.8 Who should be screened for cervical cancer?

Screening tests are not recommended for women below 30 years of age as the burden of cervical cancer is low at this age. Screening women between 30 years and 49 years of age, even once in a lifetime will substantially reduce deaths from cervical cancer. This is the most suitable age to screen women as the majority of high grade precancerous lesions are detected between these ages. The upper age limit of screening may be different across countries. Pregnancy is not the ideal time to perform screening. Screening should be deferred till 6 weeks after childbirth. Women who have had a hysterectomy and did not have pre-cancer or cancer of cervix in the post-operative specimen need not be screened for cervical cancer.
1.4.9 What is the optimum interval between two rounds of screening?

The interval between two rounds of screening in screen negative women will depend on the screening test used. In VIA-based programmes, the interval for rescreening VIA negative women should be 3–5 years. In HPV detection-based programmes, the interval for rescreening HPV negative women should be at least 5 years. The interval can be extended up to 10 years if resources to repeat the HPV test frequently are limited. Recommendations of the national protocol of the respective countries should be followed in this regard.

- **Women and girls who are HIV positive and have initiated sexual activity should be screened as soon as they are detected HIV positive regardless of age.**
- **In HIV positive women, screening interval should not exceed 3 years.**

1.4.10 Is it necessary to take informed consent?

Every woman should be appropriately counselled before screening so that she can make an informed decision to undergo the procedure. Explicit consent is required prior to screening. The consent may be verbal or written depending on the existing regulations of the country and the recommendations of the programme protocol.

1.4.11 What are the recommendations of the local cervical cancer screening protocol

The key factors related to the choice of screening test, target population for screening, interval between screening tests and management options should be discussed from the national cervical cancer screening protocol of the respective country, if available. Such protocols may exist for the region or the province at sub-national levels from where trainees have been selected. Accordingly, the protocol that trainees need to follow should be discussed.

**Points to remember**

- Cervical cancer is a major cause of morbidity and mortality in the country/region.
- Cervical cancer can be prevented by systematic screening of target populations and ensuring treatment of positive cases.
- Screening should be organized rather than opportunistic or sporadic.
- An organized screening programme must have a protocol that will clearly indicate the target population, frequency of screening and the screening test to be used.
- There are several screening tests and screening options; each has advantages and disadvantages.
- Informed consent prior to screening is necessary. The nature of the consent will depend on the existing regulations.
Multiple choice questions

1. Screening is defined as application of a test on:
   a) Children, to decide their eligibility for vaccination
   b) An apparently healthy asymptomatic population to identify those with high-risk of developing a particular disease
   c) Men and women who have been treated for cancer to detect recurrence
   d) Symptomatic population to determine their suitability for chemotherapy

2. Which of the following is not the screening test for cervical cancer?
   a) Pap test
   b) VIA
   c) Colposcopy
   d) HPV DNA

3. Advantages of HPV DNA testing over VIA are the following, except:
   a) Higher sensitivity
   b) More objective
   c) Gives immediate results
   d) Has higher accuracy in post-menopausal women

4. All the following statements are true for cervical cancer, except:
   a) Second most common cancer among Asian women
   b) More common in women who never had sexual relations
   c) Has a curable precancerous stage
   d) Mortality can be significantly reduced by systematic screening of women

5. Which of the following statements is true about the organized screening programme?
   a) Effective if high coverage (nearly 80%) of population at risk is achieved
   b) In an organized screening programme, screening tests are offered to women who visit health facilities for different reasons
   c) Opportunistic screening has a high participation rate
   d) Organized screening programme is less cost effective

Answer key
1 – b
2 – c
3 – c
4 – b
5 – a
Module 2: Anatomy and physiology of the female genital tract

2.1 Module overview

This module is designed to help mid-wives and other paramedical workers, nurses and clinicians know the anatomy of the female pelvis with special reference to the uterine cervix. The module describes the physiological changes occurring in the epithelium of the cervix that contribute to the development of neoplasias of cervix. The module is meant to be used by trainees in conjunction with the WHO Guidance book for further reading, refer Chapter 1 – Background; Section 1.2 – Female pelvic anatomy and physiology and Practice Sheet 5.2).

2.2 Module contents

- Gross anatomy of female external and internal genitalia
- Microscopic features of cervical epithelium and concept of squamocolumnar junction (SCJ)
- Metaplasia and concept of transformation zone (TZ)
- Features of normal TZ
- Changes in TZ during pregnancy and menopause
- Group learning activities
  - Identification of parts of the uterus and cervix on ZOE model
  - Practice speculum examination on ZOE model
  - Recognition of microscopic anatomy on digital images

2.3 Learning objectives

By the end of this module, trainees will be able to:

- describe the anatomy of the uterine cervix and its relation with other pelvic organs;
- explain the changes occurring on the lining epithelium of the cervix that are relevant to the pathogenesis of neoplasias of the cervix;
- describe the physiological changes of the cervix occurring during pregnancy and menopause;
- recognize different parts of the female genitalia to help them perform various procedures.
2.4 Key points for discussion

2.4.1 What are the different parts of the female genital tract?

The female genital tract comprises the internal genital organs that lie within the pelvis (the lower part of the abdominal cavity) and the external genitalia that is visible from outside. The internal organs comprise the uterus, two ovaries, two fallopian tubes and the vagina (Fig. 2.1). The uterus and the vagina lie in between the urinary bladder and urethra anteriorly and the rectum and anal canal posteriorly (Fig. 2.2). The external genitalia comprises the vulva, vaginal opening (introitus) and the urethral opening (Fig. 2.3).

2.4.2 Describe the gross anatomy of the uterine cervix

The cervix is the lower one third of the uterus and is narrow and conical in shape. It measures 3–4 cm in length, and 2.5 cm in diameter (Fig. 2.4). The lower end of the cervix projects through the anterior wall of the vagina, which divides the cervix into an upper supra-vaginal portion, and a lower vaginal portion.
The vaginal portion (portio vaginalis) of the cervix protrudes into the vagina from its anterior wall. During speculum examination, only this part of the cervix is visible.

The cervical canal or endocervix is situated at the centre of the cervix. The canal opens into the vagina through an opening known as the external os. In nulliparous women, the external os is round in shape (Fig. 2.5) and in parous women it is slit-like (fish mouth appearance) (Fig. 2.6). The portion of the cervix lying beyond the external os is called the ectocervix. This is the portion of the cervix that is readily visible on speculum examination.

2.4.3 Describe the microscopic anatomy of the normal cervix

The cervix is composed of epithelium (surface lining) and underlying stroma (deeper fibrous tissue) separated by a thin barrier called basement membrane.

The ectocervix is lined by non-keratinized stratified squamous epithelium. The epithelium has multiple (15-20) layers of cells and appears pale pink in colour. The squamous epithelium is divided into basal, parabasal, intermediate and superficial layers from below upwards (Fig. 2.7). From the basal to the superficial layer, squamous epithelial cells become more flat, larger in size and have smaller nuclei. The cells of the superficial and intermediate layers contain abundant glycogen as a sign of normal maturation of the squamous epithelium.

The endocervix is lined by columnar epithelium (Fig. 2.8) composed of a single layer of tall cells with dark-staining nuclei close to the basement membrane. On visual examination, columnar epithelium appears red in colour with a granular velvet like surface. The epithelium forms several invaginations into the substance of the stroma, resulting in the formation of endocervical crypts (sometimes referred to as endocervical glands). The crypts lined by columnar epithelium may extend 5–8 mm into the stroma.

The columnar epithelium at its lower limit meets the squamous epithelium. The junction between the two epithelia is known as the squamocolumnar junction (SCJ) (Fig. 2.9). The SCJ is usually visible as a sharp border located near the external os. The position of the SCJ in relation to the external os changes with age (Fig. 2.10), pregnancy and use of oral contraceptive pills. At birth, it is close to the external os. From puberty and throughout reproductive life, the uterus grows under the influence of oestrogen. As a result, the SCJ relocates to lie at variable distances from the external os on the ectocervix. During peri- and post-menopausal period, the cervix shrinks due to the waning effect of oestrogen. As a result the SCJ moves inside the endocervical canal.

Fig. 2.7: Schematic diagram of normal squamous epithelium
Fig. 2.8: Schematic diagram of normal columnar epithelium

- Crypt opening
- Basement membrane
- Columnar cells
- Crypt

Fig. 2.9: Squamocolumnar junction

- Squamous epithelium
- Squamocolumnar junction
- Columnar epithelium
- Villus
- Crypt

Photo courtesy PGIMER, Chandigarh, India
2.4.4 What are the physiological changes of the cervical epithelium?

The cervix enlarges under the influence of oestrogen at puberty and during pregnancy. As a result, columnar epithelium becomes visible on the ectocervix and the SCJ moves out on the ectocervix. This condition is known as ectropion (Fig. 2.11) or ectopy.

The columnar epithelium on the ectocervix becomes exposed to the acidic environment of the vagina. This causes destruction of the columnar epithelium and its gradual replacement by the newly formed squamous epithelium. This process through which the columnar epithelium on the ectocervix is gradually replaced with squamous epithelium is called squamous metaplasia.

Squamous metaplasia usually begins at the SCJ at the distal limit of the ectopy (original SCJ) and gradually moves inwards (centripetally) towards the external os (Fig. 2.12). The SCJ formed between the metaplastic...
squamous epithelium and the columnar epithelium is known as the new SCJ. The area between the original SCJ and the newly formed SCJ as a result of metaplasia is the transformation zone (TZ).

During the peri-menopausal period and after menopause, the cervix shrinks due the lack of oestrogen and consequently, the SCJ moves inside the endocervical canal from the external os. In post-menopausal women, the SCJ is often invisible on visual examination (Fig. 2.13).

2.4.5 What are the features of normal TZ?

The proximal extent of the TZ is the new SCJ and is easy to identify. Tongue like projections of the thin newly formed metaplastic squamous epithelium is a feature of the normal TZ. Patent crypts appear as small openings on the TZ. Some of the crypts are blocked by the metaplastic epithelium, which leads to formation of retention cysts known as nabothian follicles or cysts (Fig. 2.14). Nabothian cysts appear as bluish or white cysts (pimples on the cervix) and are physiological. The crypt openings and nabothian cysts are features of normal TZ. The position of the crypt opening or the nabothian cyst farthest from the SCJ helps to identify the outer limit of the TZ (Fig. 2.15).
2.4.6 What are the changes of TZ in pregnancy and menopause?

During pregnancy the cervix enlarges, becomes congested and the columnar epithelium extends to the ectocervix (ectropion). The SCJ is easily visible on the ectocervix (Fig. 2.16).

During the peri-menopausal period and after menopause, the cervix shrinks due to the lack of oestrogen. Due to the shrinkage of the cervix, SCJ moves inside the endocervical canal from the external os. In post-menopausal women, the SCJ is often invisible on visual examination.

2.5 Group learning activities

2.5.1 Identification of parts of the uterus and cervix on ZOE model
2.5.2 Practise speculum examination on ZOE model
2.5.3 Recognition of microscopic anatomy on digital images

Steps of speculum examination on a ZOE model (Fig. 2.17)

- Wash hands with soap and water
- Wear disposable or high-level disinfected gloves on both hands
- Select an appropriate sized bi-valve speculum
- Dip it into clean water or available lubricant
- Retract the labia minora with one hand
- Insert the speculum keeping the blades closed and angled posteriorly
- Open the blades until the cervix is fully visualized
- Fix the blades of the speculum by tightening the screws
- See the cervix with the oval shaped external os at the centre
- Perform the necessary procedures (collect cervical sample for HPV test or apply probe of cryotherapy on the cervix)
- Loosen the screws and close the blades of the speculum
- Gently remove the speculum
a) Wear disposable or HLD gloves on both hands
b) Select an appropriate sized bi-valve speculum
c) Dip it into clean water or available lubricant
d) Retract the labia minora with one hand
e) Insert the speculum keeping the blades closed and angled posteriorly
f) Open the speculum blades until the cervix is fully visualized
g) After examination, loosen the screw and gently remove the speculum

Fig. 2.17: Steps of speculum examination on a ZOE model
Common difficulties encountered during speculum examination and their solutions

<table>
<thead>
<tr>
<th>Problems encountered</th>
<th>Suggested solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient does not allow insertion and feels pain</td>
<td>Reassure her, select a smaller sized speculum, use more lubricant and be gentle.</td>
</tr>
<tr>
<td>Cervix is not visualized or partially visualized</td>
<td>Close the speculum partially, loosen the screw and manoeuvre to expose the cervix. Choose a bigger sized speculum if required.</td>
</tr>
<tr>
<td>Cervix is not seen properly due to laxity of the vaginal wall</td>
<td>Use a bigger sized speculum and open it to the maximum limit to stretch the vaginal wall. Alternatively slip a non-lubricated condom or cut finger stall (thumb) of a glove on the speculum blades (Fig. 2.18) and cut the tip. Then insert the speculum in the vagina. Lateral vaginal wall retractors can also be used.</td>
</tr>
</tbody>
</table>

Fig. 2.18: Cut thumb of glove on speculum blades

Points to remember

• The cervix is the lower part of the uterus that projects through the anterior wall of the vagina.
• The cervix is covered by squamous epithelium and columnar epithelium that meet at the SCJ.
• The columnar epithelium on the ectocervix is replaced by squamous epithelium through a process known as metaplasia.
• The area of the cervix where metaplasia occurs is known as the TZ.
• TZ can be identified by certain features like crypt openings, nabothian follicles, etc.
• In postmenopausal women, the SCJ moves into the endocervical canal and part of the TZ may not be visible.
Multiple choice questions

1. The new squamocolumnar junction (SCJ) on the cervix is where the:
   a) Vagina meets the cervix
   b) Columnar epithelium meets the squamous epithelium
   c) Ectocervix meets the cervical os
   d) Columnar epithelium meets metaplastic squamous epithelium

2. Abnormal changes of the cervix, such as dysplasia, almost always develop in the:
   a) Ectocervix
   b) Transformation zone
   c) Endocervix
   d) Cervical os

3. Which of the following is a false statement for microscopic anatomy of the cervix?
   a) Ectocervix is lined by non-keratinized stratified squamous epithelium
   b) Ectocervix is lined by single layer squamous epithelium
   c) Endocervix is lined by columnar epithelium
   d) Squamous epithelium is divided into basal, parabasal, intermediate and superficial layers

4. All the following are true for the anatomy of the cervix, except:
   a) Cervix is 1–2 cm in length
   b) Cervix is the lower one third of uterus
   c) External os is slit like in multiparous women
   d) Cervix has supravaginal and infravaginal portions

5. The following is a true statement about the transformation zone:
   a) Often invisible during pregnancy
   b) Easily visible on the ectocervix in menopausal women
   c) Nabothian cysts are features of a normal transformation zone
   d) Position of crypt openings help to identify the inner limit of transformation zone

Answer key
1 – d 2 – b 3 – b
4 – a 5 – c
Module 3: Pathogenesis of cervical cancer with special reference to HPV infection

3.1 Module overview
This module is designed to train paramedical workers, midwives, nurses and clinicians about how the HPV infection leads to the development of pre-cancers of the cervix, which may progress to cervical cancer unless treated. Trainees will get an overview of the natural history of cervical cancer that is essential to understand the principles of detection and treatment of cervical precancerous conditions. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading, refer Chapter 1 – Background; Section 1.3 – Natural history of cervical cancer).

3.2 Module contents
- Risk factors for cervical cancer
- Epidemiology of HPV infection
- Mechanism of carcinogenesis by HPV infection
- Natural history of cervical intra-epithelial neoplasia

3.3 Learning objectives
By the end of this module, trainees will be able to:
- list the various risk factors for cervical cancer;
- narrate the role of HPV infection in cervical cancer;
- describe the mode of transmission of HPV infection;
- explain the natural history of cervical cancer originating from HPV infection.

3.4 Key points for discussion
3.4.1 Which categories of women are at higher risk of developing cervical cancer?
- Women above the age of 40 years who have ever been sexually active
- Women whose sexual debut is at a very young age
- Women who have sex with multiple partners or women whose partners have multiple sex partners
- Women who have too many children, specially at a young age
- Women belonging to the lower socioeconomic strata of society
- Women who have never been screened for cervical cancer
• Women who smoke
• Women who have a lower genital tract infection with Chlamydia/HSV
• HIV infected women and women with poor immunity

Most important cause for cervical cancer is persistent infection with human papillomavirus (HPV) that is transmitted through sexual contact. In fact, high-risk HPV infection is the necessary cause of cervical cancer which implies that cervical cancer cannot occur without HPV infection.

### 3.4.2 What is human papillomavirus (HPV)?

HPV (Fig. 3.1) is a double stranded DNA virus. Structurally the virus has two main components – a covering of protein and a double DNA (containing genetic material) within. HPVs are classified into nearly 130 different types (genotypes). Depending on their potential to cause malignancy, the HPV types are grouped as non-oncogenic (do not cause cancer) and oncogenic (may cause cancer). The oncogenic HPV types are also known as high-risk types.

Some facts about HPV infection and cancer

- Fifteen high-risk HPV types have been identified: Types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82.
- All cervical cancers are caused by any of the high-risk HPV types (single or multiple types).
- High-risk HPV types are also associated with vulval, vaginal, anal and oropharyngeal cancers in women.
- In men, HPV can cause oropharyngeal, anal and penile cancers.
- Types 16 and 18 cause approximately 65–85% of all cervical cancers worldwide.
- HPV types 6 and 11 are the most common low risk types and cause nearly 90% of genital warts in both sexes.

### 3.4.3 Will all women infected with high-risk HPV types develop cervical cancer?

HPV is the necessary cause of cervical cancer, which signifies that cervical cancer is always initiated by persistent infection from high-risk HPV types. However, all the women with HPV infection do not develop cervical cancer, as majority of the infected women will clear the infection through their natural immunity. In fact, cervical cancer is a rare outcome of HPV infection.
3.4.4 How does HPV infection spread?

HPV infection spreads through sexual contact. It is the most common sexually transmitted infection in men and women. Penetrative sex is not necessary for the virus to be transmitted between sex partners. The virus can be transmitted through genitalia-to-genitalia, skin-to-skin or skin-to-genitalia contact.

Women are at highest risk of acquiring HPV infection when they initiate their sexual life. Majority of the infected women clear the infection due to natural immunity in the body. It takes nearly 1–2 years to clear HPV infection. Women who cannot clear the infection and have pre-cancer infection of the cervix are at the highest risk of developing cervical cancer.

Male circumcision and use of condoms partially prevent transmission of HPV and offer some protection from cervical cancer.

3.4.5 How can a woman know if she has HPV infection?

HPV infection by itself does not have any symptoms. Symptoms appear only when the infection causes diseases like genital warts or cancer in its advanced stage.

3.4.6 How does HPV cause cervical cancer?

HPV enters through small breaks in the cervical epithelium near the squamocolumnar junction and infects cells of the basal layer of the squamous epithelium. The virus divides within the cells and the viral division is synchronized with epithelial cell division. As epithelial cells divide, mature and move towards the surface, the replicating viruses also move with them and finally come out of the epithelium (Fig. 3.2). Since most women can clear the viral infection due to their natural immunity, they do not get cervical neoplasia. The malignant process starts if the infection is persistent and viral DNA become integrated into the host DNA. Such integration leads to the production of harmful onco-proteins (proteins causing cancer) in the cervical epithelial cells. These onco-proteins disrupt the normal regulatory mechanisms of cell division and this initiates the process of carcinogenesis.

Fig. 3.2: Normal life cycle of HPV infection
3.4.7 What are the precancerous conditions of the cervix?

Persistent HPV infection and unregulated divisions of the squamous cells of cervical epithelium lead to a pre-cancer condition known as cervical intraepithelial neoplasia (CIN), previously known as dysplasia. Depending on the severity of the abnormality and extent of involvement of the thickness of the squamous epithelium, the CIN lesions are graded into CIN 1, CIN 2 or CIN 3 (Fig. 3.3).

In CIN 1 (mild dysplasia), abnormal dysplastic cells are limited to the lower one third of the epithelium. In CIN 2 (moderate dysplasia) and CIN 3 (severe dysplasia, stage O cervical carcinoma in situ), the cervical epithelial abnormalities extend up to the middle third and the upper third respectively.

CIN lesions do not always progress to cancer and a good number of them may spontaneously regress. It has been estimated that the possibility of regression of CIN 1, CIN 2 and CIN 3 lesions are 57%, 43% and 32% respectively. While the CIN 1 lesions rarely progress to invasive cancer, the possibility of progression of CIN 2 or CIN 3 lesions are high unless treated. CIN 1 lesions are also known as low grade squamous intraepithelial lesions (LSIL) because of the low potential for progression. CIN 2 and CIN 3 lesions are grouped together as high grade squamous intraepithelial lesions (HSIL) as a large number of them will progress if left untreated. The time interval between the HPV infection and the development of cervical cancer varies and is at least 10 years (Fig. 3.4).

Precancerous lesions arising from the columnar epithelium are referred to as adenocarcinoma in situ (AIS). Cervical precancerous conditions do not cause any symptoms and are detected only by special tests.

Fig. 3.3: Grades of cervical intraepithelial neoplasia (CIN)

Photos courtesy PGIMER, Chandigarh, India
3.4.8 What vaccines can be given to protect against HPV?

Two types of vaccines are available for the prevention of HPV infection (Table 3.1). HPV vaccination of girls before the initiation of sexual activity is an important method of preventing cervical cancer and should be an integral part of any comprehensive cervical cancer control programme. WHO recommends HPV vaccination of girls ideally at age 9–13 years. As the vaccines do not protect against all types of HPV, screening is required later in life even in the vaccinated population. Fig. 3.5 shows the composition of bivalent and quadrivalent vaccines.

Table 3.1: Characteristics of HPV vaccines

<table>
<thead>
<tr>
<th>Type of vaccine</th>
<th>Quadrivalent</th>
<th>Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV types targeted by the vaccine</td>
<td>HPV 6, 11, 16, 18</td>
<td>HPV 16, 18</td>
</tr>
<tr>
<td>Dose and route of administration</td>
<td>0.5 ml, intramuscular, upper arm, deltoid</td>
<td>0.5 ml, intramuscular, upper arm, deltoid</td>
</tr>
<tr>
<td>Schedule</td>
<td>0, 2, 6 months</td>
<td>0, 1, 6 months</td>
</tr>
<tr>
<td>Schedule (9–13 years of age) *WHO recommendation</td>
<td>0 and 6 months</td>
<td>0 and 6 months</td>
</tr>
</tbody>
</table>

*Girls aged over 15 years without prior vaccination will need three doses of HPV vaccine. Refer to strategic framework for comprehensive control of cancer cervix in South-East Asia region, WHO 2015 for further reading.
Fig. 3.5: Composition of bivalent and quadrivalent vaccines

a: Bivalent vaccine

- **Antigens**
  - HPV 16 VLPs
  - HPV 18 VLPs

- **Adjuvant**
  - Salt ([Al(OH)]

b: Quadrivalent vaccine

- **Antigens**
  - HPV 16 VLPs
  - HPV 18 VLPs
  - HPV 6 VLPs
  - HPV 11 VLPs

- **Adjuvant**
  - Aluminium salt (amorphous aluminium hydroxyphosphate sulphate)

**Points to remember**

- Infection from high-risk HPV is necessary but not sufficient cause of cervical cancer.
- HPV is a very common sexually transmitted virus and majority of the infected women will clear the virus due to natural immunity.
- Women who cannot clear the infection and have persistent infection with any of the high-risk types of HPV will develop cervical neoplasia.
- Cervical intra epithelial neoplasia (CIN) is the premalignant condition of cervix and is classified into CIN 1, CIN 2 and CIN 3 depending on the severity of the disease.
- CIN 2 and CIN 3 lesions have high probability of progression and must be treated. CIN 1 lesions can be followed up as they are mostly transient.
Multiple choice questions

1. All of the following are risk factors for cervical cancer, except:
   a) Multiple sexual partners
   b) HIV infection
   c) Smoking
   d) Bacterial vaginosis

2. HPV
   a) Is a DNA virus
   b) Is a RNA virus
   c) Infects columnar epithelium only
   d) Causes only warts

3. Which of the following are high-risk HPV viruses?
   a) 16, 18, 31, 33
   b) 6, 11
   c) 13, 18, 23, 60
   d) 18, 32, 43, 44

4. HPV 16 and 18 are responsible for:
   a) 30–40% of cervical cancers
   b) 40–50% of cervical cancers
   c) 60–70% of cervical cancers
   d) >90% of cervical cancers

5. The following statement is true about precancerous conditions of the cervix:
   a) Always progress to cancer
   b) In CIN 1, abnormal dysplastic cells are limited to the basal one third of the epithelium
   c) 90% of CIN 2 lesions regress spontaneously
   d) CIN 3 lesions do not need treatment

Answer key

1 – d  
2 – a  
3 – a  
4 – c  
5 – b
Module 4: Counselling

4.1 Module overview
This module is designed to train paramedical workers, midwives, nurses and clinicians in the art and techniques of counselling women attending cervical cancer screening facilities for screening and treatment. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading, refer Chapter 3 – Community mobilization, education and counselling; Section 3.5 – Counselling and Practice Sheets 3.4, 3.5, 5.1 and 5.7).

4.2 Module contents
• Necessity of counselling
• Being a good counsellor
• Steps of counselling
• Counselling messages
• Group learning activities:
  ▪ Role play
• Checklist for counselling

4.3 Learning objectives
By the end of this module, trainees will be able to:
• state the concept and importance of counselling;
• demonstrate counselling of women prior to and after screening;
• demonstrate counselling of women prior to and after treatment of cervical pre-cancers.

4.4 Key points for discussion
4.4.1 What is counselling?
Counselling is face-to-face, confidential communication in which the counsellor helps a client to make decisions and then to act on them. Counselling during cervical cancer screening is essential to educate and inform women and help them to make an informed decision to undergo different procedures.

4.4.2 Why is counselling necessary for cervical cancer screening?
Women coming for cervical cancer screening need appropriate information about the disease, the tests they have to undergo and the treatment procedures that may be necessary. They need counselling so that they can make an informed decision about participation. Women in developing
countries usually have less knowledge about cervical cancer and its screening methods. There is a feeling of embarrassment about undergoing gynaecological check-ups and many women are scared of the tests and procedures. Individual face-to-face counselling by health service providers is valuable in motivating women not only to benefit from screening, but also to receive treatment and undergo follow-up if the test results are positive. Low levels of information and poor communication between patients and health professionals may lead to negative psychological consequences in women with abnormal results. Adequate and appropriate information regarding the implications of a positive test and the availability of safe and effective treatment can help women overcome this negative feeling. Thus, counselling ensures women’s compliance to services, improves their morale and raises their self-esteem by allowing them to decide for themselves.

4.4.3 How to be a good counsellor

A good counsellor should do the following things:

- Listen to what the woman has to say and encourage her to express her concerns without interrupting her.
- Encourage the woman to ask questions and give clear answers in a calm, reassuring manner.
- Ask open-ended questions (that begin with who, what, where, when, why, or how) to encourage the woman to give a more complete and meaningful response.
- Use simple language that the woman will not find difficult or embarrassing.
- Avoid using medical terms as much as possible.
- Talk to the woman in a friendly way, develop a cordial relationship, and assure her that the conversation is confidential.
- Use supportive nonverbal communication, such as nodding, smiling and maintaining eye contact throughout.
- Be sensitive to any cultural and religious considerations.
- Give the woman written information (if available and appropriate) to remind her of instructions.

Strategies for counselling

- **Individual counselling**
  - Ensures privacy
  - Allows responding to personal questions
  - Allows addressing specific needs
4.4.4 What messages should be conveyed to a woman while counselling her for VIA?

A woman who wants to be tested by VIA and undergo treatment if necessary, should be given the following information:

- The cervix is a part of the uterus situated in the lower part of the abdomen
- Cervical cancer is a preventable disease
- Risk factors and causes for cervical cancer
- The role and importance of VIA testing
- Procedures to be used, as well as their risks and benefits
- Steps of cryotherapy/cold coagulation, if the VIA test is abnormal
- The need to attend a higher facility, if required
- Consequences of not being tested and/or treated
- Necessity of consent for the procedures

Ensure privacy during counselling to protect the dignity of the woman and to encourage her to communicate freely.
4.4.5 What are the steps of counselling?

See Skills Checklists 4.6.1, 4.6.2 and 4.6.3,

4.5 Group learning activities

4.5.1 Role play

Counselling cards and flip chart should be used for role plays.

Role play 1: Counselling a woman to undergo VIA

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles.
  - Pushpa, a 40-year-old woman having two children, who attended the OPD of the district hospital as she often had backaches
  - Rakhi, a doctor who treats Pushpa for backache and also advises her to take a screening test for cervical cancer
  - Sheela, a nurse at the screening clinic
- The entire group, including the role players, should know the following background situation:
  
  *Pushpa has been advised by Dr Rakhi to have a cervical cancer screening test known as VIA. Pushpa is not sure if this test will benefit her. She is curious to know more about the test. Dr Rakhi sends her to nurse Sheela, who explains the details of VIA as a screening test.*

Focus of the role play

The focus of the role play is the interaction between Pushpa who has been advised to undergo VIA as a screening test for cervical cancer, and nurse Sheela who explains details about the test. While treating Pushpa for backache, Dr Rakhi asks Pushpa whether she knows about a test named VIA and if she ever had the test. When Pushpa tells her that she is not aware of any such a test, Dr Rakhi informs her that all women above 30 years of age should have the test and advises her to go and meet the nurse named Sheela who would provide her with information about the test. Sheela greets Pushpa warmly and makes her sit comfortably. She asks if Pushpa has heard about the disease, cervical cancer, and screening tests such as VIA. Pushpa says that she has never heard of either the disease or the test. Sheela goes on to explain what cervical cancer is, its cause, women who are at risk of getting cervical cancer, and the necessity of screening tests like VIA that can reduce the risk of getting cervical cancer. She explains that it takes approximately 10–15 years for cervical cancer to develop. The disease has a precancerous stage that can be detected by special tests like VIA. She informs Pushpa that even if cervical pre-cancers are detected, they can be treated by very simple methods. Sheela reassures Pushpa that the test is painless, takes only a few minutes and she will be informed of the test results immediately.

Time allotted for the role play: 10 minutes
Role play 2: Counselling a woman who has a negative VIA test result

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Kay, a 36-year-old woman having two children, who underwent the VIA test
  - Su, the nurse who performed VIA test at the primary health centre
  - Thinza, a community health worker who counselled Kay for VIA
  - Lwin, Kay’s spouse who accompanies her
- The entire group including the role players should know the following background situation:

  Kay underwent VIA test at a primary level health centre. The test was negative. Su explains what a negative VIA test means and what should be done in the future.

Focus of the role play

The focus of the role play is the interaction between Kay, who has tested negative on VIA, and nurse Su, who performed the test on Kay. After completing the VIA test, Su asks Kay to sit in the counselling room. She also asks her to call in her family, if present. Accordingly, Kay calls her spouse, Lwin, into the counselling room. Su informs them that Kay is doing well and her VIA test result is negative. This means that she does not have cervical cancer or a precancerous condition at present. She also informs them that Kay’s chances of developing cancer in the next 3 years are very minimal. She advises them that Kay should undergo VIA test every 3 years to reduce the risk of getting cervical cancer. Su informs them that if Kay develops symptoms like irregular bleeding, postcoital bleeding or foul smelling discharge per vagina at anytime, she should report early to the hospital and consult a doctor. Thinza, the community health worker who had motivated Kay to attend the screening clinic for VIA, also reassures Kay that she need not worry as she does not have cervical pre-cancer or cancer now. She once more informs Kay of the necessity of repeat VIA test at periodic intervals of 3 years.

Time allotted for the role play: 10 minutes

Role play 3: Counselling a woman who is positive on VIA test and eligible for cryotherapy

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Mary, a 36-year-old woman having two children, who has a VIA positive test result
  - Catherine, the nurse who performed VIA and advised treatment by cryotherapy
  - Stephen, Mary’s spouse who accompanies her
• The entire group including the role players should know the following background situation:

Mary, a 36-year-old woman, has taken the VIA test and is detected to have a positive test result. Catherine, the nurse who did the VIA test, informs Mary that her problem could be easily treated at the same visit by a simple treatment method known as cryotherapy. Catherine informs her about the treatment method, side effects and possible complications. She answers Mary’s questions and helps her to take a decision to undergo the treatment.

Focus of the role play

The focus of the role play is the interaction between Mary, whose VIA test is positive, and nurse Catherine, who explains that Mary has a minor problem that can be easily taken care of by a simple treatment method known as cryotherapy.

After completing the VIA test, Catherine asks Mary to sit in the counselling room. She also asks her to call in her family, if present. Accordingly Mary calls her spouse, Stephen, in to the counselling room. Catherine informs that Mary’s VIA test is positive. She reassures the couple that the test result does not mean that Mary has cervical cancer, but she does have a minor problem which could be an early change (pre-cancer) that has a possibility of developing into cervical cancer later. Catherine explains that this change in Mary’s cervix can be easily treated by a method known as cryotherapy that is very effective in curing these early changes. She informs them that cryotherapy is a very safe procedure and has minimum complications and is not painful. During the treatment Mary will only feel a cold sensation in the vagina. The treatment takes only a few minutes to complete. There is no need of anaesthesia or any other medication before the procedure. She also informs Mary that after treatment, she will have a watery vaginal discharge (that can also be blood-stained) for about 4 weeks. She advises the couple to avoid sexual intercourse for about 4 weeks. She informs them that Mary will have to come for a follow-up visit after 1 year. Mary and Stephen are convinced by Catherine’s information and agree to treatment by cryotherapy. Catherine hands them a consent form that Mary is required to sign before the treatment.

Time for role play: 10 minutes

Role Play 4: Counselling a woman who is suspicious of invasive cancer on VIA

Participants and background situation for role play

• Trainees should be selected from the group to perform the following roles:
  – Rehana, a 45-year-old lady with five children, who has undergone a VIA test at a primary healthcare centre
  – Fatima, a nurse at the primary healthcare centre who performs VIA
The entire group, including the role players, should know the following background situation:

*Rehana has undergone VIA test at the primary health centre. Her VIA test result is suspicious of invasive cervical cancer. Fatima informs her of the VIA test findings and advises her to attend a specialized centre as soon as possible for further evaluation and treatment. Fatima addresses Rehana’s fear and reassures her that the disease can be successfully treated, if diagnosed at an early stage.*

**Focus of the role play**

The focus of the role play is the interaction between a nurse, Fatima, who performs VIA at a primary health centre and Rehana, who has undergone VIA at the centre. After the procedure, Fatima asks Rehana to accompany her to the counselling room to discuss her VIA test results, thus ensuring Rehana’s right to privacy, and confidentiality. She informs Rehana that she suspects the presence of an abnormality on her cervix that could be a cancer. Fatima explains the necessity of attending a specialized cancer centre where there are adequate facilities for diagnosis and treatment. Fatima briefs her about the investigations that may be done at the centre for diagnosis. She may be examined by colposcope that gives a magnified vision of the cervix and a very small piece of tissue from the affected area may be taken for confirmation of diagnosis. If the test confirms the presence of the disease then the necessary treatment can be done at the specialized centre. Fatima identifies and addresses Rehana’s concerns, doubts and fears regarding the investigation procedures. Fatima then arranges for referral to the designated centre. She gives the referral form to Rehana and tells her about the location, day and time when she should visit the centre for necessary investigation and management.

**Time allotted for the role play:** 10 minutes

### 4.6 Skill development

#### 4.6.1 Steps for counselling a woman for VIA (VIA is negative)

<table>
<thead>
<tr>
<th>Steps Case</th>
<th>Counselling prior to VIA</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Provide general information about preventing cancer by early detection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Explain the importance of cervical cancer screening</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Explain how VIA test and cryotherapy can prevent cervical cancer
5. Give information about pelvic examination and how it is done
6. Describe how VIA test is done and the possible test results
7. Explain the treatment options if VIA test is not normal
8. Respond to the woman's possible concerns about:
   - Pelvic examination
   - VIA test
   - Cryotherapy
9. Ask about any religious belief or attitude that may affect the woman's decision to take a VIA test

**Post-VIA counselling: VIA test is negative**

10. Help the woman to get up from the table and be comfortably seated
11. Discuss the results of VIA test and the significance of the negative test
12. Tell her when to return for the next screening
13. Tell her to contact the clinic immediately if any symptoms like postcoital bleeding, inter-menstrual bleeding or foul smelling discharge per vaginum occur
14. Assure her that she can return to the clinic for any medical advice or attention, if required
15. Tell her to maintain her records carefully

*The highlighted steps are considered critical*

Score achieved: Facilitator's signature

*Facilitator's remarks*
### 4.6.2 Steps for counselling a woman for VIA (VIA is positive and eligible for cryotherapy)

<table>
<thead>
<tr>
<th>Skills Checklist: Counselling skills in VIA and cryotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td><strong>Counselling prior to VIA</strong></td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
</tr>
<tr>
<td>2. Provide general information about preventing cancer by early detection</td>
</tr>
<tr>
<td>3. Explain the importance of cervical cancer screening</td>
</tr>
<tr>
<td>4. Explain how VIA test and cryotherapy can prevent cervical cancer</td>
</tr>
<tr>
<td>5. Give information about the pelvic examination and how it is done</td>
</tr>
<tr>
<td>6. Describe how VIA test is done and the possible test results</td>
</tr>
<tr>
<td>7. Explain the treatment options if VIA test is not normal</td>
</tr>
<tr>
<td>8. Respond to the woman’s possible concerns about:</td>
</tr>
<tr>
<td>• Pelvic examination</td>
</tr>
<tr>
<td>• VIA test</td>
</tr>
<tr>
<td>• Cryotherapy</td>
</tr>
<tr>
<td>9. Ask about any religious belief or attitude that may affect the woman’s decision to take the VIA test</td>
</tr>
<tr>
<td><strong>Post-VIA counselling: VIA test is positive and the woman is eligible for cryotherapy</strong></td>
</tr>
<tr>
<td>10. After completing VIA, ask the woman if she is more comfortable discussing the test results while lying down or sitting up on the table</td>
</tr>
<tr>
<td>11. Ask her if she would prefer to have her husband/partner or any other family member present with her</td>
</tr>
<tr>
<td>12. Inform about the VIA test findings and the significance of a positive test</td>
</tr>
<tr>
<td>13. Give her (along with any family member, preferably her husband) detailed information about how treatment will benefit her</td>
</tr>
<tr>
<td>14. Tell her how she will be benefit by getting cryotherapy in the same sitting</td>
</tr>
<tr>
<td>15. If the woman is not ready to have treatment on the same day, give her the option of coming back on another specified day. Emphasize the need for treatment</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
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<tr>
<td>16.</td>
</tr>
<tr>
<td>17.</td>
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<tr>
<td>18.</td>
</tr>
<tr>
<td>19.</td>
</tr>
<tr>
<td>20.</td>
</tr>
</tbody>
</table>

**Post-cryotherapy counselling**

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>21.</td>
<td>Provide the woman with instructions for self-care at home</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 22. | Inform that she should seek medical attention if she experiences the following within 4 weeks of cryotherapy:  
- Fever with shaking chills and/or >38 °C temperature  
- Foul smelling purulent discharge  
- Severe lower abdominal pain/cramps  
- Vaginal bleeding >2 days or with clots other than expected menstrual bleeding |   |   |
| 23. | Advise complete abstinence for 4 weeks, and if complete abstinence is not possible, provide instructions for using condoms/sanitary pads |   |   |
| 24. | Tell her to maintain her records carefully |   |   |
| 25. | Ensure that the woman has understood the instructions fully |   |   |
| 26. | Answer any questions |   |   |
| 27. | Schedule a follow-up visit |   |   |

*The highlighted steps are considered critical

Score achieved:   
Facilitator’s signature

**Facilitator’s remarks**
### Steps for counselling a woman for VIA and further referral to a higher centre (VIA is positive and the woman is ineligible for cryotherapy)

<table>
<thead>
<tr>
<th>Skills Checklist: Counselling skills in VIA and referral</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td><strong>Counselling prior to VIA</strong></td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
</tr>
<tr>
<td>2. Provide general information about preventing cancer by early detection</td>
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<tr>
<td>5. Give information about the pelvic examination and how it is done</td>
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<td>7. Explain the treatment options if VIA test is not normal</td>
</tr>
<tr>
<td>8. Respond to the woman’s possible concerns about:</td>
</tr>
<tr>
<td>• Pelvic examination</td>
</tr>
<tr>
<td>• VIA test</td>
</tr>
<tr>
<td>• Cryotherapy</td>
</tr>
<tr>
<td>9. Ask about any religious belief or attitude that may affect the woman’s decision to have a VIA test</td>
</tr>
<tr>
<td><strong>Post-VIA counselling: VIA test is positive and the woman is not eligible for cryotherapy</strong></td>
</tr>
<tr>
<td>10. Help the woman to get up from the table and be comfortably seated</td>
</tr>
<tr>
<td>11. Ask her if she would like her husband/partner, or any other family member, to be present with her</td>
</tr>
<tr>
<td>12. Inform her about the VIA test findings and the significance of the positive test</td>
</tr>
<tr>
<td>13. Explain the treatment required and how the treatment will benefit her</td>
</tr>
<tr>
<td>14. Give detailed information of the referral centre (including the clinic days and timings) that she needs to visit for further check-up</td>
</tr>
<tr>
<td>15. Explain in brief that she will undergo colposcopy and may have treatment if abnormalities are suspected on colposcopy</td>
</tr>
</tbody>
</table>
16. If cancer is suspected on VIA, inform the woman about that and explain to her the necessity of early treatment. Give specific information on the nearest centre where she can get cancer treatment facilities.

17. Tell her that she should preferably be accompanied by her husband/partner or any other family member at her next visit.

18. Tell her to maintain her records carefully.

19. Encourage the woman to ask questions and respond with care.

*The highlighted steps are considered critical.

Score achieved: Facilitator’s signature

Facilitator’s remarks

Points to remember

- Counselling is face-to-face, confidential communication.
- Counselling can be done for a group, individual or couple.
- A woman should be given information on cervical cancer, screening methods and treatment procedures if the screening test is positive.
- Listen to what the woman has to say and encourage her to express her concerns.
- Ask open-ended questions.
- Use simple language. Talk to the woman in a friendly manner, develop a cordial relationship, and assure her that the conversation is confidential.
- Use supportive non-verbal communication, such as nodding and smiling and maintain good eye contact throughout.
- Be sensitive to any cultural and religious considerations.
Multiple choice questions

1. Counselling should involve all, except:
   a) Confidentiality
   b) Privacy
   c) Paraphrasing
   d) Regular use of medical terminology

2. During counselling prior to VIA, the client should be told about all, except:
   a) Importance of VIA testing
   b) Available treatment options if VIA turns out to be positive
   c) Risk factors for cervical cancer
   d) Possibility of missing invasive cancer on VIA

3. A true statement about counselling prior to colposcopy is:
   a) Counselling involves face-to-face communication
   b) Counselling is an optional component of a screening programme
   c) Women always get scared due to counselling and opt out of screening
   d) During counselling, women should not be told about treatment side-effects

4. During counselling of a VIA positive woman who is eligible for cryotherapy, she should be told about all, except:
   a) Significance of VIA positivity
   b) Need for treatment in the form of cryotherapy
   c) Side-effects of cryotherapy
   d) There is no need to undergo further check-ups after treatment

5. Which of the following is a false statement about post-cryotherapy advice?
   a) Complete abstinence for 4 weeks
   b) Report immediately if light bleeding occurs
   c) Use sanitary napkins for a few days after treatment
   d) Report if purulent vaginal discharge occurs

Answer key

1 – d  
2 – d  
3 – a  
4 – d  
5 – b
Module 5: Screening by visual inspection with acetic acid (VIA)

5.1 Module overview

This module is designed to train paramedical workers, midwives, nurses and clinicians to perform VIA as a screening test for cervical cancer and take decisions on treatment or referral for further diagnostic work. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading, refer Chapter 5 – Screening and treatment of cervical pre-cancer; Section 5.3.2 – Visual screening methods and Practice Sheet 5.5).

5.2 Module contents

- Principles of VIA
- Equipment/instruments required
- Consumables required
- Steps of VIA
- VIA test outcome categories
- Documentation of VIA findings
- Common benign conditions of the cervix detected during VIA
- Common lower genital tract infections detected before VIA
- Post-VIA tasks and follow-up
- Group learning skills:
  - Image recognition skill
  - Arrangement of instrument tray for VIA
  - Preparation of dilute acetic acid
- Skills checklist for steps of VIA

5.3 Learning objectives

By the end of this training programme, trainees will be able to:
- describe the organization of VIA services in the clinic;
- list steps of the VIA procedure;
- describe benign conditions and infections of the cervix and vagina;
- demonstrate how to counsel women before and after VIA;
- list infection prevention practices during VIA procedure.
5.4 Key points for discussion

5.4.1 What is VIA?

VIA is the naked eye inspection of the cervix after application of 3–5% acetic acid using a good light source. The test is an outpatient procedure and does not require anaesthesia. VIA is safe, rapid, reliable, and inexpensive.

There is no evidence that use of magnification improves the performance of VIA.

5.4.2 How does VIA work?

Dilute acetic acid (3–5%) when applied on the cervix causes coagulation of the proteins on the surface epithelium. The coagulated protein becomes prominent as a dense white patch. Normal cervical epithelium contains very little protein to be coagulated by acetic acid. Therefore, no white patch is seen after application of acetic acid on a normal cervix. Pre-cancers of cervix contain more protein which gets coagulated by acetic acid and gives a white appearance. The higher the grade of cervical pre-cancer, the denser is the intensity of the white patch. In cervical cancer, a growth is present that may or may not be white.

5.4.3 What are the instruments and consumables required for VIA?

<table>
<thead>
<tr>
<th>Equipment/instruments required for VIA</th>
<th>Consumables required for VIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examination table</td>
<td>Gloves (sterile gloves after high-level disinfection/disposable)</td>
</tr>
<tr>
<td>Focusing light (halogen lamp or lamp with 100 watt bulb)</td>
<td>Cotton swabs or cotton tipped swab sticks</td>
</tr>
<tr>
<td>Galipot</td>
<td>Dilute acetic acid (3–5%) solution (freshly prepared)</td>
</tr>
<tr>
<td>Instrument tray or container</td>
<td>Lubricant jelly</td>
</tr>
<tr>
<td>Appropriate sized self retaining bivalve speculum</td>
<td>Waste disposal bag</td>
</tr>
<tr>
<td>Sponge holding forceps</td>
<td>VIA screening form for documentation</td>
</tr>
<tr>
<td>Stop watch</td>
<td>Chlorine solution (0.5%)</td>
</tr>
</tbody>
</table>

Fig. 5.1: VIA requirements
5.4.4 Who are the clients for VIA?

All women within the eligible age attending the cervical cancer screening clinic for the first time should have VIA, provided the screening protocol recommends the test. VIA can be done during menstruation if the woman is not bleeding heavily. VIA should not be done during pregnancy or within 6 weeks of childbirth. VIA need not be repeated if the woman had a negative VIA test within the previous three years. Women who have had a hysterectomy for benign conditions also do not require screening with VIA.

All women in the target age group who visit a health facility for any reason should receive information on cervical cancer screening and be encouraged to undergo VIA.

5.4.5 What are the steps of VIA?

Refer to Skills Checklist 5.6.1. Page 72

5.4.6 How to interpret the results of VIA?

Look for changes on the cervix after applying acetic acid for 1 minute. If there is no white patch seen after 1 minute the test is negative, which indicates that the cervix does not have any pre-cancer or cancer. If there is a white patch, it may or may not be positive. Refer to Table 5.1 and pictorial chart to find out how to categorize white patches as negative or positive. Any growth or ulcer on the cervix which bleeds at touch will be considered as suspected cancer.

Table 5.1: VIA test outcome categories

<table>
<thead>
<tr>
<th>VIA category</th>
<th>Description of the findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>No acetowhite area</td>
</tr>
<tr>
<td></td>
<td>Transparent or faint patchy acetowhite areas without definite margins</td>
</tr>
<tr>
<td></td>
<td>Nabothian cysts becoming acetowhite</td>
</tr>
<tr>
<td></td>
<td>Faint line like acetowhiteing at the junction of columnar and squamous epithelium</td>
</tr>
<tr>
<td></td>
<td>Acetowhite lesions far away from the TZ</td>
</tr>
<tr>
<td>Positive</td>
<td>Distinct, opaque acetowhite area</td>
</tr>
<tr>
<td></td>
<td>Margins should be well-defined, may or may not be raised</td>
</tr>
<tr>
<td></td>
<td>Abnormality close to the SCJ in the TZ and not far away from the os</td>
</tr>
<tr>
<td>Suspected cancer</td>
<td>Obvious growth or ulcer on the cervix</td>
</tr>
<tr>
<td></td>
<td>Acetowhite area may not be visible because of bleeding</td>
</tr>
</tbody>
</table>
5.4.7 How to document VIA findings

Fig. 5.2: Documentation of VIA findings

Squamocolumnar junction visible?
(1: Yes, fully 2: Yes, partially 3. No)

VIA findings:
(1: Negative 2: Positive 3: Invasive cancer)

Number of quadrants involved:
(1: 1–2 quadrants 2: 3 quadrants 3: 4 quadrants)

• Space encircled by the outer continuous line indicates ectocervix
• Ectocervix is divided into 4 quadrants (Q1, Q2, Q3, Q4) by intersecting lines
• Innermost circle with continuous line indicates external os

Document the VIA results as follows:
• Note the visibility of SCJ (fully, partially or not visible)
• Indicate squamocolumnar junction with a dotted line (as shown in Fig. 5.2)
• Indicate any acetowhite area with a continuous line (as shown in Fig. 5.2), if required.
• Note the VIA test outcome (negative, positive or suspected cancer)
• Indicate the number of quadrants involved (1–2 quadrants; 3 quadrants; or 4 quadrants) if there is any acetowhite area

5.4.8 What are the benign conditions of the cervix commonly detected at VIA?

While performing VIA, the provider may encounter various benign conditions of the cervix (and vagina) that may or may not require treatment. These can be infective or noninfective. Some of these conditions are confused with cervical pre-cancers or cervical cancer.

Infective conditions of cervix (and vagina) include:

Cervico-vaginal infections

An inflamed cervix (also called cervicitis) appears red and swollen with pus coming out from the external os. Inflamed areas may bleed on contact. The cervix is often tender on movement. A forgotten foreign body like pessary or tampon can induce inflammation of the cervix and vagina. The most common pathological condition of the cervix and vagina is inflammation caused by various microbial agents. The common infective agents are Candida albicans (fungus) (Fig. 5.3a), Trichomonas vaginalis (protozoa) (Fig. 5.3b), Chlamydia trachomatis (bacteria), Neisseria gonorrhoea
(bacteria), *Gardnerella vaginalis* (bacteria) (Fig. 5.3c), *Escherichia coli* (bacteria) and *Streptococci* (bacteria). Rarely, *Herpes simplex* virus can also infect the cervix. Infection from these pathogens can cause foul smelling vaginal discharge, itching and pain over the introitus, pain during sexual intercourse and lower abdominal pain. During examination, discharge may be seen coming out of the introitus and the vulva may be red and inflamed. On speculum examination, the characteristics of the discharge seen in the vagina and that covering the cervix can often confirm the diagnosis. An inflamed cervix (also called cervicitis) appears red and swollen with pus coming out from the external os. Inflamed areas may bleed on contact. The cervix is often tender on movement.

**Fig. 5.3: Cervico-vaginal infections**

<table>
<thead>
<tr>
<th>Photo</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image 1" /></td>
<td>a) Thick curdy white discharge of candidiasis**</td>
</tr>
<tr>
<td><img src="image2.png" alt="Image 2" /></td>
<td>b) Frothy foul smelling discharge of trichomoniasis*</td>
</tr>
<tr>
<td><img src="image3.png" alt="Image 3" /></td>
<td>c) Grey-white discharge of bacterial vaginosis*</td>
</tr>
</tbody>
</table>

*Photo courtesy PGIMER, Chandigarh, India
**Photos reproduced with permission from Atlas of Colposcopy and Management of Cervical Pre-cancers. IARC, Lyon. (Forthcoming)*

**Genital warts**

Genital warts (condyloma) are caused by infection from low-risk HPVs. More than 90% of genital warts are caused by HPV types 6 and 11. Warts can affect the external genitalia, vagina and cervix and are frequently multiple. Warts on the vulva and vagina appear as greyish, multiple, soft growths with surface often looking like that of a cauliflower. Cervical condyloma usually appears as a distinctly lumpy, irregular lesion on the surface of the affected area. The colour may be bright white and the surface irregular, pitted or spiky. Sometimes,
warts may be flat lesions with irregular margins and become visible as white patches with irregular margins only after application of acetic acid on the cervix (Fig. 5.4). Warts by themselves do not progress to malignancy. Extensive warts, however, may hide high-grade lesions in the deeper tissue.

Non infective conditions of the cervix

Polyps

Cervical polyp (Fig. 5.5) is a localized overgrowth of the endocervical columnar epithelium and may be visible as a single or multiple reddish soft tumour(s) protruding from the external os. A patient with polyps may present with abnormal menstrual bleeding or post-coital bleeding. Polyps are usually mobile and can be pushed in different directions to reveal the SCJ. Polyps do not have any potential to become malignant. In rare cases, fibroid of the cervix may protrude as a firm, immobile polypoid mass (fibroid polyp) through the external os.

Leukoplakia

Leukoplakia (Fig. 5.6) is a well-demarcated white patch on the cervix often raised from the surface. Leukoplakia is visible to the naked eye even before the application of acetic acid. Usually leukoplakia is idiopathic (no cause can be ascertained) and indicates excessive keratin deposition in the superficial layers of the cervical epithelium. It may also be caused by chronic irritation (as in uterine prolapse), HPV infection and cervical pre-cancers or cancer. A leukoplakia on the TZ close to SCJ is often due to cervical neoplasia and should be referred for colposcopy. Leukoplakia without underlying neoplasia requires no treatment.
### 5.4.9 How to detect and manage common lower genital tract infections

Common lower genital tract infections, causative organisms, findings on speculum examination and treatment are summarized in Table 5.2.

**Table 5.2: Common lower genital tract infections seen during VIA (Treatment as per CDC guidelines)**

<table>
<thead>
<tr>
<th>Infection</th>
<th>Common symptoms</th>
<th>Findings on speculum examination</th>
<th>Causative organism</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial vaginosis</td>
<td>Excessive vaginal discharge with fishy smell</td>
<td>Grey white or yellow discharge with fish-like odour</td>
<td>Bacteria</td>
<td>Tab Metronidazole 500 mg orally, 2 times a day for 7 days OR Tinidazole: 2 gm orally once daily for 2 days OR Tinidazole 1 g orally once daily for 5 days</td>
</tr>
<tr>
<td>Candidiasis</td>
<td>Itching around the vulva, burning following urination, white, curd-like vaginal discharge</td>
<td>Thick or thin curdy white discharge</td>
<td>Fungus – Candida albicans is most common</td>
<td>Intravaginal Agents: Miconazole 100 mg vaginal suppository, one suppository daily for 7 days OR Miconazole 200 mg vaginal suppository, one suppository for 3 days Oral agent: Fluconazole 150 mg orally in a single dose</td>
</tr>
<tr>
<td>Trichomoniasis</td>
<td>Profuse vaginal discharge – may be foul-smelling, vulvar itching and burning with urination</td>
<td>Frothy, yellowish or greenish vaginal discharge, Red spots on the cervix (strawberry cervix)</td>
<td>Protozoa – Trichomonas vaginalis</td>
<td>Metronidazole 2 g orally in a single dose OR Tinidazole 2 g orally in a single dose</td>
</tr>
<tr>
<td><strong>Chlamydial infection</strong></td>
<td>Usually asymptomatic. Symptoms that may occur include copious vaginal discharge, pain in the abdomen, painful sexual intercourse, fever, painful urination or frequent urge to urinate</td>
<td>Copious yellow discharge containing mucus or pus, cervix bright red in colour and bleeds easily on gentle touch with a swab</td>
<td><strong>Bacteria - <em>Chlamydia trachomatis</em></strong></td>
<td><strong>Azithromycin 1 g orally in a single dose</strong> OR <strong>Doxycycline 100 mg orally twice a day for 7 days</strong> OR <strong>Erythromycin base 500 mg orally four times a day for 7 days</strong> OR <strong>Levofloxacin 500 mg orally once daily for 7 days</strong> OR <strong>Ofloxacin 300 mg orally twice a day for 7 days</strong></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Gonorrhoea</strong></td>
<td>Majority of women do not have symptoms. Some women have symptoms like vaginal discharge, lower abdominal pain or pain during intercourse</td>
<td>Cervix appears red with purulent discharge seen at external os, may have associated purulent discharge from urethra</td>
<td><strong>Bacteria – <em>Neisseria gonorrhoea</em></strong></td>
<td><strong>Ceftriaxone 250 mg IM in a single dose</strong> PLUS <strong>Azithromycin 1 g orally in a single dose</strong> IF Ceftriaxone is not available: <strong>Cefixime 400 mg orally in a single dose</strong> PLUS <strong>Azithromycin 1 g orally in a single dose</strong></td>
</tr>
</tbody>
</table>

Current partners should be referred for presumptive therapy.
5.4.10  **How to advise a woman who has a negative VIA test**

- Inform the woman that her VIA test is negative, which means that she does not have cervical cancer and has very low risk of having cervical cancer within the next 5 years.
- She should have the same test done after 5 years or earlier if recommended by the national screening protocol.
- Inform the woman of the early symptoms of cervical cancer and advise her to consult a physician if she has any of these symptoms.
- Hand over the card containing the written report and the date for repeat screening and advise her to keep it carefully and bring it at the next visit.

5.4.11  **How to manage and advise a woman who has tested positive on VIA**

Please refer to Module 7.

5.4.12  **What are the measures to be taken to prevent infection during and after VIA?**

Please follow Checklist 5.6.1 and see Module 10 for details.

5.5  **Group learning activities**

<table>
<thead>
<tr>
<th>5.5.1</th>
<th>Image recognition (flash cards/digital images)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>▪ Identification of features of normal cervix, TZ and SCJ</td>
</tr>
<tr>
<td></td>
<td>▪ Distinguishing between VIA negative and positive cases</td>
</tr>
<tr>
<td>5.5.2</td>
<td>Arrangement of instrument tray for VIA</td>
</tr>
<tr>
<td>5.5.3</td>
<td>Preparation of dilute acetic acid</td>
</tr>
</tbody>
</table>
5.5.3 Preparation of 100 ml of 5% acetic acid (Fig. 5.7)

Ingredients required
- Glacial acetic acid – 5 ml
- Distilled water – 95 ml

Apparatus and consumables required
- Graduated measuring cylinder (capacity 100 ml)
- Glass container for storing 5% acetic acid 10 ml syringe
- Pair of gloves
- 10 ml syringe

Preparation
Carefully pour 5 ml of glacial acetic acid into the measuring cylinder (5 ml can be measured with a syringe). Add 95 ml of distilled water into the cylinder and mix thoroughly. Pour the dilute acetic acid in the container.

Labelling
Label container as ‘5% dilute acetic acid’ and mention the date of preparation

Storage
Bottle containing acetic acid should be kept tightly capped. Unused acetic acid should be discarded at the end of the day

Caution: It is important to dilute the glacial acetic acid since the undiluted acid causes severe chemical burns, if applied to the epithelium or skin.

To prepare 3% acetic acid add 3 ml of glacial acetic acid to 97 ml of water.
To prepare 4% acetic acid add 4 ml of glacial acetic acid to 96 ml of water.
Fig. 5.7: Preparation of 5% dilute acetic acid

a) Wear gloves

b) Measure 5 ml of glacial acetic acid

c) Pour acetic acid into a measuring cylinder

d) Add 95 ml of distilled water

e) Pour dilute 5% acetic acid into a glass bottle

f) Label the bottle with the date of preparation
### 5.6 Skill development

#### 5.6.1 Steps of VIA

<table>
<thead>
<tr>
<th>Skills Checklist: Clinical skills in VIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td><strong>Preparation for VIA</strong></td>
</tr>
<tr>
<td>1. Keep necessary equipment ready (see list of equipment)</td>
</tr>
<tr>
<td>2. Check availability of consumables (see list of consumables)</td>
</tr>
<tr>
<td>3. Ensure that the light source is ready to use</td>
</tr>
<tr>
<td>4. Arrange instruments and supplies on high-level disinfected tray or container</td>
</tr>
</tbody>
</table>

#### Counselling and consent

5. Follow Checklist 4.6 for counselling

6. **History taking (ask questions/check records)**

7. Personal information: Name, age, husband’s name, address, telephone number and LMP
   - Obstetric history
   - History of past illness

8. History of previous cervical cancer screening test

9. Ask for any of the following symptoms: Persistent foul smelling white discharge, post-coital bleeding, post-menopausal bleeding, irregular menstrual bleeding

10. **Record all relevant information on case record form**

#### Step-wise VIA procedure

11. Check that the woman has emptied her bladder

12. Help her on to the examining table, help her to undress and drape her

13. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air-dry them
14. Put one pair sterile disposable gloves on both hands

15. Inspect external genitalia and check urethral opening for discharge.

16. Select speculum of appropriate size and lubricate the blades with lubricant jelly or saline

17. Insert speculum and adjust it so that the entire cervix can be seen

18. Fix speculum blades in the open position so that the speculum will remain in place with the cervix in view

19. Adjust the light source so that you can see the cervix clearly

20. Examine the cervix for cervicitis, ectropion, nabothian cysts, growth, ulcers or contact bleeding

21. Identify the cervical os, squamocolumnar junction (SCJ) and transformation zone (TZ)

22. Soak a clean swab in 3–5% acetic acid and apply it to the cervix

23. Wait for 1 minute for the acetic acid to be absorbed and any acetowhite change to appear

24. Inspect the SCJ carefully

25. Look for any new white patch (acetowhite area) appearing on the cervix

26. If there is an acetowhite area, look for the following features
   - Density
   - Margin characteristics
   - Location in relation to SCJ or external os
   - Number of quadrants involved

27. When visual inspection has been completed, use a fresh swab to remove any remaining acetic acid from the cervix and vagina and dispose-off the swab

28. Remove the speculum
29. Help the woman to get up from the examination table and sit comfortably

**Post-VIA tasks**

30. Dispose-off the swabs in appropriate disposal bags
31. Immerse the speculum in 0.5% chlorine solution
32. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out
33. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air-dry
34. Record the VIA test results and other findings in the woman's case record form
   - If acetowhite change is present, draw a map of the cervix and the diseased area on the record
   - If VIA test is negative, follow Checklist 4.6.1 for counselling
   - If VIA test is positive or cancer is suspected, follow Checklists 4.6.2 or 4.6.3 as appropriate for counselling

*The highlighted steps are considered critical*

Score achieved: Facilitator's signature

*Facilitator's remarks*
Points to remember

- VIA is the naked eye inspection of the cervix after application of 3–5% acetic acid.
- VIA is safe, rapid, reliable and inexpensive.
- Acetic acid acts by coagulating the protein of the surface epithelium.
- Pre-cancers contain more protein which gets coagulated and gives an acetowhite appearance.
- Wait for at least 1 minute for acetic acid to be absorbed and acetowhite area to appear.
- Distinct acetowhite opaque area indicates a positive test.
- Common benign conditions of the cervix include cervicovaginal infections and inflammations, cervical polyp, leukoplakia and genital warts.
- VIA negative women should get a repeat test done after 5 years.
Multiple choice questions

1. Following are the principles of VIA, except:
   a) 3–5% acetic acid causes coagulation of proteins on the surface epithelium that appear as a white patch
   b) Normal cervical epithelium does not become white as it contains very little protein to be coagulated by acetic acid
   c) It requires anaesthesia
   d) Higher the grade of cervical pre-cancer, denser is the intensity of the white patch

2. VIA negative means:
   a) Transparent or faint patchy acetowhite areas without definite margins
   b) Nabothian cysts becoming acetowhite
   c) Faint line like lace to whitening at the junction of the columnar and squamous epithelium
   d) All of the above

3. The following equipment and supplies are needed for VIA, except:
   a) A bright light source to examine the cervix
   b) A speculum, high level disinfected (need to be sterile)
   c) Dilute acetic acid solution (3–5%)
   d) Ball electrodes

4. Acetic acid for VIA should be:
   a) Diluted to 10%
   b) Freshly prepared
   c) Refrigerated
   d) Glacial acetic acid

5. To conduct VIA, after applying 3–5% acetic acid to the cervix, the provider needs to wait for acetowhiteness to appear after:
   a) 1 second
   b) 1 minute
   c) 1 hour
   d) None of the above

Answer key
1 – c       2 – d       3 – d
4 – b       5 – b
Module 6: HPV detection test and cervical sample collection technique for HPV test

6.1 Module overview
This module is designed to give an overview of different HPV detection tests commonly used for cervical cancer screening to paramedical workers, midwives, nurses and clinicians. The module also teaches providers to collect samples from the cervix for HPV detection tests and to interpret the test results. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 5 – Screening and treatment of cervical pre-cancer; Section 5.3 (a–d) and Practice Sheet 5.4).

6.2 Module contents
- Types of HPV detection tests
- Equipment/instruments required
- Consumables required
- Steps of cervical sample collection
- Sample transportation and storage
- Interpretation of test results
- Group learning activities:
  - Practise cervical sample collection for HPV test on ZOE model
  - Checklist for steps of cervical sample collection

6.3 Learning objectives
By the end of this training programme, trainees will be able to:
- describe organization of HPV detection services in the clinic;
- competently describe collection of samples for HPV test;
- describe handling, transport and storage of samples;
- demonstrate counselling women before and after HPV test;
- list infection prevention practices during the sample collection procedure.

6.4 Key points for discussion
6.4.1 What are the different HPV detection tests?
For cervical cancer screening, only tests that can detect the presence of high-risk (oncogenic) types of HPV are useful. There are different test methods available. Majority of the tests detect the presence or absence of DNA of the high-risk HPV types. Few tests are available to detect HPV RNA. A positive HPV test indicates the presence of at least one high-risk type of HPV, but most of the tests do not specify which type is present. However, some of the recently available tests identify
the specific HPV types 16 and 18 in addition to detecting the presence of any of the high-risk HPV types. Additional knowledge of the presence of HPV types 16 and 18 helps to identify the women with highest risk of developing cervical neoplasias.

Detection of high-risk HPV does not necessarily mean that pre-cancer or cancer is present. It simply indicates that there is HPV infection and the woman is at higher risk of having/developing cervical neoplasia compared to HPV negative women.

6.4.2 Who are the clients for HPV test?

All women within the eligible age attending the cervical cancer screening clinic for the first time should have HPV test, provided the screening protocol recommends the test. HPV test should be avoided during menstruation and the woman should be asked to come back when menstruation stops. The test should not be done during pregnancy or within 6 weeks of childbirth. HPV test need not be repeated if the woman had a negative HPV test within the last five years. Women who have had a hysterectomy for benign conditions also do not require screening with HPV test.

6.4.3 What are the instruments and consumables required for HPV detection test?

**Equipment/instruments required for HPV detection test**

- Examination table
- Focusing light
- Instrument tray or container
- Appropriate sized self retaining bivalve speculum
- Sponge holding forceps
- Brush or broom type of sampling device

**Consumables required for HPV detection test**

- Soap and water for washing hands/hand sanitizer
- Gloves (sterile/disposable gloves after high-level disinfection)
- Cotton swabs
- Sterile warm water
- Containers with specimen transport medium
- Waste disposal bag
- Case record form, consent form, client screening card
- Chlorine solution (0.5%)

![Fig. 6.1: Requirements for HPV detection test](image)
6.4.4 What are the steps of cervical sample collection for HPV test?
Refer to Skills Checklist 6.6.1.

6.4.5 How to store the cervical sample after collection

Please check the sample storage instructions written on the bottle containing the sample transport medium. The sample usually can be stored at room temperature for a few days. However, if the ambient temperature is high (>300 °C) place the bottles in an ice-box or in the refrigerator (not in the freezer compartment), if available.

6.4.6 How to transport specimens to the laboratory

Specimens can be transported to the laboratory at room temperature. If the ambient temperature is high (>300 °C), the samples should be transported in a closed ice-box or a vaccine carrier. The specimens must have the laboratory requisition forms accompanying them. For details of specimen transfer, please refer to the instructions from the manufacturer of the test kit.

6.4.7 How to interpret the results of the test

The test results delivered from the laboratory are either negative or positive. Negative test result indicates that the woman does not have high-risk HPV infection or has HPV infection not sufficient to cause cervical pre-cancer or cancer. The positive result indicates that the woman has high-risk HPV infection of the cervix that is significant enough to place her at risk of having cervical neoplasia. Sometimes the test results may show a cut-off level. A cut-off level of 1.0 pg/ml is taken as the threshold of a positive test. If the test result also mentions the presence of HPV types 16 and/or 18, the woman is at higher risk since these two types are most carcinogenic.

<table>
<thead>
<tr>
<th>Self-sampling for HPV Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women can be taught to collect the sample themselves from the upper vagina for HPV test using a soft brush. A midwife, paramedical worker or nurse explains the steps to the woman using a pictorial guide and hands over the labelled container and the brush to her. The woman collects the sample in the privacy of her house or in the clinic and hands over the container to the health professional. Self-sampling can improve compliance of eligible women as they need not visit the health facility for the test. Self-sampling reduces the programme cost as the requirement for pelvic examination is substantially reduced and fewer health professionals are engaged.</td>
</tr>
</tbody>
</table>
6.4.8 Is there any treatment to be advised for HPV infection?

There is no treatment for the virus itself, but the body’s immune system is usually able to fight it off within a few years. There are treatments, however, for the diseases the virus causes, e.g. warts, CIN or cervical cancer, etc. Therefore, the woman must be further examined to detect the presence of any of these diseases and managed accordingly. If the woman does not have any of these diseases she should be followed-up. The details of the examination and follow-up of HPV positive women are discussed in Module 7.

6.4.9 How to advise a woman who has tested negative after HPV test

- Inform the woman that her HPV test is negative, which means that she does not have cervical cancer and has very low risk of having cervical cancer within the next 5 years at least.
- She should have the same test done after 5 years or later as recommended by the National Screening Protocol.
- Inform the woman of the early symptoms of cervical cancer and advise her to consult a physician if she has any of these symptoms.
- Give her the card containing the written report and advise her to keep it carefully and bring it to the next visit.

6.4.10 How to manage and advise a woman who has tested positive on HPV test

Please refer to Module 7.

6.4.11 What are the messages to be conveyed to a woman while counselling her for HPV test?

While counselling a woman for HPV test, the following information should be conveyed:

- cervical cancer is a preventable disease;
- common risk factors for cervical cancer;
- HPV infection is the cause of the cancer;
- HPV infection is transmitted sexually and is very common in sexually active men and women;
- need for cervical cancer screening;
- role and importance of HPV testing;
- procedures to be followed while taking samples for the HPV test;
- how and when to get the test results;
- implications of positive and negative tests;
- necessity of further check-up if the test is positive;
- necessity of informed consent.
6.5 Group learning activities

6.5.1 Practise cervical sample collection for HPV test on ZOE model

Fig. 6.2: Steps of sample collection for HPV test on ZOE model

- a) Wear disposable gloves
- b) Insert speculum to expose the cervix
- c) Insert brush into external os and rotate in a clock-wise direction
- d) Place brush into the vial containing specimen transport medium
- e) Snap at score line on the shaft and tighten the cap
- f) Immerse speculum in 0.5% chlorine solution
- g) Remove gloves by turning them inside out
6.6 Skills development

6.6.1 Steps of cervical sample collection technique for HPV test

| Skills Checklist: Clinical skills on cervical sample collection technique for HPV test |
|----------------------------------|---|---|---|---|
| **Steps** | **Case** |
| Preparation for HPV test | 1 | 2 | 3 | 4 |
| 1. Keep necessary equipment ready (see list of equipment) |   |   |   |   |
| 2. Check availability of consumables (see list of consumables) |   |   |   |   |
| 3. Ensure that the light source is ready to use |   |   |   |   |
| 4. Arrange instruments and supplies on high-level disinfected tray or container |   |   |   |   |
| Counselling |   |   |   |   |
| 5. Greet the woman respectfully and introduce yourself |   |   |   |   |
| 6. Make the woman sit comfortably and tell her about the necessity of HPV test and the procedure |   |   |   |   |
| 7. Explain what the test results might be and what follow-up or treatment might be necessary |   |   |   |   |
| 8. Listen to her problems and concerns and respond to her queries |   |   |   |   |
| 9. Obtain informed consent if required by the regulations |   |   |   |   |
| History taking (ask questions/check records) |   |   |   |   |
| 10. Personal information: Name, age, husband’s name, address, telephone number and LMP |   |   |   |   |
| • Obstetric history |   |   |   |   |
| • History of past illness |   |   |   |   |
| • History of previous cervical cancer screening test |   |   |   |   |
| 11. Ask for any of the following symptoms: Persistent foul smelling white discharge, post-coital bleeding, post-menopausal bleeding, irregular menstrual bleeding |   |   |   |   |
| 12. Record all relevant information on the case record form |   |   |   |   |
## Step-wise cervical sample collection procedure for HPV test

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>Fill in the HPV test requisition form</td>
</tr>
<tr>
<td>14.</td>
<td>Label the sample collection vial with the patient's name, screening ID, date of sample collection</td>
</tr>
<tr>
<td>15.</td>
<td>Check that the woman has emptied her bladder</td>
</tr>
<tr>
<td>16.</td>
<td>Help her on to the examining table, help her to undress and drape her</td>
</tr>
<tr>
<td>17.</td>
<td>Wash hands thoroughly with soap and water and dry with clean, dry cloth or air-dry</td>
</tr>
<tr>
<td>18.</td>
<td>Put one pair of new sterilized disposable gloves on both hands</td>
</tr>
<tr>
<td>19.</td>
<td>Inspect external genitalia and check urethral opening for discharge</td>
</tr>
<tr>
<td>20.</td>
<td>Select speculum of appropriate size and lubricate the blades with warm water only and NOT lubricant jelly</td>
</tr>
<tr>
<td>21.</td>
<td>Insert speculum and adjust it so that the entire cervix can be seen</td>
</tr>
<tr>
<td>22.</td>
<td>Fix the speculum blades in the open position so that the speculum will remain in place with the cervix in view</td>
</tr>
<tr>
<td>23.</td>
<td>Adjust the light source so that you can see the cervix clearly</td>
</tr>
<tr>
<td>24.</td>
<td>Examine the cervix for cervicitis, ectropion, nabothian cysts, growth, ulcers or contact bleeding</td>
</tr>
<tr>
<td>25.</td>
<td>If a large quantity of discharge or mucus is present, gently remove by dabbing with a dry cotton swab without disturbing the epithelium</td>
</tr>
<tr>
<td>26.</td>
<td>Identify the external os of the cervix</td>
</tr>
<tr>
<td>27.</td>
<td>Insert the sample collection brush/broom into the external os until the outer bristles touch the ectocervix (Do not insert the brush/broom completely into the endocervical canal)</td>
</tr>
<tr>
<td>28.</td>
<td>Gently rotate the brush/broom in a clock-wise direction 3–5 times (check manufacturer’s instructions)</td>
</tr>
</tbody>
</table>
29. Remove the brush/broom from the canal while avoiding contact with the outside of the specimen transport tube/vial or any other object

30. Insert the end of the brush/broom into the specimen transport tube/vial

31. If using a brush – snap off the shaft of the brush at the score line, leaving the end of the brush inside the tube

32. If using a broom – detach the broom from the end of the shaft leaving it inside the vial

33. Replace/tighten the cap on the tube/vial securely

34. Place the tube/vial in a specimen bag/container for transport to the laboratory

35. Remove the speculum

36. Help the woman to get up from the examination table and sit comfortably

**Post-HPV sample collection tasks**

37. Dispose-off the swabs in appropriate disposal bags

38. Immerse the speculum in 0.5% chlorine solution

39. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out

40. Wash hands thoroughly with soap and water and dry with clean, dry cloth or air-dry

41. Arrange for specimen transfer to the laboratory as per instructions of the test kit manufacturer

42. Inform the woman when (day/time) to collect the test report

43. Discuss the necessity of referral and/or treatment if the test report is positive

*The highlighted steps are considered critical*

Score achieved: Facilitator’s signature

_Facilitator’s remarks_
Points to remember

- Majority of the tests detect DNA of high-risk HPV type.
- Only a few tests are available that detect HPV RNA.
- A sample can be stored at room temperature for a few days.
- A negative test indicates that the woman does not have high-risk HPV infection or has HPV infection insufficient to cause cervical pre-cancers.
- There is no treatment for the virus itself.
- Treatment is available for diseases caused by HPV infection.
- Women with negative tests should have a repeat test done after 5 years.
### Multiple choice questions

1. **HPV test is useful because:**
   - a) It can detect other sexually transmitted infections
   - b) Test positive women can be given antibiotics to treat the infection
   - c) Results are available instantly
   - d) Can efficiently detect high grade cervical precancerous lesions and cervical cancers

2. **HPV testing is not recommended in women less than 30 years of age because:**
   - a) HPV test is painful for young women
   - b) High prevalence of transient HPV infection at this age
   - c) HPV cannot be reliably tested in young women
   - d) Cervical premalignancies and cancers in young women are not caused by HPV

3. **At what temperature, should samples for HPV detection tests be stored immediately after collection?**
   - a) Room temperature
   - b) 4 °C
   - c) -20 °C
   - d) -8 °C

4. **What is the cut-off level for a positive HPV test done by Hybrid Capture 2 method?**
   - a) 1 pg/ml
   - b) 5 pg/ml
   - c) 10 pg/ml
   - d) 12 pg/ml

5. **During cervical sample collection for HPV testing, which of the following statements is true?**
   - a) Lubricate the speculum with lubricant jelly
   - b) Insert the brush completely into the endocervical canal
   - c) Rotate the brush in clockwise direction
   - d) Rotate the brush 8–10 times to collect the sample

### Answer key

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>1</td>
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<td>2</td>
<td>b</td>
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<td>3</td>
<td>a</td>
</tr>
<tr>
<td>4</td>
<td>a</td>
</tr>
<tr>
<td>5</td>
<td>c</td>
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</table>
Module 7: Management of women with positive VIA or HPV test

7.1 Module overview
This module is designed to give an outline of management of women with positive VIA test or HPV detection test to paramedical workers, midwives, nurses and clinicians. The module also teaches providers the different options available to treat cervical pre-cancers. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading, refer Chapter 5 – Screening and treatment of cervical pre-cancer; Section 5.7 – Linking screening and treatment in practice and Annex 7 and 8).

7.2 Module contents
- Management of VIA positive women
- Management of HPV positive women
- Importance of reducing the number of visits for screening
- Treatment options for cervical pre-cancers
- Follow-up of women after treatment
- Group learning activities:
  - Case studies

7.3 Learning objectives
By the end of this training programme, trainees will be able to:
- make decisions based on VIA findings;
- make decisions based on HPV test results;
- advise test positive and test negative women;
- choose appropriate treatment for screen positive women;
- advise appropriate follow-up after screening or treatment.

7.4 Key points for discussion
7.4.1 What are the different treatment options for cervical pre-cancer?
Cervical pre-cancers can be treated either by ablation of the TZ or by excising the TZ. All CIN 2 and CIN 3 lesions need to be treated. CIN 1 lesions can be followed-up yearly and require
treatment if they persist for more than 2 years or progress in size and severity. Ablative treatment can be performed by cryotherapy or cold coagulation, the details of which have been discussed in Modules 8 and 9. The excisional treatment is known as loop electrosurgical excision procedure (LEEP). In this procedure a thin metallic wire (loop) powered by an electro-surgical unit is used to remove the entire TZ along with the lesion. Confirmation of diagnosis by histopathology is not essential to treat CIN lesions. Treatment is recommended on the basis of colposcopy diagnosis (screen, diagnose with colposcopy and treat) or abnormal screening tests (screen and treat).

7.4.2 How to manage a woman with a positive VIA test

A woman with a positive VIA test can be treated immediately or she may be referred for colposcopy for further evaluation and treatment if necessary, depending on the protocol of the programme. (Fig. 7.1) Women with VIA findings suspicious of invasive cancer should be referred to the appropriate facility for biopsy and further management without any delay.

7.4.3 What is the screen and treat approach?

If the protocol of the programme recommends treating VIA positive women without colposcopy, every woman tested positive on VIA needs to be assessed for suitability of treatment by cryotherapy. A woman with lesions suitable for cryotherapy (as per the criteria listed in Chapter 8) should be treated at the same visit by cryotherapy, if she gives consent for the procedure. This strategy of screening and treatment at the same visit is known as the screen and treat approach. It is also known as the single visit approach (SVA). The alternative to SVA is colposcopy for all VIA positive women and treatment based on colposcopy diagnosis (screen, diagnose and treat).

7.4.4 What are the advantages of the screen and treat approach?

Screen and treat reduces the number of visits to the clinic as screening and treatment are completed at the same sitting. This is very convenient for women and ensures compliance of screen positive women to treatment. Thus screen and treat approach improves the efficiency of the programme and also saves resources by reducing referral of women to higher centres.

7.4.5 What are the disadvantages of screen and treat?

Some VIA positive women may not have CIN (false positives). These false positive women will be treated unnecessarily (over treatment). Since cryotherapy as a treatment procedure has very few complications, over treatment is acceptable. The benefits of ensuring treatment outweigh the insignificant risk of treatment side effects.

7.4.6 What is to be advised to woman not eligible for cryotherapy?

If a woman has a lesion that is not suitable for cryotherapy, she needs further check-up by colposcopy. She should be referred to a centre where colposcopy facilities are available.
7.4.7 How to manage a woman with positive HPV test?

A woman with a positive HPV test may be advised immediate treatment or triaging with VIA depending on the protocol of the programme. In the first algorithm (immediate treatment) the eligibility for cryotherapy should be checked after applying 3–5% acetic acid to the cervix. Another option to manage the HPV positive woman may be direct referral to colposcopy, if facilities exist. (Fig. 7.2)

If resources are available and it is programmatically feasible, HPV positive women can have pap smear cytology (liquid based) or HPV genotyping from the same samples collected for the HPV test. Women with abnormal cytology or with HPV 16 or HPV 18 detected on genotyping are referred for colposcopy. Women with normal cytology are recalled after 1 year for repeat HPV test. However, this management algorithm is not feasible in most low and middle income countries.
7.4.8 What are the steps to be followed if the protocol recommends immediate treatment?

If the protocol recommends immediate treatment, first apply 5% acetic acid and look for any acetowhite area on the TZ. Check eligibility criteria for cryotherapy if an acetowhite area is detected. If the acetowhite lesion fulfills the criteria for cryotherapy or if there is no acetowhite lesion and the SCJ is entirely visible on the ectocervix, perform cryotherapy. If the acetowhite area is not eligible for treatment by cryotherapy or if the SCJ is within the endocervix refer the woman for colposcopy. If colposcopy is not feasible the cervix may be treated by LEEP without colposcopy guidance.

Fig. 7.2: Flowchart for management of HPV positive women

HPV positive

Check programme guidelines

Recommends treatment

Apply 3–5% acetic acid to the cervix

Check for the following criteria

* i. Entire lesion is on the ectocervix
  * ii. Does not cover more than 3 quarters of the cervix
  * iii. All margins of the lesion are visible
  * iv. Lesion can be fully covered by the cryoprobe tip
  * v. No suspicion of cancer

Fulfils criteria and/or there is no acetowhite area

Cryotherapy

Does not fulfil criteria

Refer for colposcopy

Recommends VIA

VIA

VIA positive

Repeat HPV test after 1 year

VIA negative
7.4.9 What are the steps to be followed if the protocol recommends VIA?

Perform VIA on HPV positive women. If VIA is positive, manage according to the flowchart of management of VIA positive women. The woman should be advised to have a repeat HPV test after 1 year, if VIA is negative. This strategy is also known as triaging of HPV positive women by VIA.

In the strategy of immediate treatment, all HPV positive women need to be treated. Acetic acid is applied only to determine the method of treatment (by cryotherapy or by LEEP). In the strategy of triaging by VIA, only HPV positive women who are also VIA positive are treated. In both the strategies women suspected to have invasive cancer need appropriate referral for biopsy and management without any delay.

7.4.10 Is there any treatment alternative to cryotherapy?

Lesions suitable for cryotherapy can also be treated by cold coagulation. The details of the procedure are described in Module 9. Research studies have observed that cold coagulation is as effective as cryotherapy and has a similar safety profile. The advantages of cold coagulation over cryotherapy are that cold coagulation does not require supply of refrigerant gas and the treatment time is less. However, cold coagulation is not yet recommended for routine use. It may be used if refrigerant gas is not available for cryotherapy.

7.4.11 How to follow-up women after treatment

• Women treated for positive VIA or HPV tests (screen and treat approach) should be followed-up after 1 year.
• The screening test performed at the initial visit should be used for follow-up.
• Women negative on follow-up screening should be sent for routine screening as per the programme protocol.
• Women positive on follow-up screening should preferably be re-treated with LEEP (or CKC).
• If the woman has a histology diagnosis of either CIN 3 or adenocarcinoma in situ, screening should be repeated every year for 3 consecutive years. If all the screening tests are negative, she should be referred back to the routine screening programme.

**Note:** VIA or HPV positive women can be treated on the basis of colposcopy and/or histopathology diagnosis depending on the facilities available. Detailed algorithms of management are given in Figs. 7.3 and 7.4.
Fig. 7.3: Management of screen positive women based on colposcopy and histology diagnosis

VIA/HPV test positive

Colposcopy; biopsy if lesion suspected

Histopathology diagnosis

Colposcopy and/or biopsy normal

CIN 1

Follow-up

Persistent for 1 year/disease progression

Repeat screening after 3–5 years for VIA and after 5 years for HPV test

CIN 2/3

Cryotherapy/LEEP/CKC

Follow-up at 9–12 months (screening test/colposcopy)

Micro-invasive CA

CKC/LEEP

TREATMENT based on stage

Invasive CA

Follow-up
Fig. 7.4: Management of screen positive women based on colposcopy diagnosis alone (See and Treat Strategy)

1. **Screening test positive**
   - **Colposcopy**

2. **Normal**
   - Repeat screening after 3–5 years for VIA and after 5 years for HPV test

3. **Suspected CIN**
   - Assess if lesion is suitable for cryotherapy
     - i. Entire lesion is on ectocervix
     - ii. Occupying <75% of the cervix
     - iii. TZ type 1
     - iv. Can be covered by cryoprobe
     - v. No suspicion of cancer
   - Suitable for cryotherapy
   - Cryotherapy (biopsy optional)
   - Follow-up at 9–12 months (screening test/colposcopy)

4. **Invasive CA**
   - Treatment based on stage
   - Follow-up

5. **Not suitable for cryotherapy**
   - CKC/LEEP
   - Follow-up at 9–12 months (screening test/colposcopy)
7.5 Group learning activities

7.5.1. Case studies

Case study 1 (Time allotted: 10 minutes)

Case history: A 32-year-old woman attends a primary health centre for VIA test. After application of 5% acetic acid the cervix looks as below:

Question:
1. What is the outcome category of VIA? (Describe the findings)
2. How will you manage her?
3. How will you follow-up?

Answers:
1. VIA test result is negative. Thin white line seen around the external os represents the SCJ.
2. Reassure and counsel her.
3. Woman needs to undergo VIA test every 3 years (according to National Protocol); she should report early in case of any symptoms.

Case study 2 (Time allotted: 10 minutes)

Case history: A 38-year-old woman with two children attends the primary health centre for VIA test. After application of acetic acid the cervix looks as below:

Question:
1. What is the outcome category of VIA? (Describe the findings)
2. How many quadrants of the cervix does the acetowhite area occupy?
3. Does she require any treatment? If yes, how will you treat her?
4. What are the alternate options for management other than immediate cryotherapy?

Answers:
1. VIA test is positive. There is an acetowhite area on the posterior lip of the cervix extending from 5–7 o’clock, has well defined margin and is attached to the SCJ.
2. There is two quadrant involvement (or in %).
3. Yes, she requires treatment that can be done by an ablative method. She can be treated by cryotherapy as the acetowhite area involves only two quadrants of the cervix, entire lesion is present on the ectocervix, both outer and inner margins of the lesion are visible and the lesion can be adequately covered by the largest cryoprobe.
4. The woman can undergo colposcopy and biopsy (if facility is available) to confirm the diagnosis and then subsequently go for treatment depending on her biopsy report.

Case study 3
(Time allotted: 10 minutes)

Case history: A 49-year-old multiparous woman attends the screening clinic with the complaint of postmenopausal bleeding per vaginum. Below is the finding on her speculum examination.

Question:
1. What is the most likely diagnosis (describe the findings)?
2. How will you manage the case?

Answers:
1. Suspicious of cervical cancer. There is a cauliflower like friable growth replacing almost the whole of the cervix. It bleeds to touch.
2. She should be referred to a higher centre for histological confirmation of diagnosis. The stage of the disease should be determined and treated accordingly.

Points to remember

- Women with positive VIA test should be treated with cryotherapy at the same visit, if eligible.
- Ineligible women should be referred for colposcopy.
- HPV positive women should be assessed for immediate cryotherapy or advised VIA, depending on the protocol of the programme.
- CIN can be treated by either an ablative method like cryotherapy or excisional method like LEEP.
- Women treated for positive VIA/HPV should be followed-up after 1 year.
- Women positive on follow-up screening should preferably be treated with LEEP/cold knife conization.
- If the woman has the histology diagnosis of either CIN 3 or adenocarcinoma in situ, screening should be repeated every year for 3 consecutive years.
### Multiple choice questions

**1. Following VIA testing, if the result is negative:**

- a) Let the woman know that she is free from cervical cancer lifelong
- b) Advise the woman to have a HPV test if she can afford it
- c) The woman need not be informed about the test results
- d) Advise the woman to have VIA after 3–5 years depending on the programme recommendations

**2. Management of VIA positive women includes all, except:**

- a) Cryotherapy at the same visit
- b) Colposcopic guided biopsy followed by treatment based on biopsy report
- c) Colposcopy followed by LEEP at the same visit if high grade lesions are suspected
- d) Cold knife conization at the same sitting

**3. HPV positive women can be managed by:**

- a) Cryotherapy, if there is an acetowhite area on the ectocervix suitable for cryotherapy
- b) Cryotherapy, if no acetowhite area is visible and SCJ is on the ectocervix
- c) Antibiotics for 1 month
- d) Doing VIA and further management based on VIA results

**4. When should a VIA positive woman undergoing cryotherapy have repeat screening?**

- a) At 1 year
- b) At 2 years
- c) At 3 years
- d) At 5 years

**5. Disadvantage of screen and treat approach is:**

- a) Over treatment
- b) High complication rate
- c) Reduced number of visits to healthcare facilities
- d) Reduced referral rate

---

### Answer key

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>1</td>
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<td>5</td>
<td>a</td>
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</tbody>
</table>
Module 8: Treatment of cervical pre-cancers by cryotherapy and follow-up

8.1 Module overview
This module is intended to train paramedical workers, midwives, nurses and clinicians on the principles and technique of cryotherapy, which is an ablative method of treatment for cervical pre-cancers. The module is to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 5 – Screening and treatment of cervical pre-cancer; Section 5.5.1 – Cryotherapy; Practice Sheet 5.10; and Annex 8).

8.2 Module contents
- Principles of cryotherapy
- Instruments and consumables required
- Eligibility criteria for cryotherapy
- Steps of cryotherapy
- Post-treatment advice and follow-up
- Advantages and disadvantages of cryotherapy
- Management of treatment complications
- Troubleshooting
- Sterilization of equipment
- Group learning activities:
  - Knowing the cryotherapy unit and its maintenance
  - Simulated learning
  - Role play
- Checklist for treatment by cryotherapy

8.3 Learning objectives
By the end of this module, trainees will be able to:
- describe all the parts of a cryotherapy unit;
- identify eligibility criteria for treatment with cryotherapy;
- perform the technique following the correct steps;
- recognize probable treatment complications;
- offer appropriate management of complications;
- perform appropriate follow-up after treatment;
- follow infection prevention practices during cryotherapy.
8.4 Key points for discussion

8.4.1 How does cryotherapy work?

Cryotherapy is an ablative technique for treatment of ectocervical lesions. It uses the freezing effect of compressed refrigerant gases like nitrous oxide (N\textsubscript{2}O) or carbon dioxide (CO\textsubscript{2}) to destroy the abnormal TZ of the cervix. The compressed gas is delivered on to the surface of ectocervix through cryoprobes made up of highly conductive metals (like silver or copper). The flow of gas through the narrow aperture of the cryoprobe and its subsequent release on the surface of the ectocervix produces a significant drop in temperature. This causes severe damage to cells by crystallization of water and denaturation of proteins inside the cells. If good contact is established between the cryoprobe tip and the surface of the ectocervix, the N\textsubscript{2}O system achieves colder temperature than CO\textsubscript{2} system.

8.4.2 What are the instruments and consumables required for cryotherapy?

**Equipment/instruments required for cryotherapy**

- Cryosurgical unit:
  - Cryoprobes
  - Cryogun
  - Gas conveying tube
  - Pressure gauge
  - Gas cylinder connector
- Examination table
- Focusing light (halogen lamp or lamp with 100 watt bulb)
- Instrument tray
- Appropriate sized self retaining bivalve speculum
- Sponge holding forceps
- Gas tanks containing compressed refrigerants

**Consumables required for cryotherapy**

- Gloves (sterile/ disposable gloves after high-level disinfection)
- Cotton swabs, cotton tipped swabs sticks
- Dilute acetic acid (3–5%) solution (freshly prepared)
- Lubricant jelly
- Waste disposal bag
- Chlorine solution (0.5%) or 2% glutaraldehyde
- Case record form

*Fig. 8.1: Requirements for cryotherapy*
8.4.3 Which lesions can be treated by cryotherapy?

**Eligibility criteria for cryotherapy**

- Entire lesion should be visible on the ectocervix
- Lesion should be adequately covered by the largest cryoprobe
- Lesion should not extend to the endocervical canal or vagina
- Lesion should not occupy more than 75% of the cervix
- No evidence or suspicion of cancer
- No evidence or suspicion of glandular abnormality
- Woman should not be pregnant at the time of treatment
- Woman should not have pelvic inflammatory disease at the time of treatment
- Woman should not be menstruating at the time of treatment

8.4.4 How to perform cryotherapy step-by-step

Refer to Skills Checklist 8.6.1.

8.4.5 What are the post-treatment instructions and follow-up plans?

- Inform the woman that she may have watery vaginal discharge (that can be blood-stained also) for about 4 weeks
- Advise her to use sanitary napkins to avoid staining of the clothes
- Advise the woman to avoid sexual intercourse for about 4 weeks (if abstinence is not possible, advise her to use condoms during intercourse)
- Advise her not to use vaginal tampons or douches for 4 weeks
- Ask the woman to report to the health facility if she suffers from any of the following symptoms within 4 weeks of treatment:
  - fever with temperature >38 °C or with chills and rigors
  - foul smelling purulent vaginal discharge
  - severe lower abdominal pain/cramps
  - vaginal bleeding for more than 2 days or with clots (except during the expected time of menstruation)
- Inform the woman that she should return for follow-up after 1 year
8.4.6 What are the advantages and limitations of cryotherapy?

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective</td>
<td>Cannot be used to treat large lesions or lesions extending</td>
</tr>
<tr>
<td></td>
<td>to the endocervix</td>
</tr>
<tr>
<td>Inexpensive</td>
<td>Destruction leaves no tissue sample for confirmatory</td>
</tr>
<tr>
<td></td>
<td>diagnosis</td>
</tr>
<tr>
<td>Non-physicians can perform</td>
<td>Difficult to determine exact amount of tissue destroyed</td>
</tr>
<tr>
<td>No anaesthesia required</td>
<td>Requires access to regular supply of refrigerants</td>
</tr>
<tr>
<td>No electricity required</td>
<td></td>
</tr>
<tr>
<td>Associated with few side</td>
<td></td>
</tr>
<tr>
<td>effects and complications</td>
<td></td>
</tr>
</tbody>
</table>

8.4.7 What are the treatment side effects/complications and how can you manage them?

Complications after treatment with cryotherapy are extremely rare. Some of the side effects that a woman may experience during or early after treatment are:

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramping during treatment</td>
<td>• Before the procedure, counsel the patient to expect some degree of cramping during and after the procedure</td>
</tr>
<tr>
<td></td>
<td>• Cramping can be reduced by giving a mild analgesic like paracetamol, orally, half an hour before treatment.</td>
</tr>
<tr>
<td></td>
<td>• Analgesics can be given after the procedure if the woman complains of persistent pain.</td>
</tr>
<tr>
<td>Fainting attack</td>
<td>• Make the woman lie down for about 30 minutes.</td>
</tr>
<tr>
<td></td>
<td>• Reassure her and make sure she is feeling all right before letting her go home.</td>
</tr>
<tr>
<td>Vaginal discharge (profuse, watery)</td>
<td>• Reassure the woman that this is expected after treatment.</td>
</tr>
<tr>
<td></td>
<td>• Ask her to use sanitary napkins for comfort</td>
</tr>
<tr>
<td>Acute pelvic infection</td>
<td>• Send swab from vaginal discharge for culture, if feasible</td>
</tr>
<tr>
<td></td>
<td>• Start empirical treatment with antibiotics</td>
</tr>
<tr>
<td></td>
<td>• Give supportive treatment</td>
</tr>
<tr>
<td>Spotting/light bleeding</td>
<td>• Reassure the woman that this is expected after treatment</td>
</tr>
<tr>
<td></td>
<td>• Ask her to use sanitary napkins for comfort</td>
</tr>
</tbody>
</table>

*Stenosis of cervix (late complication) is extremely rare. The treatment has no association with infertility and does not increase the risk of having a premature delivery.*
8.4.8 What are the common problems encountered during cryotherapy and how can you manage them?

<table>
<thead>
<tr>
<th>Problems</th>
<th>Reason</th>
<th>Suggested solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas stops flowing</td>
<td>Gas tank is empty</td>
<td>Arrange for a new gas cylinder</td>
</tr>
<tr>
<td></td>
<td>Nozzle is blocked by impurities in the CO₂ gas</td>
<td>Dip the tip of the nozzle in a small bowl of water and flush it by pressing the trigger of the cryogun until the blockage is cleared (Fig. 8.2a)</td>
</tr>
<tr>
<td>Gas leakage from the hand unit</td>
<td>The washer/O-ring is either missing or is broken</td>
<td>Change washer/O-ring (usually provided by the manufacturer in the cryo unit) and put in a new appropriate sized washer (Fig. 8.2b)</td>
</tr>
<tr>
<td>Pressure gauge indicator is in the yellow zone (Fig. 8.2c)</td>
<td>Inadequate gas in the cylinder</td>
<td>Stop performing cryotherapy and change the gas cylinder</td>
</tr>
<tr>
<td>Difficulty in exposing the cervix</td>
<td>Laxity of vaginal walls</td>
<td>• Put a condom or the cut finger of a glove on the speculum (Fig. 8.2d)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insert lateral vaginal wall retractors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Use a wooden spatula to push away vagina from between the blades of the speculum</td>
</tr>
</tbody>
</table>

Fig. 8.2: Problems encountered during cryotherapy and suggested solutions

a) Dip the nozzle in water and press the trigger to clear blockage
b) Change the washer to stop gas leakage from the hand unit
c) Stop cryotherapy if the pressure gauge indicator is in the yellow zone
d) Put a cut finger of a glove on the speculum to expose the cervix
8.4.9 How to decontaminate the cryotherapy unit

After treatment by cryotherapy, the cryo probe should be sterilized thoroughly before re-using it. This can be done by following these simple steps.

• Decontaminate by wiping with ethyl alcohol 60–90%
• Dip the probe in clean water
• Scrub any visible biological matter on the probe tip with a cotton swab and wash with clean water
• Soak the probe in any one of the following chemicals:
  ▪ 0.1% chlorine solution for 20 minutes
  ▪ 2% glutaraldehyde for 20 minutes
  ▪ 6% hydrogen peroxide solution for 30 minutes
• Rinse the probe thoroughly with sterile water
• Air-dry or dry it with a sterile cloth

Clean the cryoprobe shaft and the rest of the cryotherapy unit by wiping with cotton soaked in 60–90% ethyl or isopropyl alcohol.

Make sure that the inside hollow part of the cryoprobe is completely dry before the next use (water inside the probe may freeze and the probe could crack, thus interfering with proper treatment).

8.5 Group learning activities

8.5.1 Knowing the cryotherapy unit
8.5.2 Simulated learning
8.5.3 Role play

8.5.1 Knowing the cryotherapy unit

The different parts of the cryotherapy unit (Fig. 8.3) along with their functions and uses are listed below.

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Name of part</th>
<th>Function</th>
<th>How to use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Hand unit</td>
<td>Allows and controls the flow of gas into the cryoprobe</td>
<td>Slip the cryoprobe over the nozzle of the hand unit and secure by tightening</td>
</tr>
<tr>
<td>2.</td>
<td>Trigger</td>
<td>Controls the flow of gas through the hand unit</td>
<td>Press to allow flow of gas and release to stop flow</td>
</tr>
<tr>
<td></td>
<td><strong>Handle grip</strong></td>
<td>Part of the hand unit that is held by the operator</td>
<td>Hold the handle grip during the entire procedure</td>
</tr>
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<td>--------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Cryoprobe</strong></td>
<td>Delivers the refrigerant on to the surface of the cervix and has two parts – cryotip and cryo shaft</td>
<td>Apply the cryoprobe connected to the hand unit on the TZ of the cervix for freezing effect</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Cryotip</strong></td>
<td>Metal tip of the cryoprobe that covers the surface of the cervix and induces the freezing effect</td>
<td>Select the cryotip of appropriate size and shape and press it onto the cervix without touching the vagina</td>
</tr>
<tr>
<td>6.</td>
<td><strong>Cryo shaft</strong></td>
<td>Part of the cryoprobe that attaches the cryotip to the hand unit</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Gas conveying tube</strong></td>
<td>Connects the hand unit to the pressure gauge and allows the gas to flow</td>
<td>The flexible tube remains connected</td>
</tr>
<tr>
<td>8.</td>
<td><strong>Pressure gauge</strong></td>
<td>Monitors the pressure of gas flowing to the hand unit. It has an indicator and three colour zones – yellow, green and red.</td>
<td>On opening the gas cylinder if the indicator moves to: Green zone – gas pressure is adequate Yellow zone – pressure too low Red zone – gas pressure is too high</td>
</tr>
<tr>
<td>9.</td>
<td><strong>Gas cylinder connector</strong></td>
<td>Attaches the gas cylinder to the cryotherapy unit</td>
<td>Insert the inlet of the connector into the slot of the gas cylinder valve. Tighten the attachment by screwing in the tightening knob of the connector</td>
</tr>
<tr>
<td>10.</td>
<td><strong>Washers or O-rings</strong></td>
<td>Prevent leakage of gas from the system. Washers need to be replaced if they become defective, causing leakage of gas</td>
<td>Make sure that the washers are fitted in between the cryoprobe and hand unit and also between the gas cylinder connector and the cylinder</td>
</tr>
</tbody>
</table>
8.5.2 Simulated learning

Trainees must practise doing cryotherapy on the LEEP trainer under the guidance of a facilitator. The details of practising with a LEEP trainer are discussed in the *Facilitators’ guide*.

8.5.3 Role play

Counselling cards and flip chart should be used for role plays.

**Role play 1: Counselling a woman for follow-up care after cryotherapy**

Participants and background situation for the role play

- Trainees should be selected from the group to perform the following roles:
  - Amy, a 36-year-old woman having three children, underwent cryotherapy
  - Rita, doctor who performed cryotherapy
- The entire group including the role players should know the following background situation:
Amy underwent a VIA test at a primary health centre. Her VIA test result was positive and she had cryotherapy done by Dr Rita in the same sitting as the VIA test. Dr Rita provides any with information about the after-care of cryotherapy and subsequent follow-up visits.

Focus of the role play

The focus of the role play is the interaction between Amy who had just undergone cryotherapy and Dr Rita who performed cryotherapy. Dr Rita asks Amy if she is feeling all right and if it is okay for her to get down from the table and sit on a chair. Amy says that she is fine and sits on the chair and asks the doctor about what to do next. Dr Rita tells Amy that the procedure went well and she can go home after resting at the clinic for some time. Dr Rita informs her that, like many other women having the procedure, she may notice a watery or blood-mixed vaginal discharge for up to 4 weeks for which she may need to use sanitary pads. She advises Amy to have a bath regularly, keep the area clean and wear clean clothes. She should avoid having sexual intercourse for the next 4 weeks. Condoms should be used if sexual relation cannot be avoided. Although the chances of complications are minimal, she should be aware and if she notices any of the following symptoms, should attend the hospital promptly:

- If the bleeding is too heavy
- If discharge becomes excessive and smelly
- If she develops abdominal pain or fever

Dr Rita thanks Amy and advises her to attend the primary health centre after 1 year for a repeat VIA test.

Time allotted for the role play: 10 minutes

Role play 2: Managing a woman who has come to the clinic with abdominal pain within 1 week of cryotherapy

Participants and background situation for the role play:

- Trainees should be selected from the group to perform the following roles:
  - Meena, a 36-year-old woman, having three children, who underwent cryotherapy
  - Preeti, doctor who performed cryotherapy
- The entire group including the role players should know the following background situation:
Focus of the role play

The focus of the role play is the interaction between Meena, who has abdominal pain 5 days after undergoing cryotherapy, and Dr Preeti, who had provided her the treatment. Meena did not have any complication during or immediately after cryotherapy. She was advised to go home with proper instructions on self-care after cryotherapy. Now, 5 days after cryotherapy, Meena has reported to the clinic with pain in her abdomen. Dr Preeti asks Meena whether she has any foul smelling discharge, or fever associated with pain. Meena says that she has only pain that is tolerable but she is scared that there may be something wrong. She also says that her pain is not associated with excessive bleeding, discharge or fever. Dr Preeti carefully takes her history and finds that her menstrual period is due in a day’s time. She examines her thoroughly and finds no abnormality on speculum examination. She reassures Meena that, in the absence of fever or discharge or bleeding, she need not be worried about the pain. Most likely it is from the menstrual period that is due in a day’s time and prescribes a mild analgesic to relieve her symptoms. Dr Preeti advises her to report back immediately if she develops fever or discharge or bleeding along with the abdominal pain. Those symptoms mostly indicate infection for which she may require treatment with antibiotics.

Time allotted for the role play: 10 minutes

8.6 Skill development

Steps of cryotherapy

<table>
<thead>
<tr>
<th>Skills Checklist: Cryotherapy</th>
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<tbody>
<tr>
<td>Steps</td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
</tr>
<tr>
<td>2. Explain to the woman why the treatment is recommended and describe the procedure</td>
</tr>
<tr>
<td>3. Exclude pregnancy by asking LMP or if amenorrhoea is present. Do a urine pregnancy test if necessary</td>
</tr>
<tr>
<td>4. Tell her about the side effects to expect and the alternatives to cryotherapy</td>
</tr>
<tr>
<td>5. Obtain informed consent for cryotherapy</td>
</tr>
</tbody>
</table>
### Getting ready

6. Check that instruments, supplies and light source are available and ready to use

7. **Check that cryotherapy instruments and gas tanks are ready for use**

8. Tell the woman what is going to be done and encourage her to ask questions

9. Check that the woman recently (not more than 30 minutes earlier) has emptied her bladder

10. Help her on to the examination table and drape her

11. Wash hands thoroughly and air-dry them

12. Put on new sterile examination or high-level disinfected surgical gloves

13. Arrange instruments and supplies on a high-level disinfected tray or container

### Cryotherapy

14. Insert an appropriate sized speculum and fix blades so that the entire cervix can be seen clearly

15. Move the light source so that the cervix can be visualized clearly

16. **Apply 5% dilute acetic acid and identify:**
   - SCJ
   - TZ and area to treat
   - Limits of the lesion

17. **Choose a cryotherapy probe of the correct size so that the entire lesion is covered**

18. Smear the cryoprobe tip with saline or any lubricant jelly

19. Apply the cryoprobe with the tip of the probe placed on the external os of the cervix

20. **Take precautions so that the cryoprobe tip does not inadvertently touch any part of the vagina**

21. **Check for adequate pressure (40–70 kg per cm²) in the gas tank, indicated by the green zone in most models of the equipment**

22. Press the trigger of the cryogun to release gas and keep it pressed for 3 minutes
23. **Inspect the cervix to ensure that the ice ball forming on the cervix extends outside the rim of the cryoprobe by 4–5 mm**

24. Release the trigger and let the ice thaw for 5 minutes

25. Repeat the procedure of freezing for another 3 minutes

26. Release the trigger to stop gas flowing and wait for the cryotip to detach from the cervix on its own

27. Remove cryoprobe from the vagina

28. Remove speculum and place it in 0.5% chlorine solution for 10 minutes

**Post-cryotherapy tasks**

29. Close the gas cylinder valve

30. Detach the cryoprobe, clean it and put it in chemical disinfectant

31. Decontaminate the cryotherapy unit with alcohol

32. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out:
   - If disposing off the gloves, place them in a leak-proof container or plastic bag.
   - If reusing surgical gloves, submerge them in 0.5% chlorine solution for 10 minutes for decontamination

33. Wash hands thoroughly with soap and water and air dry them

34. Check to be sure that the woman is not having excessive cramps

35. **Advise about post-treatment care and follow-up instructions**

36. **Complete the documentations to record the treatment**

*The highlighted steps are considered critical*

Score achieved: Facilitator’s signature

Facilitator’s remarks
During the cryotherapy procedure, the cylinder will become cold, and moisture may form on the outside of the cylinder. White grains of ice may come out of the exhaust port. This is normal and will not interfere with the operation of the cryotherapy unit.

Points to remember

• Cryotherapy is an ablative method for treatment of ectocervical precancerous lesions.
• It uses the freezing effect of compressed refrigerant gases – \( \text{N}_2\text{O}/\text{CO}_2 \).
• Cryotherapy destroys the TZ by crystallization of water and denaturation of proteins.
• The entire lesion should be visible on the ectocervix, fully covered by the cryoprobe, occupying less than 75% of ectocervix with no suspicion of cancer.
• Watery discharge or spotting can occur until 4 weeks after cryotherapy.
• Complete abstinence should be followed for 4 weeks after the procedure.
• Follow-up is recommended after 1 year of the treatment.
• The woman should report immediately if she has any of the following symptoms: foul smelling discharge, fever of more than 38 °C, heavy vaginal bleeding or severe lower abdominal pain occur within 4 weeks of treatment.
• Anaesthesia is not required.
Multiple choice questions

1. Cryotherapy involves use of:
   a) \( \text{CO}_2 + \text{N}_2\text{O} \)
   b) \( \text{CO}_2 + \text{NO}_2 \)
   c) \( \text{CO}_2 + \text{O}_2 \)
   d) \( \text{N}_2\text{O} + \text{O}_2 \)

2. The following is a true statement about cryotherapy:
   a) Uses the freezing effect of refrigerant gases to destroy abnormal epithelium
   b) Is an excisional technique
   c) Can treat early cervical cancer
   d) Tissue is obtained by histopathological examination

3. Advantages of cryotherapy are all, except:
   a) No tissue is available for histopathological examination
   b) Profuse watery discharge for a few weeks
   c) Depth of tissue destruction cannot be determined
   d) No anaesthesia is required

4. The following is a true statement for cryotherapy procedure:
   a) 5–3–5 minute double freeze technique is used
   b) Pressure of refrigerant gas should be 40–70 kg/cm
   c) Ice ball is not formed at the end of the procedure
   d) Pull off cryotip immediately at the end of procedure

5. Following are the warning signs for a woman to return to the health facility immediately after cryotherapy, except:
   a) Foul-smelling or pus-coloured vaginal discharge
   b) Severe lower abdominal pain
   c) Fever for more than 38 °C
   d) Spotting or light bleeding

Answer key

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<tbody>
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<td>4</td>
<td>b</td>
<td>5</td>
</tr>
</tbody>
</table>
Module 9: Treatment of cervical pre-cancers by cold coagulation and follow-up

9.1 Module overview

This module is intended to train paramedical workers, midwives, nurses and clinicians on the principles and technique of cold coagulation, which is an ablative method of treatment for cervical pre-cancers.

Cold coagulation as a method of treatment of cervical precancerous conditions is not yet universally approved. However it can be practiced in situations where cryotherapy is not feasible due to non-availability of refrigerants.

9.2 Module contents

- Principles of cold coagulation
- Instruments and consumables required
- Eligibility criteria for cold coagulation
- Steps of cold coagulation
- Post-treatment advice and follow-up
- Advantages and disadvantages
- Troubleshooting
- Management of treatment complications
- Sterilization of equipment
- Group learning activities:
  - Knowing the cold coagulation equipment
  - Simulated learning
  - Role play
- Checklist for treatment by cold coagulation

9.3 Learning objectives

By the end of this module, trainees will be able to:

- describe all parts of the cold coagulator;
- identify eligibility criteria for treatment with cold coagulation;
- perform cold coagulation following correct steps;
- recognize probable treatment complications;
• offer appropriate management of complications;
• advise appropriate follow-up after treatment;
• list appropriate infection prevention practices during cold coagulation.

9.4 Key points for discussion

9.4.1 How does cold coagulation work?

Cold coagulation is an ablative technique for treatment of ectocervical lesions. It uses a metallic probe heated to 100–120 °C to cause thermal destruction of cervical tissue. The depth of tissue destruction achieved by the heated probe exceeds 4 mm after 30 seconds of cold coagulation.

9.4.2 What are the instruments and consumables for cold coagulation?

<table>
<thead>
<tr>
<th>Equipment/instruments required for cold coagulation</th>
<th>Consumables required for cold coagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cold coagulator</td>
<td>• Gloves (sterile disposable gloves)</td>
</tr>
<tr>
<td>• Metallic probe</td>
<td>• Cotton swabs, cotton tipped swab sticks</td>
</tr>
<tr>
<td>• Wire for electrical connection</td>
<td>• Dilute acetic acid (3–5%) solution</td>
</tr>
<tr>
<td>• Examination table</td>
<td>(freshly prepared)</td>
</tr>
<tr>
<td>• Focusing light</td>
<td>• Lubricant jelly</td>
</tr>
<tr>
<td>• Instrument tray</td>
<td>• Waste disposal bag</td>
</tr>
<tr>
<td>• Self retaining bivalve speculum</td>
<td>• Chlorine solution (0.5%) or 2% glutaraldehyde</td>
</tr>
<tr>
<td>• Lateral vaginal wall retractors</td>
<td>• Electricity</td>
</tr>
<tr>
<td>• Sponge holding forceps</td>
<td>• Case record form, consent form</td>
</tr>
</tbody>
</table>

Fig. 9.1: Requirements for cold coagulation
9.4.3 Which lesions can be treated by cold coagulation?

**Eligibility criteria for cold coagulation**

- Entire lesion should be visible on the ectocervix
- Lesion should not extend to the endocervical canal or vagina
- Lesion should not occupy more than 75% of the cervix
- No evidence or suspicion of cancer
- No evidence or suspicion of glandular abnormality
- Woman should not be pregnant at the time of treatment
- Woman should not have pelvic inflammatory disease at the time of treatment
- Woman should not be menstruating at the time of treatment

9.4.4 How to perform cold coagulation step-by-step

Refer to Skills Checklist 9.5.1.

9.4.5 What is the post-treatment advice and follow-up plan?

- Inform the woman that she may have watery vaginal discharge (that can be blood-stained also) for about 4 weeks
- Advise her to use sanitary napkins to avoid staining her clothes
- Advise the woman to avoid sexual intercourse for about 4 weeks (if abstinence is not possible, advise her to use condoms during intercourse)
- Advise her not to use vaginal tampons or douche for 4 weeks
- Ask the woman to report to the health facility if she suffers from any of the following symptoms within 4 weeks of treatment:
  - fever with temperature >38 °C with chills and rigors
  - foul smelling purulent vaginal discharge
  - severe lower abdominal pain/cramps
  - vaginal bleeding for more than 2 days or with clots (except during expected time of menstruation)
- Inform the woman that she should return for follow-up after 1 year
9.4.6 **What are the advantages and limitations of cold coagulation?**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective in treating CIN</td>
<td>Destruction leaves no tissue sample for confirmatory diagnosis</td>
</tr>
<tr>
<td>Non-physicians can perform</td>
<td>Difficult to determine the exact amount of tissue destroyed</td>
</tr>
<tr>
<td>No anaesthesia or hospitalization required</td>
<td>Electricity required</td>
</tr>
<tr>
<td>No noise/smoke/smell of burning tissue during treatment</td>
<td>Expensive equipment</td>
</tr>
<tr>
<td>Multiple applications to cover a big lesion is possible</td>
<td></td>
</tr>
<tr>
<td>Does not require continuous supply of refrigerants</td>
<td></td>
</tr>
<tr>
<td>Short treatment time</td>
<td></td>
</tr>
<tr>
<td>Associated with few side effects and complications</td>
<td></td>
</tr>
<tr>
<td>Easy sterilization of the metallic probe</td>
<td></td>
</tr>
<tr>
<td>Easy portability as equipment is light weight</td>
<td></td>
</tr>
</tbody>
</table>

9.4.7 **What are the treatment side effects/complications and how should they be managed?**

Complications after treatment with cold coagulation are extremely rare. Some of the side effects that a woman may experience during or immediately after treatment are:

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramping during treatment</td>
<td>• Counsel the woman before the procedure to expect some degree of cramping during and after the procedure</td>
</tr>
<tr>
<td></td>
<td>• Cramping can be reduced by giving a mild analgesic like paracetamol orally half an hour before treatment</td>
</tr>
<tr>
<td></td>
<td>• Analgesics can be given after the procedure, if the woman complains of persistent pain</td>
</tr>
<tr>
<td>Vaginal pain due to inadvertent touching of the vagina with a heated probe</td>
<td>• Make the woman lie down for about 30 minutes</td>
</tr>
<tr>
<td></td>
<td>• Give her analgesic tablets like paracetamol or ibuprofen</td>
</tr>
<tr>
<td></td>
<td>• Reassure her and make sure she is feeling all right before letting her go</td>
</tr>
</tbody>
</table>
Vaginal discharge (profuse, watery)
• Reassure the woman that this is expected after treatment
• Ask her to use sanitary napkins for comfort

Acute pelvic inflammatory disease
• Send swab from vaginal discharge for culture, if feasible
• Start empirical treatment with antibiotics
• Give supportive treatment

Spotting/light bleeding
• Reassure the woman that this is expected after treatment
• Ask her to use sanitary napkins for comfort

9.4.8 How to decontaminate and sterilize a cold coagulator probe
Decontamination and sterilization of the cold coagulator probe is easy and can be done by following these simple steps:
• Decontaminate by the probe wiping it with 60–90% ethyl alcohol
• Dip the probe in clean water
• Remove any visible matter on the probe with a cotton swab and wash it with clean water
• Wipe it dry
• Set the cold coagulator at 120 °C and heat the probe for 45 seconds

9.5 Group learning activities

9.5.1 Knowing the cold coagulator unit
9.5.2 Simulated learning
9.5.3 Role play

Stenosis of cervix (late complication) is extremely rare. The treatment has no association with infertility and does not increase the risk of having a premature delivery.
9.5.1 Knowing the cold coagulator unit

The different parts of the cold coagulator unit (Fig. 9.2) along with their functions and uses are listed below.

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Name of part</th>
<th>Function</th>
<th>How to use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Cold coagulator</td>
<td>The device is able to generate a temperature of 100 °C and has a switch, a temperature regulator and a temperature display on the front panel</td>
<td>Connect the unit to an electrical supply, preferably using a voltage stabilizer</td>
</tr>
<tr>
<td>2.</td>
<td>Switch</td>
<td>The machine is turned on or off using the switch on the front panel</td>
<td>Press the switch. The indicator light and the display light-up</td>
</tr>
<tr>
<td>3.</td>
<td>Temperature regulator</td>
<td>Rotating the knob clockwise increases the temperature setting. To reduce temperature, it has to be turned in the opposite direction</td>
<td>Rotate the regulator until the temperature shown on the display is steady at 100 °C</td>
</tr>
<tr>
<td>4.</td>
<td>Temperature display</td>
<td>Shows the temperature of the tip of the probe</td>
<td>Make sure that the display shows 100 °C before start of treatment</td>
</tr>
<tr>
<td>5.</td>
<td>Cervical probe</td>
<td>The metallic probe has a Teflon coated tip that gets heated at the temperature set by the machine</td>
<td>Connect the probe to the wire before the procedure. Hold the metal probe and apply the tip on the surface of the cervix for treatment</td>
</tr>
<tr>
<td>6.</td>
<td>Wire</td>
<td>The wire connects the probe to the machine</td>
<td>• Make sure that the wire is connected to the machine. • Attach the probe to the wire before start of treatment</td>
</tr>
</tbody>
</table>

Fig. 9.2: Parts of cold the coagulator unit
9.5.2 Simulated learning

Trainees must practise doing cold coagulation on the LEEP trainer under the guidance of a facilitator. The details of practising with a LEEP-trainer are discussed in the Facilitators' guide.

9.5.3 Role play

Counselling cards and flip chart to be used for role plays

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**Role play 1: Informed consent procedure and counselling for cold coagulation**

**Participants and background situation for the role play**

- Trainees should be selected from the group to perform the following roles:
  - Farzana, a 45-year-old woman, having five children, who has undergone VIA at a primary health centre
  - Shirin, a doctor who performs cold coagulation at the primary health centre
  - Ahmed, Farzana’s partner who accompanies her
- The entire group, including the role players, should know the following background situation:

  *Farzana has been advised by Dr Shirin at the primary health centre to have treatment with cold coagulation in view of her VIA test positive result. Dr Shirin explains the necessity of treatment with cold coagulation, how the procedure will be done, benefits and side effects to Farzana and takes informed consent.*

**Focus of the role play**

The focus of the role play is the interaction between Dr Shirin and Farzana, who has undergone VIA test and requires treatment by cold coagulation. Dr Shirin asks Farzana to sit in the counselling room and to call her family, if present. Farzana’s partner, Ahmed, joins them in the counselling room. Dr Shirin explains to the couple that Farzana’s VIA test report is positive as she has a small white patch on the cervix that could be an early change (pre-cancer) of the cervix. She informs them that it is best that this small patch be treated now, so that the future risk of this white patch developing into cancer is prevented. She gives details about the simple treatment procedure called cold coagulation where a small heated probe is applied on the cervix for a few seconds to destroy the abnormal area present on Farzana’s cervix. The procedure is not painful and does not need any anaesthesia. The entire treatment
procedure will take only a few minutes and Farzana will be able to go home the same day. Dr Shirin informs the couple that after the treatment Farzana will have watery vaginal discharge or blood-stained discharge for 2–3 weeks. She advises the couple not to have sexual intercourse for around 1 month to avoid bleeding and infection. Although the treatment complications are minimal, Farzana should report to the hospital if she has foul smelling vaginal discharge, excessive vaginal bleeding with clots and pain of lower abdomen with fever. Ahmed asks about the necessity of further check-ups after the treatment. Dr Shirin informs them that Farzana is required to come for follow-up after 1 year of treatment. She then enquires if Farzana and Ahmed have any other questions and if they agree to for Farzana’s treatment by cold coagulation. They both agree and Farzana signs the consent form.

Time allotted for the role play: 10 minutes

Role play 2: Counselling a woman for follow-up care after cold coagulation

Participants and background situation for the role play

• Trainees should be selected from the group to perform the following roles:
  – Joe, a 36-year-old woman, having three children, who underwent cold coagulation
  – Catherine, the doctor who performed cold coagulation

• The entire group, including the role players, should know the following background situation:

  Joe had VIA test at a primary health centre. Her VIA test result was positive and she had cold coagulation done by Dr Catherine in the same sitting as the VIA test. Dr Catherine provides information to Joe about the after-care of cold coagulation and subsequent follow-up visits.

Focus of the role play

The focus of the role play is the interaction between Joe, who has just undergone cold coagulation, and Dr Catherine who performed cold coagulation on Joe. Dr Catherine asks Joe if she is feeling all right and would like to get down from the table and sit on a chair. Joe says that she is feeling fine and sits on the chair and asks the doctor about what she should do next. Dr Catherine tells Joe that the procedure went well and she can go home after resting at the clinic for some time. Dr Catherine informs Joe that like many other women having the procedure, she may notice a watery or blood-mixed vaginal discharge for up to 4 weeks for which she may need to use sanitary pads. She
advises Joe to bathe regularly, keep the area clean and wear clean clothes. She should avoid having sexual intercourse for the next 4 weeks. Condoms should be used if sexual relations cannot be avoided. Although the chances of complications are minimum, if she notices any of the following symptoms she should attend the hospital promptly:

- High fever
- Foul smelling vaginal discharge
- Severe lower abdominal pain/cramps
- Vaginal bleeding for more than 2 days or with clots

Dr Catherine thanks Joe and advises her to attend the primary health centre at 1 year for repeat VIA test.

Time allotted for the role play: 10 minutes

9.6 Skill development

Skills checklist for treatment by cold coagulation

9.6.1 Steps of cold coagulation

<table>
<thead>
<tr>
<th>Skills Checklist: Cold coagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steps</strong></td>
</tr>
<tr>
<td>------------------------------------</td>
</tr>
<tr>
<td>Counselling before cold coagulation</td>
</tr>
<tr>
<td>1. Greet the woman respectfully and introduce yourself</td>
</tr>
<tr>
<td>2. Explain to the woman why the treatment is recommended and describe the procedure</td>
</tr>
<tr>
<td>3. Exclude pregnancy by asking LMP and do urine pregnancy test if amenorrhoea is present</td>
</tr>
<tr>
<td>4. Tell her about the side effects to expect and the alternatives to cold coagulation</td>
</tr>
<tr>
<td>5. Obtain informed consent for cold coagulation</td>
</tr>
<tr>
<td>Getting ready</td>
</tr>
<tr>
<td>6. Check that instruments, supplies and light source are available and ready to use</td>
</tr>
<tr>
<td>7. Check for electricity supply</td>
</tr>
<tr>
<td>8. Check that cold coagulator is connected to electricity source and is ready for use</td>
</tr>
</tbody>
</table>
9. Tell the woman what is going to be done and encourage her to ask questions
10. Check that the woman has recently (not more than 30 minutes earlier) emptied her bladder
11. Help her on to the examination table and drape her
12. Wash hands thoroughly and air-dry them
13. Put on new examination or high-level disinfected surgical gloves
14. Arrange instruments and supplies on a high-level disinfected tray or container

**Cold coagulation**

15. Insert an appropriate sized speculum and fix the blades so that the entire cervix can be seen clearly
16. Move the light source so that the cervix can be visualized clearly
17. **Apply 3–5% dilute acetic acid and identify:**
   - Squamocolumnar junction
   - Limits of the lesion
   - TZ and area to treat
18. **Set the cold coagulator at 100 °C**
19. **Apply the cold coagulator probe on the area to be treated on the cervix and heat it for 45 seconds at 100 °C**
20. Check if the entire TZ has been treated. If not, then repeat the procedure so as to treat the entire TZ including the lesion on the ectocervix. (1–5 overlapping applications of 45 seconds each can be used)
21. **Remove the probe gently taking care not to touch the vulva or vagina with the probe to avoid unnecessary burns**
22. Remove the speculum and place it in 0.5% chlorine solution for 10 minutes

**Tasks following the cold coagulation procedure**

23. Decontaminate the cold coagulator unit by wiping it with alcohol
24. Clean the probe by scrubbing it gently with a cotton swab and washing it with clean water
25. Set coagulator at 120 °C and heat the probe for 45 seconds
26. Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning them inside out.

27. If disposing-off the gloves, place them in a leak-proof container or plastic bag.

28. If reusing surgical gloves, submerge them in 0.5% chlorine solution for 10 minutes for decontamination.

29. Wash hands thoroughly with soap and water and air-dry them.

30. Check to be sure the woman is not having excessive cramps.

31. Advise about post-treatment care and follow-up instructions.

32. Complete the documentation to record the treatment.

*The highlighted steps are considered critical

Score achieved Facilitator's signature

Facilitator's remarks

Points to remember

• Cold coagulation is an ablative method for treatment of ectocervical precancerous lesions.
• It uses metallic probes heated to 100–120 °C.
• Cold coagulation causes thermal destruction of the cervical tissue.
• The entire lesion should be visible on the ectocervix, fully covered by the cryoprobe, occupying less than 75% of the ectocervix, with no suspicion of cancer.
• Watery discharge or spotting can occur until 4 weeks after cold coagulation.
• Complete abstinence should be maintained for 4 weeks after the procedure.
• Follow-up is recommended after 1 year of treatment.
• The woman should report immediately for any of the following symptoms occur within 4 weeks of treatment: foul smelling discharge, fever of more than 38 °C, heavy vaginal bleeding or severe lower abdominal.
• Anaesthesia is not required.
Multiple choice questions

1. All the statements about cold coagulation are true, except:
   a) Ablative technique
   b) Causes thermal destruction of tissue at 100–1200 °C
   c) Multiple applications to cover a large lesion can be done
   d) Requires anaesthesia

2. Woman is eligible for cold coagulation if:
   a) Entire lesion is visible on the ectocervix are occupies less than 3 quadrants
   b) Lesion occupies 90% of TZ
   c) Extension on to vaginal wall
   d) Suspicion of invasive cancer

3. If the woman has heavy bleeding post-cold coagulation, advise:
   a) Maintain sexual relations
   b) Use vaginal tampons/douches
   c) Follow-up after 4 weeks
   d) Report immediately

4. Advantage of cold coagulation is:
   a) Can treat lesions within the endocervical canal
   b) Electricity not required
   c) Tissue is obtained for confirmation of diagnosis
   d) No anaesthesia required

5. The following is a false statement regarding cold coagulation:
   a) It has variables cure rates in large lesions
   b) It should be avoided during pregnancy
   c) It is difficult to determine the exact amount of tissue destroyed
   d) Non-physicians cannot perform

Answer key
1 – d  2 – a  3 – d
4 – d  5 – d
Module 10: Infection prevention practices

10.1 Module overview
This module is intended to help gynaecologists and non-specialist clinicians to understand ways of reducing the risk of infection in colposcopy clinics and preventing transmission of infection from one woman to another or to the healthcare provider. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Annexure 3 – Infection prevention and control).

10.2 Module contents
- Importance of infection prevention practices
- Prevention of spread of infection
- Processing of instruments
- Waste disposal
- Group learning activities:
  - Hand washing
  - Preparation of 0.5% chlorine solution

10.3 Learning objectives
By the end of this module, trainees will be able to:
- list various modes of spread of infection in a health facility;
- describe the steps to be taken to prevent transmission of infection;
- follow standard work precautions for prevention of infection.

10.4 Key points for discussion

10.4.1 Why is prevention of infection important?
Infection prevention is of paramount importance in all health interventions, especially in cervical cancer screening as instruments come in contact with body fluids and secretions. Spread of infection can occur if proper precautions are not taken to prevent transmission of microorganisms from an infected person or a contaminated object to another person. All microorganisms, including normal flora, can cause infection or disease. Normal flora may cause infection when introduced into an area of the body where they are not normally found.
10.4.2 How to prevent spread of infection

As healthcare professionals are frequently exposed to potentially infectious materials, it is mandatory that appropriate infection prevention procedures are practised to reduce the risk of infection transmission. The following are standard universal precautions of infection prevention:

- washing hands before and after examining each client;
- wearing of gloves when touching broken skin, mucous membranes, blood or other body fluids, soiled instruments, gloves and medical waste;
- processing of instruments after use;
- disposal of wastes as per standard guidelines;
- safe work practices;
- maintaining environmental cleanliness.

10.4.3 How to process instruments for cervical cancer screening clinics

Several steps are involved in reducing the risk of infection transmission from used instruments and other items to healthcare workers and clients. The basic steps for processing instruments, surgical gloves and other items are as follows:

1. **Decontamination** is the first step in handling soiled surgical instruments and other items to make objects safer for handling by healthcare staff. Immediately after use, the instruments and other items should be placed in a 0.5% chlorine solution for 10 minutes (Fig. 10.1a). This step rapidly inactivates microorganisms like hepatitis B virus, hepatitis C virus and HIV and makes items safer to handle. Surfaces of the procedure table and parts of any equipment/instrument that may have come in contact with body fluids should also be decontaminated by wiping them with 0.5% chlorine solution or 90% ethyl alcohol before reuse.

2. **Cleaning** refers to scrubbing the instruments with a brush (an old tooth brush works well), using detergent and water to remove blood, other body fluids, organic material, tissue and dirt (Fig. 10.1b). In addition, cleaning greatly reduces the number of microorganisms (including bacterial endospores) on items. Items should be thoroughly rinsed with water to remove detergent residue, which can interfere with chemical disinfection. Wear utility gloves while cleaning. All staff should be careful to protect their eyes from splashing contaminated water.

3. **Sterilization** eliminates all microorganisms (bacteria, viruses, fungi, and parasites), including bacterial endospores, from instruments and other items. Sterilization should be performed on any item or instrument that comes in contact with the bloodstream or tissues under the skin. It can be performed using steam (autoclaving), dry heat, or chemicals.
High-pressure saturated steam sterilization using autoclaves (Fig. 10.1c) is ideal for sterilization. Unwrapped instruments should be exposed for 20 minutes and wrapped instruments for 30 minutes to temperatures of 121°C at a pressure of 106 kPa (15 lb/inch\(^2\)). However, the pressure settings may vary slightly from machine to machine and manufacturer’s instructions should be followed. Sterilized instruments should be put in sterile containers.

Chemical sterilization by soaking in 2% glutaraldehyde (Fig. 10.1d) for 8 hours or in 8% formaldehyde for 24 hours is an alternative to steam sterilization. Instruments thus sterilized should be rinsed with sterile water before use.

4. High level disinfection (HLD) is the process that eliminates all microorganisms (including bacteria, viruses, fungi, and parasites), but does not reliably kill all bacterial endospores, which cause diseases such as tetanus and gas gangrene. HLD is suitable for instruments and items that come in contact with broken skin or intact mucous membranes. If sterilization is not available, HLD is the only acceptable alternative.

Fig. 10.1: Processing of instruments after use for infection prevention
10.4.4 What are the methods of HLD?

HLD by boiling, steaming or using chemicals is acceptable for final processing of instruments and surgical gloves in cervical cancer screening clinics. Two methods of HLD are detailed here:

i) HLD by boiling

Boiling is a simple method of HLD that can be performed in any location that has access to clean water and a source of heating. Using this method, instruments and other items are submerged in a covered pot or boiler and the water is heated for 20 minutes after it reaches boiling point (Fig. 10.2).

Use instruments immediately or keep them in a covered, dry, high-level disinfected container. (The container used for drying the instruments can be used for storage only if there is no water in the bottom of the container). These instruments can be stored for 7 days if the container remains tightly covered and for 24 hours if the lid of the container is opened.

Steps of HLD by boiling

- Submerge the cleaned instruments in water contained in a covered pot or boiler.
- Boil the water for 20 minutes. Timing should begin when the water is at a rolling (bubbling) boil. All items should be submerged (totally covered) in water.
- Do not add or remove any item after the water begins to boil.
- After boiling for 20 minutes, remove the boiled items using high-level disinfected forceps and place them in a high-level disinfected container.
- Allow the items to cool and air dry.

ii) HLD by soaking in a chemical solution

Chemical HLD is used for heat-sensitive items or when a heat source is not available. Instruments can be soaked for 20 minutes in 0.1% chlorine solution or 2% glutaraldehyde solution, then thoroughly rinsed in water and air dried.

- **HLD in 0.1% chlorine solution** – The solution is very effective against hepatitis B virus (HBV), hepatitis C and human immunodeficiency virus (HIV), inexpensive and readily available. A major disadvantage is that chlorine solutions can discolour metals and cause rust. As chlorine solutions lose their effectiveness with time, fresh solutions should be made at least daily, or more often, if the solution is visibly cloudy. To prepare a high-level disinfected plastic container, fill the container with 0.1% chlorine solution and soak for 20 minutes. Rinse the inside of the container thoroughly with boiled HLD/sterile water. Air dry or dry the disinfected container with a sterile cloth before use.
- **HLD in 2% glutaraldehyde solution** — The contact time with the instruments for HLD is 20 minutes. The solution forms a residue on the instruments which is toxic to tissues. Any instrument soaked in 2% glutaraldehyde solution should be rinsed thoroughly with sterile/HLD water and air dried or dried with a sterile cloth before use. The solution has a shelf life of 2 weeks after preparation (follow manufacturer’s instructions). The solution is expensive.

**Steps of HLD by chemical agents**

- Decontaminate instruments that have been in contact with blood or body fluids
- Thoroughly clean and dry all instruments
- Cover all items completely with correct dilution of high-level disinfectant that has been properly stored
- Soak for 20 minutes
- Remove instruments using high-level disinfected forceps or gloves
- Rinse well with boiled HLD or sterile water and air dry/dry with a sterile cloth
- Use promptly or store for up to seven days in a high-level disinfected, covered container or up to 24 hours if the lid is opened

The instrument processing cycle is schematically shown in Fig. 10.3

**Fig.10.3: Instrument processing cycle**
Table 10.1: A guide to processing instruments used in cervical cancer screening

<table>
<thead>
<tr>
<th>Instruments/consumables</th>
<th>Process required</th>
<th>Suggested procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal speculum, biopsy forceps, endocervical curette, endocervical speculum, vulsellum forceps, insulated speculum, vaginal side-wall retractor</td>
<td>Decontamination, cleaning followed by sterilization or HLD</td>
<td>Autoclaving or HLD by boiling</td>
</tr>
<tr>
<td>Gloves</td>
<td>Decontamination, cleaning followed by sterilization</td>
<td>Autoclaving in wrapped packs</td>
</tr>
<tr>
<td>Colposcope, LEEP equipment, cryotherapy equipment, cryo gas cylinder, cold coagulator with probe, examination table, halogen lamp, instrument trolley, trays</td>
<td>Decontamination</td>
<td>Wipe with ethyl alcohol</td>
</tr>
</tbody>
</table>

10.4.5 How to decontaminate various surfaces in cervical cancer screening clinics

The surface of equipment like the cryotherapy unit, focusing lamp, patient examination table, etc. should be regularly decontaminated as these come in contact with body secretions and blood in screening clinics. Decontamination is done by wiping the surfaces with 0.5% chlorine solution or 60–90% ethyl or isopropyl alcohol or iodophores. The examination table should be decontaminated after each patient examination to prevent transmission of infection from one patient to another or to healthcare providers. The other equipment and the floor of the screening clinic should be decontaminated on a daily basis at the end of the clinic or as indicated during the clinic.

10.4.6. How to manage healthcare wastes of screening clinics

**Step-1:** After completing patient examination, and while still wearing gloves, dispose-off the contaminated objects (swabs and other waste items) in a properly marked leak proof container.

**Step-2:** Immerse both gloved hands in the bucket containing 0.5% chlorine solution and then carefully remove gloves by turning them inside out. If disposing-off the gloves, place them in the leak proof container. If the gloves are for reuse, submerge them in the chlorine solution for 10 minutes for decontamination.

**Step-3:** Daily collection of wastes from screening clinics is encouraged. Long storage of wastes within the premises should be avoided. Leak proof containers/plastic bags should be sent for proper disposal/incineration.
10.4.7 What are the different categories of biomedical wastes and methods of disposal?

There are different categories of biomedical wastes that need to be treated differently as shown in Table 10.2. Colour coding and type of containers used for disposal of biomedical waste is given in Table 10.3. The different colour coded bags for waste disposal are shown in Fig. 10.4.

<table>
<thead>
<tr>
<th>Option</th>
<th>Treatment and disposal</th>
<th>Waste category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. No. 1</td>
<td>Incineration/deep burial</td>
<td>Human tissues, organs, body parts</td>
</tr>
<tr>
<td>Cat. No. 2</td>
<td>Incineration/deep burial</td>
<td>Animal tissues, organs, body parts</td>
</tr>
<tr>
<td>Cat. No. 3</td>
<td>Local autoclaving/microwaving/incineration</td>
<td>Wastes from laboratory, human and animal cell culture used in research and infectious agents from research and industrial laboratories</td>
</tr>
<tr>
<td>Cat. No. 4</td>
<td>Disinfections (chemical treatment/autoclaving/microwaving and mutilation shredding)</td>
<td>Needles, syringes, scalpel blades, glass and other sharp items that may cause punctures and cuts</td>
</tr>
<tr>
<td>Cat. No. 5</td>
<td>Incineration/destruction and disposal of drugs in secured landfills</td>
<td>Discarded medicines and drugs used for cancer chemotherapy</td>
</tr>
<tr>
<td>Cat. No. 6</td>
<td>Incineration, autoclaving/microwaving</td>
<td>Items contaminated with blood and body fluids including cotton, gauze, dressings, sanitary napkins, etc.</td>
</tr>
<tr>
<td>Cat. No. 7</td>
<td>Disinfection by chemical treatment autoclaving/microwaving and mutilation shredding</td>
<td>Waste generated from disposable items (other than sharp items) such as tubing, catheters, intravenous sets, etc.</td>
</tr>
<tr>
<td>Cat. No. 8</td>
<td>Disinfection by chemical treatment and discharge into drain</td>
<td>Waste generated from clinic and washing, cleaning, house-keeping and disinfecting activities</td>
</tr>
<tr>
<td>Cat. No. 9</td>
<td>Disposal in municipal landfill</td>
<td>Ash from incineration of any biomedical waste</td>
</tr>
<tr>
<td>Cat. No. 10</td>
<td>Chemical treatment and discharge into drain for liquid and secured landfill for solids</td>
<td>Chemicals used in production of biological, chemicals, used in disinfection, etc.</td>
</tr>
</tbody>
</table>
Table 10.3: Colour coding and type of container for disposal of biomedical waste

<table>
<thead>
<tr>
<th>Colour coding</th>
<th>Type of container</th>
<th>Waste category</th>
<th>Treatment options as per Schedule 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
<td>Plastic bag</td>
<td>1,2,3,6</td>
<td>Incineration/deep burial</td>
</tr>
<tr>
<td>Red</td>
<td>Disinfected container/plastic bag</td>
<td>3,6,7</td>
<td>Autoclaving/microwaving/chemical treatment</td>
</tr>
<tr>
<td>Blue/white translucent</td>
<td>Plastic bag/puncture proof container</td>
<td>4,7</td>
<td>Autoclaving/microwaving/chemical treatment and destruction/shredding</td>
</tr>
<tr>
<td>Black</td>
<td>Plastic bag</td>
<td>5,9,10 (Solid)</td>
<td>Disposal in secured landfill</td>
</tr>
</tbody>
</table>

Fig. 10.4: Different colour coded bags for waste disposal

10.5 Group learning activities

10.5.1 Practising hand washing

10.5.2 Preparation of 0.5% chlorine solution

10.5.1 Practising hand washing

Supplies to be ensured:
- Soap on appropriate sieved soap dish or liquid soap
- Running water (either direct tap or bucket with tap)
- Personal clean towel

- Observe the steps of hand-washing (Fig. 10.5) carefully when your facilitator gives a demonstration of the process
- Start hand washing when your facilitator gives instructions to do so
- Apply soap and rub until good soap lather is made
- Follow the steps of hand washing as recommended
- Scrub for at least 15–20 seconds covering all surfaces
- Rinse hands thoroughly in running water
- Dry hands in air or use a personal clean towel (Air-drying is better than using a towel)
- Complete all the steps within 60 seconds
- Do not use a shared towel

Fig. 10.5: Steps of handwashing
10.5.2 Preparation of 0.5% chlorine solution

To prepare chlorine solution of a particular strength, the following formula may be used to calculate the required amount of dry powder (household bleach):

\[ \text{Grams/litre} = \left(\frac{\% \text{ of dilute solution}}{\% \text{ of concentrate of active ingredient (calcium hypochlorite)}}\right) \times 1000. \]

E.g. To make 0.5% chlorine solution from 35% of calcium hypochlorite powder:

\[ \left(\frac{0.5\%}{35\%}\right) \times 1000 = 14.2 \text{ grams of dry powder will be required to prepare 1 litre of solution.} \]

Preparation of 0.5% chlorine solution

Materials required for preparing 1 litre of 0.5% chlorine solution:

- Plastic bucket (medium size) and mug
- Wooden stirrer
- Tea spoon
- Bleaching powder kept in air tight container
- Water – 1 litre
- Utility gloves and lab apron

Steps of preparation (Fig. 10.6)

1. Put on the lab apron and wear utility gloves
2. Take 1 lit of water in the plastic bucket
3. Take 14.2 gm (approximately 3 teaspoons full) of bleaching powder and put it in the plastic mug
4. Add a little water into the mug and make a thick paste
5. Add this paste to the water in the bucket
6. Stir with the wooden stirrer until a milky white solution is made
7. Keep the solution covered
8. 0.5% chlorine solution is ready for use

Caution

- Chlorine solutions must be prepared daily as it loses strength over time.
- Clean water, free of organic matter, should be used.
- Chlorine solution should be prepared in a well-ventilated area.
- Wearing of gloves and a laboratory apron is necessary to avoid direct contact of chlorine solution with the skin.
- Plastic containers should be used for preparation and storage of the chlorine solution.

*0.1% chlorine solution can be prepared by diluting 0.5% chlorine solution 5 times. HLD water to be used for preparing 0.1% chlorine solution.
Fig. 10.6: Steps of preparation of 0.5% chlorine solution

a) Wear utility gloves
b) Take 1 litre water in a plastic bucket
c) Measure bleaching powder (approximately 3 teaspoons full)
d) Add a little water to bleaching powder and mix with stirrer to make a thick paste
e) Add this paste to the water in the bucket
f) Stir till a milky white solution is ready
g) Label with date of preparation
Points to remember

- Infection prevention is of paramount importance in all health interventions.
- The basic steps for processing instruments, surgical gloves and other items are: Decontamination, cleaning and high pressure saturated steam sterilization. HLD is acceptable as an alternative to steam sterilization.
- HLD can be done either by boiling or by a chemical method using 0.5% chlorine solution or 2% glutaraldehyde.
- Biomedical wastes should be disposed-off in designated coloured bins.
## Multiple choice questions

1. After using the speculum, it should be decontaminated for 10 minutes by soaking in:
   - a) 1.0% Savlon solution
   - b) 0.5% chlorhexidine gluconate solution
   - c) 0.5% chlorine solution
   - d) 70% ethyl alcohol solution

2. Sterilization destroys:
   - a) Bacteria
   - b) Viruses
   - c) Bacterial endospores
   - d) All of the above

3. The chemical for high level disinfection is:
   - a) 0.6% chlorine solution
   - b) 0.4% chlorine solution
   - c) 2% glutaraldehyde
   - d) 0.2% glutaraldehyde

4. How many grams of dry bleaching powder are required to prepare 1 litre of 0.5% chlorine solution from 35% of calcium hypochlorite powder?
   - a) 14.2 g
   - b) 20.4 g
   - c) 11.6 g
   - d) 28.5 g

5. What are the methods for instrument processing?
   - a) Sterilization
   - b) Chemical sterilization
   - c) High level disinfection
   - d) All of the above

## Answer key

1 – c  
2 – d  
3 – c  
4 – b  
5 – d
Module 11: Ensuring quality of services and programme monitoring in cervical cancer screening

11.1 Module overview
This module is intended to help service providers in a cervical cancer screening programme to understand the importance of ensuring quality at each level of services. The module will facilitate learning of standard operating procedures to ensure quality of services and the responsibilities of each service provider in delivering efficient and safe services. The module is meant to be used by trainees in conjunction with the WHO Guidance book (for further reading refer Chapter 2 – Essentials for cervical cancer prevention and control programmes; Section 2.2.3 – Programme implementation and Section 2.2.4 – Programme monitoring and evaluation, and Practice Sheet 2.2 – Key performance and impact indicators).

11.2 Module contents
• Ensuring quality of services by healthcare providers
• Programme monitoring and its necessity
• Indicators to monitor cervical cancer screening programme
• Quality assurance and quality control
• Framework for effective quality assurance
• Supportive supervision
• Supportive supervision guidelines and tools
• Evaluation of programme performance
• Using evaluation results for quality improvement

11.3 Learning objectives
At the end of this module trainees would be able to:
• understand the importance of quality improvement and monitoring in a cervical cancer screening programme;
• list the different components of programme monitoring to implement efficient and safe service delivery;
• describe how to improve quality of services through programme monitoring and supervision.;
• state the standard operating procedures to ensure quality of services and their individual roles;
11.4 Key points for discussion

11.4.1 How to ensure quality of services by healthcare service providers

Quality of services can be ensured if they are performed as per the recommended standards and protocols adhered to at all times by all service providers involved in the cervical cancer screening programme. Providers at different levels of the health delivery system are important stakeholders in programme implementation. Facility in-charges must inform all service providers regarding the facility being a unit of performance in the larger national/regional programme and their role in contributing to its success. Quality assured services imply that timely quality counselling and screening services are offered to the women who need these, appropriate follow-up care is provided and treatment for screen positive cases and women with invasive cancer is ensured. (Box 11.1) Healthcare providers of all cadres in a facility need to work in coordination to ensure safe and effective delivery of the services and make improvements if any gaps are identified.

Box 11.1: Role of healthcare providers in ensuring a safe and effective programme

**All service providers in a programme must:**

- keep their knowledge and skills updated by participating in relevant trainings, refresher courses, facility-level periodic technical update meetings;
- deliver relevant screening, early detection and treatment services according to the national guidelines and service protocols;
- ensure provision of services in a timely manner, maintaining confidentiality, privacy and client rights;
- adopt practices as and when updates are recommended;
- provide correct information to individuals and communities using the local language;
- ensure women avail referral services when they need and are advised;
- maintain equipment and ensure uninterrupted supply of consumables;
- follow infection prevention practices;
- maintain complete and regular records of clients. Keep registers updated;
- participate in review meetings, continue quality services and improve them if gaps are identified.

11.4.2 What is programme monitoring and why is it necessary in a cervical cancer screening programme?

Programme monitoring is the continuous oversight of all the activities related to the programme to ensure that services are delivered according to plans and the programme achieves its objectives. Effective monitoring of a cervical cancer screening programme ensures promotion of good clinical practices and provides a framework for further improvement in quality of the services. The expected benefits of a cervical cancer screening programme, in terms of significant reductions in morbidity and mortality from the disease, can only be achieved if quality is optimal at every step in the screening and treatment process.
11.4.3 What are the indicators to monitor a cervical cancer screening programme?

A set of benchmarks or indicators are used. To evaluate the performance of a programme, these indicators are classified on the basis of whether they intend to assess the process of screening, diagnosis or treatment (process indicators), the outcome of these processes (outcome or results indicator) or the final impact of the programme (impact indicators). For each of these indicators there is a standard or target against which performance is assessed. The standards are pre-decided based on experience from previous pilot projects or similar programmes in other countries or from the opinion of a group of experts. The standards may vary from programme to programme.

The core indicators used to monitor and evaluate a cervical cancer screening programme are listed in Table 11.1.

Table 11.1: Core indicators to monitor and evaluate a cervical cancer screening programme

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Type of indicator</th>
<th>Explanation</th>
<th>How to calculate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening rate</td>
<td>Performance indicator</td>
<td>Proportion of women in the target age group who were screened for the first time in a 12-month period</td>
<td>Number of women within the target age group screened for the first time in a 12-month period/ Number of women within the target age group in the population x 100</td>
</tr>
<tr>
<td>Screening test positivity rate</td>
<td>Performance indicator</td>
<td>Proportion of women detected positive by the screening test in a 12-month period</td>
<td>Number of screen positive women in a 12-month period/ Number of women screened in the same period x 100</td>
</tr>
<tr>
<td>Treatment rate</td>
<td>Performance indicator</td>
<td>Proportion of screen positive women treated in a 12-month period</td>
<td>Number of screen positive women treated in a 12-month period/ Number of women detected positive in the same 12-month period x 100</td>
</tr>
<tr>
<td>Coverage of target population</td>
<td>Result indicator</td>
<td>Proportion of eligible women who have been screened at least once. This indicator is measured through population-based surveys</td>
<td>Number of women in the target age group who have been screened at least once/Number of women in the target age group surveyed x 100</td>
</tr>
<tr>
<td>Age-specific cervical cancer incidence</td>
<td>Impact indicator</td>
<td>Number of new cases of cervical cancer detected in a defined population in a specified period of time</td>
<td>Number of cervical cancers detected in a specific age group/ Number of women in that age group x 100</td>
</tr>
</tbody>
</table>
11.4.4 What is quality assurance and what is quality control?

Quality assurance of any health programme ensures that processes and systems are developed and adhered to in such a way that good quality services are rendered and the benefit to the target population is maximized. Quality assurance (QA) is the process that refers to an overall management plan (the system) to guarantee quality. Quality control (QC) refers to the tools or the series of measurements used to assess the quality of services and facilities. QA and QC are complementary to each other and these terms have replaced traditional terminologies like monitoring and evaluation.

The complete QA process for cervical cancer screening programme involves:

- supportive supervision at various facilities;
- periodic evaluation of overall performance, based on available data;
- analysis of the outcomes to compare them against predetermined standards (targets);
- dissemination and use of the results to maximize the programme performance.

11.4.5 What is the framework for effective QA?

QA exercise leading to quality improvement is possible only when there is:

- A well-defined screening policy and a pragmatic protocol – conforming to evidence-based standards;
- a functioning system at all levels of service delivery to gather, store and disseminate health information;
- a system of supportive supervision to ensure adherence to the performance standards by all providers;
- capacity for local problem-solving implemented with the involvement of all providers;
- institution of remedial actions in a timely manner.

QA has to start from planning of the programme and should be an integral part of programme implementation. Addressing the client’s rights and taking care of service providers’ needs are key to effective QA of the programme (Fig. 11.1).

Fig. 11.1: Ensuring quality of services

<table>
<thead>
<tr>
<th>Address clients’ rights</th>
<th>Take care of providers’ needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete and accurate information</td>
<td>Good quality management</td>
</tr>
<tr>
<td>Access to services</td>
<td>Supervisory support</td>
</tr>
<tr>
<td>Informed decision-making</td>
<td>Information, training and skills development</td>
</tr>
<tr>
<td>Safety of services</td>
<td>Adequate supplies</td>
</tr>
<tr>
<td>Privacy and confidentiality</td>
<td>Equipment and infrastructure</td>
</tr>
<tr>
<td>Dignity and comfort</td>
<td></td>
</tr>
<tr>
<td>Expression of opinion</td>
<td></td>
</tr>
<tr>
<td>Continuity of care</td>
<td></td>
</tr>
</tbody>
</table>

Source: Adapted from Huezo C et al. Quality of care in family planning: Clients’ rights and providers’ needs. Advances in contraception, 1993
11.4.6 What is supportive supervision?

Supportive supervision is the sustained process of guiding, supporting and encouraging service providers to improve their performance so that they meet the defined standards of the programme. It is not a one time event but a continued process of reviewing site-level data relating to population coverage, screening and treatment rates, quality of screening tests, loss to follow-ups and non-compliance rates, rates of complications of treatment, etc. The supervisory team has to work with staff of the health facility to solve any issues identified about the quality of the services rendered. The observed deficiencies are corrected by further training and skill development.

The guiding principles of supportive supervision are the following:

- The aim of supervision is to facilitate and improve, not find faults at work.
- Staff should be complimented for work well done before pointing out deficiencies.
- Interaction with the staff should be conducted in such a manner that they are able to see and understand the same problem that supervisors can see.
- Problems should be analysed with the staff so that both the staff and team members understand the underlying causes.
- Staff should be encouraged to suggest possible solutions to identified problems. This will make them accept the solution more promptly.

11.4.7 What are the guidelines for performing supportive supervision?

The guidelines for supportive supervision of a facility providing screening/diagnostic/treatment services in a cervical cancer screening programme are given in Fig. 11.2.

Fig. 11.2: Guidelines to implement supportive supervision

<table>
<thead>
<tr>
<th>Persons responsible for supportive supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td>• External supervisors designated by the programme manager</td>
</tr>
<tr>
<td>• Staff from other facilities (peer reviews)</td>
</tr>
<tr>
<td>• Staff from the same facility</td>
</tr>
<tr>
<td>• Staff through self-assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timing of supervision</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Continuously, as part of routine work</td>
</tr>
<tr>
<td>• During team meetings</td>
</tr>
<tr>
<td>• Periodic visits by external supervisors</td>
</tr>
</tbody>
</table>
**Preparation for supervision (by external supervisors)**

- Review previous reports of supervision of the facility, if any
- Review achievements, progress of work already reported
- Decide on the issues that need special attention/improvement beforehand

**Things to do during supervision**

- Observe the performance of service providers and compare them with standards/checklists
- Provide immediate feedback while observing
- Solve problems jointly if any performance problems are identified
- Provide technical updates and guidance
- Provide on-the-job training where necessary
- Identify opportunities for improvement
- Follow-up on previously identified problems, if any

**Things to focus on in a health facility**

- Client registration
- Counselling
- Informed consent procedure
- Screening
- Treatment of pre-cancer
- Infection prevention practices
- Documentation and record keeping

**Things to do after supervision**

- Document actions and discussions
- Continue monitoring of weak areas
- Suggest definite steps to improve quality of services
- Disseminate the new strategies among all concerned for implementation

**11.4.8 What are the tools for supportive supervision?**

Certain tools are required to conduct supportive supervision at different facilities, specially by external supervisors. Every programme has to develop its own supervision tools depending on the programme strategies and programme organization. One of these tools is a facility supervision checklist, a sample of which is shown in Table 11.2. The sample checklist is for a screening clinic performing VIA and cryotherapy. Similar checklists are also to be designed for the colposcopy clinics and laboratories involved in the programme.
Table 11.2: Sample facility supervision checklist for quality assurance in a screening clinic that performs VIA and cryotherapy (screen and treat)

<table>
<thead>
<tr>
<th>Process to be checked</th>
<th>Information to be collected and/or process to be observed</th>
<th>Response/observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client registration</td>
<td>Who maintains the register?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the register up to date?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>How many women have been registered in the last x months?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>How many of them had VIA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What was the target for the last x months?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the women issued registration cards?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Where are the old used registers stored?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Check the register for neatness and completeness of entries</td>
<td></td>
</tr>
<tr>
<td>Counselling and informed consent process</td>
<td>Who does counselling of the women?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Where is counselling done?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are all the women counselled before and after the procedures?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Do the counsellors give enough time to the women?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the informed consent form filled by all clients?</td>
<td></td>
</tr>
<tr>
<td>Screening</td>
<td>Is VIA performed in the regular OPD or in a separate clinic?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Who performs VIA?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the providers following correct steps?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are they interpreting the findings correctly?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are they documenting the findings properly?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of VIA screenings done per week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of women positive on VIA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of women suspected to have cancer on VIA</td>
<td></td>
</tr>
<tr>
<td>Cryotherapy</td>
<td>Is cryotherapy facility available on a regular basis?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Who performs cryotherapy?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the steps being followed properly?</td>
<td></td>
</tr>
<tr>
<td>Infection control</td>
<td>Number of women treated in the last x months</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Number of women treated on the same day as VIA test</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the follow-up advice appropriate?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Who is responsible for infection control?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the steps appropriately followed?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is there a standard procedure for waste disposal?</td>
<td></td>
</tr>
<tr>
<td>Record keeping and data management</td>
<td>Who is responsible for record keeping?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the records stored in registers or on computers?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the records/databases up to date?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the records backed-up regularly?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the database used to track VIA positive women?</td>
<td></td>
</tr>
<tr>
<td>General aspects</td>
<td>Is the clinic clean?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the women treated with respect?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the consumables and supplies adequate?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is equipment in working condition?</td>
<td></td>
</tr>
</tbody>
</table>

Similarly, checklists are required to supervise the performance of staff involved in the programme and assess their levels of competency. A sample skills matrix for supportive supervision of staff at a primary health facility conducting VIA (screen and treat) programme is given in Table 11.3. The supervisor has to assess the knowledge, decision making capacity, attitude and skills of the service providers. A simple scale may be used to rate an individual’s performance and overall competence.
Table 11.3. Sample skills matrix for supportive supervision of staff at a health facility conducting VIA (screen and treat) programme

<table>
<thead>
<tr>
<th>Staff responsibility</th>
<th>Tasks</th>
<th>Knowledge and skills required</th>
<th>Competency level of team members (high/medium/low)*</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinic name:</strong></td>
<td><strong>Visit date:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>In charge</strong></td>
<td>Lead the team</td>
<td>Leadership qualities</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Solving problems</td>
<td>Taking action based on feedback from colleagues and QA team</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Participate in QA</td>
<td>Understanding concept of QA and responsibilities</td>
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<td>Stock-taking and ensuring regular supplies</td>
<td>Knowledge of consumables required and their sources</td>
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<td>Maintenance of equipment</td>
<td>Knowledge of the necessary equipment</td>
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<td></td>
<td>Ensuring availability of staff</td>
<td>Human resource management</td>
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<td></td>
<td>Generating reports</td>
<td>Understanding of the record keeping and health information system</td>
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<td></td>
<td>Supervise the nurses</td>
<td>Knowledge of VIA and treatment</td>
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<td></td>
<td>Manage women with treatment complications</td>
<td>Knowledge of complications and their management</td>
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<td></td>
<td>Support the in-charge in day-to-day work</td>
<td>Knowledge and skills to run the facility if necessary</td>
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<tr>
<td></td>
<td>Participate in QA</td>
<td>Understanding concept of QA and responsibilities</td>
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<tr>
<td><strong>Clinician</strong></td>
<td>Performing VIA</td>
<td>Principles, steps and interpretation of VIA</td>
<td></td>
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<tr>
<td></td>
<td>Performing cryotherapy</td>
<td>Principles and steps of cryotherapy</td>
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<td><strong>Nurse 1</strong></td>
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<td>Nurse 2</td>
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<td>Counselling</td>
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<td>Documentation after</td>
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<td>procedures, maintaining records</td>
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<tr>
<td>Infection control</td>
<td>Principles and techniques of different infection control measures</td>
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<tr>
<td>Participate in QA</td>
<td>Understanding the concept of QA and own responsibilities</td>
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<td><strong>Performing VIA</strong></td>
<td>Principles, steps and interpretation of VIA</td>
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<td><strong>Performing cryotherapy</strong></td>
<td>Principles and steps of cryotherapy</td>
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<td><strong>Counselling</strong></td>
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<td>Documentation</td>
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<td>Infection control</td>
<td>Principles and techniques of different infection control measures</td>
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<td><strong>Participate in QA</strong></td>
<td>Understanding concept of QA and own responsibilities</td>
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<td><strong>Maintaining records</strong></td>
<td>Record and data management</td>
<td></td>
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<tr>
<td><strong>Updating and backing up of database</strong></td>
<td>Computer skills</td>
<td></td>
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<tr>
<td><strong>Tracking of women</strong></td>
<td>Generating lists from database and contacting women</td>
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<tr>
<td><strong>Generating reports</strong></td>
<td>Data management and data synthesis</td>
<td></td>
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<tr>
<td><strong>Participating in QA</strong></td>
<td>Understanding concept of QA and own responsibilities</td>
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</table>

*Low competency:* Can not perform activity satisfactorily or can perform only with constant supervision and assistance

*Medium competency:* Can perform activity satisfactorily but requires supervision with or without some assistance

*High competency:* Can perform activity satisfactorily without any supervision or assistance
11.4.9 How to generate post-supervision reports

Information obtained from supportive supervision of various facilities is compiled to generate an evaluation report. The performance data collected from supervisory visits to the various facilities along with the information obtained through the health information system should be used to estimate the core indicators listed previously. It will be useful to obtain additional information like the number of women screened per month, total number of facilities offering services under the programme, total number of trained providers, number of noncompliant women, number of pre-cancers and cancers detected, etc. All these indicators and processes should be carefully assessed against the targets and expectations. A formal SWOT (strengths-weaknesses-opportunities-threats) analysis can be very useful in planning the future direction for improvement.

11.4.10 How to use evaluation results for quality improvement

The most important part of QA is to act on the basis of monitoring and evaluation reports to improve the quality of services. The ultimate aim of the QA is to adopt best practices. A quality assurance document should be prepared and shared with all facility in-charges, programme coordinators, members of the multi-disciplinary management team (MMT) and the stakeholder’s advisory group (SAG). The focus areas that need improvement should be identified and appropriate modifications should be suggested. Reorientation of staff may be required for which refresher trainings have to be organized. It is the programme manager’s responsibility to ensure that the steps suggested for quality improvement are disseminated to all facilities and the facilities take appropriate corrective actions.

The process of QA is a continuous one and is an integral part of each of the components of the cervical cancer screening programme (Fig. 11.3). Client’s rights and the provider’s needs should be the key considerations.

Fig. 11.3: Quality assurance leading to quality improvement as a dynamic process in the cervical cancer screening algorithm
Points to remember

- Programme monitoring is the continuous oversight of all activities related to the programme to ensure that the services are delivered according to plans and the programme achieves its objectives.

- A system of supportive supervision is essential to ensure adherence to performance standards by all providers.

- Screening rate, screening test positivity rate, treatment rate, coverage of target population, and age-specific cervical cancer incidence are the core indicators to monitor a cervical cancer screening programme.
Multiple choice questions

1. Which of the following is an impact indicator for a cervical cancer screening programme?
   a) Screen test positivity rate
   b) Proportion of screen positive women treated in the same sitting
   c) Proportion of screen positive women ineligible for cryotherapy
   d) Reduction of incidence of cervical cancer

2. Which of the following statements truly defines screening rate?
   a) Number of women in the target age group who were screened for the first time in an 18-month period
   b) Number of women in the target age group who were screened for the first time in a 12-month period
   c) Number of women in the target age group who were screened for the first time
   d) Number of women in the target age group who were treated for the first time in a 24-month period

3. Which of the following statements defines the age specific cervical cancer incidence most appropriately?
   a) Number of new cases of cervical cancer detected in a defined population in a specified period of time
   b) Number of old and new cases of cervical cancer detected in a defined population in a specified period of time
   c) Number of new cases of cervical pre-cancers detected in a defined population in a specified period of time
   d) Number of new cases of cervical cancer

4. All the following statements are true regarding readiness of a facility to ensure quality standards of screening services, except:
   a) Separate room for screening and treatment services
   b) Minimum waiting period for providing screening and treatment services
   c) Adequate number of service providers with appropriate training
   d) Data to be generated once in a year to assess performance of the facility

5. What is treatment rate?
   a) No. of screen positive women who were treated in a 12-month period
   b) No. of women who were treated in a 12-month period
   c) No. of women screened in an 18-month period
   d) No. of women screened and treated in an 18-month period

Answer key

1 – d  2 – b  3 – a
4 – d  5 – a
Section 4: Annex
Annex 1

Trainees’ feedback form

Training of paramedical workers, midwives, nurses and clinicians in VIA, HPV test and cryotherapy

We value your comments to evaluate and improve our training programme. Please take time to complete the feedback form

Part A:

Rate the following as per the scale starting from 1 (sub-standard) to 9 (excellent)

Training contents and materials

1. Relevance and quality of presentations and printed materials
2. Quality of practical demonstrations
3. Adequate exposure to clinical procedures
4. The number of cases for clinical procedures
5. Time spent for demonstration of procedures
6. Overall time for the sessions and course

Comments.

Facilitators

7. Expertise on the topic
8. Facilitator’s ability to stay focused on the topic
9. Time allowed for me to ask all my questions
10. My questions were appropriately answered
11. Assistance during the demonstration of procedures

Comments.
Training venue

12. The cleanliness and comfort of the venue
   1 2 3 4 5 6 7 8 9

13. Air conditioning or cooling heating settings
   1 2 3 4 5 6 7 8 9

14. Projection equipment settings (focus and view)
   1 2 3 4 5 6 7 8 9

15. The provision of food and drinks
   1 2 3 4 5 6 7 8 9

16. Clinical training facility adequately equipped
   1 2 3 4 5 6 7 8 9

Comments.

__________________________________________________________________________

Part B:

List 3 skills (or knowledge) you have improved upon during this training

1. 

2. 

3. 

How do you propose to apply the skills learnt during training at your own facility?

(Encircle the appropriate response/s)

1. I am already working at the screening/colposcopy services at my facility and my quality of work will improve

2. I will join the existing screening/colposcopy services at my facility

3. I will initiate the screening/colposcopy services at my facility

4. I will train my colleagues and support staff at my facility

Suggestions for making this training more effective in the future

1. 

2. 

3.
Annex 2

Sample informed consent form for visual inspection with acetic acid (VIA) Test

Please read the information carefully. After reading this, if you have any doubts or questions please do not hesitate to ask any of us.

Why are you here?

You are here today to have a special test that can detect an abnormal change on the cervix (lower part of the womb). Such change may turn into cancer if not treated and is known as cervical pre-cancer. The test is known as VIA and involves examination of the surface of the cervix after application of 3–5% dilute acetic acid (vinegar). The test can detect or rule out the presence of pre-cancer of the cervix. The test can also detect cancer of the cervix.

How will the test be done?

The procedure usually takes 5–10 minutes to be completed. You will be made to lie down on an examination table with your legs folded at the knees. A small spoon-like instrument (speculum) will be placed in your vagina to expose the cervix. A mild solution of vinegar will be applied on the surface of your cervix for 1 minute. If there is any pre-cancer or cancer that will be obvious as a white patch and we will be able to tell you the result immediately after the test. The test generally does not cause any pain and is safe. You may feel mild irritation during application of the vinegar solution but it is harmless and goes away on its own after a few minutes.

If your VIA test is positive (cervix shows pre-cancer change) you will be advised other tests like colposcopy (a procedure that involves magnified inspection of the cervix with an instrument named colposcope) and/or cervical biopsy (a procedure where a small piece of tissue from the abnormal area on cervix is taken for examination). If your colposcopy and/or biopsy tests are abnormal then you will be advised to take appropriate treatment.

What should you do after the test?

Generally there is no pain or discomfort after the procedure and you may continue with your day-to-day normal activity. No precautions are necessary. If the test results are normal you need to come back for the same test after 3 years unless you cross 49 years of age. If the test is positive we will explain to you where to go for further check-up and treatment.

What problems can occur during or after the test?

As stated above, you may experience brief, mild discomfort during the placement of the speculum in your vagina or during application of dilute solution of acetic acid (vinegar). Sometimes, slight vaginal bleeding (spotting) may occur.
Consent for VIA

I acknowledge that Dr/Mr/Ms …………………………. has explained the proposed procedure to me and has answered questions to my satisfaction. The risks and consequences of the test have been explained to me.

I hereby consent to the VIA test.

……………………………………………………………………………………………………………………………………………………………
Name                          Signature                          Date

……………………………………………………………………………………………………………………………………………………………
Witness’ name                          Witness’ signature                          Date
Annex 3

Sample informed consent form for VIA test and cryotherapy

Please read the information carefully. After reading this, if you have any doubts or questions please do not hesitate to ask any of us.

Why are you here?

You are here today to have a special test that can detect an abnormal change on the cervix (lower part of the womb). Such change may turn into cancer if not treated and is known as cervical pre-cancer. The test is known as VIA and involves examination of the surface of the cervix after application of 3–5% dilute acetic acid (vinegar). The test can detect or rule out the presence of pre-cancer of the cervix. The test can also detect cancer of the cervix. If the test suspects pre-cancer you may also choose to have your treatment done today.

How will the test be done?

The procedure usually takes 5–10 minutes to be completed. You will be made to lie down on examination table with your legs folded at the knees. A small spoon-like instrument (speculum) will be placed in your vagina to expose the cervix. A mild solution of vinegar will be applied on the surface of your cervix for 1 minute. If there is any pre-cancer or cancer that will be obvious as a white patch and we will be able to tell you the result immediately after the test. The test generally does not cause any pain and is safe. You may feel mild irritation during application of the vinegar solution but it is harmless and goes away on its own after few minutes.

What problems can occur during or after the test?

As stated above, you may experience brief, mild discomfort during the placement of the speculum in your vagina or during application of dilute solution of acetic acid (vinegar). Sometimes slight vaginal bleeding (spotting) may occur after the test.

What should you do if the test is normal?

If your VIA test is normal (cervix does not show a pre-cancer change or cancer) you will be advised to have the same test repeated every 3 years till you cross the age of 49 years. Generally there is no pain or discomfort after the procedure and you may continue with your day-to-day normal activity. No precautions are necessary.

What happens if the test is positive?

If the test is positive your doctor/nurse will first assess if you can be treated here today. Treatment of pre-cancer is done using a special technique called cryotherapy. The surface of your cervix will be cooled to freezing temperature using a special machine. Sometimes a the change on the cervix is big in size and cryotherapy may not be the right method to treat such condition. In that case you will be asked to visit a center where further check-up and treatment will be done.
How will cryotherapy be done?
Cryotherapy will be done immediately after the VIA test. The doctor or nurse who will be doing the test will let you know about the test result. If you agree to continue with the treatment, the equipment will be set-up. This may take a few minutes. Once the treatment starts you may hear a hissing sound as the gas passes through the machine. The whole procedure will be completed in approximately 15 minutes. After the treatment is over you will be asked to lie down for 5–10 minutes.

What problems can you expect during or after cryotherapy?
During treatment you may have mild cramp in your lower abdomen. You can go back home and continue with your day-to-day work. Sometimes you may feel a little dizzy immediately after the treatment and you may have to lie down for another 10–15 minutes. You will have a watery vaginal discharge that may last for 2–3 weeks. This is expected and not to be worried about. Please use a sanitary napkin as long as necessary. Very rarely, you may have infection or bleeding. You must contact us or any other doctor if you have high fever, lot of foul smelling vaginal discharge, moderate to severe lower abdominal pain or bleeding more than your average menstrual flow within a month. If you do not have any problems, you should come back for the test after 1 year.

Do you have to take any precautions to prevent complications?
You should not perform vaginal douching or use tampons for 1 month after the treatment. You need to avoid sexual intercourse for 1 month. You must ask your partner to use condoms in case sexual contact is unavoidable.

Consent for VIA and cryotherapy
I acknowledge that Dr/Mr/Ms…………………………… has explained the proposed procedure to me and has answered any questions that I have to my satisfaction. The risks and consequences of the test and the treatment have been explained to me.

I hereby consent to the VIA test and also to cryotherapy, if necessary.

…………………………… ………………………………… ………………………
Name Signature Date

…………………………… ………………………………… ………………………
Witness’ name Witness’ signature Date
## Annex 4

### Sample VIA screening form

**Personal details and contact information**

| 1. Date of registration (day/month/year): | [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] |
| 2. Last name: | |
| 3. First name: | |
| 4. Husband's name: | |
| 5. Age: | [ ] [ ] |
| 6. Date of birth (day/month/year): | [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] |
| 7. Address: | |
| 8. Telephone number: | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] |
| 9. Registration number: | |

**Reproductive history**

| 1. Age at marriage (in years): | [ ] [ ] |
| 2. Total number of pregnancies: | [ ] [ ] |
| 3. Last menstruation: (1. Less than 1 year; 2. More than 1 year; 3. Unknown) | [ ] |
| 4. Date of last menstruation: | [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] |

**VIA procedure**

| 1. SCJ visible: (1. Fully visible; 2. Partially visible; 3. Not visible) | [ ] |
| 2. Findings of VIA: (1. Not done; 2. Negative; 3. Positive; 4. Suspicious for cancer) | [ ] |
| 3. If positive, size of the acetowhite area: (1. < 25% of cervix; 2. 25%-50%; 3. 50%-75%; 4. >75%) | [ ] |
| 4. Can the lesion be covered by a cry–probe? (1. Yes; 2. No) | [ ] |
| 5. Is the lesion suitable for cryotherapy? (1. Yes; 2. No) | [ ] |

**VIA procedure**

| 1. Cryotherapy: (1. Not required; 2. Not suitable; 3. Performed; 4. Refused; 5. Not done due to other reasons) | [ ] |
| 2. Problem during cryotherapy: (1. None; 2. Pain; 3. Other; 4. Could not be completed) | [ ] |
| 3. Next follow-up date | [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ] |

**Referral**

| 1. Reason for referral (1. VIA+ve and not suitable for cryo; 2. VIA+ve and cryo not available; 3. Suspicious for cancer) | [ ] |
| 2. Referred to: | [ ] |

Name of health worker/nurse: ____________________________
Signature and date: ____________________________
Annex 5

Reference chart for visual inspection with acetic acid (VIA)

**VIA negative**

- No acetoacetic area
- Temporarily acetoacetic cells on epithelium
- Cervical polyp
- Nucleiic area appearing acetoacetic
- Late klar acetoacetic area
- Vesicular acetoacetic area
- Area of clear demarcation
- Acetoacetic area away from HC

**VIA positive**

- Acetoacetic area with well-defined margins attached to the HC

**Suspected cancer**

- Acetoacetic area of growth on cervix
- Acetoacetic area and bleeding on growth of the cervix
- Growth on the cervix
Cervical cancer screening and management of cervical pre-cancers

Training of health staff in VIA, HPV detection test and cryotherapy

Trainees’ handbook